CellaVision® DM9600

USER'S MANUAL 6.0

CELLAVISION

Preface

U.S. patents no. 6268611, 6341180, 7034883, 7327901, 7450762, 8914255

Swedish patents no. 0101319, 9902863, 1350568-0

German patents no. 60045076, 602004008471, 602007037624, 602008017260, 602009011617, 602010005069, 60231032, 60231032

French patents no. 1210634, 1646964, 2204686, 2310892

U.K. patents no. 1210634, 1646964, 1986046, 2204686, 2310892

Japanese patents no. 5198476, 5215474, 5461630, 5539489

Chinese patents no. 200980153358.5, 201210433235.0

Other patents pending.

Caution!

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

Note:
The Advanced RBC application is not available on all markets.

Note:
The CellaVision® Image Capture System is not available on all markets.

Article No.: PM-10830-01

Revision: 2015-07-10

Headquarters

CellaVision AB
Ideon Science Park
SE-223 70 Lund
Sweden

Phone +46 (0) 46 286 44 00

Fax +46 (0) 46 286 44 70

1 Introduction

1.1 About this User's Manual

This User's manual will guide you step-by-step through the activity sequence of normal use of CellaVision® DM9600 (also referred to as the system), aiming to give you a good understanding of the system and its features. References are made to appendices providing additional information.

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

1.2 Warnings and precautions

Study the meaning of symbols and safety alerts carefully and always use the system in the safest possible manner. Read all instructions carefully before starting to use the system. Using it without being suitably qualified, or in a manner not specified in this User's manual, may damage or deteriorate the system, cause misleading results or even lead to injury.

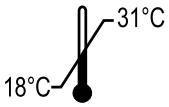
1.2.1 Safety alerts in this document

These safety alerts are used throughout this document. Make sure that you always read, understand, and obey all safety alerts.

Alert	Explanation
Warning!	May cause injury.
Caution!	May cause damage to the system.
Important!	May cause misleading results.

1.2.2 Symbols on the system

These symbols can be found on the system. Make sure that you understand the meaning of each symbol.

Symbol	Explanation
	Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	In vitro diagnostic medical device. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Temperature limitation. Indicates the temperature limits to which the medical device can be safely exposed.
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number. Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment
	Standby button
	Consult user’s manual. Indicates the need for the user to consult the user’s manual.

1.2.3 General safety information

> **Warning!**
>
> The system should be serviced by authorized personnel only.

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

- Make sure that the system is placed on a steady table and not exposed to bumps or vibrations, excessive temperature variations, or direct sunlight.
- Make sure that there is at least 20 cm clearance around the system for ventilation purposes.
- If the system is moved, authorized personnel must perform the installation of the system in the new location according to the Installation Instructions.
- Don't install or run any software not supplied with the system. It is allowed to install an anti virus program, but it is not recommended to scan the database files.
- To maintain electromagnetic compatibility, always use original CellaVision® listed spare parts and their specified components.
- Spillage of fluid on the surfaces of the system may cause malfunctions or deterioration. Wipe off spilled fluids immediately with a soft tissue.

1.3 Intended use of CellaVision® DM9600

DM9600 is an automated cell-locating device.

DM9600 automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

1.3.1 Peripheral Blood Application

The peripheral blood application (PB) is intended for differential count of white blood cells, characterization of red blood cell morphology and platelet estimation. The system automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type.

1.3.2 Body Fluid Application

DM9600 is an automated system intended for in-vitro diagnostic use.

The body fluid application is intended for differential count of white blood cells. The system automatically locates and presents images of cells on cytocentrifuged body fluid preparations. The operator identifies and verifies the suggested classification of each cell according to type.

DM9600 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

1.4 General description of CellaVision® DM9600

CellaVision® DM9600 consists of an optic unit consisting of a microscope and camera (referred to as a slide scanning unit) and a computer system containing the acquisition and classification software CellaVision DM Software. It is important that slide preparation is performed according to standardized methods (see Appendix F Slide preparation guidelines).

General functionality of the system:

- Receives order information from and sends results to the LIS.
- Scans a user-defined area on a slide.
- Locates and presents images of every located cell or object found on the smear.
- Stores images and results in a database.
- Presents an overview image of a user-defined area on a slide.

1.4.1 Peripheral Blood Application

The Peripheral Blood application is included in the CellaVision DM Software.

General functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for white blood cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of white blood cells;
- Presents and suggests morphological characteristics (precharacterization) in an overview image of red blood cells;
- Makes it possible to confirm or modify the precharacterization of red blood cell morphology;
- Presents an overview image and facilitates platelet estimation.

WBC preclassification

The system preclassifies the following WBC classes: *Band neutrophils, Segmented neutrophils, Eosinophils, Basophils, Lymphocytes, Monocytes, Promyelocytes, Myelocytes, Metamyelocytes, Blast cells, Lymphocytes variant forms* and *Plasma cells*.

The system preclassifies the following non-WBCs: *Erythroblasts (NRBC), Giant thrombocytes, Thrombocyte aggregations, Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBCs.

Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.

WBC reclassification

Besides the cell classes mentioned above, the operator can reclassify cells into the following classes: *Immature eosinophils, Immature basophils, Promonocytes, Prolymphocytes, Large granular lymphocytes, Hairy cells, Sézary cells, Other, Megakaryocytes, Not classed* and 15 user defined cell classes.

Other should be used for cells which the operator identifies as a WBC, but of a type other than those listed. WBCs put here will be included in the differential count.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

RBC precharacterization

The system precharacterizes the following RBC morphology characteristics in an overview image: *Polychromatic cells, Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes, and Poikilocytosis.*

RBC characterization

Besides the RBC morphology characteristics mentioned above, the operator can characterize to *Target cells, Schistocytes, Helmet cells, Sickle cells, Spherocytes, Elliptocytes, Ovalocytes, Tear drop cells, Stomatocytes, Acanthocytes, Echinocytes, Howell-Jolly bodies, Pappenheimer bodies, Basophilic stippling, Parasites,* and 10 user defined characteristics.

Platelet estimation

The operator counts or estimates platelets in an overview image.

Sample preparation

To perform a peripheral blood differential count a thin blood film is wedged on a glass slide (a blood smear) from a peripheral blood sample and stained with Romanowsky stain (see Appendix F Slide preparation guidelines for recommended staining recipes).

1.4.2 Advanced RBC Application

The Advanced RBC Application is an optional application which replaces the standard RBC functionality.

General functionality

- Presents and suggests morphological characteristics (precharacterization) in an overview image of red blood cells on a screen;
- Makes it possible to confirm or modify the precharacterization of the red blood cell morphology;
- Organizes, presents and suggests a morphology for every individual red blood cell image on a screen;
- Makes it possible to confirm or modify the suggested classification of the red blood cells.

Precharacterization

The system precharacterizes the following RBC morphology characteristics in an overview and individual cells image: *Polychromatic cells, Hypochromatic cells, Anisocytosis, Microcytes, Macrocytes, Poikilocytosis, Target cells, Schistocytes, Helmet cells, Sickle cells, Spherocytes, Elliptocytes, Ovalocytes, Tear drop cells, Stomatocytes, Acanthocytes, Echinocytes, Howell-Jolly bodies, Pappenheimer bodies, Basophilic stippling* and *Parasites*.

Characterization

Besides the RBC morphology characteristics mentioned above, the operator can characterize to 10 user defined characteristics.

1.4.3 Body Fluid Application

The Body Fluid application is an optional application.

General functionality

- Presents an image on a screen of every located cell or object;
- Organizes and suggests cell classification (preclassification) for the located nucleated cells;
- Makes it possible to identify, confirm or modify (reclassification) the suggested classification of the located cells;
- Presents an overview image.

Preclassification

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other*. Cells preclassified as *Basophils, Lymphoma cells, Atypical lymphocytes, Blasts* and *Tumor cells* are automatically forwarded to the cell class *Other*.

Unidentified is a class for cells and objects which the system has preclassified with a low confidence level.

The system preclassifies the following non-WBCs: *Smudge cells* and *Artefacts*. Non-WBCs are reported as number of cells or objects /100 WBCs.

WBC reclassification

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 15 user defined cell classes.

Not classed should be used for cells and objects which the operator cannot identify and wants to exclude from the differential count.

Sample preparation

Body fluid samples are prepared by using a cytocentrifuge and a staining unit. The sample is centrifuged onto a glass slide and stained with Romanovsky stain (see Appendix F Slide preparation guidelines).

1.5 Components and mechanical operation

Major parts of the system

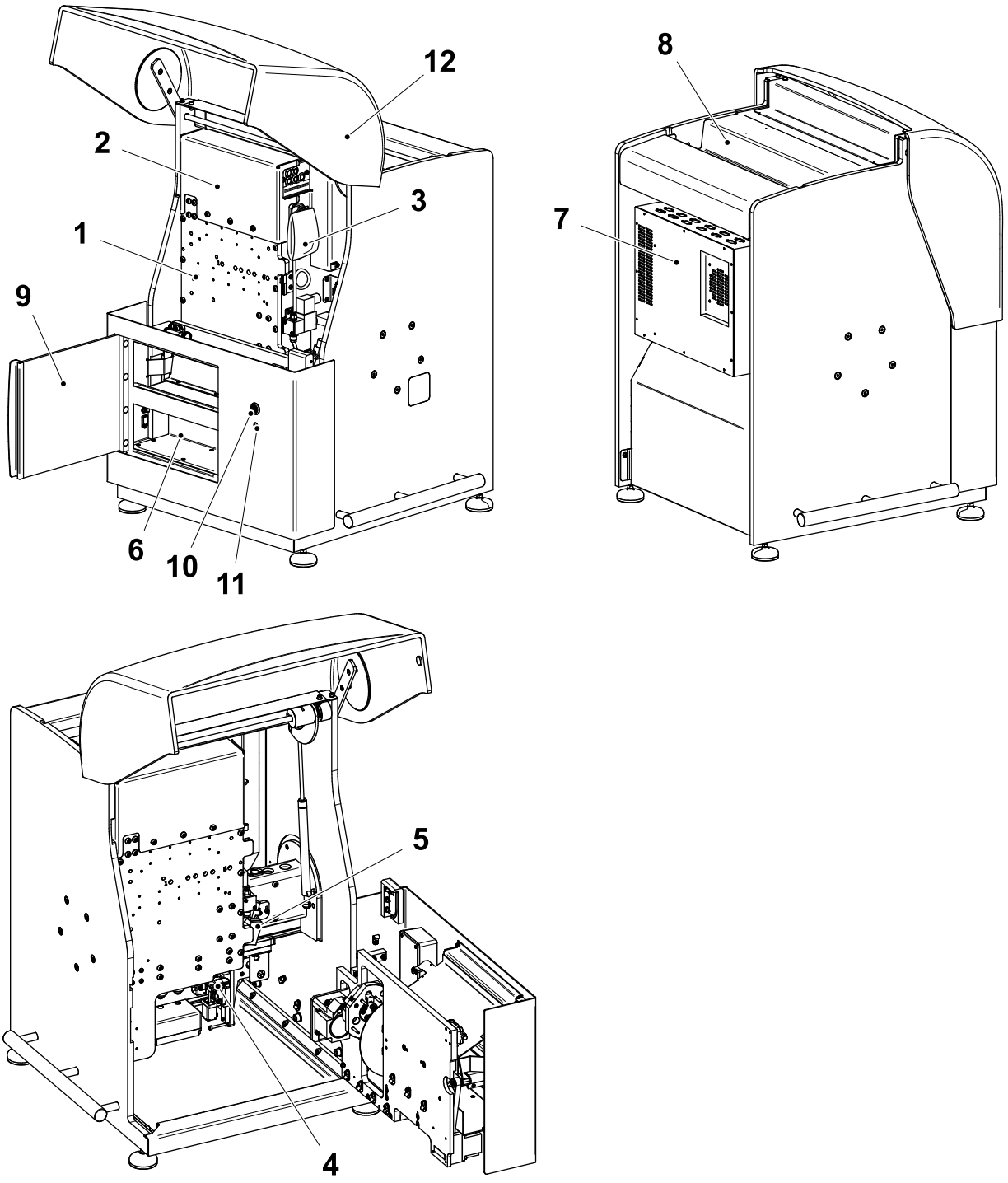
The system comprises the following major units:

- System computer
- Slide scanning unit (SSU)
  - Motorized microscope
  - Digital color camera
  - Immersion oil unit
  - Robot gripper unit
  - Barcode reader
  - Magazine feeder unit
  - Control unit
  - Casing

System computer

The system computer is a PC running Microsoft Windows and CellaVision DM Software.

Slide scanning unit



1. Motorized microscope
2. Digital color camera (inside)
3. Immersion oil unit
4. Robot gripper unit
5. Barcode reader
6. Magazine feeder unit
7. Control unit
8. Casing
9. Input hatch
10. Power switch
11. Status LED
12. Hood

> **Warning!**
>
> Never tamper with sensors or other safety devices. These make sure that the system can operate without any risk of personal injury.

Motorized microscope

The motorized microscope is an upright light microscope with a LED illumination system. It has one 10x objective and one 100x objective and intermediate optics switching between 1.0x and 0.5x magnification which combined yields images with 5x, 10x, 50x, or 100x magnification.

Digital color camera

The camera is a high-quality progressive-scan CCD color camera, for maximum image quality and high speed image acquisition.

Immersion oil unit

The unit automatically applies drops of immersion oil to a slide. An optical drop counter controls the procedure.

Robot gripper unit

The robot gripper unit enables fully automated focusing and positioning of the slide during slide processing. It also transports the slide from the magazine and back again after the slide has been processed.

Barcode reader

The barcode reader scans the barcode of both the slide and the magazine. For more information on barcodes, see A.3.5 Barcodes.

Magazine feeder unit

The unit feeds magazines, one by one, from the infeed conveyor to gripper unit and from the gripper unit to the outfeed shelf. It is equipped with a sensor that alerts the user if the outfeed shelf is full.

Control unit

The control unit controls motors, sensors, oil applying and illumination. It functions as a subordinate computer to the system computer via an unshared Ethernet connection.

Casing

The casing comprises a metal cabinet and the main hood.

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

NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines—Second Edition.* NCCLS document EP5-A2 [ISBN 1-56238-542-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

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.

Clinical and Laboratory Standards Institute. *Body Fluid Analysis for cellular Composition; Approved Guideline.* CLSI document H56-A [ISBN 1-56238-614-X]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

2 Operating procedures

2.1 Starting the system

The system computer is configured with a Windows policy restricting access to the operating system for the normal user. When starting the system computer the user will automatically be logged on to Windows and then the software logon window will be displayed.

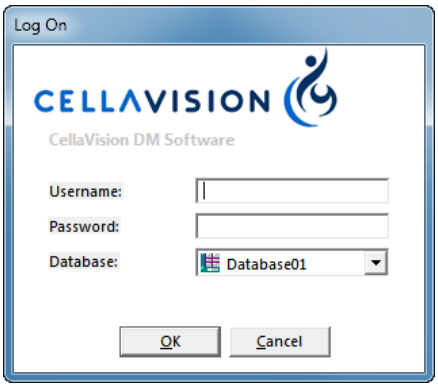
Start the system as follows:

1. Switch on the slide scanning unit.
2. Switch on the system computer.
3. Wait until the status lamp on the slide scanning unit is flashing or continuously lit (see picture in 1.5 Components and mechanical operation).
4. In the **Log On** dialog, type username, password and select the desired database. The following icons indicate available database types:


Processing database


Export database


Scan database



5. Click **OK**.

For more information on database types and how to create and manage databases, see 9.1 Database settings.

2.2 System control view

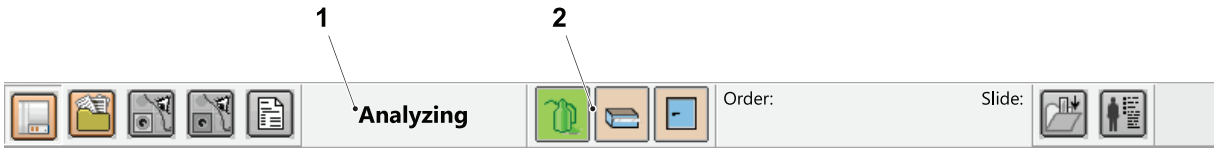
The **System Control** view shows the ongoing slide processing, gives an overview of the preclassification and presents a log of processed slide holders. The layout of the **System Control** view depends on the type of application.


Click **System Control** view in the toolbar.

Information in toolbar

System indicators show oil level, hood position etc. For a description of these indicators, see Appendix C Buttons and indicators.

System status is shown as a text: **Idle**, **Analyzing**, **Stopped**, **Paused** or **Error**.



1. System status
2. System indicators

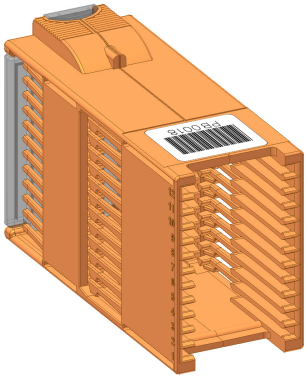
2.3 Magazines and magazine ID

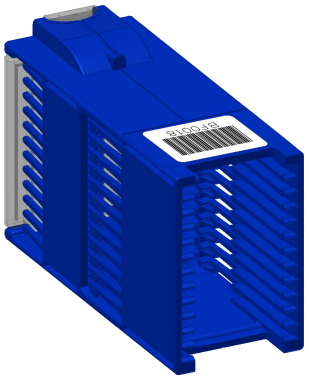
The barcode on the magazine is the magazine ID. When the system has no LIS connection, the magazine ID determines the analysis type.

- Orange magazines with barcodes consisting of prefix “PB” followed by at least three digits - a peripheral blood analysis will be performed.
- Blue magazines with barcodes consisting of the prefix “BFS” followed by at least three digits - a body fluid analysis will be performed.

Note:
A LIS order will override the magazine barcode in determining analysis type.

Note:
The magazines are supplied with barcode labels. If you replace the barcode label, the new barcode must not contain the '/' character.





2.4 Slides and order ID (slide ID)

Important!

Only slides labeled with barcodes can be processed. Use only barcode formats appropriate for the system (see A.3.5 Barcodes).

The order ID (slide ID) is the barcode printed on the slide's label.

Note:
The order ID may be up to 24 characters (ASCII) including spaces. No leading spaces are allowed. The order ID may not begin with "PB", "BFS", or "ERR".

For more information on order ID barcodes, see A.3.5 Barcodes.

When processing a slide the system searches for order data in the following order:

1. In the database, unsigned orders with the same order ID.
2. In the database, pending orders.
3. From the LIS.
4. Default values defined in the **Analysis** tab in **Settings**.

2.5 Loading slides into a magazine

> **Caution!**
>
> Use only clipped/round/beveled corner slides. Failing to do so may cause jams and excessive wear on magazines and the system.

> **Caution!**
>
> If you want to process an already processed slide, carefully wipe the oil off and make sure the barcode is clean and undamaged.

Load the slide into the magazine with the barcode upwards and towards the open end. 12 slides can be loaded into a magazine. The slide positions in the magazine are numbered 1-12 from the bottom up. Make sure that slides are fully inserted in the magazine before using the magazine.

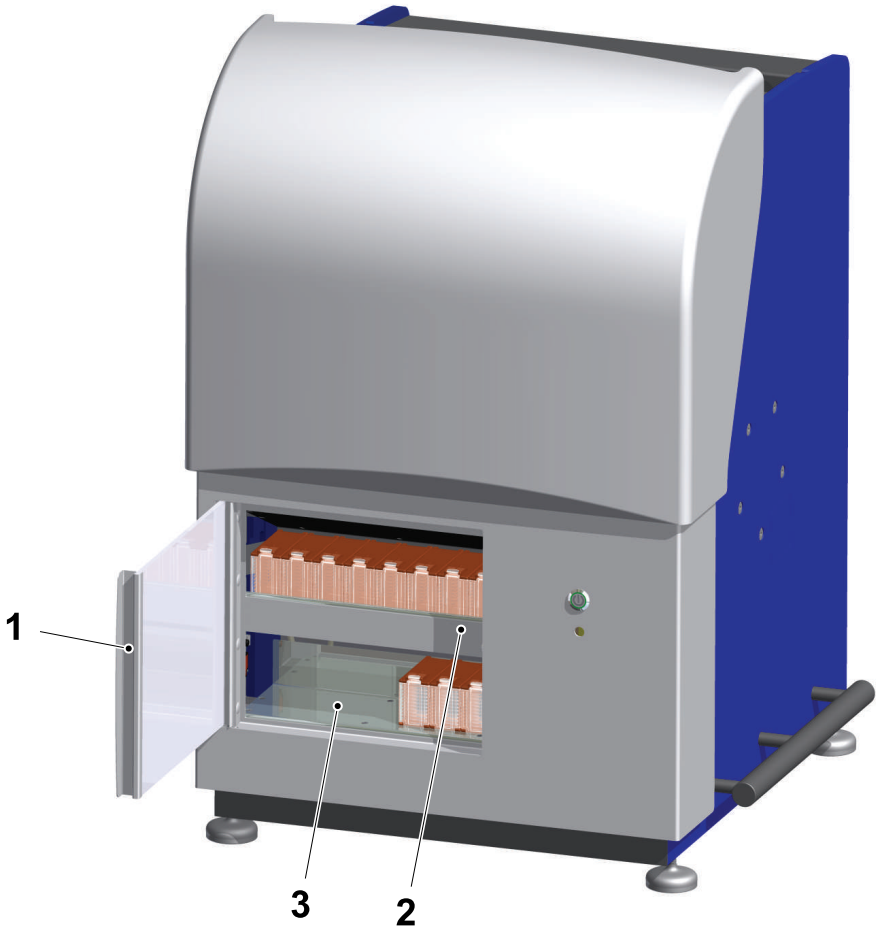
Note:
A magazine can be used 100 times. The CellaVision DM Software will display a message when a magazine has been used more than 100 times.

2.6 Processing slides

2.6.1 Adding magazine

1. Open the input hatch.
2. Put the magazines on the infeed conveyor.

   The magazines must have the barcode facing upwards and the open end of the magazine facing inwards.



1. Input hatch
2. Infeed conveyor
3. Outfeed shelf

When all slides in a magazine have been processed, the magazine is automatically ejected into the outfeed shelf.

2.6.2 Starting the slide processing

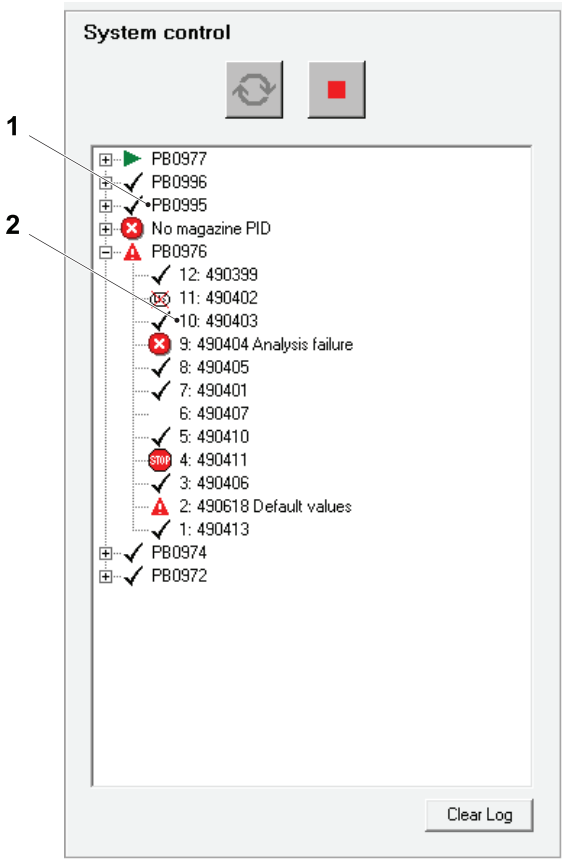
The slide processing starts automatically when you put magazines on the infeed conveyor and close the input hatch. If the system has been stopped, restarted or if an error has occurred, you must manually resume the slide processing.

Autostart – Slide processing starts automatically when you put magazines on the infeed conveyor

Stop – Stop slide processing

Start – Resume slide processing

The tree in the **System Control** panel displays a status log of processed magazines and slides.



1. Magazine
2. Slide

To empty the log of all information, click **Clear Log**.

2.6.3 Magazine status

The following information is available for each magazine:

Magazine status	Magazine ID (barcode)
⚠	PB2345678912

Explanation of symbols

▶	Processing	
✓	Finished	All the slides in the magazine have been processed with no warnings or errors.
⚠	Warning	A slide with status Warning, Stopped, Failed or Canceled exists in the magazine.
⊗	Failed	The system couldn't read a valid magazine ID from the barcode on the magazine.

2.6.4 Slide status

The following information is available for each slide:

Slide status	Slide position	Order ID (barcode)	Error or warning text
⚠	7	2345678912	Default values

Explanation of symbols

▶	Processing	
✓	OK	The slide has been processed with no warning or error.
⚠	Warning	The slide has been processed with a warning. Results exist.
STOP	Stopped	Slide processing stopped by user. No results exist.
⊗	Error	All ordered analyses failed. No results exist.
LIS	Canceled	The slide was canceled in the LIS. The slide has not been processed.

Slide information dialog

Double-click on a slide to open the **Slide information** dialog. Additional information on the processed slide, for example the cause of an error, is displayed here.

2.7 Ejecting magazine

You can eject the magazine that is currently being processed.

1. In the **System control** view, click **Stop**  .
2. When you receive the “Stop the analysis of the current magazine?” message, click **Yes**.
3. On the **Tools** menu, click **Eject Magazine**.
4. When you receive the “Eject magazine?” message, click **OK**.

   The magazine is ejected to the outfeed shelf.

2.8 Shutting down the system

Shut down the system as follows:

1. Eject and remove the magazine from the system.
2. On the **File** menu, click **Exit**.
3. Turn off the system computer.
4. Turn off the slide scanning unit.

3 Quality control

3.1 Cell location test for peripheral blood

The cell location test verifies that the quality of the slide preparation process is good enough to allow the system to locate the cells needed for the analysis. It also verifies the system's ability to locate cells.

> **Important!**
>
> Run a cell location test at least once a day. Also run a cell location test after any changes in the staining procedure or the staining solutions.
>
> This will help to prevent misleading results caused by the system failing to locate cells.
>
> For a system with a high work load, it is recommended to run cell location tests more often.

When you run a cell location test, the system will try to locate a monolayer on a peripheral blood slide and will then try to locate 200 nucleated cells (that is, WBCs and NRBCs) in that monolayer. It will then show you overview images, with the located cells marked.

You can verify that the system has located all nucleated cells, by examining the overview images and counting any cells that have not been located by the system. The system will then calculate how many percent of the nucleated cells that have been located.

To prepare and process a cell location slide

1. Use a freshly stained slide from a blood sample with a WBC count within the normal range:
   - A WBC count above 7×10^9/L is recommended (with a lower concentration, the test will take longer time).
   - If the system cannot locate at least 100 nucleated cells on the slide, the test result will be discarded.
   - The percentage of non-nucleated cells must not exceed 50% of the total number of objects on the slide.

     Non-nucleated cells are all objects that the system doesn't preclassify as being a WBC or an NRBC, for example smudge cells.
2. Put a barcode with an order ID beginning with "QC" on the slide.

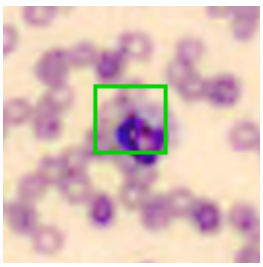
   Barcode labels with "QC" order ID are available from your local vendor.
3. Put the slide in a magazine, put the magazine in the system and process the slide.
4. When the slide has been processed, examine the cell location slide as described later in this section.

To examine a cell location slide

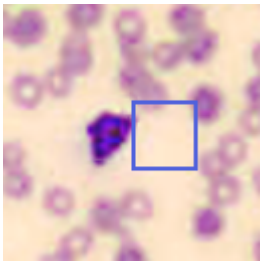
1. On the **Tools** menu, click **Cell location**.
2. In the **Cell location slides** list, click the cell location slide that you want to examine.

   The CellaVision DM Software will open the first image from that cell location slide.
3. In the overview image, count any nucleated cells that have *not* been located by the system and enter the number in the **WBCs + NRBCs missed** text box.

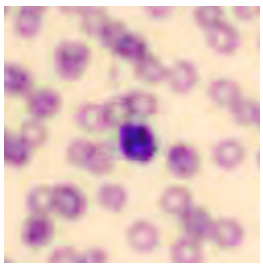
   A cell is located if it is marked with a green, blue or black box.



Located



Located



Not located

For detailed information on how to see if a cell is located or not, see 3.1.1 Explanation of markings.

4. Click the **Next** button  to show the next image on the slide, and repeat this procedure from step 3.
5. When you have examined all the images in the list, the system will automatically calculate the results of the cell location test.

   The result of the cell location test is now displayed under **Total results** as **Ratio of WBCs + NRBCs found**.
6. If you want to print the results of the cell location test, click the **Print results** button.
7. When you have examined the slide, evaluate the result as described later in this section.

The cell location test is saved for at least five days, then it is deleted by the system. The three most recent cell location tests are always saved, even if they are older than five days.

- To review a saved test, click the slide ID in the **Cell location slides** list.

The system keeps track of the results of the 30 latest cell location tests.

- To view a chart of the 30 latest results, click **Show history.**

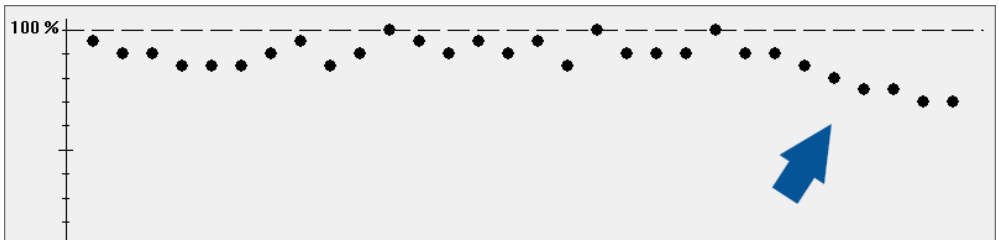
To evaluate the cell location results

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

   For performance characteristics for the system, when using standardized staining and smear preparation procedures, see A.2 Performance specification.

2. Click **Show history**.

3. Check the **Cell location history** chart for any downward trend.



A downward trend in the cell location results.

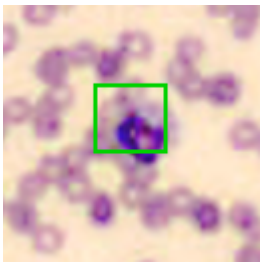
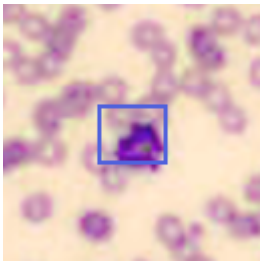
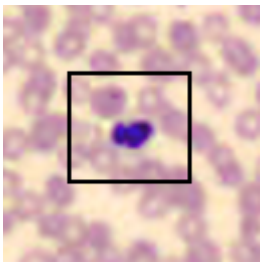
> **Important!**
>
> Do not process any slides if the result of the cell location test is not within your laboratory's established limits or if the cell location history chart shows a downward trend.

For information on how to resolve cell location problems, see the troubleshooting section 11.3 Cell location problems.

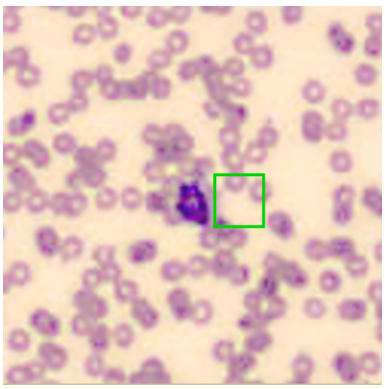
When all cell location problems have been resolved, run another cell location test. If that test is within your laboratory's established limits and any downward trend has been broken, you can continue processing slides.

3.1.1 Explanation of markings

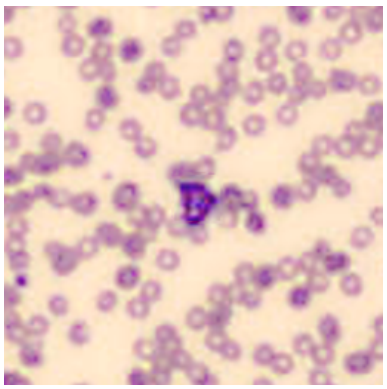
The color of the box indicates how the systems has preclassified the located object. It is possible to compensate for objects incorrectly preclassified as nucleated cells, see 3.1.2 Manual correction. However, the crucial factor in the cell location test is that every cell is located, not that each cell is correctly preclassified.

Marking	Color	Meaning
	Green	This object has been located and has been preclassified as a nucleated cell (WBC or NRBC).
	Blue	This object has been located and has been preclassified as *not* being a nucleated cell. It may be, for example, a non-nucleated cell or a smudge cell.
	Black	This object has been located but has not been preclassified and is not included in the cell location test. This is because enough nucleated cells have already been located and this object is not needed.

The box is not 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, that cell has been located.

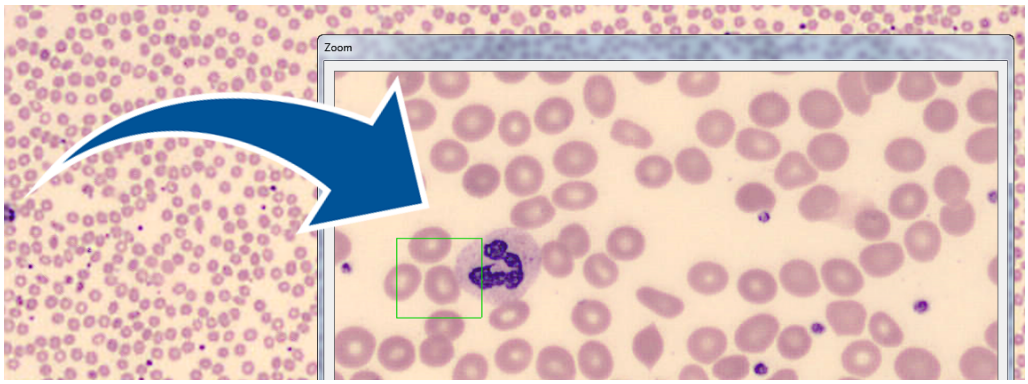


This object has been located by the system because it has a box next to it.



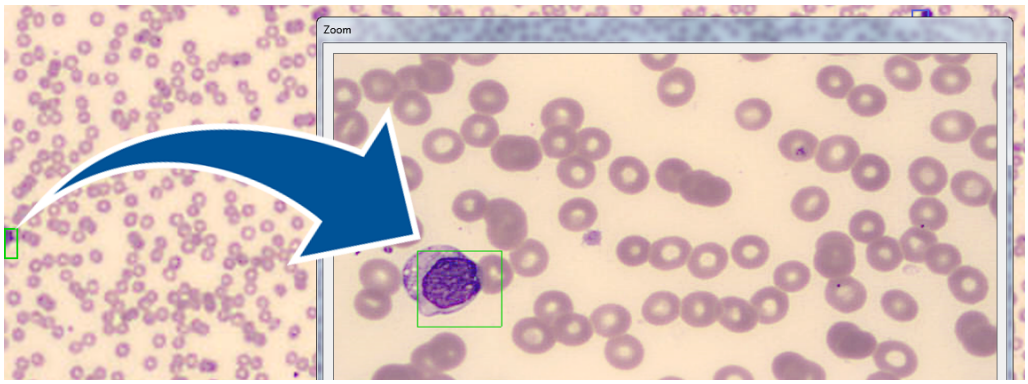
This object has not been located by the system because there is no box.

If a cell is near the edge of the overview image, double-click it to view a magnified image of the area around it. The associated box may be outside the overview image.



This object has been located but the box is outside the overview image.

In the same way, if a box is near the edge, the associated cell may be outside the overview image.



This object has been located but is outside the overview image.

The symbols in the **Cell location slides** list have these meanings:

- All images from this slide have been examined and all nucleated cells were located by the system.
- All images from this slide have been examined but not all nucleated cells were located by the system.
- Slide error, possibly due to a failure in slide processing (for example if the system was not able to locate enough nucleated cells).

  For more information on the error, click the slide in the list. The cause of the error is displayed in the text box under **Total results**.

The symbols in the **Overview images** list have these meanings:

- This image has been examined and all nucleated cells were located by the system.
- This image has been examined but not all nucleated cells were located by the system.

3.1.2 Manual correction

If the system incorrectly preclassified any objects as nucleated cells (that is, marking them with a green box instead of a blue box), you can manually correct the total result.

Do not correct for objects marked with a black box. Those are already excluded from the calculation.

To correct for incorrectly preclassified nucleated cells

1. To calculate the correct number of WBCs and NRBCs, subtract the number of objects incorrectly preclassified as nucleated cells from the number of **WBCs + NRBCs found** displayed under **Total results**.

   Correct number = WBCs and NRBCs found - incorrectly preclassified nucleated cells

   For example, if the system 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** box, enter the correct number of WBCs + NRBCs.

   The system will then use this number for the calculation.

3.2 Cell location test for body fluids

The cell location test verifies the quality of the slide preparation process and the function of the system.

The system will try to locate the WBCs on a body fluid slide. It will then show you an overview image, with the located cells marked.

You can verify that the system has located all WBCs, by examining the overview image and counting any WBCs that have not been located by the system. The system will then calculate how many percent of the WBCs that have been located.

> **Important!**
>
> Run a cell location test at least once a day. Also run a cell location test for each new type of body fluid specimen analyzed in the laboratory and after any changes in the staining procedure or the staining solutions.

For the definition of body fluid specimens, see CLSI H56—*A Body Fluid Analysis for Cellular Composition; Approved Guideline*.

To prepare and process a cell location slide

1. Use a freshly stained body fluid sample with a total number of nucleated cells less than 12 000.
2. Process the slide like a regular body fluid slide.

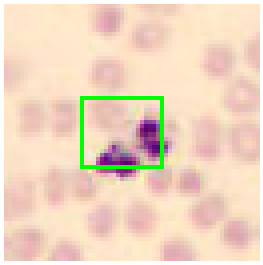
   It is recommended that you order 10x + 50x overview images for the slide.

   Note:
   QC labels are not required for running a cell location test on body fluid slides.
3. When the slide has been processed, examine the slide as described later in this section.

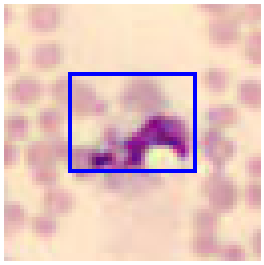
To examine a cell location slide

1. Open the slide from the **Order** list in the **Database** view.
2. Click the **Overview** tab and then click the **Cell location** tab.
3. In the overview image, count any WBCs that have *not* been located by the system.

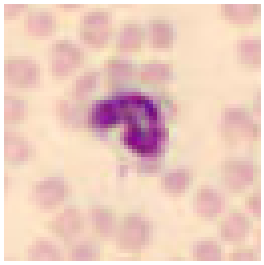
   A WBC is located if it is marked with a green, blue, or black box.



Located



Located



Not located

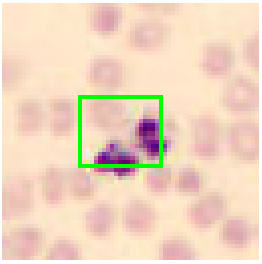
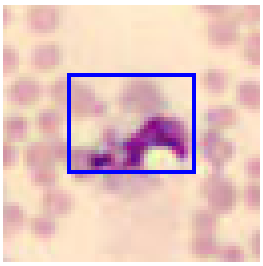
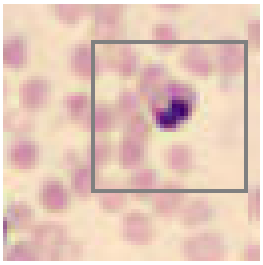
   For detailed information on how to see if a WBC is located or not, see 3.2.1 Explanation of markings (body fluid).
4. Use the navigation controls to view the entire cell location section of the overview image.

   The cell location test uses only a section of the overview image. That section is highlighted in the **Navigation** window.
5. If there are WBCs that *have not* been located by the system (that is, WBCs that are *not* marked with a box), count them and enter the number in the **WBCs missed** box.
6. The system will automatically calculate the results of the cell location test.

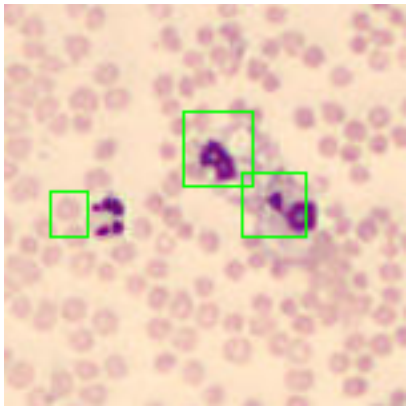
7. If you want to print the results of the cell location test, click the **Print results** button.
8. Check that the result of the cell location test is within your laboratory's established limits.

   For performance characteristics for the system, when using standardized staining and smear preparation procedures, see A.2 Performance specification.
9. If the result of the cell location test is not within your laboratory's established limits, see the troubleshooting section 11.3 Cell location problems.

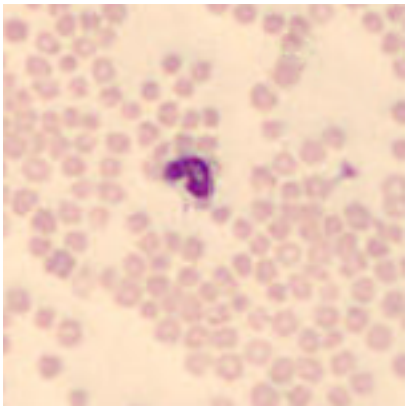
3.2.1 Explanation of markings (body fluid)

Marking	Color	Meaning
	Green	This object has been located and has been preclassified as a WBC. The last WBC located by the system is marked with both a green and a black box.
	Blue	This object has been located and has been preclassified as *not* being a WBC cell.
	Black	This object that has been located but has not been preclassified and is not included in the cell location test. This is because enough nucleated cells have already been located and this object is not needed. The last WBC located by the system is marked with both a green and a black box.

The box is not 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, that cell has been located.



These three objects have all been located by the system because each object has a box next to or around it.



This object has not been located by the system because there is no box.

3.3 Self tests

The system performs self tests during startup of the software, and at certain points during the operation of the system. When the software starts, the system is checked before the operator can start analyses. During this phase, both the hardware and the software components are tested for anomalies, as well as various requirements for the operation of the system. If the LIS communication is enabled, the program will also check the connection to the LIS.

After each slide the system has processed, it checks the positioning of the motors. While the program is running, the database size is compared intermittently to the rules set for archiving or automatic deletion of old entries, thus ensuring that the database is kept at a reasonable and maintainable size.

The communication with, and response of the hardware, is tested continuously during the operation of the system, and a message will inform the operator if an error occurs during slide processing or other operations on the system.

4 Verifying processed slides

4.1 Peripheral blood

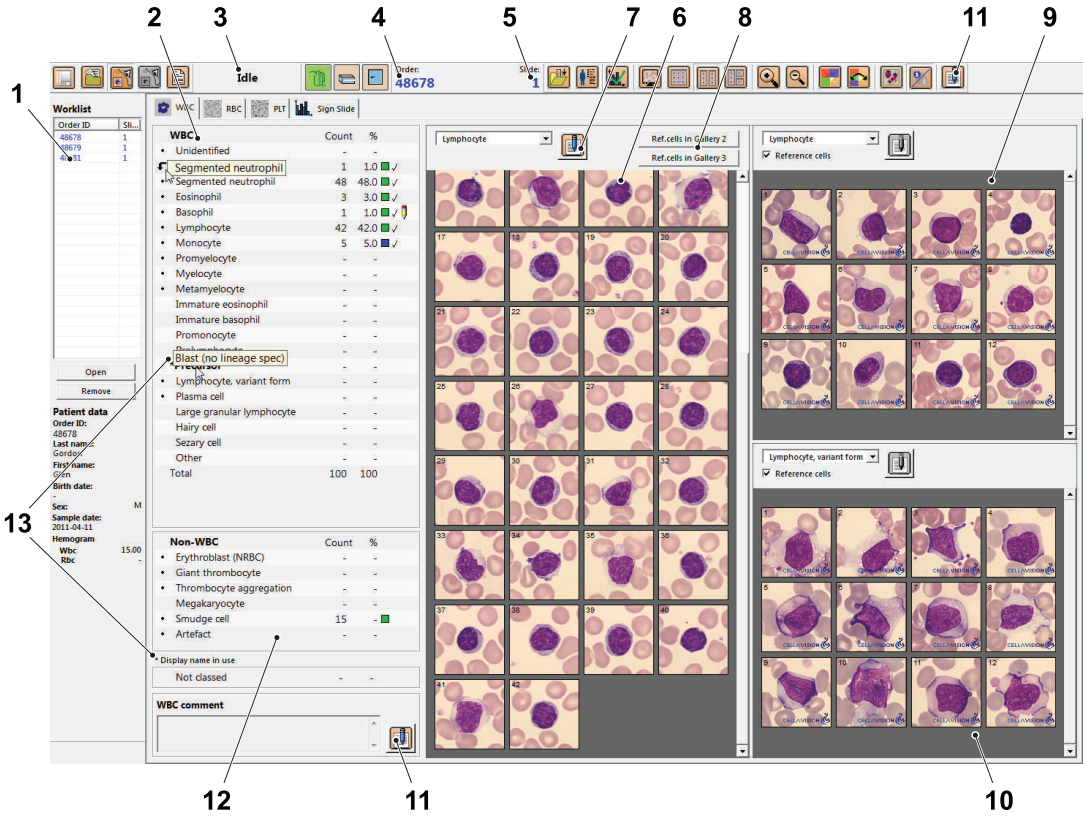
Opening an unsigned slide leads directly to the **Verification** view, where various tabs can be selected in order to review WBC, RBC and PLT and to sign the slide. To open a slide, see 6.1.3 Opening an order or a slide.

Click **Verification** view in the toolbar.

Note:
It is possible to add user defined WBC cell classes and RBC morphologies and to change the cell class names to custom display names. To do this, contact your service technician.

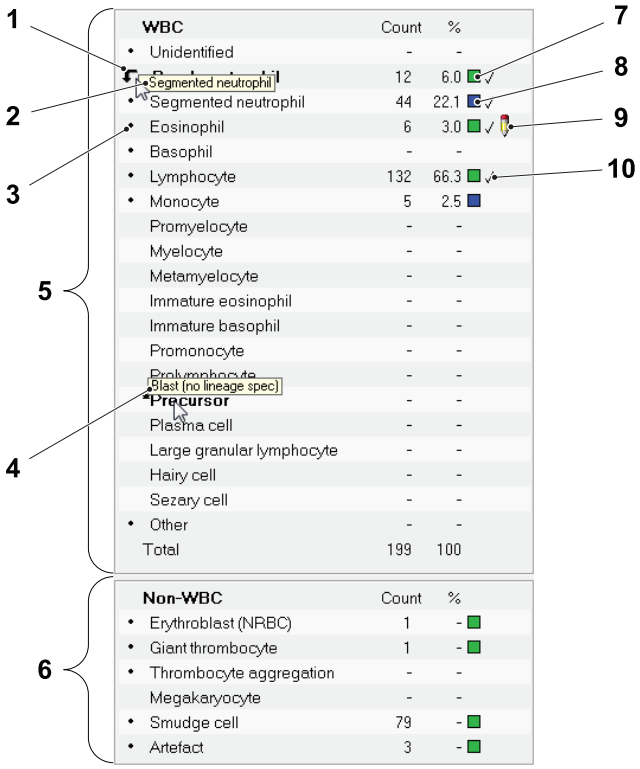
4.1.1 White blood cell classification

You can view all WBCs identified by the system. You may also reclassify WBCs and add comments.



1. Worklist
2. WBC panel
3. System status
4. Order ID
5. Slide number
6. Main gallery
7. Add cell class comment
8. Shortcuts to reference cells
9. Gallery 2
10. Gallery 3
11. Add WBC comment
12. Non-WBCs panel
13. Display names in use

All cell classes handled by the system are displayed in this figure. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot or an arrow.



1. Arrow indicating a cell class that is automatically forwarded
2. Destination cell class
3. Preclassified by the system
4. Display name in use, original name in tooltip
5. WBC panel
6. Non-WBC panel
7. Green - Contains no reclassified cells or objects.
8. Blue - Contains at least one reclassified cell or object.
9. Pen icon - Indicates Cell class comments.
10. Tick mark - All cells have been viewed.

An arrow ↶ indicates that preclassified WBCs are automatically forwarded to another cell class. Place the cursor over the arrow to see the destination cell class.

For information on how to set up the system to automatically forward cell classes, see 9.3.4 Reclassification settings. These cell classes can be forwarded:

Band neutrophil to *Segmented neutrophil*

Metamyelocyte to *Segmented neutrophil*

Lymphocyte, variant form to *Lymphocyte*

Plasma cell to *Lymphocyte*

Blast cell, Metamyelocyte, Myelocyte and *Promyelocyte* to *Other.*

Customizing views

Galleries:

WBCs are presented, by class, in galleries. The main gallery is always shown, together with up to two additional galleries. Click **WBC galleries** to change the number of galleries.

WBC Galleries

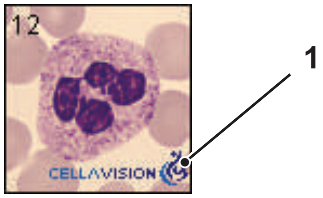
To view the cells in a cell class, click that cell class in the **WBC** or **Non-WBC** panel. The cells will be displayed in **Gallery 1**. You can also right-click the cell class to display the cells in **Gallery 2** or use the drop-down list in each gallery.

The system keeps track of all WBCs viewed by the operator. A tick mark appears when all WBCs of a cell class have been displayed. It is not possible to sign the slide unless all cell classes have been viewed.

Reference cells:

A library of reference cells for different cell classes is provided with the system. These cells are marked with a CellaVision® logo. The main gallery always displays WBCs from the slide, while the others show reference cells when the checkbox **Reference cells** is selected. The main gallery has shortcuts to display reference cells in the other galleries. Click **Ref.cells in Gallery 2** and the 2nd gallery will display reference cells of the cell class selected in the main gallery.

Reference cells for body fluids are not provided with the system.



1. Indicates reference cell provided with the system

You may expand this library by saving WBCs from processed slides as custom reference cells.

1. Right-click on the WBC.

2. Select **Save as custom ref. cell** in the menu.

3. Restart the software.

The WBC will be displayed at the top of the 2nd or 3rd galleries, followed by the reference cells provided with the system. If you want to organize your custom reference cells, see 9.7 Reference cells settings.

Cell class comments:

Click **Comment** in the galleries to add a cell class comment. A pen icon will appear to the right in the **WBC** and **Non-WBC**s panels. Click this icon to view, edit or add more comments (see 4.1.5 Comments).

WBC full screen view:

Click **WBC full screen** view to display all WBCs sorted by class.

WBC full screen view

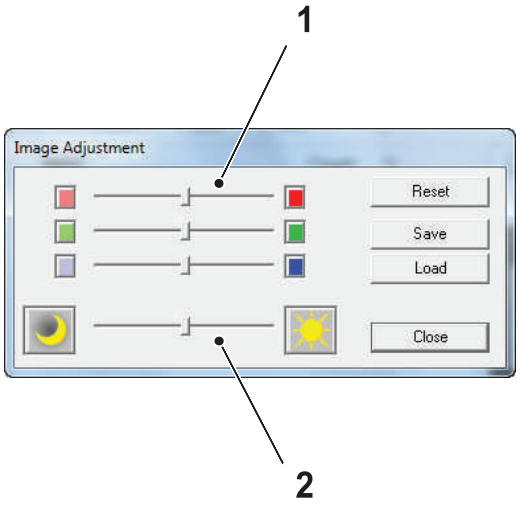
Note:

Cell classes that have been fully displayed in WBC Full Screen view will also be tick marked.

Adjusting image color and brightness:

Click **Color/Brightness** to display the **Image adjustment** dialog.

Color/Brightness



1. Color sliders
2. Brightness

Brightness: Adjusts the brightness of the image.

Reset: Restores original settings.

Save: Stores individual settings.

Load: Gets individual settings.

Individual settings can also be switched using **Toggle color/brightness**.

Toggle Color/Brightness

Adjusting magnification:

Click **Zoom in** or **Zoom out** to change the magnification in all galleries and in the **WBC full screen view**.

 Zoom in

 Zoom out

You may also double-click on a WBC to enlarge it, and use the scroll wheel to zoom in or out.

Display names in use:

It is possible to edit the display names for the WBC classes. To do this, contact your service technician.

Move the mouse pointer over the cell class in the WBC panel to show the original name.

Reclassifying white blood cells

Reclassify WBCs by dragging and dropping them from one gallery to another:

1. Place cursor over the cell image.
2. Click and hold down left mouse button.
3. Move cursor to the destination gallery then release button.

You may also drag and drop cells to the WBC and Non-WBCs panels. Press Ctrl or Shift to select multiple cells.

Reclassified cells always appear at the top of the gallery.

A cell class containing at least one reclassified cell is marked blue in the WBC and Non-WBCs panels. If a cell is reclassified to its own cell class, it is considered reclassified and moved to the top of the gallery.

Note:
You can never reclassify WBCs on a signed slide.

Cell marker

When the Cell Marker function is turned on, a green square marking the cell the system has identified, appears in every cell image. The **Cell Marker** is used to split cells and identify duplicate cells.

 Cell Marker

Splitting cells:

Occasionally the system fails to separate WBCs that are close to each other, and more than one cell in an image will be outlined by the cell marker (green square). These cells should be split so that each can be identified by the operator. With the cursor over the image, use the right-click menu and select **Split cells**. A dialog appears explaining the procedure. The appearance of the green square is not changed for split cells. Instead a copy of the same image is created, and a red cross will mark the cell which is to be identified.

Cells created by splitting can always be removed, using the right-click menu.

Identify duplicate cells:

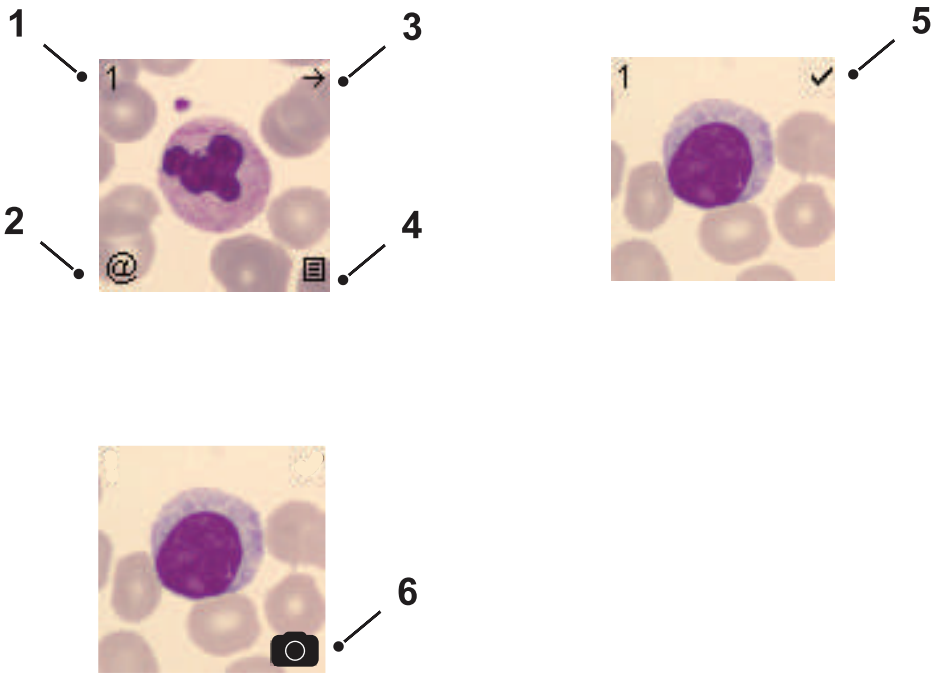
If the green square outlines only part of a cell, the system has only used this part for cell identification. There is a risk that the system has identified the other part of the cell as a completely different cell, thus the same cell can be counted more than once.

To make sure duplicate cells are not included in the differential count it is recommended to screen all cell images for duplicate cells when a green square only covers part of a cell. A duplicate cell should be removed from the differential.

See 11 Troubleshooting for more information.

WBC attributes

Each cell is associated with attributes.



1. Sequential number in the cell class
2. Selected for e-mail
3. Forwarded from another cell class
4. Cell comments exist
5. Reclassified cell
6. The image has been manually captured on a CellaVision® Image Capture System

WBC attributes are shown by default. Click **WBC attributes** to show/hide them.

Note:
It is not possible to hide the CellaVision® Image Capture System symbol.

 WBC Attributes

Right-click menu:

You can right-click on a cell to display a shortcut menu with these options:

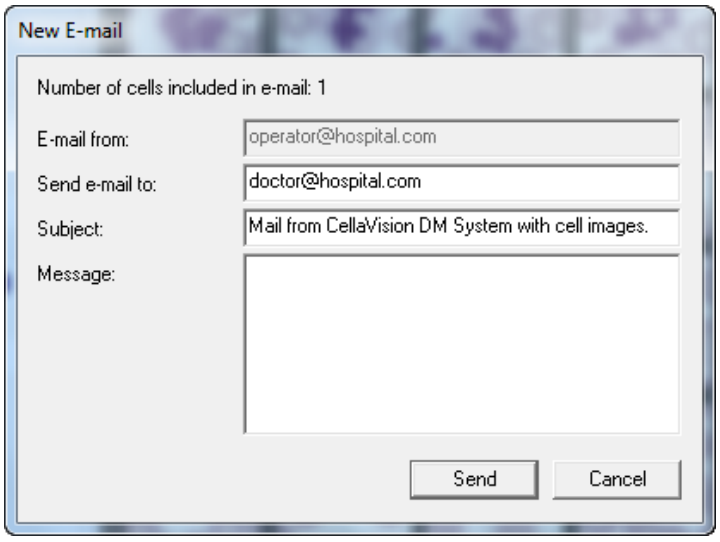
1. **View DM's 1st, 2nd and 3rd suggestions of classification**.
2. **Reclassify cell**.
3. **Add/view cell comments** (see 4.1.5 Comments).
4. **Split cell** or **remove split cell**.
5. **Select cell for e-mail**.
6. **Save cell as custom reference cell**.
7. **Save images to disk**.

Note:
All alternatives are not available for images captured on a CellaVision® Image Capture System.

E-mail

You may send cell images by e-mail.

1. Select **Select for e-mail**, using the right-click menu.
2. Select **Tools/Send E-mail** and the **New e-mail** dialog appears.



For default values, see **E-mail** tab in **Settings**.

3. If desired, change receiver address.
4. If desired, add **Subject** and **Message**.
5. Click **Send**.

Note:
You may only send cells from one slide in each e-mail.

Note:
No patient data is sent in the e-mail.

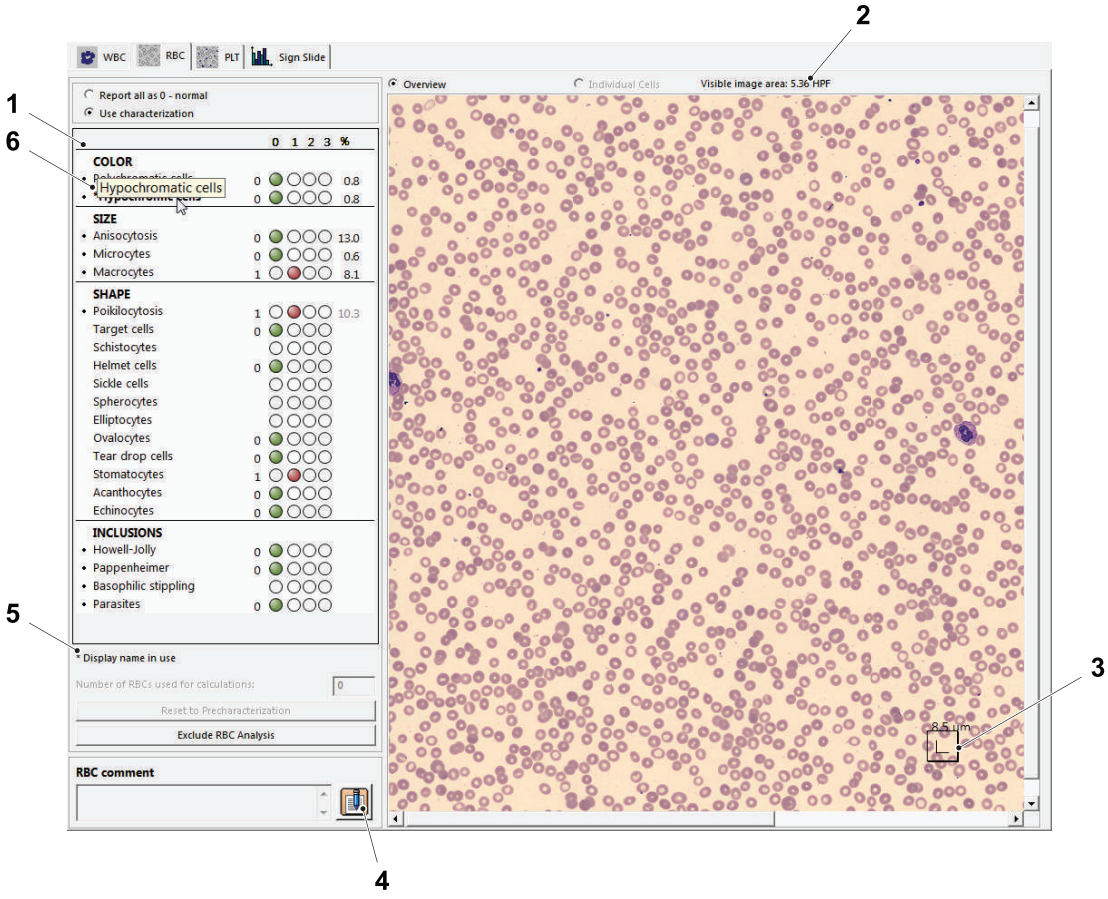
Save cell images to disk

You can save cell images from any order to, for example, your local hard drive or a USB flash drive. For more information on how to save cell images, see 6.1.8 Save cell images to disk.

4.1.2 Red blood cell characterization

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22 mm ocular).

See 9.3.2 RBC precharacterization settings.



1. RBC panel
2. Visible Image Area
3. Ruler
4. Add RBC comment
5. Display names in use
6. Original name in tooltip

RBC panel:

The RBC panel is used for characterization of the RBC morphology. All morphologies handled by the system are listed. Morphologies precharacterized by the system are marked with a small dot.

The columns labeled 0 to 3 grade the morphology characteristics.

Normal	Green dot in column 0 indicates a normal level.
Slight	Red dot in column 1 indicates that the morphology is present at a low level.
Moderate	Red dots in column 1-2 indicate that the morphology is present at a moderate level.
Marked	Red dots in column 1-3 indicate that the morphology is present at a high level.

The rightmost column shows the percentage of RBCs in the overview image with the characteristic in question. If the precharacterization is overridden by manual characterization, the percentage is shown dimmed.

Note:
You can never change the RBC characterization on a signed slide.

Note:
The RBC precharacterization is not available for images captured on a CellaVision® Image Capture System .

Visible image area:

The visible image area is shown in numbers of estimated microscopic high power fields (HPF). If you zoom in or out and then open another slide, the magnification of the red blood cell overview image will be the same as the previous.

Ruler:

In the bottom right-hand corner of the RBC image there is a ruler that represents the size limits for a normal RBC. By default, the ruler shows the upper size limit. Double-click the ruler to change it to the lower size limit. The size (in micrometers) is displayed above the ruler. The ruler can be moved around the RBC image by moving the mouse pointer (in either zoom mode or scroll mode) over the ruler, depressing the left mouse button and then by dragging it to its desired placement.

Display names in use:

It is possible to edit the display names of RBC morphologies. To do this, contact your service technician.

Move the mouse pointer over the morphology in the RBC panel to show the original name.

Customizing the red blood cell overview image

Change the magnification of the image by using these buttons:


Zoom in


Zoom out


Entire RBC image - Shows the entire RBC image.

Navigate the image by switching between different control modes. The mouse pointer changes accordingly.



Zoom mode – Hold left mouse button down and zoom in or out by moving the mouse pointer up or down.



Scroll mode – Hold left mouse button down and pan in any direction using the mouse.

You can double-click in the RBC image to enlarge a limited area, and then use the scroll wheel to zoom in and zoom out.

You can also click the **RBC grid** button to zoom in to approximately 1 HPF and navigate the image using the arrow keys. A small navigation grid is displayed in the top left corner of the overview image. The color of the navigation grid indicates what sections of the images have been viewed.


RBC grid


Navigation grid

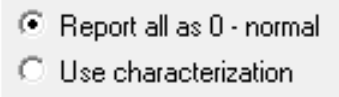
Green – Section has been viewed

Blue – Section is currently being viewed

Red – Section has not been viewed

Characterizing red blood cell morphology

There are two ways to report the RBC result:



1. Report all as normal
   a) Select radio button **Report all as 0 - Normal**.
2. Use characterization
   a) Select radio button **Use characterization**.
   b) If you disagree with a precharacterization, click the dot that corresponds to your opinion.

Click **Reset to Precharacterization** to restore the precharacterization result done by the system. All manual characterization will be lost.

If you want to remove a specific type of morphology from the report, deselect the dot by clicking on it.

Excluding the red blood cell analysis

Click **Exclude RBC Analysis** to exclude the RBC analysis results from the slide.

4.1.3 Red blood cell characterization using the Advanced RBC Application

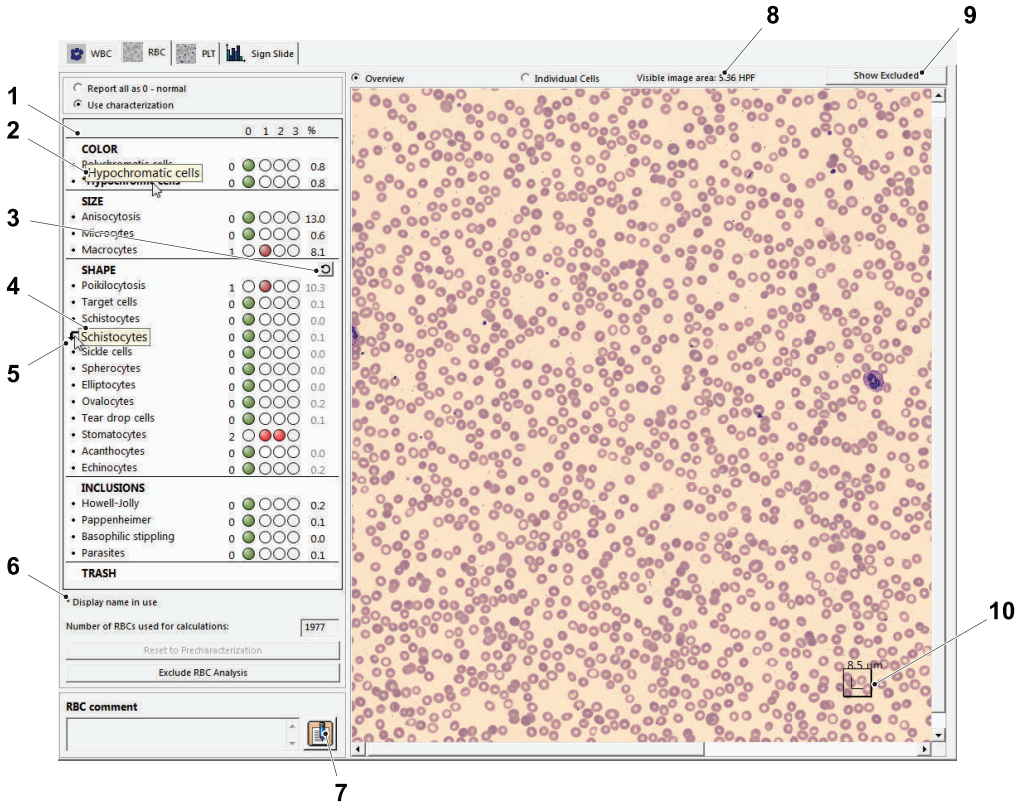
RBC precharacterization using the Advanced RBC Application is only available for slides processed on a system with the Advanced RBC Application activated.

Overview

Click **Overview** to view the RBC overview image.

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22 mm ocular).

See 9.3.2 RBC precharacterization settings.



1. RBC panel
2. Original name (display names in use)
3. Reset to automatic grading
4. Destination morphology
5. Auto-forwarded morphology
6. Display names in use
7. Add RBC comment
8. Visible image area
9. Show excluded
10. Ruler

The rightmost column shows the percentage of RBCs in the overview image with the characteristic in question. If the automatic grading is overridden by manual grading, the dots are shown in a lighter color and the percentages for

the other morphologies in the group are dimmed. Click if you wish to go back to use automatic grading.

RBCs automatically precharacterized by the system are marked with a small dot or an arrow.

Click on a morphology or a morphology group to highlight these cells. The same cells will still be highlighted if you switch to view cells in the Individual cells view.

Note:
You can never change the RBC characterization on a signed slide.

Note:
The RBC precharacterization is not available for images captured on a CellaVision® Image Capture System .

Visible image area:

The visible image area is shown in numbers of estimated microscopic high power fields (HPF). If you zoom in or out and then open another slide, the magnification of the red blood cell overview image will be the same as for the previous slide.

Show excluded objects:

Click **Show Excluded** to highlight objects that are not included in the analysis.

Move cells to Trash from the overview image:

Click a morphology group or a morphology. Hold down Ctrl and, in the overview image, click each highlighted cell you want to move to Trash. Press Delete.

Ruler:

In the bottom right-hand corner of the RBC image there is a ruler that represents the size limits for a normal RBC. By default, the ruler shows the upper size limit. Double-click the ruler to change it to the lower size limit. The size (in micrometers) is displayed above the ruler. The ruler can be moved around the RBC image by moving the mouse pointer (in either zoom mode or scroll mode) over the ruler, depressing the left mouse button and then by dragging it to its desired placement.

For information on how to change the size limits for a normal RBC, see 9.3.2 RBC precharacterization settings.

Auto-forwarded morphology:

In settings, see 9.3.4 Reclassification settings, you may choose to auto-forward precharacterized RBCs to another morphology as follows:

Helmet cells to *Schistocytes*

Ovalocytes to *Elliptocytes*

An arrow indicates that precharacterized RBCs are auto-forwarded to another morphology. Place the cursor over the arrow to see the destination morphology.

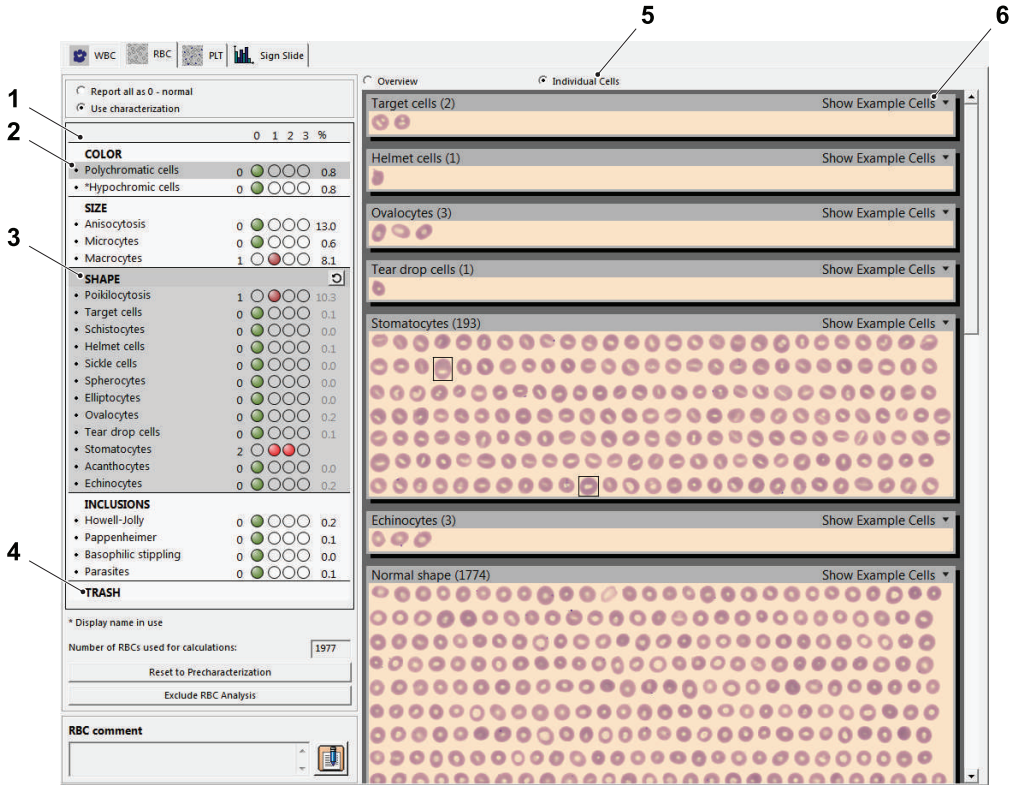
Display names in use:

It is possible to edit the display names of RBC morphologies. To do this, contact your service technician.

Move the mouse pointer over the morphology in the RBC panel to show the original name.

View individual cells

Click **Individual cells** to view the classified cells individually.



1. RBC panel
2. Morphology (selected)
3. Morphology group (selected)
4. Trash
5. Show individual cells
6. Show example cells

Click on one of the morphology groups in the list to the left to view the cells within that group.

Click on one of the morphologies under another group in the list to the left to view two morphologies at the same time. A black box appears around those cells. The same cells will still be highlighted if you switch to view the cells in the Overview image.

Double-click on a cell image to view an enlarged image, including the surrounding parts of the image. Use the scroll wheel to zoom in or out.

Reclassify Red Blood Cells:

Reclassify RBCs by dragging and dropping them from one morphology to another:

1. Place the cursor over the cell image.
2. Click and hold down the left mouse button.
3. Move the cursor to the destination gallery then release the button.

You may also drag and drop cells to the RBCs panels or use the right-click menu.

Press Ctrl or Shift to select multiple cells.

Reclassified cells will appear at the top of the gallery and be marked with a small triangle in the right top corner. Click on the reclassified cell to view the preclassification.

Note:
If a morphology has been manually graded it is not possible to reclassify cells within that specific group.

Select cells based on their morphology:

1. Click a morphology group and then click a morphology within that group.
2. Hold down Ctrl and click a morphology in a different group.

   For example, to select all target cells that are macrocytes, click **Shape**, click **Target cells**, and then hold down Ctrl and click **Macrocytes**.
3. To reclassify the selected cells, drag them to any morphology.

   To reclassify the selected cells to a morphology within the same group, you can also right-click any of the cells and then click a morphology.

Trash:

Drag and drop objects to **Trash** to exclude them from the analysis.

Example Cells:

Right-click on a cell to **Save as custom example cell**.

Click on the small arrow next to **Show Example Cells** and choose a morphology in the drop-down list to view the example cells.

Right-click on a saved custom example cell to **Remove from example cells**.

Customizing the red blood cell overview image

Change the magnification of the image by using these buttons:


Zoom in


Zoom out


Entire RBC image – Shows the entire RBC image.

Navigate the image by switching between different control modes. The mouse pointer changes accordingly.



Zoom mode – Hold left mouse button down and zoom in or out by moving the mouse pointer up or down.



Scroll mode – Hold left mouse button down and pan in any direction using the mouse.

You can double-click in the RBC image to enlarge a limited area, and then use the scroll wheel to zoom in and zoom out.

You can also click the **RBC grid** button to zoom in to approximately 1 HPF and navigate the image using the arrow keys. A small navigation grid is displayed in the top left corner of the overview image. The color of the navigation grid indicates what sections of the images have been viewed.


RBC grid


Navigation grid

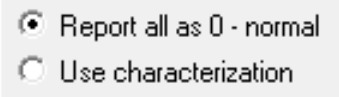
Green – Section has been viewed

Blue – Section is currently being viewed

Red – Section has not been viewed

Characterizing red blood cell morphology

There are two ways to report the RBC result:



1. Report all as normal
   a) Select radio button **Report all as 0 - Normal**.
2. Use characterization
   a) Select radio button **Use characterization**.
   b) If you disagree with a precharacterization, click the dot that corresponds to your opinion. You can also reclassify individual cells, as described earlier in this chapter.

Click **Reset to Precharacterization** to restore the precharacterization result done by the system. All manual characterization and classification will be lost.

If you want to remove a specific type of morphology from the report, deselect the dot by clicking on it.

Excluding the red blood cell analysis

Click **Exclude RBC Analysis** to exclude the RBC analysis results from the slide.

4.1.4 Estimating platelets

The complete PLT overview image (same image as for RBC) corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22 mm ocular). The overview image is divided into 4, 9, or 16 grid squares as defined by the grid size. The grid size options are 2×2, 3×3 and 4×4. The 4×4 grid size gives the largest magnification of the image. There are as many entry fields as there are grid squares.

Help lines can make it easier to count the platelets in each grid square. To show or hide the help lines, click the **Help lines** button.

The help lines are only a visual aid and does not affect the calculation of the platelet concentration.

Note:
Help lines are not available for images captured on a CellaVision® Image Capture System.

There are two methods to calculate the PLT concentration:

- Count the platelets in each grid square of the PLT overview image and then enter either the number of platelets for each grid square or an estimated average number of platelets per grid square.
- Manually estimate the concentration of platelets and choose a concentration level (significantly decreased, decreased, normal, or increased).

You can change which method to use in the PLT analysis settings, see 9.3.5 PLT settings.

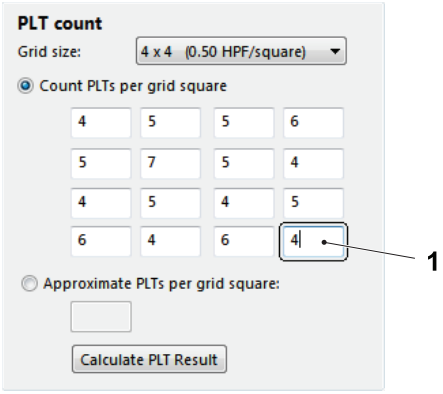
Note:
The setting for the PLT calculation method applies to all slides in an order once one of them is opened for the first time. Once a slide has been opened, this setting can't be changed for any slides in that order.

Note:
For images captured on a CellaVision® Image Capture System, you can only use the manual estimation method .

Counting platelets in the overview image

PLT count:

The estimation of the PLT concentration is based on the number of PLTs, which must be counted manually. You can choose to count the number of PLTs in each grid square or to specify an approximate number of PLTs per grid square.



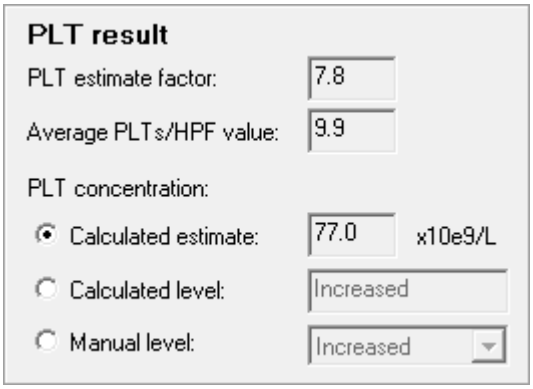
1. Entry field

1. Counting PLTs per grid square
   a) Select the **Count PLTs per grid square** radio button.
   b) Select the entry fields one by one, count the PLTs in the image window and type the number in the entry field. You can use Tab and Shift+Tab to move between entry fields.
2. Specifying an approximate PLT count per grid square
   a) Select the **Approximate PLTs per grid square** radio button.
   b) Use the entry fields to view different grid squares.
   c) Estimate the average PLT count per grid square and type this value in the field.

Note:
It is not possible to count PLTs per grid square or to specify an approximate PLT count per grid square for images captured on a CellaVision® Image Capture System.

PLT result:

1. Click **Calculate PLT Result** in the **PLT Count panel**.



2. If you wish to report the PLT results calculated from the number of PLTs per HPF, you have two choices:
   - Select **Calculated estimate** to report a concentration. The estimate is calculated as [Average PLTs/HPF value] x [PLT estimate factor].
   - Select **Calculated level** to report one of four levels: **Significantly decreased**, **Decreased**, **Normal** or **Increased**.
3. If you wish to override the calculated PLT results, select **Manual level** and choose one of the four levels.

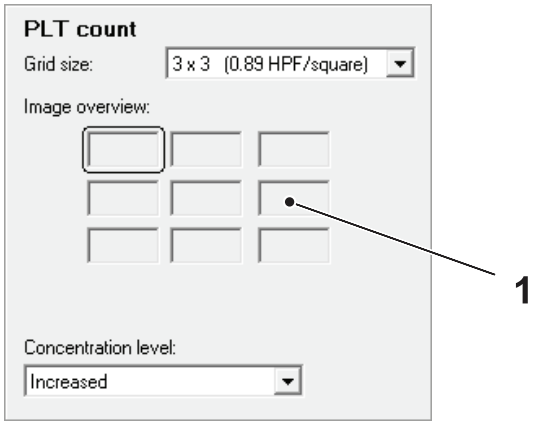
> **Important!**
>
> You must determine and enter a PLT estimate factor before you can use the system to calculate PLT concentration. By default, the PLT estimate factor is set to 0.
>
> For information on how to set the PLT estimate factor, see To calculate and set the PLT estimate factor in 9.3.5 PLT settings.

Note:
In the calculations, several decimals are used. The presented results are truncated to 1 decimal.

Note:
It is not possible to calculate a PLT result for images captured on a CellaVision® Image Capture System.

Estimating the platelet concentration level

The PLT concentration level can be estimated by setting it to four levels: **Significantly decreased**, **Decreased**, **Normal** or **Increased** directly from viewing the image.

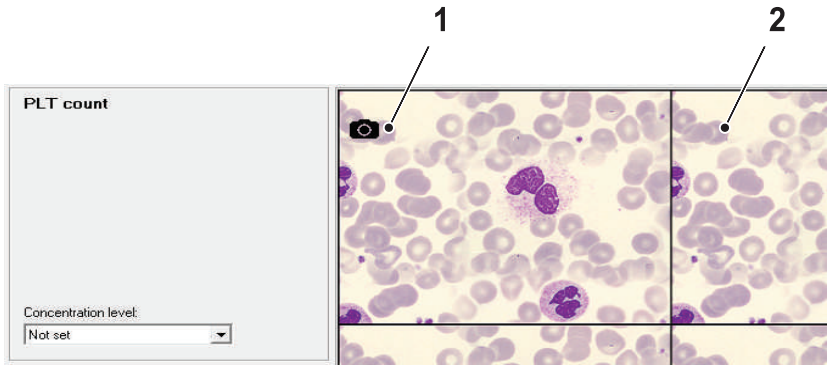


1. Entry field

1. Use the entry fields to view all parts of the overview image.
2. Select **Concentration level**.

Images captured on a CellaVision® Image Capture System:

The PLT concentration level can be estimated by setting it to four levels: **Significantly decreased**, **Decreased**, **Normal,** or **Increased** directly from viewing the image.



1. The image has been manually captured on a CellaVision® Image Capture System
2. Square

Select **Concentration level**.

> **Important!**
>
> The area covered by each square may vary between different CellaVision® Image Capture Systems.

Excluding the platelet analysis

Click **Exclude PLT Analysis** to exclude PLT analysis results from the slide.

4.1.5 Comments

For each slide, you can add comments to the WBC, RBC and PLT results. For WBC analyses, you can also add comments to cell classes and individual cells.

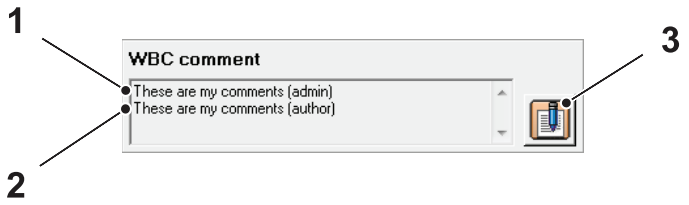
WBC, RBC and PLT comments are added in the **Verification** view in each tab respectively.

Cell class and cell comments are added in the **WBC tab** in **Verification** view.

Note:
All comments, except comments on individual cells, are printed in the report.

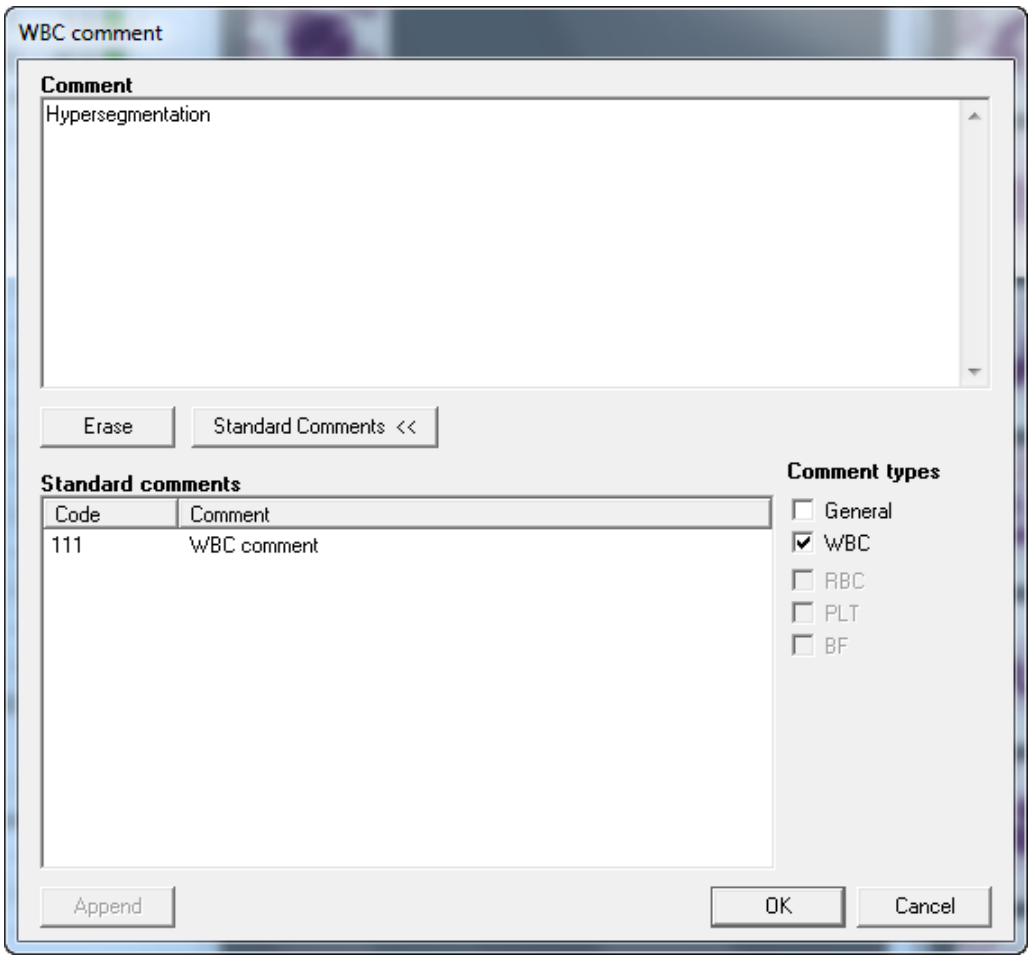
Adding comments

The system records the author of each comment, except for comments to cell classes and individual cells. If another operator logs in, each comment is tagged with the name of the operator who wrote it. An operator can view all comments but can only edit his/her own.



1. Comment added by operator "admin".
2. Comment added by operator "author".
3. Add WBC comments.

Click **Comments** to add comments to WBC, RBC and PLT.



You may write and edit comments in the **Comment** box. Click **Standard Comments** to show or hide standard comments. Double-click on a standard comment to add it to the **Comment** box. You may also select a standard comment and click **Append**.

You may activate the Comment types you want to display. Standard comments of type WBC, RBC or PLT will only be available in the respective tab. Standard comments can be added and edited in **Settings,** see 9.6 Standard comment settings.

To clear comments, click **Erase**.

4.1.6 Pathology review

You can mark any slide for pathology review. This will allow a pathologist to easily find and review the slide. When you mark a slide for pathology review, you can also write a comment to the pathologist. The pathologist can then reply to your comment, after performing the review.

Both signed and unsigned slides can be marked for pathology review.

Comments from the pathology review will not be sent to the LIS.

The pathology review function might be disabled by your service technician.

To mark a slide for pathology review

1. Open the slide you want to mark for pathology review.
2. Click the **Pathology review** button  .
3. In the **Pathology review** dialog box, in the lower text box, type a comment describing what you want the pathologist to look for, and then click **OK**.

   The system will add your user name to your comment.
4. Close the slide.

   In the **Database** view, the slide is now marked with a P in the **Comment** column.

To review slides marked for pathology review

In the **Database** view, slides marked for pathology review have a P in the **Comment** column.

1. In the **Database** view, in the **Search criteria** list, click **View marked for pathology review** and then click **Search**.

   You can also click the header in the **Comment** column, to place slides marked for pathology review at the top of the list.
2. Open a slide marked for pathology review.
3. You will receive a message including the comment from the user who marked the slide for pathology review.
4. Review the slide.
5. Click the **Pathology review** button  .
6. In the **Pathology review** dialog box, in the upper text box, you can read all previous pathology review comments for this slide.
7. In the lower text box, type a reply based on your review.

   The system will add your user name to your comment.
8. Select the **Pathology review completed** check box and click **OK**.
9. Close the slide.

   In the **Database** view, the slide is now marked with a P.

To see the comments from the pathologist

When the pathologist has reviewed the slide, it will be marked with a P in the **Database** view.

1. Open the slide.
2. You will receive a message including the comment from the pathologist and the original comment from the user who marked the slide for pathology review.

3. If you want the pathologist to review the slide again, click to clear the **Pathology review completed** check box, and then, in the lower text box, type a comment describing what you want the pathologist to look for.
4. Click **OK**.

4.1.7 Order data

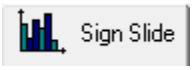
To edit order data, click **Order data** in the toolbar.

The **Order data** dialog can also be accessed by right-clicking on an order in the database view.

The Order ID can only be edited if it starts with “ER”.

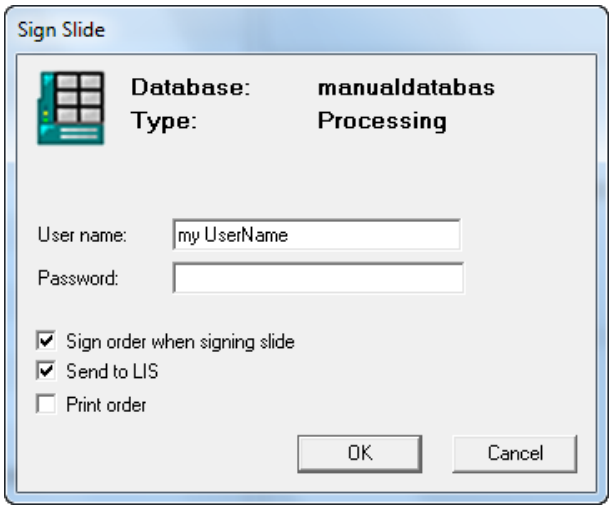
4.1.8 Signing a slide

A summary of the ordered analyses is presented in the **Sign Slide** tab.



The signing procedure is as follows:

1. Click **Sign**. The **Sign Slide** dialog appears.



2. Enter **User name** and **Password**.
3. If the slide is the only slide in the order, select the **Sign the order when signing slide** check box.
4. If you want to send the results to the LIS after signing the slide, select the **Send to LIS** check box.
5. If you want to print the results, select the **Print order** check box.
6. Click **OK**.

Note:
If the slide is part of a multi-slide order, all slides in the order must be signed before the operator is given the option to sign the order.

Note:
Slide data cannot be changed after signing. Comments may still be added.

If all ordered analyses have been viewed when the **Sign Slide** tab is selected, the **Sign Slide** dialog will automatically appear.

When the last slide is signed in a multi-slide order, the operator has the option to sign the order.

You can change the default settings for the check boxes in the **Sign Slide** dialog. For more information on how to do this, see 9.5 Order signing settings.

White blood cells, red blood cells and platelets

Before signing a slide, all ordered analyses must have been viewed by the operator. The following conditions must be fulfilled:

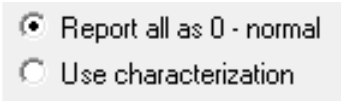
WBC:

- All cell classes must have been viewed, i.e. there should be tick marks after each cell class.
- No WBCs may remain in **Unidentified**.

RBC:

An RBC characterization must be reported or excluded from the analysis:

- Report a characterization, by selecting one of the following options:



or:

- Click **Exclude RBC Analysis**.

PLT:

A PLT concentration must be reported or excluded from the analysis:

- Report a PLT concentration as described in 4.1.4 Estimating platelets.

or:

- Click **Exclude PLT Analysis**.

4.2 Body fluids

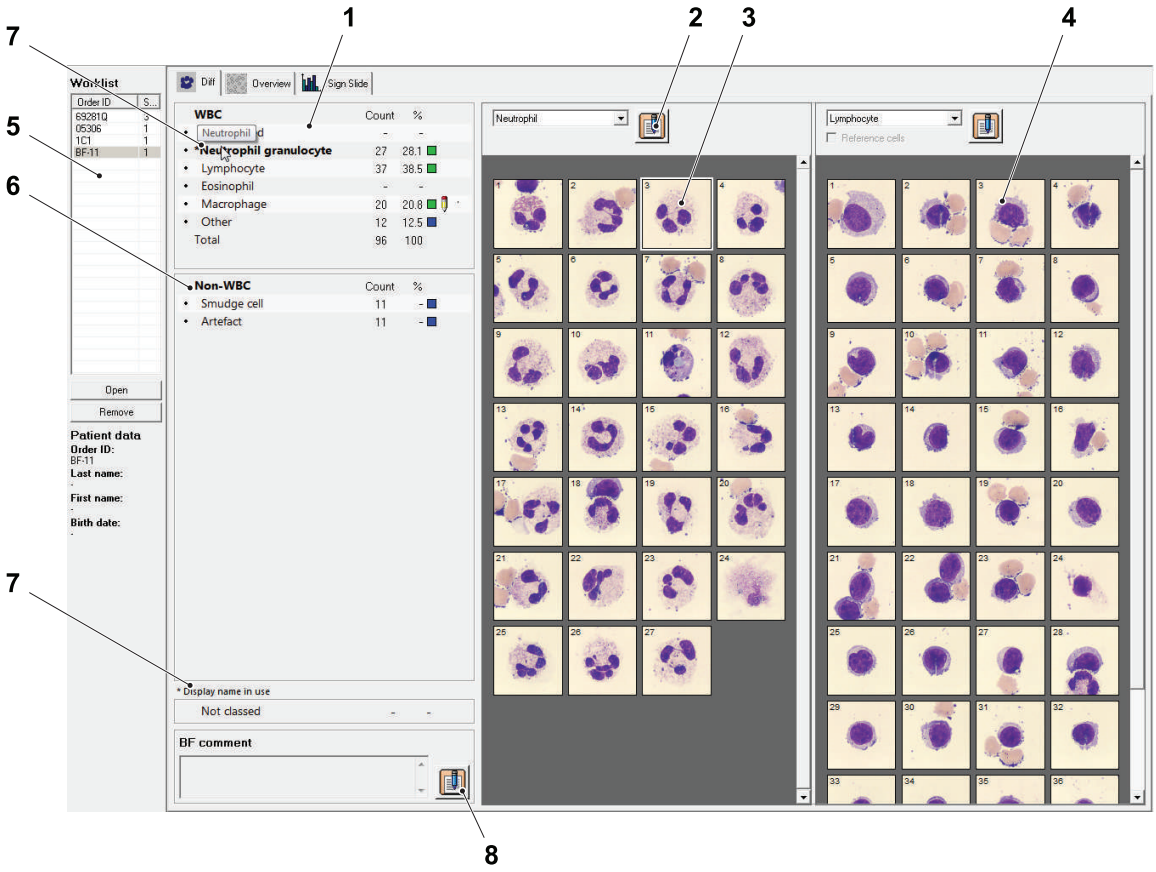
Opening an unsigned slide leads directly to the **Verification** view, where the tabs for **Overview**, **WBC** and **Sign Slide** are shown. To open a slide, see 6.1.3 Opening an order or a slide.

 Click **Verification view** in the toolbar.

Note:
With DMConfiguration tool it is possible to add user defined WBC cell classes, add user defined Non-WBC classes and to change the cell class names to custom display names. To do this contact your service technician.

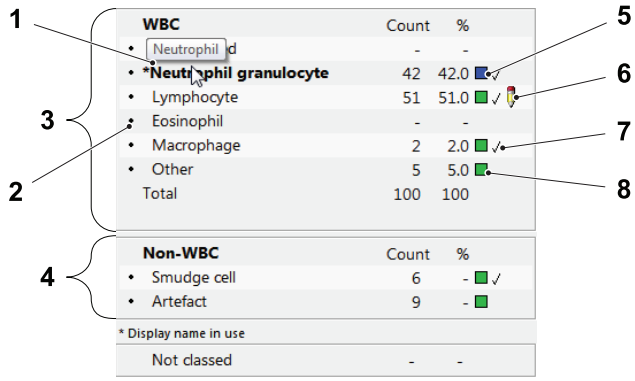
4.2.1 Body fluids differential

You can view and reclassify all cells identified by the system.



1. WBC panel
2. Add cell class comment
3. Main gallery
4. 2nd gallery
5. Worklist
6. Non-WBCs panel
7. Display names in use (original name in tooltip)
8. Add BF comment

All cell classes handled by the system are displayed in the figure below. WBCs and non-WBCs automatically preclassified by the system are marked with a small dot.



1. Display name in use (original name in tooltip)
2. Preclassified by the system
3. WBC panel
4. Non-WBC panel
5. Blue - Contains at least one reclassified cell or object
6. Pen icon - Indicates Cell class comments
7. Tick mark - All images have been viewed
8. Green - Contains no reclassified cells or objects

Customizing views

To Customize views, see Customizing views under 4.1.1 White blood cell classification.

Reclassifying cells

To reclassify cells, see Reclassifying white blood cells under 4.1.1 White blood cell classification.

E-mail

To email cell images, see E-mail under 4.1.1 White blood cell classification.

Copying images to disk

To copy cell images, see 6.1.8 Save cell images to disk.

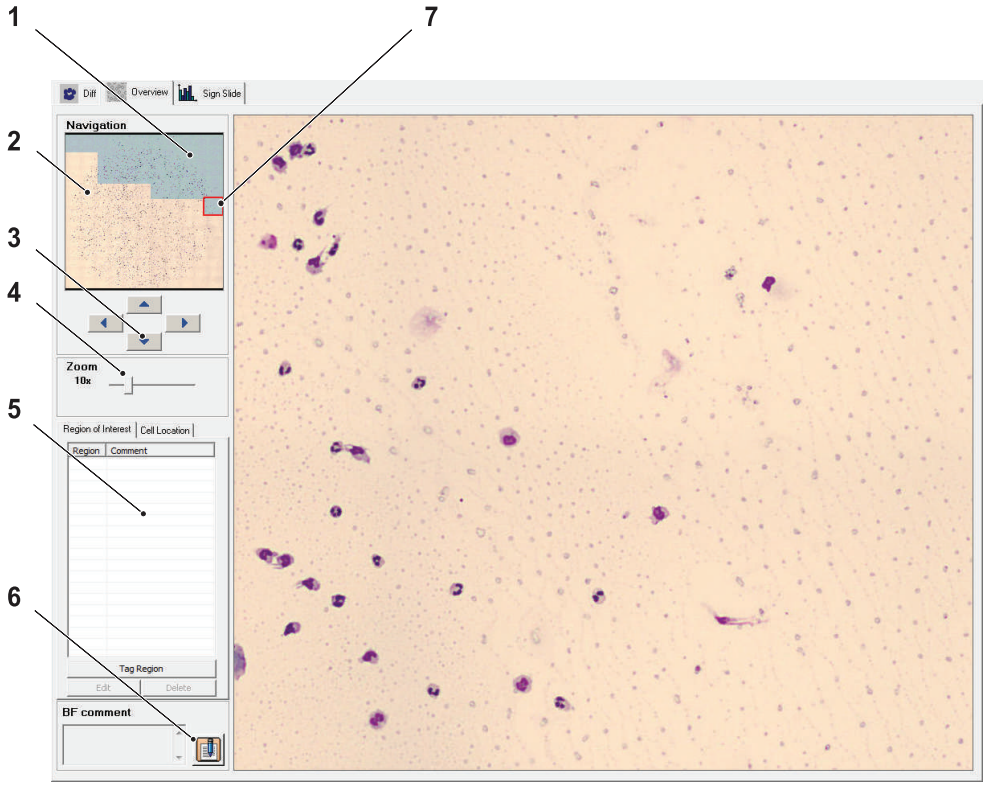
4.2.2 Body fluids overview image

The body fluid overview image displays the entire sample area.

See 9.3.6 BF analysis settings for more information.

The overview image can be used to find cells of interest and for getting an overall impression of the sample. The overview image can either have one 10x zoom level or both 10x and 50x zoom levels. Using both zoom levels will increase the processing time.

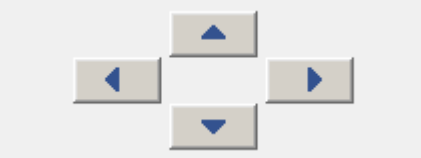
See 9.3.1 Default processing settings for more information.



1. Trace
2. Mini map
3. Navigation buttons
4. Zoom panel
5. Region of interest panel
6. Add BF comment
7. Current position

Navigating in the overview image

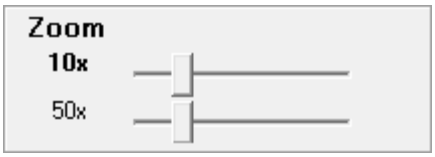
Navigate in the overview image by using the keyboard arrow buttons or the navigation buttons.



The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the **Mini map**. Click on the **Mini map** to enlarge another part of the sample. A blue trace in the **Mini map** indicates which parts of the overview image that have been viewed by the operator

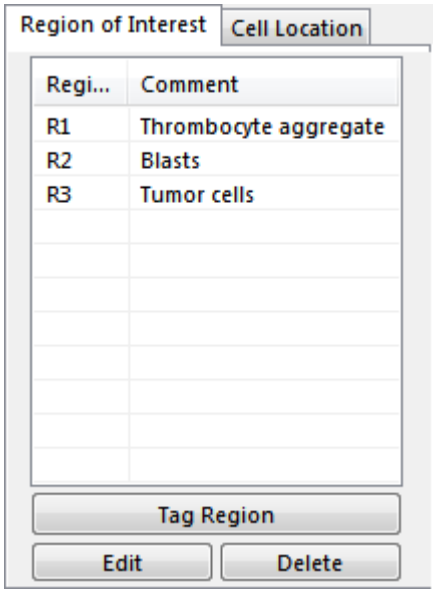
Hold left mouse button down and scroll in any direction using the mouse.

Switch between the two zoom levels by right-clicking in the overview image. Adjust the zoom level by dragging the sliders in the **Zoom** panel.

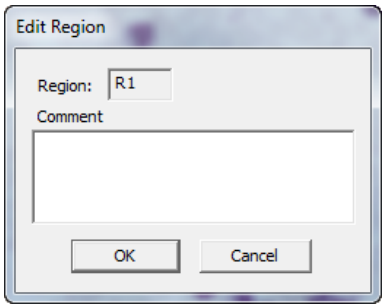


Tagging regions of interest

The image shown in the right part of the screen can be saved as a region of interest for later reference.



1. To save the current image, click **Tag region**.
2. Add a comment as an identifier for the region of interest and click **OK**.



Save regions of interest to disk

You can save a region of interest as an image to, for example, your local hard drive or a USB flash drive.

The region of interest will be saved as a JPEG image file that you can then print, use in presentations, or edit using third-party applications.

1. In the **Overview** view, in the **Region of interest** list, right-click the region of interest that you want to save, and then click **Copy the image to disc**.
2. In the **Copy image to disk** dialog box, in the **Destination path** text box, enter the location where you want to save the image. You can click the **Browse** button (...) to browse for a location.
3. Click **OK**.

4.2.3 Comments

Comments can be added to the Overview, the differential result, each cell class and all individual cells.

Note:
All comments, except comments on individual cells, are printed in the report.

Adding comments

To add a comment, click **Comment**. For more details, see 7.2.5 Adding comments.

 Comments

4.2.4 Pathology review

For information on how to mark a slide for pathology review, see 4.1.6 Pathology review.

4.2.5 Order data

To view or edit the order data, see 4.1.7 Order data.

4.2.6 Signing a slide

The Body Fluid differential is presented in the **Sign slide** tab. To sign a slide, see 4.1.8 Signing a slide.

5 Reporting results

For detailed information on settings, see 9.4 Report settings.

Click **Report** view in the toolbar.

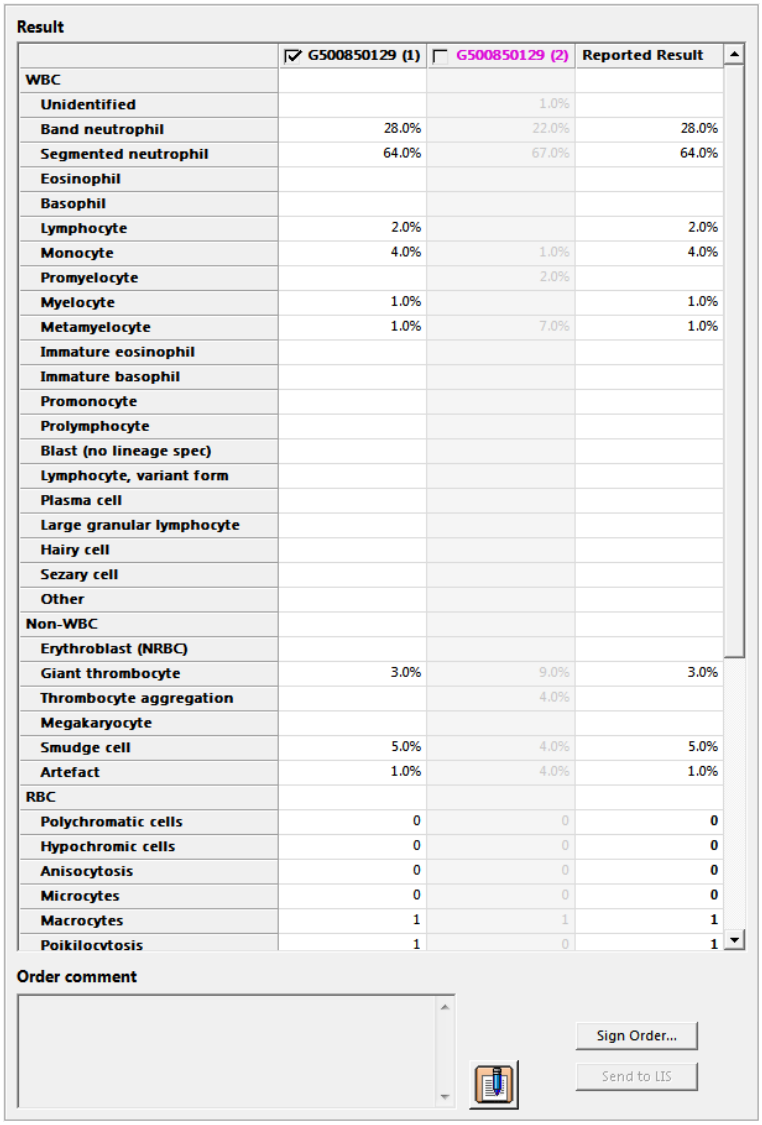
Compare slide results and exclude slides from the reported result in the **Report** view. You can also:

- Sign or cancel an order
- Send order data to the LIS
- Write a general comment on the order
- Preview the report by clicking on the Report Preview tab.

5.1 Merging slides

Compile analysis results for the whole order based on one or several slides in the **Slide merge** tab. You can also view all comments associated with an order.

Result panel



Here you see the results of each slide in the order. In the **Reported Result** column you see the summarized results. An unsigned slide has a slide ID written together with slide number in cerise color.

Including and excluding slides in the reported result

Signed slides are automatically included in the reported result. To include or exclude a slide, select or clear the check box next to the Slide ID.

When excluding slides, a dialog is shown where you may write a comment explaining the exclusion.

You can't sign an order if it contains more than one slide and at least one of the slides has a confirm cell counter result flag. Exclude all but one slide or exclude all slides that has a confirm cell counter result flag.

Note:
Only signed slides can be included.

Changing the reported result

It is possible to change the RBC results and the PLT concentration for the order, if reported as a level. Changeable results are written in bold text.

1. Click on the result to change.
2. Change the value in the dialog.
3. Click **OK**.

Note:
If you include or exclude a slide, all manually changed values will be replaced by new, automatically calculated values.

Comment panel

View all comments associated with the order in the **Comment** panel. All comments will be included in the report. Note that only the beginning of the comment is shown. To view the whole comment, click on it.

It is not possible to edit comments in this panel.


Comment

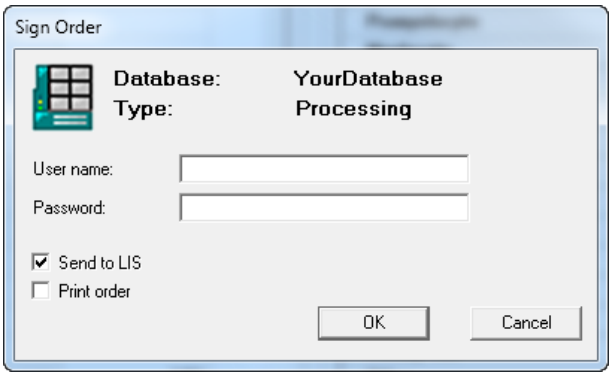
	MT Order 100 (1)	MT Order 100 (2)
Exclusion comment		
WBC comment		
WBC cell class comments		
Unidentified		
Band neutrophil		
Segmented neutrophil		
Eosinophil		
Basophil		
Lymphocyte		
Monocyte		
Promyelocyte		
Myelocyte		
Metamyelocyte		
Immature eosinophil		
Immature basophil		
Promonocyte		
Prolymphocyte		
Blast (no lineage spec)		
Lymphocyte, variant form		
Plasma cell	Comment to this cellclass	
Large granular lymphocyte		
Hairy cell		
Sezary cell		
Other		
Non-WBC cell class comments		
Erythroblast (NRBC)		
Giant thrombocyte		
Thrombocyte aggregation		
Megakaryocyte		
Smudge cell		
Artefact		

5.2 Report preview

Click on the tab **Report preview** to preview the report. The report's format is template based and can be selected in the settings. See 9.4 Report settings for more details.

5.3 Signing an order (result)

1. Click **Sign order**.



2. If not prefilled, type **User name** and **Password**.
3. Select whether the order should be sent to the LIS or printed or both.
4. Click **OK**.

5.4 Sending an order to the LIS

If the LIS is activated in the **Analysis** tab in **Settings**, it is possible to send signed order results to the LIS.

1. Open a signed order.
2. Select the **Slide Merge** tab in the **Report** view.
3. Click **Send to LIS**.

5.5 Canceling an order

Sign the order with no included slides to cancel it.

1. Open the order in the **Database** view.
2. Select the **Slide Merge** tab in the **Report** view.
3. Make sure no slides are included.
4. Click **Sign order**. The **Sign order** dialog appears.
5. Sign the order as described in 5.3 Signing an order (result).

Note:
When the order is sent to the LIS the order will be reported as canceled.

6 Database

Click **Database** view in the toolbar.

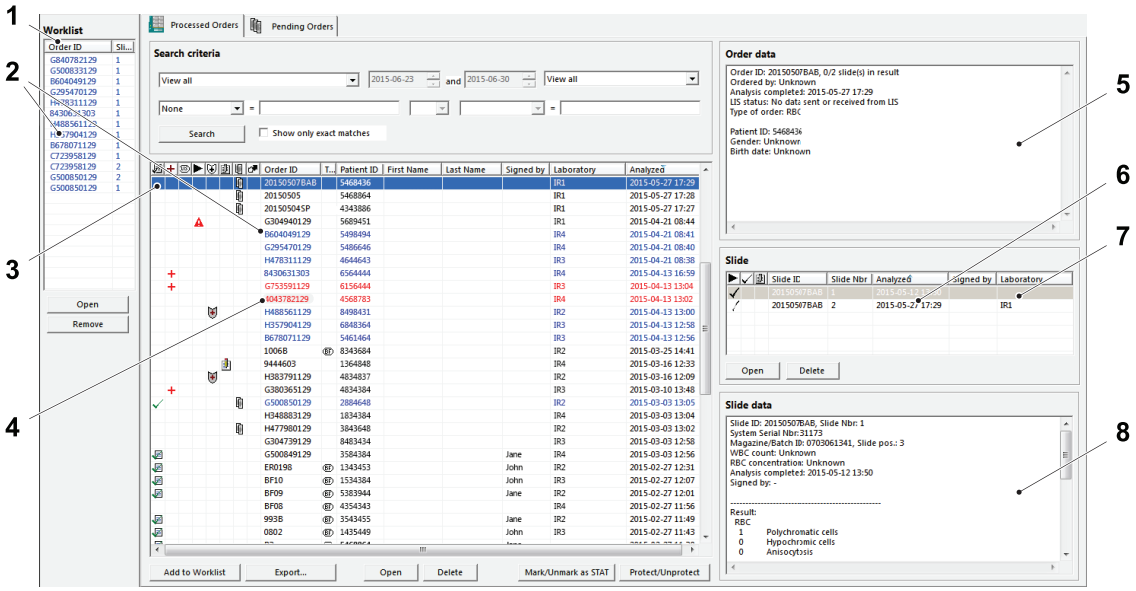
Processed and pending orders are stored in the database. Switch between the two using the tabs **Processed orders** and **Pending orders**.

6.1 Processed orders

You can search for and open processed orders and slides stored in the system. Orders are displayed according to the **Search criteria**. For more information on search criteria, see 6.1.5 Searching for an order or a slide.

In the **Processed orders** tab and **Worklist** the text colors indicate:

- Blue: order or slide that you have opened or added to your worklist.
- Red: order that is locked by another user.
- Highlighted in blue or grey: order or slide that is selected.

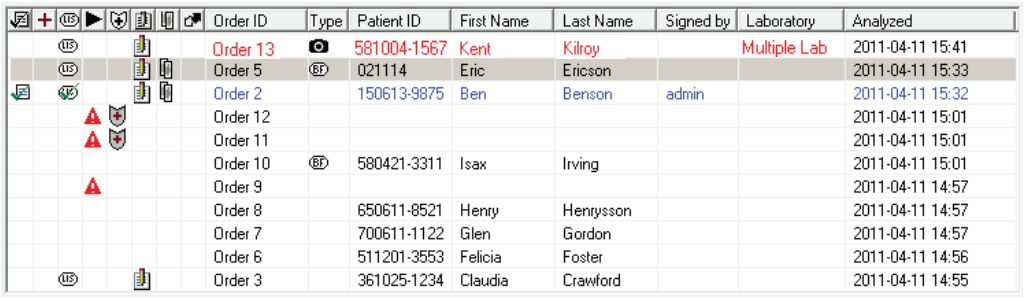


1. Worklist
2. Order or slide that you have added to your worklist (written in blue text)
3. Selected order (marked blue or grey)
4. Order locked by another user (written in red text)
5. Data for selected order
6. Slides in selected order
7. Selected slide (marked blue or grey)
8. Data for selected slide

An order or slide opened by another operator is written in red text. In the **Order data** and **Slide data** panels, **Locked by** indicates who has opened the order or slide (the person logged on to Windows) and on which computer.

6.1.1 Order list

The **Order list** displays an overview of the orders. Click on the column headers to sort the list. The date and time in the column **Analyzed** corresponds to the processing date for the last processed slide in an order.



Order ID	Type	Patient ID	First Name	Last Name	Signed by	Laboratory	Analyzed
Order 13		581004-1567	Kent	Kilroy		Multiple Lab	2011-04-11 15:41
Order 5	BF	021114	Eric	Ericson			2011-04-11 15:33
Order 2		150613-9875	Ben	Benson	admin		2011-04-11 15:32
Order 12							2011-04-11 15:01
Order 11							2011-04-11 15:01
Order 10	BF	580421-3311	Isax	Irving			2011-04-11 15:01
Order 9							2011-04-11 14:57
Order 8		650611-8521	Henry	Henrysson			2011-04-11 14:57
Order 7		700611-1122	Glen	Gordon			2011-04-11 14:57
Order 6		511201-3553	Felicia	Foster			2011-04-11 14:56
Order 3		361025-1234	Claudia	Crawford			2011-04-11 14:55

Order status

Empty field	No slide is signed.
✓	At least one slide is signed.
	Order is signed.
	Order is canceled.

STAT mark +

Empty field	Not a STAT order.
+	Order is marked as a STAT order.

LIS status	
Empty field	No data sent or received
	Data received
	Waiting to send result
	Result is sent
	Failed to send result
	Result is successfully sent

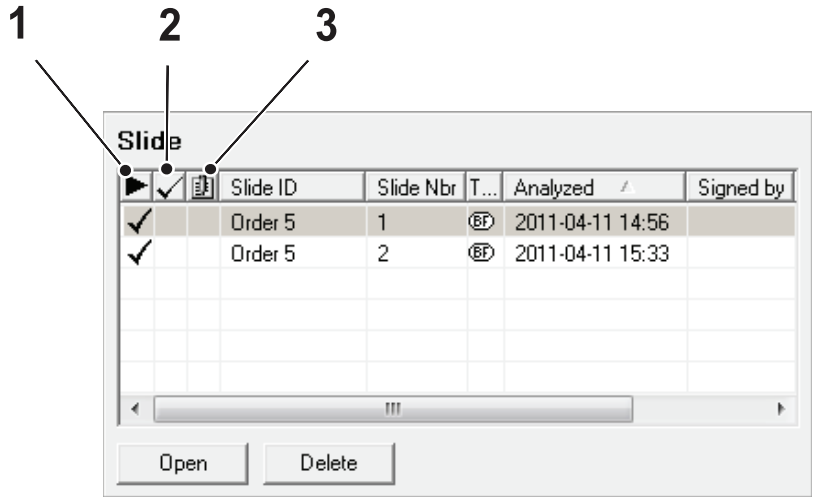
Process status	▶
Empty field	All slides in the order have been processed successfully.
	The system has failed to process at least one of the slides in the order.
	The operator has stopped the processing of at least one of the slides in the order.
	All slides in the order have been processed but at least one of the slides has been processed with a warning.

Archive status	
Empty field	Order is unprotected.
	Order is protected. Order and slides in this order cannot be deleted or archived.
	Order is archived.
	All images except **Region of interest** images have been deleted (only applicable for scan databases).

Comments	
Empty field	No comments.
	Comments exist.
P	At least one slide in the order is marked for pathology review.
	Pathology review has been completed.
Multi-slide status	
Empty field	One slide in order.
	More than one slide in order.
C	The order contains a cell counter confirmed result.
Transfer Tool status	
Empty field	Not marked for Transfer Tool.
	Marked for Transfer Tool.
Order type	
Empty field	Peripheral blood order.
	CellaVision® Image Capture System order.
	Body fluid order.

6.1.2 Slide list

Comments, slide- and process status are indicated in the slide list.



1. Process status
2. Slide status
3. Comments

Process status ▶

✓	The slide has been processed successfully.
STOP	The operator has stopped the processing of the slide. No results exist.
⚠	The required numbers of WBCs were not found, one of the ordered analyses failed, or the order was not found in the LIS, so the slide has been processed with the default values.
⊗	The system has failed to process the slide. No results exist.

Slide status ✓

Empty field	Not signed.
✓	Signed.

Comments

Empty field	No comments.
	Comments exist.
P	Slide is marked for pathology review.
P✓	Pathology review has been completed.

6.1.3 Opening an order or a slide

Opening an order automatically opens a slide belonging to it. In the same manner, opening a slide automatically opens the order it belongs to. The currently opened order and slide are always shown in the toolbar.

1. Order status
2. Slide status

Double-click on an order in the **Order list**, and the first unsigned slide of that order opens. You can also click an order and then click **Open**. In the **Slide** list you can open specific slides in the same way.

You may close the order and slide using the **Close order/slide** button in the toolbar:

 Close order and slide

6.1.4 Protecting an order

You can protect orders to prevent slides from being auto-deleted or archived.

1. To select the orders that you want to protect, do one of the following:
   - To select a consecutive group of orders, click the first order, press and hold down the Shift key, and then click the last order.
   - To select non-consecutive orders, press and hold down the Ctrl key, and then click each order that you want to select.
2. Click **Protect/Unprotect**, or right-click and then click **Protect/Unprotect**.

6.1.5 Searching for an order or a slide

You can use the search function to find orders in the database. In the **Search criteria** list, click:

- **View all** to see all orders in the database.
- **View unsigned** to see orders that have not yet been signed.
- **View marked for pathology review** to see orders that have been marked for pathology review.
- **View latest** to see orders that are less than one week old.
- **View between** to see orders processed within a specified interval of time. Use the date boxes to specify the time interval.
- **View BF** to see body fluid slides.
- **View CellaVision Image Capture System** to see slides captured with the CellaVision Image Capture System.

You can also refine your search by, for example, patient data, order data, and comments. You can also specify a laboratory in the drop-down list to the right.

When you have entered all relevant search criteria, click **Search** to show the orders in the order list.

6.1.6 Deleting an order or a slide

A selected order or slide can be deleted by pressing Delete. Select multiple orders or slides using Ctrl or Shift. When all slides in an order have been deleted, the order is automatically deleted.

A signed slide can't be deleted from a multi-slide order, unless you delete the entire order.

Note:
You need to be logged on as a user with access level Administrator to delete signed orders. Deleting an order deletes all slides in the order, signed or not.

6.1.7 Exporting orders

You can export signed orders to an export database.

When you export signed orders, you can choose to not include any patient identifying data. You can also, once you have exported the orders, change the order ID in the export database.

You can only export signed orders, from a processing database or from another export database. You can't export orders from a scan database.

For information on how to create an export database, see 9.1 Database settings.

The auto-delete and archiving functions don't remove orders from export databases. If the system is set up to automatically delete or archive orders, the export databases will not be affected.

To export orders to an export database

1. In the **Database** view, on the **Processed orders** tab, select the orders you want to export.
2. Click **Export**.
3. In the **Export selected orders** windows, in the **Database list**, select the database you want to export the orders to.
4. To automatically delete the orders from the processing database after they are exported, select the **Delete orders after export** check box.
5. To export the orders without any patient identifying data, select the **Don't export patient identification information** check box.
6. To export the orders without any images, select the **Don't export images** check box.
7. Click **Export**.

To change the order ID on exported orders

1. On the **File** menu, click **Log off**, and then click **Yes**.
2. Log on to the export database.
3. In the **Database** view, under **Processed orders**, right-click the order you want to change, and then click **Edit order data**.
4. In the **Order ID** text box, type the new order ID.
5. Click **OK**.

6.1.8 Save cell images to disk

You can save cell images from any order to, for example, your local hard drive or a USB flash drive. Choose to either save all images from one order or to select and save a few WBC images from a specific class.

Each WBC image and any overview image will be saved as a JPEG image file that you can then print, use in presentations, or edit using third-party applications.

No patient data will be included with the images.

To save all images from an order to disk

1. In the **Database** view, right-click the order and click **Copy images to disk**.
2. In the **Copy images to disk** dialog box, in the **Destination path** text box, enter the location where you want to save the images. You can click the **Browse** button (...) to browse for a location.
3. If you want to save all WBC images, select **WBC images**.
4. If you want to save the RBC and PLT overview image and any mini map images, select **Overview images**.
5. Click **OK**.

To save a selection of WBC images to disc

1. Open the slide that contains the WBC images that you want to save.
2. In the **WBC panel**, click the cell class that contains the images you want to save.
3. To select the cell images that you want to save, do one of the following:
   - To select a consecutive group of cells, click the first cell, press and hold down the Shift key, and then click the last cell.
   - To select non-consecutive cells, press and hold down the Ctrl key, and then click each cell that you want to select.
4. Right-click one of the selected cells and click **Copy images to disk**.
5. In the **Copy images to disk** dialog box, in the **Destination path** text box, enter the path to where you want to save the images. You can click the **Browse** button (...) to browse for a location.
6. Click **OK**.

6.1.9 Printing orders

Print order data and data for all slides belonging to it by selecting the order or slide of choice in the **Database** view and then **Print** in the **File** menu.

Note:
Order results exist only if the order contains at least one signed slide.

6.1.10 Worklist

You can simplify and speed up your workflow by adding slides that you want to review, to your **Worklist**. When you sign a slide, it will be removed from your worklist and the next available slide in the worklist will open automatically. Slides that you add to your worklist will also open faster, because they will be loaded in the background while you work.

When you add slides to your worklist, these slides will be locked for other users. This means that other users can't sign slides that you have added to your worklist, unless you remove the slides from your worklist or exit the CellaVision DM Software.

You can set up the system to automatically add peripheral blood slides to your worklist as soon as they are processed, see 9.3.7 Worklist setting (body fluid slides can't be automatically added to the worklist).

Slides that are automatically added to the worklist are not locked for other users and will not be loaded from the database, until you open them.

The worklist is available in the **Database** view and in the **Verification** view.

All slides will be removed from the worklist when you exit the CellaVision DM Software.

To manually add slides to the worklist

1. In the **Processed orders** tab, do one of the following:
   - To select a consecutive group of orders, click the first order, press and hold down the Shift key, and then click the last order.
   - To select non-consecutive orders, press and hold down the Ctrl key, and then click each order that you want to select.
2. Click **Add to worklist**.

   All slides from each order will be added to the worklist.

To remove slides from the worklist

1. In the **Worklist**, do one of the following:
   - To select a consecutive group of orders, click the first order, press and hold down the Shift key, and then click the last order.
   - To select non-consecutive orders, press and hold down the Ctrl key, and then click each order that you want to select.
2. Click **Remove**.

To manually open a slide from the worklist

- In the **Worklist**, click the slide you want to open and then click **Open**.

  You can also double-click the slide.

To hide or show the worklist

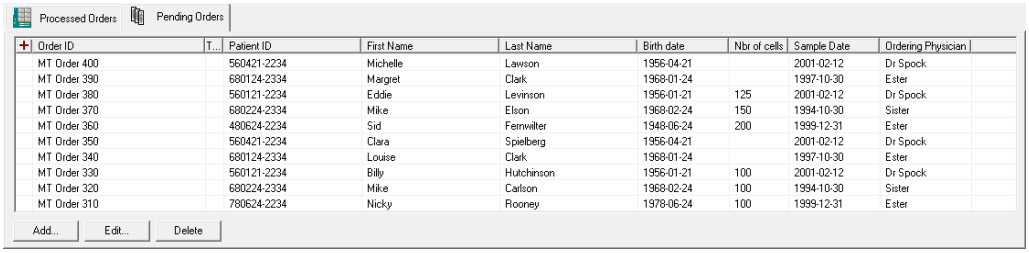
- On the **View** menu, point to **Status bar** and then click **Worklist**.

  You can also press Ctrl+W.

6.2 Pending orders

The tab **Pending Orders** contains a list of all pending orders. A pending order is an order that has been manually added to the database, but not yet processed. This is useful when you do not have a connection to the LIS.

When an order has been processed it will be removed from the **Pending Orders** list and added to the **Processed Orders** list.



STAT mark	+
Empty field	Not a STAT order.
+	Order is marked as a STAT order.
Order type	
Empty field	Peripheral blood order.
BF	Body fluid order.

Click **Add** to add a new pending order.

Double-click on a pending order, or click **Edit**, to view or edit the order data.

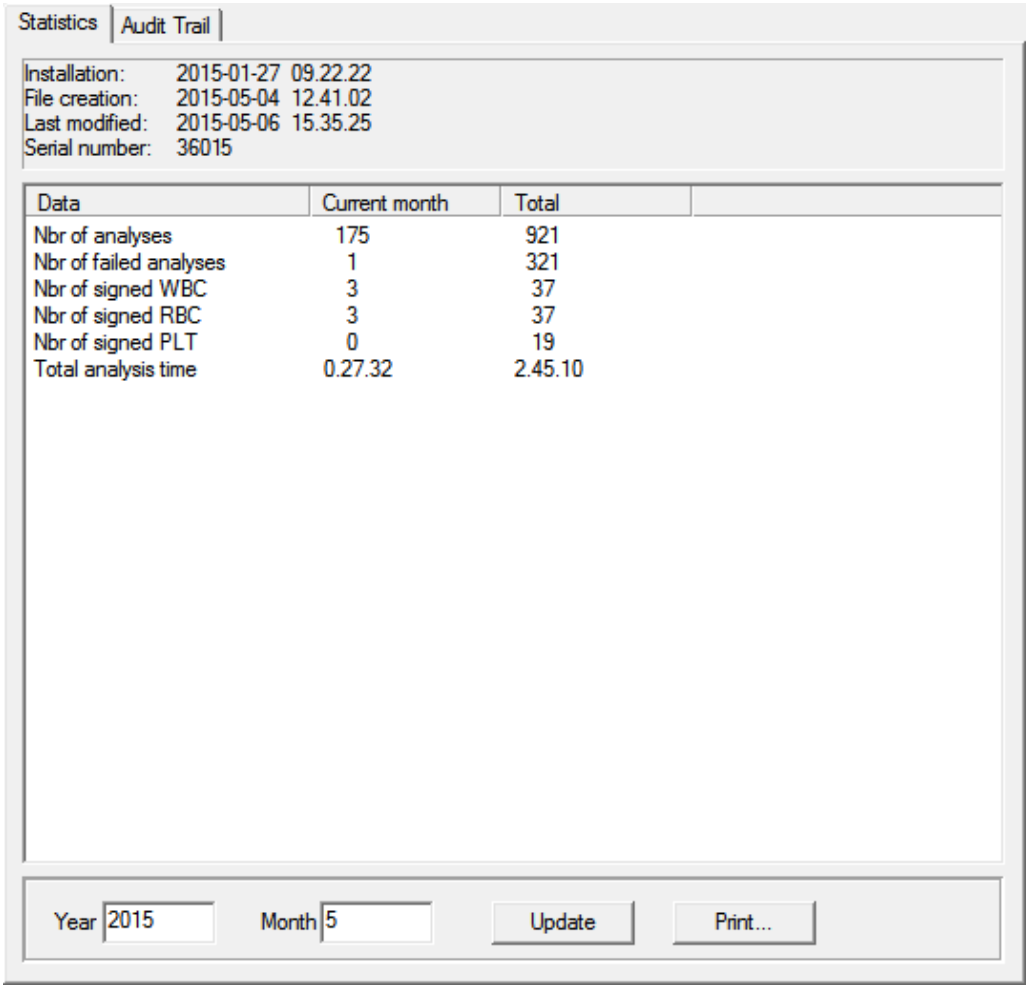
The order ID and Patient ID may be up to 24 characters (ASCII) including spaces. No leading spaces are allowed. The Order ID must not begin with:

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

6.3 Usage log

The system continuously saves data of processed slides and stores it in a **Usage log**. To view the log select **Tools** and **View log**.

6.3.1 Statistics



The **Statistics** page contains dates and times of program installation and creation and modification of the Usage log. It also displays the number of successfully processed and failed slides, the number of signed analyses and the total processing time.

6.3.2 Specification

The **Specification** page is only accessible to users with access level administrator. It contains a list of dates and times for events that have occurred in the system, e.g. start and completion of slide processing and hardware malfunctions.

6.3.3 Audit trail

The **Audit Trail** page contains a list of dates and times for which users have logged on to or off from the system, deleted a slide, and marked a slide for pathology review or marked the pathology review as finished.

6.4 Export log files

It is possible to export all logging information from the system, including the images and results from cell location tests. If a system error occurs, this information is needed for troubleshooting.

You can either burn the log files to a CD or save them to a folder.

To export log files to a CD

1. Make sure that the system is idle (that is, the system status is **Idle** or **Error**).

   If the system is not idle, the log file for the control unit (CCU) might be incomplete.
2. On the **Tools** menu, click **Export log files**.
3. Put a recordable CD in the drive.
4. Click **Export to CD** and then click **Export/Burn**.

To export log files to a folder

1. Make sure that the system is idle (that is, the system status is **Idle** or **Error**).

   If the system is not idle, the log file for the control unit (CCU) might be incomplete.
2. On the **Tools** menu, click **Export log files**.
3. Click **Export to LAN**.
4. To compress all log files into a single .zip-file, select the **Compress files before export** check box.
5. In the text box, enter the location where you want the exported log files to be stored. You can also click the browse button (**…**) and browse for a location.
6. Click **Export/Burn**.

6.5 Backup and recovery of the database

It is important to back up the database often. If a hard disk crash occurs, the whole database will be lost. It will only be possible to recover the data up to the time when the last backup was made. For more information, see CellaVision® IT Configuration Guidelines or contact your local vendor.

7 Digital slides

> **Important!**
>
> The digitized image generated provides a general overview of the prepared sample within the intended use of the applications. All other use is for research use only and not for use in diagnostic procedures.

7.1 Scanning a slide

Make sure that a scan database is available on your system. To create a scan database, see 9.1 Database settings.

Log on to a scan database, see 2.1 Starting the system.

To change the default scan area and magnification, see 9.10 Digital slides settings.

7.1.1 Slide requirements

Use slides as specified in A.3.3 Slides and either orange or blue CellaVision slide magazines.

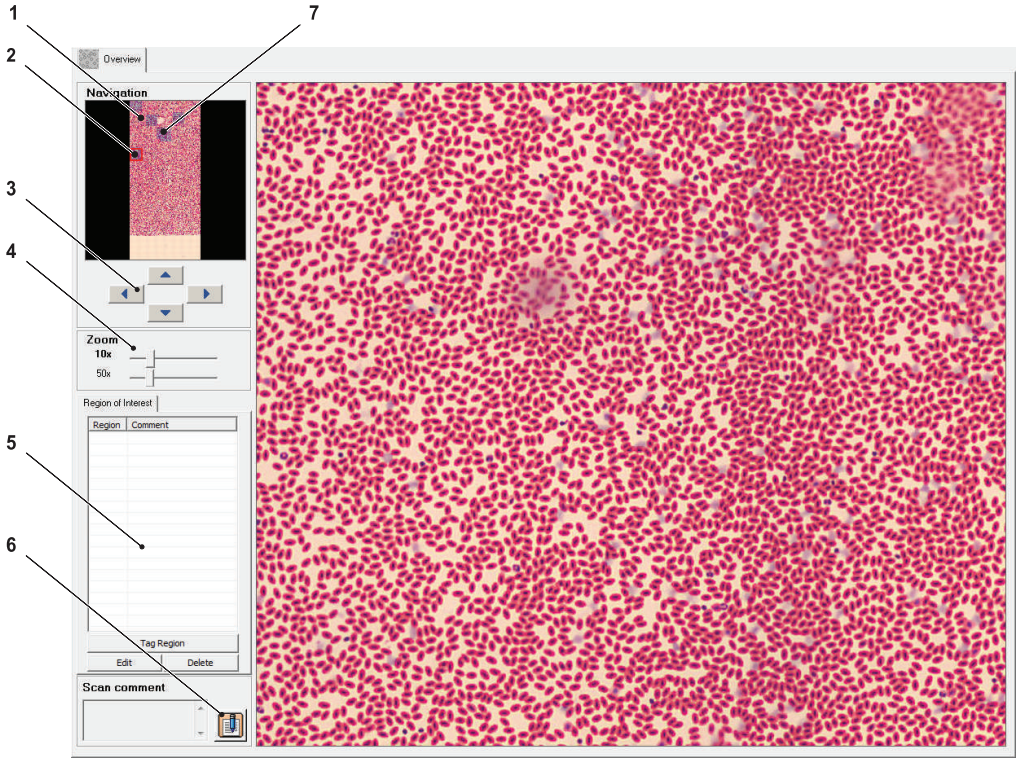
You can use cover slips, as long as the total thickness of the slide and the cover slip is within the requirements. If you use cover slips, make sure the scan area is within the cover slip area.

7.2 Scan overview image

Opening a scanned slide leads directly to the **Scan verification view.** To open a slide, see 6.1.3 Opening an order or a slide.

7.2.1 Overview

The **Mini map** shown in the **Overview** displays the entire sample area. To enlarge a specific area of the sample, click in the **Mini map**. The magnified area will be displayed in the large image on the screen. On the **Mini map**, a red rectangle marks the area requested for enlargement. A blue trace marks an already viewed area.

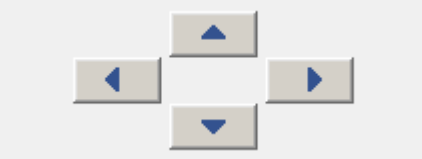


1. Mini map
2. Current position
3. Navigation buttons
4. Zoom panel
5. Region of interest panel
6. Add scan comment
7. Trace

The enlarged area can either have a 10x zoom or a combined 10x and 50x zoom. Using both zoom levels will increase the processing time.

7.2.2 Navigating

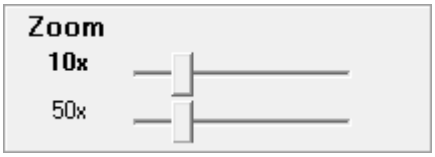
Move in the **Mini map** by using the keyboard arrows or the **Navigation buttons**.



The image shown in the right part of the screen is an enlargement of the area inside the red rectangle shown in the **Mini map**. Click on the **Mini map** to enlarge another part of the sample. A blue trace in the **Mini map** indicates which parts of the overview image that have been viewed by the operator.

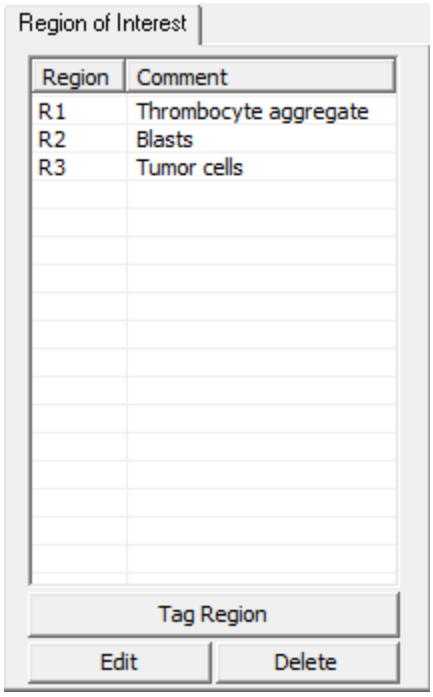
Hold left mouse button down and scroll in any direction using the mouse.

Switch between 10x and 50x zoom levels by right-clicking in the enlarged image. Adjust the zoom level by dragging the sliders in the **Zoom** panel.

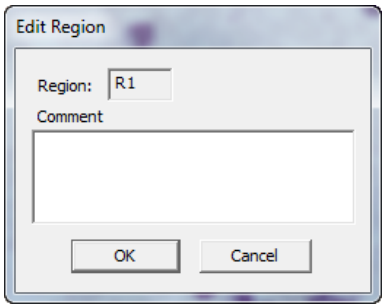


7.2.3 Tagging regions of interest

To save an enlarged area as a region of interest for later reference, click **Tag region**.



Identify your region of interest by adding a comment.



7.2.4 Copying regions of interest to disk

You can copy a region of interest to disk.

1. Select a tagged region of interest in the list.
2. Right-click and select **Copy the image to disk**.
3. Specify the destination path where you want the image to be saved.
4. Click **OK**.

7.2.5 Adding comments

To add a comment to the overview, click **Scan comment**.

Scan comment

7.2.6 Order data

To view information about the order, e.g. scanned area and comments, click **Order data** in the toolbar. The **Order data** dialog can also be accessed by right-clicking on an order in the database view.

To view or edit order data, click **Order data** in the toolbar.

7.3 Database view

To view processed and pending orders, click **Database** view.

Database view

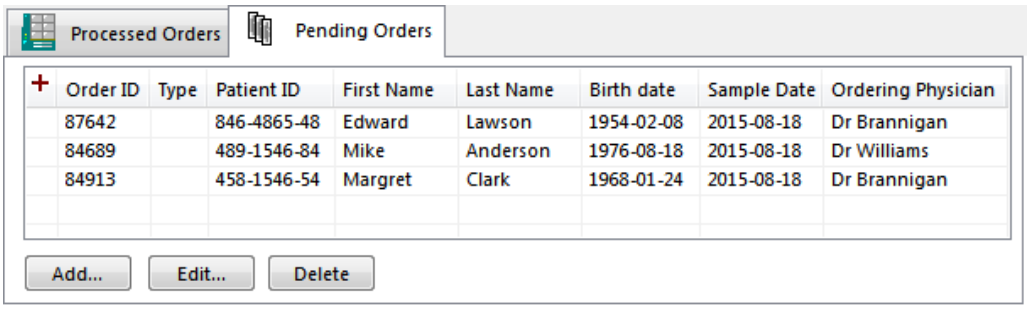
7.3.1 Processed orders

Scanned slides are automatically signed. For more details about processed orders, see 6.1 Processed orders.

7.3.2 Pending orders

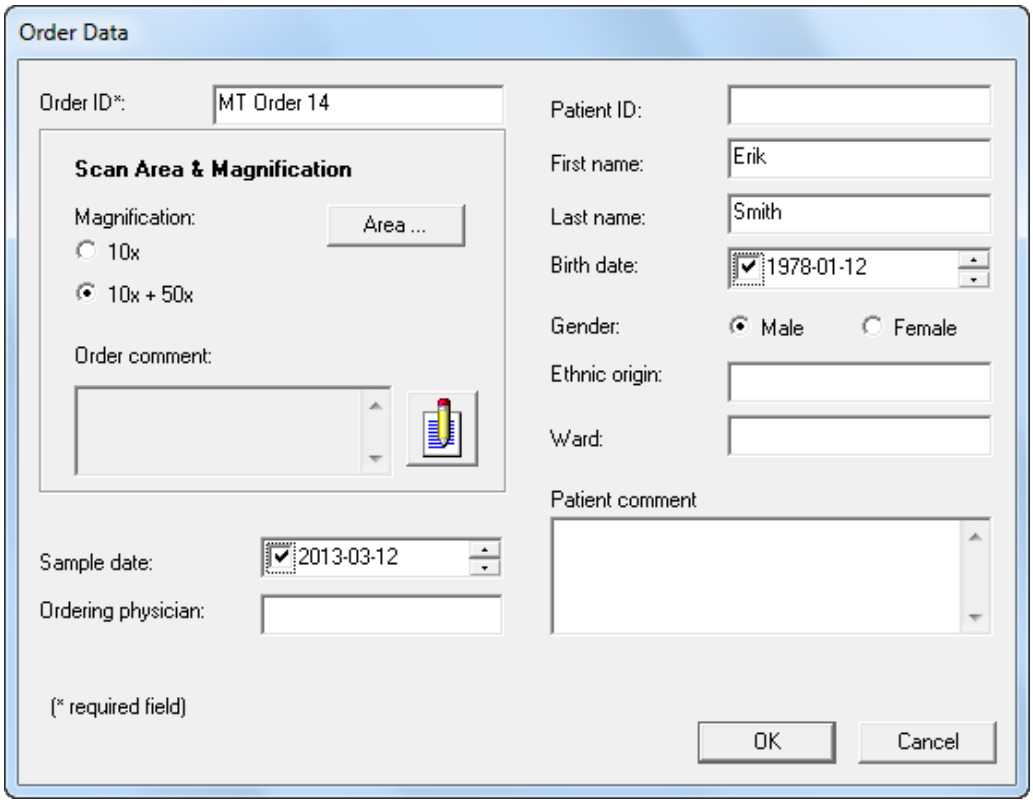
The tab **Pending Orders** contains a list of all pending orders. A pending order is an order that has been manually added to the database, but not yet processed. Pending orders are useful when defining scan area for individual slides.

When an order has been processed it will be removed from the **Pending Orders** list and added to the **Processed Orders** list.



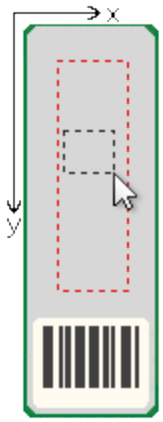
To add an order, click **Add**.

To view or edit order data, double-click on an order or click **Edit**.



To define the scan area for the slide, click **Area**, then do one of the following:

- Enter values in the text boxes to specify the scan area.
- Use the mouse to drag a rectangle on the slide. The rectangle must be within the red dotted rectangle on the slide.



You can use the mouse to drag a rectangle for the area you want to scan.

If you do not define a scan area, the default scan area will be used. For information on how to change the default scan area, see 9.10 Digital slides settings.

8 System information

In the toolbar, click **Help** and then **System Information** for information about your system.

The information presented depends on your system and installed software. Some of the following information is present in the **System Information** dialog:

- Serial number of your system.
- The type of Artificial Neural Network (ANN) used.
- The computer name.
- The computer's IP address.
- Free disk space.
- Free physical and virtual memory.
- Total physical and virtual memory.
- The size of the database.
- The CCU firmware version.
- Licensed software.
- License expiry date.

9 Customizing the system

> **Important!**
>
> Most settings that you can change in the CellaVision DM Software will affect all systems and review stations using the same database.

These settings will affect all systems and review stations using the same database:

- Database settings
- Archiving settings
- User account settings
- Analysis settings, except BF analysis area
- Report settings
- Order signing settings
- Standard comment settings
- Reference cells settings
- LIS settings
- Digital slides settings

Depending on your access level, you might not have access to all settings. For information on what access level you need to change certain settings, see Appendix E User access levels.

Some settings might also be disabled by your service technician.

9.1 Database settings

The system uses a database to store all images and order data.

It is recommended that you always keep a backup of the database. If you use the archiving function, described later in this section, you will not be able to access the orders in the archive if the database is lost.

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

These database types are available:

- *Processing database.* A database for processing slides.
- *Scan database.* A database for creating digital slides.
- *Export database.* A database that is used when you want to export orders from another database. This type can't be used for processing slides.

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

Note:
Having many databases on a system will reduce the system performance.

9.1.1 Manage databases

You can create a database on the system computer or connect to a database on a server (running the CellaVision Server Software) or on another system.

To view a list of databases and connections to databases

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

  The symbols in the list have these meanings:

  - Database on the system computer
  - Connection to a database on a server or on a different system computer

To create a new database

Note:
When you create a new database, the new database will inherit certain settings from the database you are currently logged on to. Log on to the new database and make sure that all settings are correct, before you start processing slides.

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** box, type a name for the new database.
4. In the **Description** text box, you can type 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 the browse button (**…**) and browse for a location.

   Note:
   You can only create a database 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** box, type the name of the remote database.
4. In the **Description** text box, you can type a descriptive text for the remote database.
5. In the **Remote computer** box, type the name of the computer where the remote database is located.

   If you do not know the name of the remote computer, open the CellaVision DM Software on that computer and then, on the **Help** menu, click **System information**.
6. Click **OK**.

Note:

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 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**.

9.1.2 Manage database size

> **Important!**
>
> Make sure that there is always free disk space available on the partition where the database is stored. If that partition becomes full, it will no longer be possible to use the system.

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

This section explains how you can set up the system to automatically remove images from the database. You can choose to:

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

You should also manually remove failed and old unsigned orders from the database, at regular intervals.

The factors to consider when you set up the system to automatically remove images from the database are:

- The number of slides that are processed (and added to the database) each day.
- The maximum capacity for the database, that is:
  - 200 GB (approximately 40 000 peripheral blood slides) for a database located on a server running CellaVision Server Software.
  - 20 GB (approximately 4 000 peripheral blood slides) for a database located on the system computer.
- The time the laboratory requires signed orders to be saved.

For example, if you process 200 peripheral blood slides per day, it will take 20 days to reach the maximum capacity of 4 000 slides. You should then set up the system to auto-delete signed orders after 20 days.

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

When an order is archived, the images belonging to that order are moved from the database to an archive. The archive is typically stored on a server. You will still be able to open and view slides that have been archived.

Note:
The archiving function is not a back up function.

It is recommended that you always keep a backup of the database. You will not be able to access orders in the archive if the database is lost.

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

You can protect individual orders from being auto-deleted or archived. For more information, see 6.1.4 Protecting an order

You can also manually export orders from the database. For more information, see 6.1.7 Exporting orders.

If you at any time exceed the maximum capacity for the database, you need to compress the database. For more information on compressing a database, see 9.1.3 Database compression.

To see the size of the database

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

To set up the system 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)** box, enter the number of days to keep signed orders in the database before they are deleted.
3. Click **Delete the orders** and then click **Close**.

To set up the system 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 the number of days to keep the images of signed orders in the database before they are moved to the archive.
3. Click **Archive those orders**.
4. In the **Archive location** text box, enter a path to the disk or server where you want to store the archived images.

   This path must be accessible from the system computer or server where the database is located.
5. Under **Images to archive**, choose what images and how many images 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). This table explains which cell classes belong to each category:

PB cell images

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

BF cell images

WBCs	Non-WBCs
Neutrophils	Artefacts
Lymphocytes	Smudge cell
Eosinophils	User defined Non-WBCs
Macrophages	
User defined WBCs	
Other	

To set up the system 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 the **Automatically delete orders that are older than** check box and then, in the text box, enter the number of days to keep digital slides in the database.
3. If you want to keep regions of interest, select the **For orders containing regions of interest, keep the order data and the regions of interest** check box.

   The order data and the regions of interest will be kept in the database, but the overview image from that slide will be deleted.

9.1.3 Database compression

> **Important!**
>
> Make sure that no users are logged on to the database you want to compress. This includes users logged on via CellaVision DM Software on other DM systems, via CellaVision Remote Review Software, and via the CellaVision Server Software.

When images are removed from the database (manually, by auto-delete, or by archiving), the database will still allocate 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.

While a database is being compressed, no clients can use or connect to that database. For this reason, you can't compress the database that you logged on to when you started the CellaVision DM Software. Any users still connected to the database when you start the compression will receive an error message.

To compress a database

1. Make sure that no users are logged on to the database you want to compress.
2. Start the CellaVision DM Software.
3. Log on to another database (*not* the database you want to compress) as a user 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 click **Compress**.
6. In the **Compress database** dialog, check that the value for **Avaliable on harddisk** is at least the same as **Original size**.

   If the value for **Avaliable 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. A database larger than 10 GB may take several hours to compress.

9.2 User account settings

> **Important!**
>
> The user account settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can create user accounts with different access levels, for everyone who needs access to the system. If you need to, you can at any time change the access level, full name, password and email address for existing users. But you can't change a users user name.

If there is a user account that is not being used, you can deactivate or remove that user account.

User accounts are valid for the database on which they were 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. Click **New**.
3. In the **User information** dialog box, in the **User** box, type a unique user name for the new user.
4. In the **Full name** box, type the name of the new user.
5. In the **Password** and the **Password again** box, type a password for the new user.
6. In the **Email** box, type the new user's e-mail address.
7. In the **Access level** list, select the level of authorization you want to give the new user.
8. Make sure that the **Account active** check box is selected.
9. Click **OK**.

User names and passwords must consist only of the characters A–Z, a–z, and 0–9. Passwords and user names may start either with letters or numbers. The following words must not be used as user names: *create, get, grant, if, in, is, local, of, on, or, out, select, set, sys, sysadm, system, table, to, update,* and *user.*

There are six levels of user authorization:

- *Observer*. Only allowed to view images and results.
- *User*. Can verify WBC, RBC, and PLT results, but can't sign slides.
- *Authorized*. Can verify WBC, RBC, and PLT results and sign slides and orders.
- *Restricted*. Same as Authorized, but with restricted database access.

  For information on database access for the restricted user, see 9.2.1 Options for restricted users
- *Administrator*. Full access to the system.
- *Service*. Full access to the system, except no access to patient data or user settings.

For a full reference of user access levels, see Appendix E User access levels.

To change a user account

1. On the **Tools** menu, click **Settings** and then click the **Users** tab.
2. Click the user name in the list and click **Edit**.
3. In the **User information** dialog box, do 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. Click to clear the check box next to user account that you want to deactivate.

   You can at any time activate the user account, by selecting the check box.

To remove a user account

1. On the **Tools** menu, click **Settings** and then click the **Users** tab.
2. Click the user name in the list and click **Delete**.

9.2.1 Options for restricted users

> **Important!**
>
> The options for restricted users apply to all systems that use the same database. This means that your changes may affect other systems.

Users with access level **restricted** (restricted users) can verify results and sign slides and orders (same as **authorized**). But they do not have full access to the database.

In the database view, you can allow restricted users to search for slides by patient ID, order ID, or both. Restricted users can't search for slides by any other criteria, such as patient name or ordering physician.

Restricted users can view signed slides. You can also allow restricted users to view unsigned slides.

For a full reference of what restricted users are allowed to do, see Appendix E User access levels.

To change search options for restricted users

1. On the **Tools** menu, click **Settings** and then click the **Users** tab.
2. Under **Options for Restricted users**, choose what you want the restricted user to be able to do.
   - If you want restricted users to be able to find, open, and view unsigned slides, select the **Allow Restricted users to view unsigned slides** check box.
   - Select if you want restricted users to be able to search for slides and orders by **Patient ID**, **Order ID**, or both.

9.3 Analysis settings

> **Important!**
>
> The analysis settings apply to all systems that use the same database. This means that your changes may affect other systems.
>
> The RBC analysis area settings will only apply to your CellaVision® DM9600 and won't affect other systems.

9.3.1 Default processing settings

> **Important!**
>
> The default processing settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can change how the system processes a slide if the order ID isn't in the database (in the **Pending orders** list) or in the LIS, by setting the default analysis values.

To set the default values

Note:
*These values are only used for 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. In the **Number of WBCs to count** box, type the number of WBCs you want the system to locate.
3. Under **Type of order** select the check boxes for the analyses you want to perform on the slide.

9.3.2 RBC precharacterization settings

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

For a system with the Advanced RBC application, you can also change what RBC morphology groups to use to characterize the morphology.

> **Important!**
>
> The RBC limits for the Advanced RBC Application aren't set at installation. You must set the RBC limits, as described later in this section, before you can perform RBC analysis.

To enable RBC precharacterization

1. On the **Tools** menu, click **Settings**.
2. Depending on your system configuration, do one of the following:
   - On a system with the Advanced RBC Application, click the **Advanced RBC** tab.
   - On a system with the standard RBC functionality, click the **RBC precharacterization** tab.
3. Select the **Enable RBC precharacterization** check box.

To change what RBC morphology groups to use for the Advanced RBC application

The Advanced RBC application can characterize and grade the RBC morphology by shape, color, size, and inclusions. The shape morphology group is always used, but you can choose whether to characterize and grade by color, size, and inclusions, or not.

This setting affects both the automatic and the manual grading. This means that if you make one of the morphology groups unavailable, you won't be able to manually grade by the morphology characteristics in that group.

1. On the **Tools** menu, click **Settings** and then click the **Advanced RBC** tab.
2. Select how you want to characterize and grade the RBC morphology by selecting one or more of the check boxes:
   - **Enable RBC color group** to characterize and grade the RBC morphology by color.
   - **Enable RBC size group** to characterize and grade the RBC morphology by size.
   - **Enable RBC inclusion group** to characterize and grade the RBC morphology by inclusions.

To change RBC grading and size limits

This procedure is valid for systems using the standard RBC functionality. For systems with the Advanced RBC Application, see To change grading, size, and anisocytosis limits for the Advanced RBC Application later in this section.

Important!

You have to set your own RBC limits according to your standards.

Important!

Changing the grading limits and the size limits will affect all systems using the database.

1. On the **Tools** menu, click **Settings** and then click the **RBC precharacterization** tab.
2. In the **Grading limits** area, enter grading limits (in percent) for grades 1, 2, and 3 for each of the RBC types.
3. In the **Size limits** area, enter the smallest and largest size (in micrometers) for a cell to be regarded as normal.

   Smaller cells will be regarded as microcytes and larger cells as macrocytes.

Poikilocytosis. Presence of abnormally shaped red blood cells.

Anisocytosis. Variation in size among red blood cells.

The default values are set according to O'Connor (1984).

To change grading, size, and anisocytosis limits for the Advanced RBC Application

Important!

You have to set your own RBC limits according to your standards.

Important!

Changing the grading limits and the size limits will affect all systems using the database.

1. On the **Tools** menu, click **Settings** and then click the **Advanced RBC** tab.
2. Click **RBC Limits**.
3. To set all limits to CellaVision default values, click **Set limits**.

   The default values are based on Gulati, Gene. 2009. *Blood Cell Morphology Grading Guide.* American Society for Clinical Pathology.
4. To manually set the limits, do the following:
   - In the **Grading limits** area, enter grading limits (in percent) for grades 1, 2, and 3 for each of the RBC types.
   - In the **Size limits** area, enter the smallest and largest size for a cell to be regarded as normal.

     Smaller cells will be regarded as microcytes and larger cells as macrocytes.
   - In the **Anisocytosis** area, enter limits for variation in cell area in percent.

Poikilocytosis. Presence of abnormally shaped red blood cells.

Anisocytosis. Variation in size among red blood cells.

The red blood cell distribution area width is a measure of the variation of red blood cell area that is reported as part of a standard complete blood count.

9.3.3 RBC analysis area settings for the Advanced RBC Application

On a system with the Advanced RBC Application, you can change the aspect ratio of the RBC analysis area so that the RBC overview image fits your monitor.

To change the aspect ratio of the RBC analysis area

1. On the **Tools** menu and click **Settings** and then click the **Advanced RBC** tab.
2. Under **Size of RBC analysis region**, select the aspect ratio that best matches your monitor:
   - **Normal** for 4:3 monitors.
   - **Wide** for 16:9 (wide screen) monitors.

9.3.4 Reclassification settings

> **Important!**
>
> The reclassification settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can set up the system to automatically forward cells of certain classes or types to other specific cell classes or types after the preclassification or precharachterization.

To set up the system to forward WBCs

1. On the **Tools** menu, click **Settings** and then click the **PB reclassification** tab.
2. Select the check boxes for the cell classes you want the system to automatically forward.

To set up the system to forward RBCs

This functionality is only available on systems with the Advanced RBC Application.

1. On the **Tools** menu, click **Settings** and then click the **PB reclassification** tab.
2. Select the check boxes for the cell types you want the system to automatically forward.

9.3.5 PLT settings

> **Important!**
>
> The PLT settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can change which of these two methods to calculate the PLT concentration you want to use:

- Count the platelets in each grid square of the PLT overview image and then enter either the number of platelets for each grid square or an estimated average number of platelets per grid square.
- Manually estimate the concentration of platelets and choose a concentration level (significantly decreased, decreased, normal, or increased).

If you decide to count platelets, you need to specify the intervals for when the PLT concentration is considered 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 tab, such as the number of grid squares and how the PLT concentration is calculated and reported.

> **Important!**
>
> You must determine and enter a PLT estimate factor before you can use the system to calculate PLT concentration. By default, the PLT estimate factor is set to 0.
>
> For information on how to set the PLT estimate factor, see To calculate and set the PLT estimate factor later in this section.

To set up the system for manual PLT concentration estimation

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 the **Use only manual PLT concentration estimation** check box and then click **Close**.

To change the intervals for the PLT concentration levels

1. On the **Tools** menu, click **Settings** and then click the **PLT** tab.
2. Under **Intervals for average PLTs/HPF value** enter the values for when the PLT concentration is to be considered significantly decreased, decreased, normal, and increased.

To change the default properties for the PLT view

These settings change the way the PLT view looks and functions. You can temporarily change any of these values from the PLT view, while performing the analysis.

1. On the **Tools** menu, click **Settings** and then click the **PLT** tab.
2. In the **Grid size** box, choose how many grid squares you want to divide the PLT image into.
3. In the **PLT count** box, choose if you want to count or approximate the number of PLTs.
   - **Count PLTs per grid square** will let you type the number of PLTs for each grid square as you view it.
   - **Approximate PLTs per grid square** will let you approximate the number of PLTs per grid square manually, and then type the average number of PLTs per grid square.
4. In the **PLT concentration** box, choose how you want to report the PLT concentration.
   - **Calculated estimate** will report the calculated number of PLT per litre, based on the counted or estimated number of PLTs per grid square.
   - **Calculated level** will report 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** will let you choose a level of PLT concentration (increased, normal, and so on) manually.

To calculate and set the PLT estimate factor

1. Use a cell counter to perform automated PLT counts on 30 consecutive blood samples.
2. Prepare and stain one smear for each sample.
3. Process the slides with the smears in the system.
4. Perform PLT analysis on the processed slides and let the system calculate the average PLTs/HPF values for each sample.
5. Calculate the conversion factor for each sample by dividing the PLT value from the cell counter by the average PLTs/HPF value from the system.
6. Calculate the *PLT estimate factor* (the average conversion factor), by adding the conversion factor for each sample and dividing by 30.
7. On the **Tools** menu, click **Settings** and then click the **PLT** tab.
8. In the **PLT estimate factor** box, type the calculated PLT estimate factor, and then click **Close**.

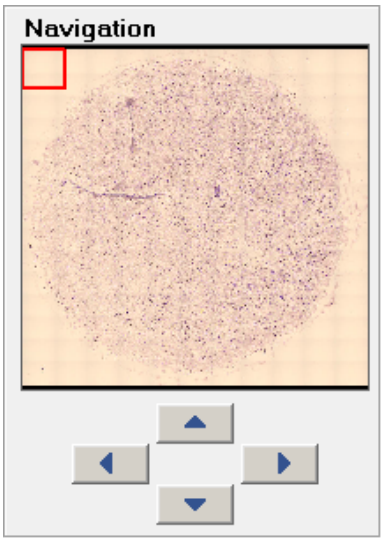
   By default, this is set to 0 (zero).

9.3.6 BF analysis settings

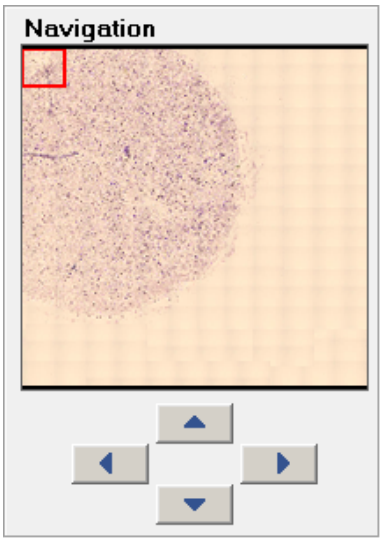
You need to set the position and the diameter of the BF analysis area to match the position of the sample spot on your BF slides, before you process BF slides for the first time, or if you change your method for preparing BF slides.

To set the position and diameter of the BF analysis area

1. In the **Tools** menu, click **Settings** and then click the **BF analysis area** tab.
2. Under **Centrifuge**, select the type of centrifuge you use to prepare BF slides, and then click **Close**.
3. Prepare and process a BF slide. Make sure that the sample spot is positioned in a way that is representative for your preparation method.
4. Open the processed slide, and then click the **Overview** tab.
5. In the **Navigation** frame, check that:
   - The sample spot is centered in the frame.
   - There is approximately 1 mm of empty space between the edges of the sample spot and the frame.

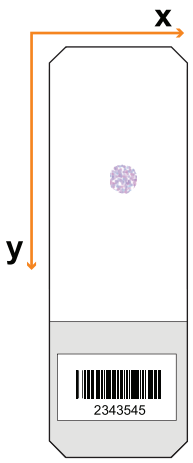


This sample spot is centered and is the right size.



This sample spot is not centered and is too small.

6. If the sample spot is not centered, do this to adjust the position of the BF analysis area:
   a) In the **Tools** menu, click **Settings** and then click the **BF analysis area** tab.
   b) Change the values in the **X offset** box and in the **Y offset** box to adjust the position of the BF analysis area.



Orientation of the X axis and Y axis on the slide.

7. If the empty space around the sample spot is too small or too large, do this to adjust the diameter of the BF analysis area:
   a) In the **Tools** menu, click **Settings** and then click the **BF analysis area** tab.
   b) Increase or decrease the value in the **Diameter**.

> **Caution!**
>
> Increasing the diameter of the BF analysis area will increase the processing time and will require more database space. For example, if you increase the diameter from 6 mm to 8 mm, each BF overview image will take up 78% more space in the database.

8. Click **Close** and then restart the CellaVision DM Software.

9. Delete the order with the BF slide from the database.

> **Important!**
>
> You must delete the order from the database before you process the slide again. If you don't delete the order, the settings from the previous processing will be used, which means that your changes to the BF analysis area won't apply.

10. If you made any changes to the BF analysis area, process the BF slide again and repeat this procedure from step 4.

9.3.7 Worklist setting

> **Important!**
>
> The worklist settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can set up the system to automatically add PB slides to the worklist for all logged on users, as soon as the slides are processed.

Note:
This feature is intended for setups with a single DM system and isn't recommended to use if you share a database between several systems.

BF slides can't be automatically added to the worklist.

To set up the system to add PB slides to the worklist

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

9.4 Report settings

> **Important!**
>
> The report settings apply to all systems that use the same database. This means that 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**.

9.5 Order signing settings

> **Important!**
>
> The order signing settings apply to all systems that use the same database. This means that 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.

9.6 Standard comment settings

> **Important!**
>
> The standard comment settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can create standard comments that you can add to any of the analyses (WBC, RBC, PLT, or BF). You need to assign a unique identifier (code) to each standard comment and you can choose if you want the system 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** box, type a unique code to identify the comment.
4. Under **Comment type**, click what type of analysis you want to use the comment for, or click **General** if you want to be able to use the comment for any analysis.
5. In the **Comment** text box, type the comment text.
6. Click **OK**.
7. Select the **Include code in comment** check box, if you want the code to be inserted before the comment text.
8. Select the **Always show expanded** check box, if you want to see the list of standard comments in the comments dialog box.

To change 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 change, and then click **Modify**.

To remove 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 remove, and then click **Delete**.

9.7 Reference cells settings

> **Important!**
>
> The reference cell settings apply to all systems that use the same database. This means that your changes may affect other systems.

You can add a cell as a custom WBC reference cell for PB or BF, in the WBC view while verifying a processed slide. For information on how to add custom reference cells from a processed slide, see Reclassifying white blood cells in section 4.1.1 White blood cell classification.

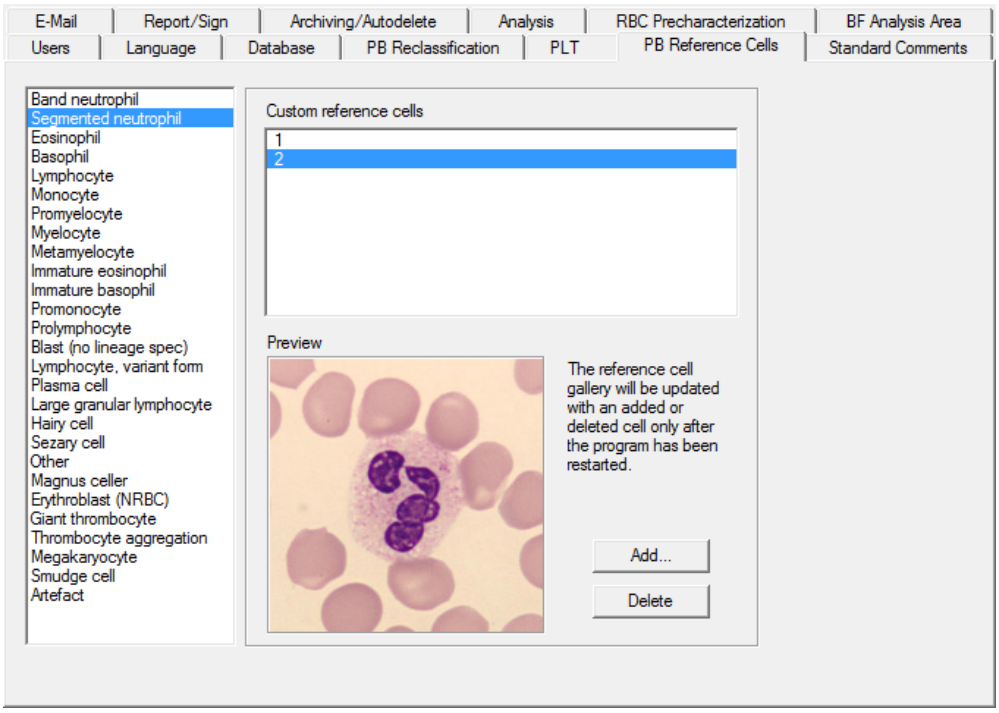
You can also add an image from your computer as a reference cell.

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 use 24-bit .bmp images or .jpg images.

5. The reference cell you added appears in the **Preview** frame.
6. If you want to add a comment to the reference cell, click **Comment**.
7. Click **Close** and then restart the CellaVision DM Software.



The PB Reference cells settings dialog box.

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. Click **Close** and then restart the CellaVision DM Software.

9.8 LIS settings

You can enable the system to interact with a laboratory information system (LIS). The system will then retrieve order data from the LIS and send results back to the LIS. Before you can enable the LIS functionality, the connection to the LIS needs to be set up by a service technician.

To enable LIS

1. On the **Tools** menu, click **Settings** and then click the **Analysis** tab.
2. Select the **Enable LIS** check box.
3. Click **Close** and then restart the CellaVision DM Software.

9.9 E-mail settings

You can set up the system to let you send WBCs via e-mail. The e-mail settings only apply to your CellaVision® DM9600 and will not affect other systems.

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, you can type an e-mail address to be pre-filled when you open the **New e-mail** dialog box. You can always change this address in the the **New e-mail** dialog box, before sending the e-mail.
3. In the **Mail server** text box, type the address to the mail server you want to use. If you do not know the address to the mail server, contact your local IT technician.
4. In the **E-mail from** text box, type the e-mail address that you want to appear as the sender of all e-mails from the system.

Note:
The E-mail setting will be the used for everyone who uses this CellaVision® DM9600, even by someone using a different user account or a different database.

9.10 Digital slides settings

> **Important!**
>
> The digital slides settings apply to all systems that use the same scan database. This means that your changes may affect other systems.

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

You can change the default scan area and magnification for new orders that you add to the database (in the **Pending orders** list). The system will also use these values 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 different magnification than the default.

To set the default magnification

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

9.11 Language settings

You can change the language for the CellaVision DM Software user interface and the language for the User's manual. You can choose from languages that were installed during the installation of the system.

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. If you can't find the language in the list, contact your service technician.
3. Click **Close** and then restart the CellaVision DM Software.

To change the language for the User's manual

1. On the **Tools** menu, click **Settings** and then click the **Language** tab.
2. Under **Language for the online manual**, choose a language from the list. If you can't find the language in the list, contact a service technician.
3. Click **Close** and then restart the CellaVision DM Software.

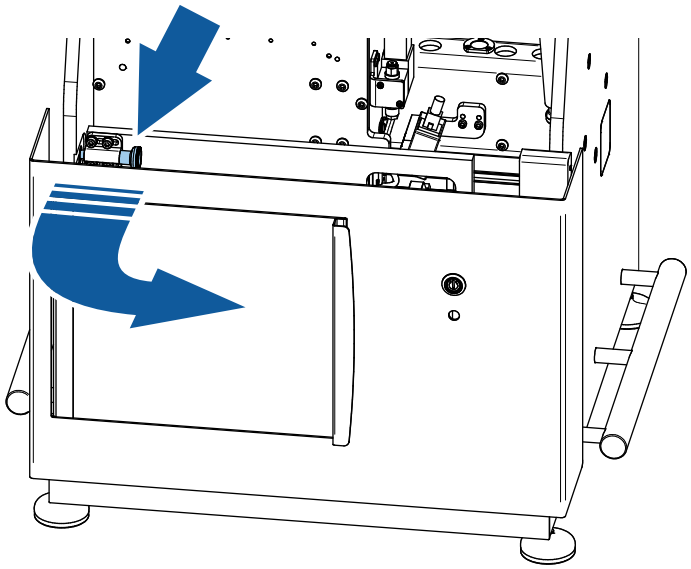
10 Maintenance

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

10.1 Weekly maintenance

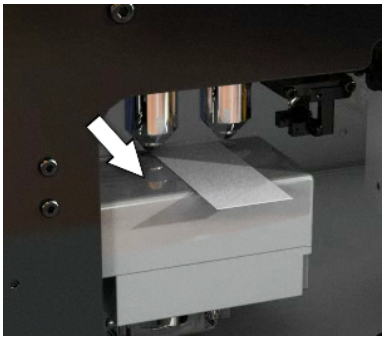
10.1.1 Clean objectives and LED table

1. Open the hood.
2. Pull out the stop pin and open the magazine feeder.



3. Gently wipe the LED table with a soft lint free cloth.

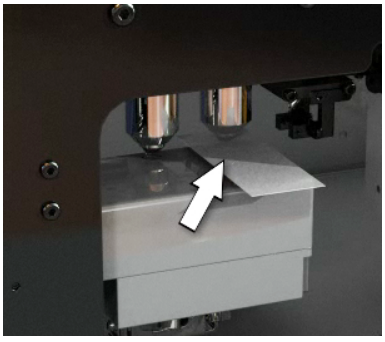
> **Caution!**
>
> Do *not* use any solvents when cleaning the LED table.



The LED table

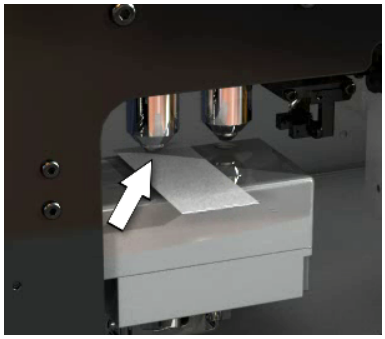
4. Use a new lens paper and gently wipe the lens of the dry 10x objective.
   If necessary, use isopropyl alcohol to clean lens of the dry 10x objective.
   Discard the lens paper after use.

> **Important!**
>
> Do not get immersion oil or any other contamination on the dry 10x objective. Oil or other contamination on the dry 10x objective have a negative effect on the image quality and can cause misleading results or errors in the slide processing.



The dry 10x objective

5. Use a new lens paper and gently wipe the lens of the 100x objective.
   If necessary, use isopropyl alcohol to clean lens of the 100x objective.
   Discard the lens paper after use.



The 100x objective

6. Process two slides and then immediately delete the two slides from the database. This will wet the lens of the 100x objective and help to prevent air bubbles between the lens and the immersion oil.

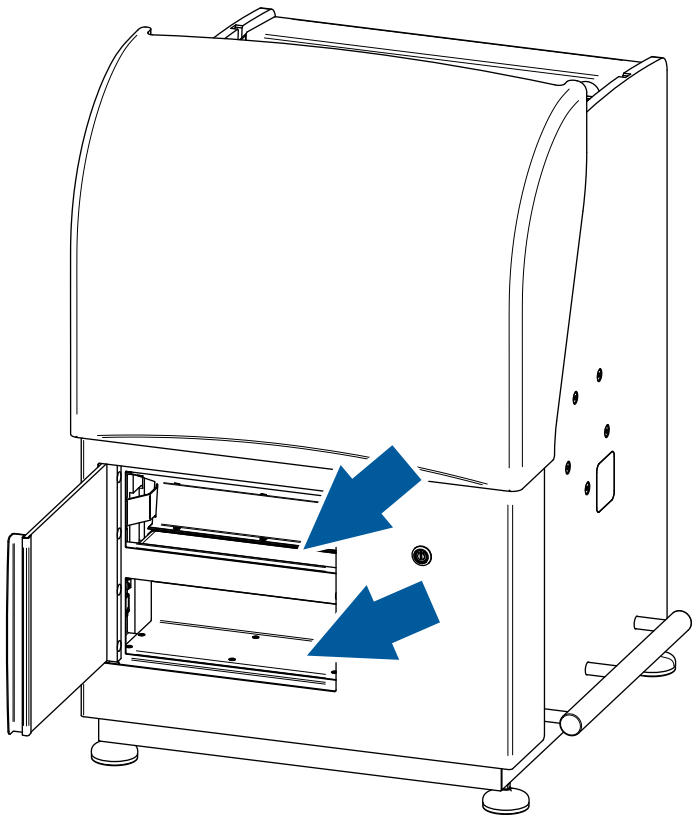
> **Important!**
>
> Make sure that you delete the two slides from the database. This will help prevent result mix-up and misleading results.

7. Run a cell location test, as described in 3.1 Cell location test for peripheral blood.

> **Important!**
>
> Make sure that the results of the cell location test is within your laboratory's established limits, before processing any slides for analysis.
>
> Cleaning the objectives can cause air bubbles or contaminants to appear on the lens. This will have a negative effect on the image quality and the cell location performance and can cause misleading results or errors in the slide processing.

10.1.2 Clean magazine feeder

1. Open the input hatch.
2. Wipe the infeed conveyor and the outfeed shelf with a moist cloth.



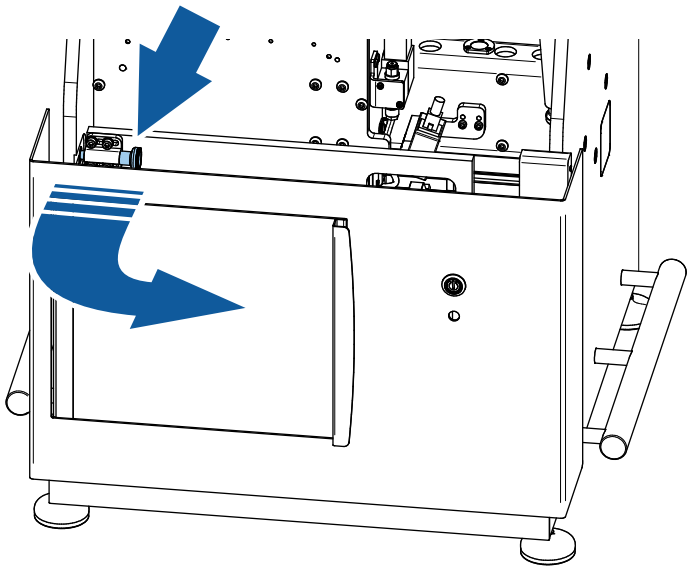
10.1.3 Clean hood

Wipe the hood with a moist cloth when necessary.

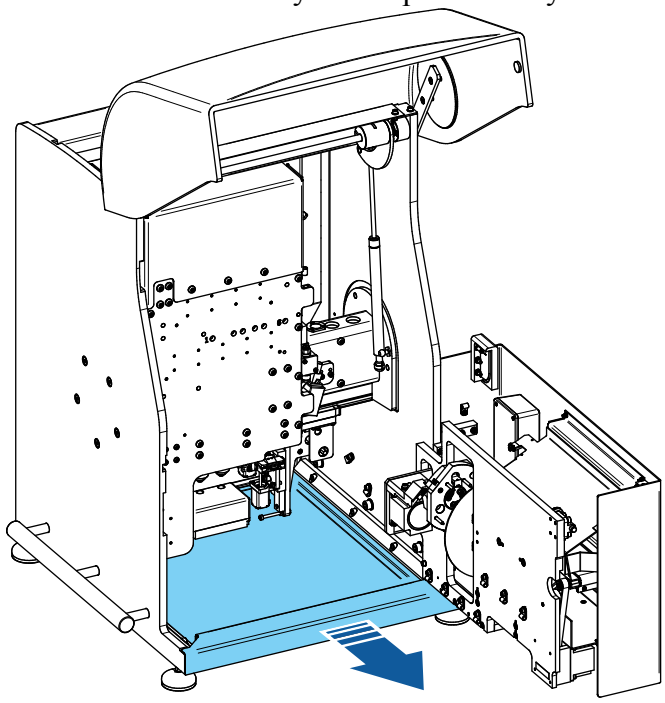
> **Caution!**
>
> Use water only when cleaning the hood.

10.1.4 Clean bottom tray

1. Open the hood.
2. Pull out the stop pin and open the magazine feeder.



3. Pull out the bottom tray and wipe clean any immersion oil.



10.1.5 Delete unsigned orders

Delete unsigned and failed orders to minimize the size of the database.

10.1.6 Restart system computer

Restart the system computer at least once a week.

10.2 Preventive maintenance

No preventive maintenance by the user is necessary. Preventive maintenance is to be performed by CellaVision® authorized personnel.

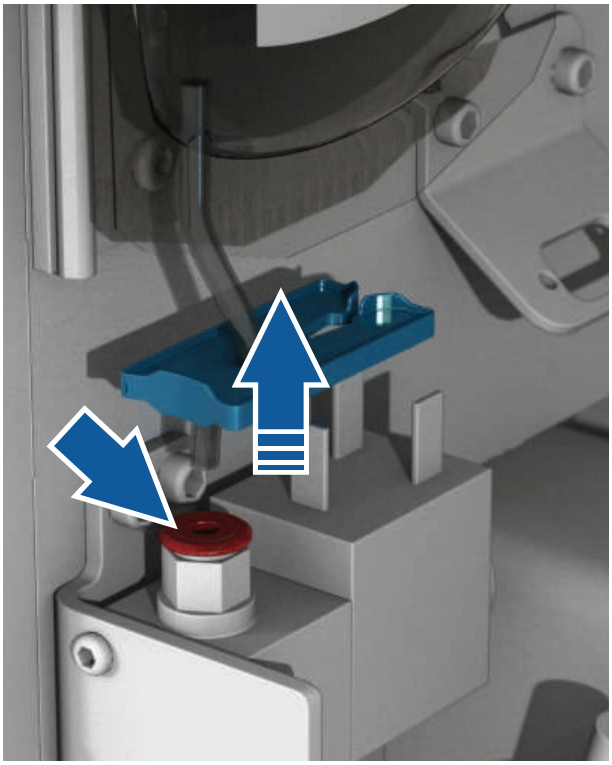
10.3 Remedial maintenance

10.3.1 Change immersion oil pack

> **Warning!**
>
> The oil may cause sensitization by skin contact. We recommend using gloves.

> **Caution!**
>
> Use only the immersion oil specified in A.3.1 Immersion oil.

1. Open the hood.
2. Put a clip on the hose.
3. Push down on the oil hose connection and pull out the hose.



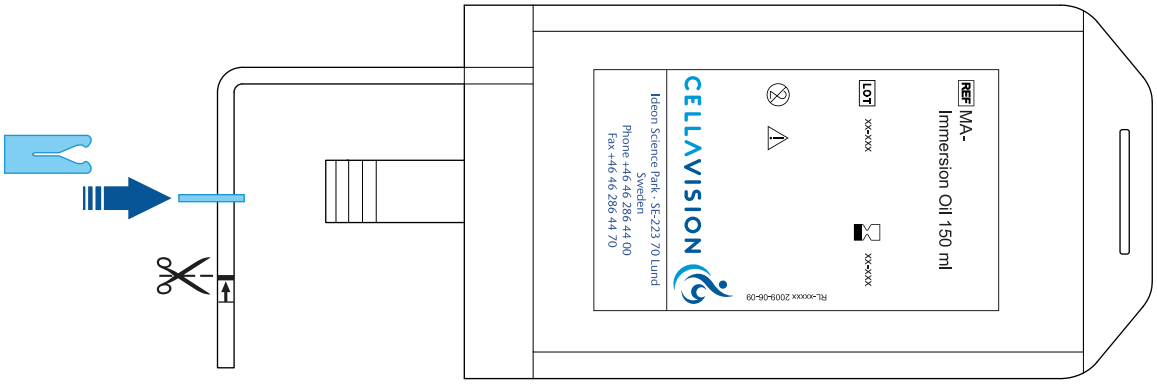
4. Remove and discard the old oil pack.

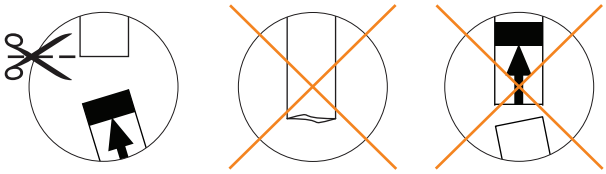
   For information on how to dispose of the old oil pack, see B.3 Disposal information.

5. On the new oil pack, put the clip on the hose.

6. Cut the hose above the line where the arrow points.

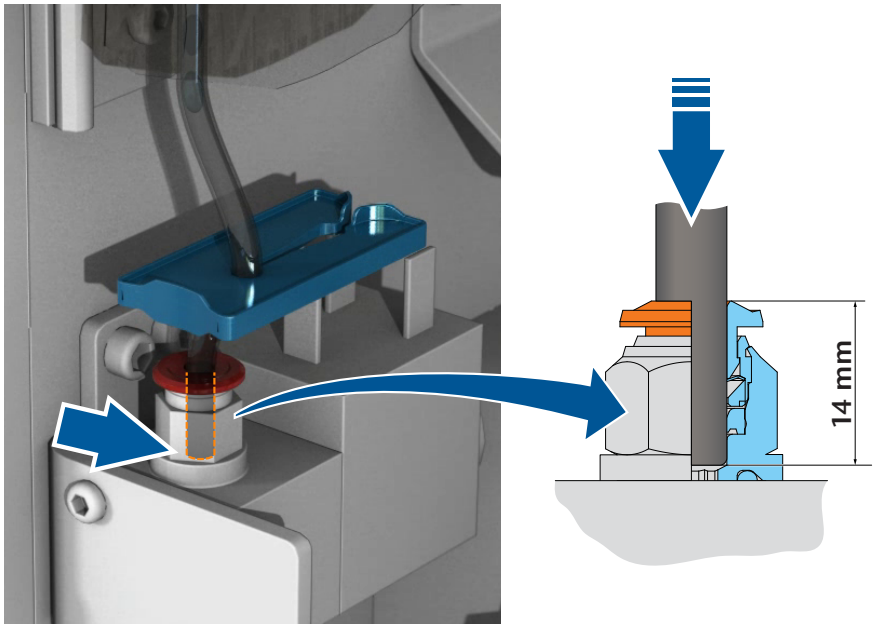
   Make sure that the cut is straight and that there are no remnants of the arrow sticker left on the hose.





7. Put the new oil pack in place.

8. Push the hose into the oil hose connection. Make sure that you push the hose all the way down.



9. Remove the clip from the hose.

10.Start the CellaVision DM Software.

11.On the **Maintenance** menu, click **Oil**.

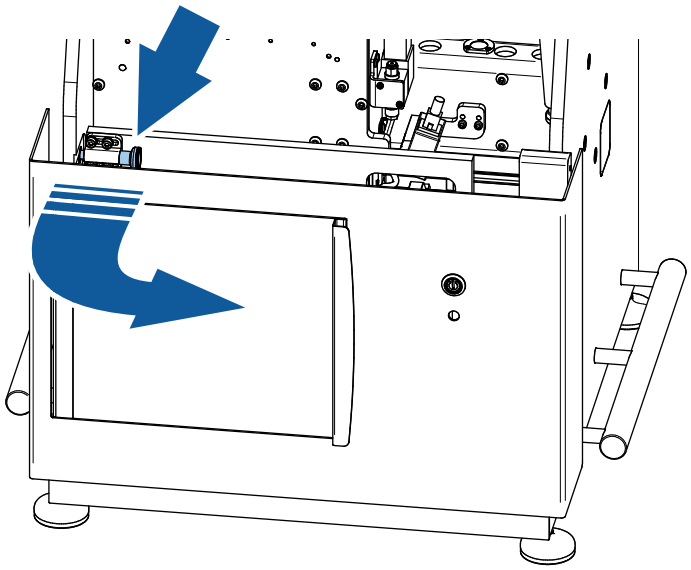
12.If the old oil pack ran dry and all hoses are empty, click **Prime Oil**.

13.Click **Reset Oil Drop Counter**.

10.3.2 Remove stuck slide from the gripper

> **Warning!**
>
> A broken slide can cause serious cuts and poses a danger of infection. Always use protective gloves and tweezers when removing glass shards from the system.

1. On the **Maintenance** menu, click **Gripper Service**.
2. In the **Go to gripper service position** dialog, click **OK**.
3. Wait until you receive the "The gripper is in service position" message.
4. Open the hood.
5. Pull out the stop pin and open the magazine feeder.



6. Remove the slide.
7. Close the hood and the magazine feeder.
8. Restart the slide scanning unit and CellaVision DM Software.

10.4 Database performance

To maintain a high database performance, it is very important to control the size of the database. It is also recommended to restart the system computer at

least once a week. It is allowed to install an antivirus program, but it is not recommended to scan the database files.

10.4.1 Check database size

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

   For information on how to reduce the size of the database, see 9.1.2 Manage database size.

11 Troubleshooting

If a problem occurs, follow these steps

1. Observe any unusual circumstances surrounding the problem.
2. Note any error messages displayed.
3. Follow the troubleshooting charts later in this chapter.
4. If the problem remains, contact your vendor for assistance.

11.1 General processing problems

Problem	Cause	Action
WBC images are not centered on the cell, but the cell can still be seen.	System needs calibration or alignment.	Contact your local vendor's technical support.
Incomplete analysis Less than the ordered number of cells are collected.	Low WBC count in sample.	Prepare and process more slides from the same sample.
	Too small monolayer area found.	Prepare the slides with longer blood films.
	Artefacts (staining precipitates) on the slide.	Make sure that the reagents are changed according to the recommendations in Appendix F Slide preparation guidelines.
	Dust on the objectives.	Clean the objectives, see 10.1.1 Clean objectives and LED table.
Incomplete analysis Could not find RBC monolayer.	No monolayer on slide.	Make sure that the slides are prepared according to the recommendations in Appendix F Slide preparation guidelines.
Incomplete analysis No RBC/PLT image is saved.	Excessive amount of small artefacts in the smear.	Make sure that the slides are prepared according to the recommendations in Appendix F Slide preparation guidelines.
Analysis failure View the **Slide Information** dialog for more details.	No monolayer found.	Make sure that the slides are prepared according to the recommendations in Appendix F Slide preparation guidelines.
	Oil or dust on the objective.	Clean the objectives, see 10.1.1 Clean objectives and LED table.

Problem	Cause	Action
Light error when using 10x/50x/100x magnification.	Too dark or too thick smear.	Make sure that the slides are prepared according to the recommendations in Appendix F Slide preparation guidelines.
Images are not in focus.	Dust on the objective.	Clean the objectives, see 10.1.1 Clean objectives and LED table.
Seemingly normal slides get slide status **Empty or no slide PID**.	There was a problem when reading the barcode.	See 11.4 Barcode problems.
Seemingly normal slides get slide status **Invalid slide PID**.	The order ID is too long.	Make sure that the order ID follows the specification in A.3.5 Barcodes.
Database access is slow.	The database service needs to be restarted.	If you use a local database service, restart the system computer.
		If you use the CellaVision Server Software, restart the server.
	The database is too large.	Keep the database size below the maximum allowed size, see 10.4 Database performance.
	The database files are fragmented.	Compress the database, see 9.1.3 Database compression.
	Large network delays.	Make sure that the network connections are stable.
		Make sure that the network communication delays are small.
Body fluid sample spot is not centered.	Incorrect configuration of BF analysis area.	Configure the BF analysis area settings, see 9.3.6 BF analysis settings.
	The sample spot location varies too much between samples.	Make sure your sample preparation process produces slides where the sample spot is always in the same location.
The analysis area does not cover the entire body fluid sample spot.	Incorrect configuration of BF analysis area.	Configure the BF analysis area settings, see 9.3.6 BF analysis settings.

Problem	Cause	Action
Seemingly normal scan slides get slide status **Analysis failure**, with the additional information "No image data in scanned area".	Too little specimen on the slides.	Prepare a slide with more specimen.
	Wrong area selected.	Select the correct area and process the slide again.
Same cell counted more than once or duplicate cell images are shown by the system.	Sample contains disintegrated cells or smudge cells and the system identifies different parts of a cell as two or more different cells.	To minimize the amount of disintegrated cells, make sure the blood films are prepared within four hours of blood collection, see Appendix F Slide preparation guidelines. To minimize the amount of smudge cells, verify your smear preparation process. To be able to identify and exclude duplicate cells, activate the Cell Marker function during verification, see Reclassifying white blood cells.
Cells are split into two or more parts.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.

11.2 LIS errors

Problem	Cause	Action
Default values The slides are analyzed with default values even though LIS is used for order information.	The orders are not in the LIS.	Make sure that orders for the slides that are to be processed are already available in the LIS.
	The connection to the LIS is broken.	Check the connection to the LIS.
LIS status:	The connection to the LIS has been broken.	Check the connection to the LIS. Results are automatically resent when connection is established.

11.3 Cell location problems

Cell location problems peripheral blood

Problem	Cause	Action
Too many non-nucleated cells.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify smear preparation process.
	Too many artefacts.	Increase wash step.
		Filter the stain.
		Make sure that the stain has not exceeded the expiration date.
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining reagents.
Too few nucleated cells located.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Too short smear.	Prepare longer smears.
	Poor smear quality.	Verify smear preparation procedure.
Too many missed cells.	Dirt or oil on the 10x objective.	Clean the 10x objective, see 10.1.1 Clean objectives and LED table.
	Too high WBC count.	Do not process slides with a WBC count that exceeds 100 × 10^9/L.
	Poor staining.	Verify staining procedure.
	System needs calibration or alignment.	Contact your local vendor's technical support.
Long processing time.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Poor staining.	Verify staining procedure.
A cell is marked with more than one box.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.

Cell location problems body fluids

Problem	Cause	Action
Too many non-WBCs.	Too many smudge cells.	Run another slide with less smudge cells.
		Verify sample preparation process.
		Decrease centrifuge speed.
	Too many artefacts.	Increase wash step.
		Filter the stain.
		Make sure that that the stain has not exceeded the expiration date.
	Cells misclassified as non-nucleated cells.	Run another slide and if the problem remains prepare new staining reagents.
Too few WBCs located.	Few WBCs in sample.	Use a larger sample volume.
Nearly all boxes are far from the cells.	Calibration error.	Contact your local vendor's technical support.
Too many missed cells.	Too many WBCs in the sample.	Do not process slides where the number of WBCs exceeds the recommended amount.
	Poor staining.	Verify staining procedure.
A cell is marked with more than one box.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.

11.4 Barcode problems

Problem	Cause	Action
The barcode could not be read.	There is no quiet zone.	Make sure there is a quiet zone according to specifications (and that the barcode is not printed too close to a logotype, if applicable).
	The contrast between the bars and the background is too low.	Adjust the printer.
		Use slides with a white, smooth, frosted area.
	The barcode could not be read due to bad print quality.	Clean the printer head in the barcode printer.
		Replace the printer ribbon in the barcode printer.
	The barcode is damaged (barcode cells are missing).	Adjust the printer.
		Use slides with a white, smooth, frosted area.
	The barcode reader is not connected.	Make sure that the barcode reader cable is connected to both the barcode reader and the control unit. Restart the CellaVision DM Software.
	No barcode found.	Check positioning and size of the barcode, see A.3.5 Barcodes.
	Blurry barcode, caused by immersion oil on the barcode.	Make sure the barcode is resistant to immersion oil.
		Print the barcode as defined in A.3.5 Barcodes.
The magazine is not detected by the system.	A tissue left on the bottom tray disturbs the barcode reader.	Remove the tissue from the bottom tray.

11.5 Staining problems

Problem	Cause	Action
The RBCs appear bright red, the white cells will appear indistinct with pale blue rather than purple nuclei, and brilliant red eosinophilic granules will be seen microscopically.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.
	Use of stain, buffer or wash water that is too acidic.	The pH of the buffer may need to be checked with a pH meter and adjusted.
	The increased acidity is due to exposure of the stain or buffer to acid fumes.	Use a new batch of stain or buffer.
Pale, inadequately-stained RBCs, nuclei or eosinophilic granules.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.
The RBCs appear blue or green, 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 are blue or gray.	Overstaining.	Decrease the fixation time.
		The amount of stain used may need to be decreased (shorten the staining time) and the amount of buffer increased (increase the stain/buffer time).
	Inadequate washing.	Increase the wash step.
	Too high an alkalinity of stain or buffer.	The pH of the buffer may need to be checked with a pH meter and readjusted to a lower pH.
	Thick blood smears.	Prepare a thinner blood smear.

Problem	Cause	Action
Samples have dark areas of stain or other artefacts.	The blood smear was not completely dry when it was stained.	Make sure that the blood smear is completely dry before staining it.
	Dirty slides.	Use clean slides.
	Inadequate washing (not washing enough to remove the metallic scum).	Increase wash step.
	A stain is forming precipitate in the solution.	Filter the stain.
		Make sure that that the stain has not exceeded the expiration date.
Same cell counted more than once or duplicate cell images are shown by the system.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.
Cells are split into two or more parts.	Understaining.	The fixation and staining time may need to be increased.
	Overwashing.	The washing technique may need to be corrected so that it is adequate but not excessive.

11.6 General startup problems

Problem	Cause	Action
Logging on to the system takes time.	The database is too large.	Keep the database size below the maximum allowed size, see 10.4 Database performance.
	The database files are fragmented.	Compress the database, see 9.1.3 Database compression.
	Large network delays.	Make sure that the network connections are stable.
		Make sure that the network communication delays are small.

11.7 Error message list

Startup error messages

Error message	Cause	Action
The program has already been started and you cannot start another until the previous one is closed.	The CellaVision DM Software is already running or has recently been closed.	Make sure the CellaVision DM Software is closed. Then wait 10 seconds and try again.
Could not log on to the system. Make sure you typed your user name and password correctly.	Wrong user name or password.	Check your user name and type your password again.
	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.	There was a problem connecting to the local database service.	Restart the system computer.
	The database server could not be reached.	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.	There was a problem connecting to the local database service.	Restart the system computer.
	The database server could not be reached.	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 9.1.1 Manage databases or the IT Configuration Guidelines.

Startup error messages (cont'd.)

Error message	Cause	Action
Disk space exhausted.	The database is located on the C drive.	Move the database to the E drive.
	The partition where the database is located is full.	Reduce the size of the database, see 10.4 Database performance.
		Add more disks to the server.
The system is not ready.	Temporary software error.	Restart the slide scanning unit and the system computer.
The configuration of the control unit is incorrect.	The control unit has lost its configuration.	Contact your local vendor's technical support to configure the control unit.
Communication failure.	No connection between the slide scanning unit and the system computer.	Check the cable between the slide scanning unit and the system computer.
		Check the power connection to the slide scanning unit.
		Restart the slide scanning unit and the CellaVision DM Software.
The hood or the input hatch was open during start-up.	The hood or the input hatch was open.	Make sure that the magazine feeder, the hood and the input hatch are closed. Restart the slide scanning unit and the CellaVision DM Software.
Jam error occurred during initialization.	At least the motor specified in the message reported a positioning failure.	Restart the slide scanning unit and the CellaVision DM Software.
Infeed motor failure.	The magazine was placed upside down on the infeed conveyor.	Place the magazine with barcode facing upwards and the open end of the magazine facing inwards.
Internal error.	Temporary software error.	Restart the slide scanning unit and the system computer.

Startup error messages (cont'd.)

Error message	Cause	Action
Temperature is too high.	The air filter is dirty.	Check that the air filter on the back of the slide scanning unit is not dirty.
		Contact your local vendor’s technical support to replace the filter.
	The fan in the control unit is defective.	Contact your local vendor’s technical support to replace the fan.
File system or registry failure.	The file system or registry is corrupt.	Reinstall the CellaVision DM Software. Follow the instructions provided with the CellaVision Software Pack disc.
A slide was detected in the gripper during start-up.	A slide is in the gripper.	Move the gripper to the service position and remove the slide, see 10.3.2 Remove stuck slide from the gripper. Restart the slide scanning unit and the CellaVision DM Software.
An unknown error occurred when archiving slides. One or more slides has not been archived.	One or more slides are 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 auto-delete old slides. One or more slides could not be deleted.	One or more slides are 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.	The server or the system computer where the database is located, can’t connect to the archive.	Check the network connection.
	The archive files have been moved.	Move the archive files back.
		In the **Archiving location** text box, enter the new path to the archive files.

Hardware errors during slide processing, slide handling or maintenance

Error message	Cause	Action
This operation can not be performed at this time.	Communication error between slide scanning unit and system computer.	Restart the slide scanning unit and the CellaVision DM Software.
Communication failure.	No connection between the slide scanning unit and the system computer.	Check the cable between the slide scanning unit and the system computer.
		Check the power connection to the slide scanning unit.
		Restart the slide scanning unit and the CellaVision DM Software.
Temperature is too high.	The air filter is dirty.	Check that the air filter on the back of the slide scanning unit is not dirty.
		Contact your local vendor's technical support to replace the filter.
	The fan in the control unit does not function.	Contact your local vendor's technical support to replace the fan.
Oil dispensing failed.	The oil bag is empty.	Change the immersion oil pack, see 10.3.1 Change immersion oil pack.
File system or registry failure.	The file system or registry is corrupt.	Reinstall the CellaVision DM Software. Follow the instructions provided with the CellaVision Software Pack disc.
Internal error.	Temporary software error.	Restart the slide scanning unit and the system computer.
Magazine eject failure.	The magazine is stuck.	Remove the magazine manually. Restart the slide scanning unit and the CellaVision DM Software.

Hardware errors during slide processing, slide handling or maintenance (cont'd.)

Error message	Cause	Action
Positioning failure.	At least the motor specified in the message reported a positioning failure.	Move the gripper to the service position and remove the slide, see 10.3.2 Remove stuck slide from the gripper. Restart the slide scanning unit and the CellaVision DM Software.
	The slide is stuck or broken.	Move the gripper to the service position and remove the slide, see 10.3.2 Remove stuck slide from the gripper. Restart the slide scanning unit and the CellaVision DM Software.
	Magazine is broken, and fragments are blocking the slide.	Remove the magazine and all slides. Load the slides into a new magazine. Restart the slide scanning unit and the CellaVision DM Software.
	The barcode could not be read after the slide was processed.	Wipe off oil from the barcode label.
Verify that the hood is closed.	The hood was open.	Close the hood.
The gripper has unexpectedly lost the slide.	The gripper has dropped a slide.	Pull out the bottom tray and remove the slide. Restart the slide scanning unit and the CellaVision DM Software.
The slide could not be returned to the magazine.	The magazine is broken, and fragments are blocking the slide.	Move the gripper to the service position and remove the slide, see 10.3.2 Remove stuck slide from the gripper. Discard the magazine. Restart the slide scanning unit and the CellaVision DM Software.
Barcode reader failure.	The barcode reader cable is disconnected.	Make sure that the barcode reader cable is connected to both the barcode reader and the control unit. Restart the CellaVision DM Software.
A slide is not fully inserted in the magazine.	Slides not fully inserted.	Eject the magazine and make sure that all slides are fully inserted. Restart the slide scanning unit and the CellaVision DM Software.

Errors during slide processing

Error message	Cause	Action
No camera found.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the CellaVision DM Software.
No connection to the database service. Check your network connection and verify that the service is running.	The connection with the database has been lost.	If the text “No connection” is displayed in the lower right corner of screen, wait up to a minute for the connection to be re-established, then start the slide processing again.
		Check the network connection.
		If you use a database on the system computer, restart the system computer.
		If you use the CellaVision Server Software, restart the server.
There was a problem when accessing the database.	The order ID contains non-ASCII characters.	Make sure that the order ID follows the specification in A.3.5 Barcodes.
Critical internal error during cell collection.	Temporary software error.	Restart the slide scanning unit and the system computer.
Critical internal error.	Temporary software error.	Restart the slide scanning unit and the system computer.
Camera initialization error.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the CellaVision DM Software.
Barcode reader failure.	The barcode reader cable is disconnected.	Make sure that the barcode reader cable is connected to both the barcode reader and the control unit. Restart the CellaVision DM Software.

Appendix A - Specifications

Important!

In order to always keep the instrument in compliance with current device registrations, it is a prerequisite to always use original CellaVision® listed spare parts and their specified components. All original CellaVision® listed spare parts are safe to use in accordance with regulatory requirements and approvals. CellaVision® will not be liable under any warranty (whether express or implied, by law or otherwise) regarding an instrument containing components which are not original CellaVision® listed spare parts. CellaVision® will not be liable for any malfunction of an instrument containing components which are not original CellaVision® listed spare parts. CellaVision® will not be liable for any lack of compliance with current device registrations regarding an instrument containing components which are not original CellaVision® listed spare parts.

A.1 System specification

A.1.1 Climate specification

The CellaVision® DM9600 is designed to be safely operated in the following environment:

Temperature	18 °C to 31 °C (64 °F to 88 °F)
Relative humidity	20% to 80%, non-condensing
Altitude	Up to 2 000 m
Indoor use only	

A.1.2 Physical specification SSU

Weight	93 kg
Width	58 cm (22.8 inches)
Depth	56 cm (22.0 inches)
Height	79 cm (31.1 inches)

A.1.3 Electric specification (monitor not included)

Voltage input	100 to 240 VAC
Voltage frequency	50 to 60 Hz
Current input, system computer	1.4 to 0.7 A
Current input, slide scanning unit	0.6 to 0.3 A
Total current input for the system	2.0 to 1.0 A
Total power consumption	240 W (820 BTU/h)
Pollution degree	2
Installation category	II
Over voltage category	II
Mains supply voltage fluctuation	Not to exceed ±10% of nominal voltage

The system complies with the emission and immunity requirements described in the IEC 61326-2-6: 2005 (EN 61326-2-6:2006)

The system complies with the requirements described in the IEC 61010-2-101:2002 (EN 61010-2-101:2002)

Warning!

The system must be connected to grounded electrical sockets only.

Warning!

The main power supply cords and plugs for the slide scanning unit and for the system computer must comply with any national regulations.

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 the proper operation.

Caution!

The electromagnetic environment should be evaluated prior to operation of the device.

Important!

External computing devices connected to the LAN, FireWire, or PC Card communication connector of the system computer must be Limited Power Source and SELV circuit according to the standards UL 60950 for the US, CAN/CSA-C22.2 No. 60950 for Canada and IEC60950-1 for other countries.

A.1.4 Noise specification

Sound level (average), at one meter away from the SSU	43 dBA

A.2 Performance specification

Performance specification peripheral blood

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

Throughput[1]: Approximately 30 slides per hour for complete orders containing RBC, PLT and 100 WBCs.

Results of short-term imprecision found in a clinical evaluation on 230 patient samples, based on NCCLS standard H20-A

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	3.8	Basophils	0.7
Band neutrophils	1.6	Lymphocytes	3.4
Eosinophils	1.0	Monocytes	2.0

Limitations: Distinctions between band and segmented neutrophils, metamyelocytes and myelocytes, myelocytes and promyelocytes, lymphocytes and lymphocyte variant forms are subject to variations among individual operators.

Performance specifications for the Advanced RBC application are included in the application pack.

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

Performance specification body fluid

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

Throughput[2]:

- Approximately 15 slides per hour for orders (100 WBCs) containing only 10x overview images (analysis area 6 mm in diameter).
- Approximately 3 slides per hour for orders (100 WBCs) containing both 10x and 50x overview images (analysis area 6 mm in diameter).

To evaluate the Accuracy and Short-term imprecision of the Body Fluid application, a comparison study was conducted at two sites with five operators. The Body Fluid application running on the CellaVision® DM1200 was compared with the reference method, the Body Fluid application run on a CellaVision® DM96. 200-cell differential counts were performed by qualified blood examiners. The study was performed according to CLSI document EP9-A2—*Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* The short-term imprecision was calculated as defined in CLSI document H56-A—*Body Fluid Analysis for Cellular Composition; Approved Guideline*. The results are presented in the tables.

Accuracy results for the Body Fluid application

Specimen	Cell class	Slope	Intercept (%)	R^2	# of samples
CSF	Neutrophils	1.0005	0.16	0.9919	62
	Lymphocytes	0.9703	0.27	0.9897	62
	Eosinophils	0.7573	0.05	0.7893	62
	Macrophages	0.9944	-0.44	0.9821	62
	Other cells	0.9843	1.15	0.9435	62
Serous fluid	Neutrophils	0.9967	0.63	0.9896	151
	Lymphocytes	0.9879	-0.28	0.9813	151
	Eosinophils	1.1326	-0.002	0.9763	151
	Macrophages	1.0099	-0.37	0.9809	151
	Other cells	0.9432	0.06	0.9261	151
Synovial fluid	Neutrophils	1.0007	0.15	0.9959	47
	Lymphocytes	0.9891	1.10	0.9786	47
	Eosinophils	0.7701	0.04	0.9262	47
	Macrophages	0.9551	0.06	0.9586	47
	Other cells	0.5027	0.19	0.1735	47

2. Depending on WBC concentration, number of non-WBCs and the quality of the smear.

Short-term imprecision results for the Body Fluid application

Specimen	Cell class	SD (%)
CSF	Neutrophils	3.1
	Lymphocytes	3.9
	Eosinophils	0.6
	Macrophages	3.0
	Other cells	2.8
Serous fluid	Neutrophils	3.2
	Lymphocytes	6.3
	Eosinophils	0.9
	Macrophages	6.7
	Other cells	1.1
Synovial fluid	Neutrophils	3.3
	Lymphocytes	5.3
	Eosinophils	0.1
	Macrophages	5.6
	Other cells	1.0

A reproducibility study was conducted at three different sites on three different instruments, each site processing the samples in duplicates. The study was performed during 20 days at each site and run by in total 10 operators. The results are an extract from the study and based on preclassification data presented in the next table.

Reproducibility data

Sample ID	Specimen	Cell class	Average (%)	S_D (Reproducibility %)	CV[3] (Reproducibility %)
A	CSF	Neutrophils	74.8	1.4	2
		Lymphocytes	3.2	0.6	—
		Eosinophils	0.5	0.7	—
		Macrophages	20.5	1.6	8
		Other cells	0.4	0.3	—
B	Serous fluid	Neutrophils	61.4	1.5	2
		Lymphocytes	16.8	1.2	7
		Eosinophils	4.0	1.0	—
		Macrophages	13.4	1.1	8
		Other cells	1.7	0.5	—

Performance specification scan

Throughput data and disk space requirements for the scanned slides

Scan area size	Overview images	Processing time	Disk space
5 × 5 mm	10x	1.5 min.	10 MB
5 × 5 mm	10x + 50x	12 min.	130 MB
10 × 10 mm	10x	3 min.	45 MB
10 × 10 mm	10x + 50x	45 min.	500 MB

The given values are approximate. Processing time and required disk space vary depending on the sample.

3. Coefficient of variation (CV) is only presented for results where the average is higher than 10%

A.3 Materials specification

A.3.1 Immersion oil

Use CellaVision® Immersion Oil Pack, 150 mL. One oil pack is enough for approximately 3 000 slides.

Firefighting procedures

Attribute	Value
Flash point	>300ºF / 149ºC
Upper explosive limit	N/A
Lower explosive limit	N/A
Fire fighting media	Carbon dioxide, foam and dry chemical
Unusual fire and explosion hazards	Containers should be kept cool in the event of fire

A.3.2 Stain

Use May Grünwald Giemsa, Wright, or Wright-Giemsa.

For staining recipes, see F.3 Recommended staining recipes.

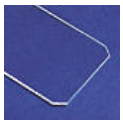
A.3.3 Slides

Use slides manufactured according to ISO 8037/1-1986 or JIS R 3703:1998.

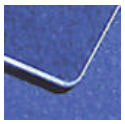
Attribute	Value
Material	Glass
Length	75.0 to 76.0 mm
Width	25.0 to 26.0 mm
Thickness	0.9 to 1.2 mm
Labeling	The slide must be labeled with a barcode, as specified in A.3.5 Barcodes.
Other	Ground edges and clipped or round corners

Caution!

Use slides with ground edges and clipped or round corners. Slides with sharp corners or sharp edges can prevent the free movement of slides in the system and can cause damage to the system.



Slide with clipped corners



Slide with round corners

Images provided by Erie Scientific (www.eriesci.com)

A.3.4 Magazines

Use CellaVision slide magazines.

A magazine can be used 100 times. The CellaVision DM Software will display a message when a magazine has been used more than 100 times.

Caution!

Discard magazines that have been used 100 times. If a magazine is used too many times, it can can cause damage to the system.

CellaVision slide magazines are delivered with a barcode label with a magazine ID. If you need to change the barcode label, the new magazine ID must contain only ASCII characters and must not contain a slash mark (/). The barcode label must be printed according to the specifications in A.3.5 Barcodes.

A.3.5 Barcodes

All slides must be labeled with an order ID in the form of a barcode. The barcode must contain only the order ID and no other order data.

Example of slides with barcode.

Note:
Magazines are delivered with a barcode label already attached.

The order ID may be up to 24 characters (ASCII), including spaces. It must not begin with:

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

The barcode can be printed 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 the barcode is printed directly onto a slide, it must be printed on a white, smooth, frosted area of the slide.

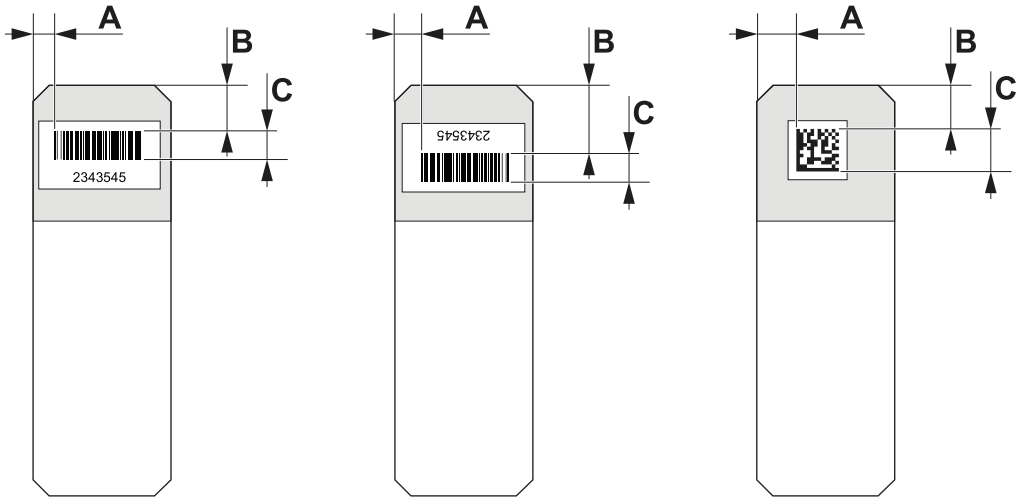
If, for some reason, you can't print barcodes with order ID, you can use preprinted barcode labels with the prefix "ER". The system will let you manually enter an order ID for all slides beginning with the letters "ER". You can order these preprinted labels from your local vendor.

Important!

Do not get immersion oil on the barcode. Immersion oil may prevent the system from reading the barcode correctly.

The barcode must be placed within the measurements specified in this illustration. There must also be at least 1 mm between the edge of the slide and the actual label.

Linear barcodes must be aligned so that the bars are parallel to the long edge of the slide, as in this illustration.



Placement of barcodes.

Barcode placement	Measurement
Distance from long edges	A ≥ 3 mm + quiet zone
Distance from short edge	B ≥ 6 mm (+ quiet zone for 2D barcodes)
Barcode width	C ≤ 18 mm

For information about quite zones, see Quiet zone later in this chapter.

Note:
It is recommended to make the barcode width as large as possible, without exceeding the specification.

Supported linear barcodes

The system supports these standards for linear barcodes:

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

Supported 2D barcodes

The system 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

These barcode resolutions have been verified by CellaVision AB.

Quiet zone

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

There must be a blank region, free from all markings, surrounding the barcode. This region is called a “quiet zone”. The minimum size of the quiet zone is specified in the table above.

Example of barcodes with the words “QUIET ZONE” written in the quiet zone, for illustrative purposes.

Appendix B - Storage and handling

B.1 Storage

The system shall be stored within the following climate condition:
–10 °C to 60 °C (14 °F to 140 °F). The relative humidity should be between 20% and 80% with no condensation allowed at 40 °C (104 °F).

B.2 Transporting the system

The system shall be packaged, transported and unpacked by CellaVision AB authorized personnel or carrier only. We recommend saving the package for possible future transports.

The system must be acclimatized to operating conditions for 24 hours, see A.1 System specification for climate specification, before taken into operation.

B.3 Disposal information

Magazines

As combustible plastics (PC + PBT).

Oil pack

As combustible plastics (PVC/DEHP).

Not completely empty packaging can contain remnants and should therefore be handled as hazardous waste according to local regulations.

Completely empty packaging can be recycled.

The system

Please contact your local vendor.

Appendix C - Buttons and indicators

If you place the mouse-pointer over a button or indicator, you can see a short description of the button in the status bar (in the bottom left-hand corner of the screen).

Buttons

Button	Name	Comment
	CellaVision DM Software	
	System control view	Keyboard shortcut F4
	Database view	Keyboard shortcut F5
	Verification view	Keyboard shortcut F6 Only available when an order is open.
	Report view	Keyboard shortcut F7 Only available when an order is open.
	Close order and slide	
	Order data	
	Pathology review	
	Help lines	Enables help lines for PLT estimate.
	Confirm cell counter results	
	Comments	
	WBC full screen view	
	WBC galleries	
	Zoom mode	

Buttons (cont'd.)

Button	Name	Comment
 	Zoom out/Zoom in	
	Scroll mode	
	Color/Brightness	Adjusts image color and brightness.
	Toggle color/brightness	Toggles between the default color and brightness settings and your personal settings.
	Cell marker	Shows/Hides square for cell identification.
	WBC attributes	Shows/Hides WBC attributes.
	Entire RBC Image	Shows the entire RBC image.
	RBC grid	View the RBC image in sections
	Start	
	Stop	

Indicators

Indicator	Name	Comment
	Autostart	Automatic start of slide processing.
	Oil Level Indicators	Indicates an empty oil pack.
		Indicates need for changing oil pack.
		Indicates a full oil pack.
	Outfeed Shelf	Indicates room left in the outfeed shelf.
		Indicates a full output drawer.
	Hatch Indicator	Indicates all hatches closed.

Keyboard shortcuts

Shortcut	Action
Ctrl+W	Show or hide the worklist.
F1	Open the user's manual
F4	System control view
F5	Database view
F6	Verification view Only available when an order is open.
F7	Report view Only available when an order is open.

Appendix D - Recommended workflow

Laboratories handle their peripheral blood differential counts in different ways making it hard to suggest one general workflow suitable for all laboratories. See flowcharts of the three workflows below.

Note:
Before using the shortcuts F6 and F7 an order must be selected.

D.1 Recommended settings

(see 9.5 Order signing settings)

1. Single slide differentials

   Pre-fill password: Enabled

   Sign order when signing the slide: Enabled

   Send order to LIS when signed: Enabled

   Review the cells in the WBC Galleries.

2. Confirmation of cell counter results – Quickly scanned slides for verification of cell counter results.

   Pre-fill password: Enabled

   Sign order when signing the slide: Enabled

   Send order to LIS when signed: Enabled

   Review the analysis type you want to confirm and then click **Confirm cell counter results**.

    Confirm cell counter results

   Note:
   *When using the **Confirm cell counter result** for any analysis type (WBC, RBC, or PLT) the normal sign slide checks (cells in the Unidentified class, all cells reviewed etc.) are disabled.*

   Note:
   When using Confirm Cell Counter Results the results sent to the LIS are: a WBC confirmation flag, a RBC confirmation flag and/or a PLT confirmation flag.

   For a slide it is possible to report the WBC result and a RBC confirmation flag and a PLT result or any other combination.

3. Duplicate slide differentials– An order consists of two slides. Two persons sign one slide each.

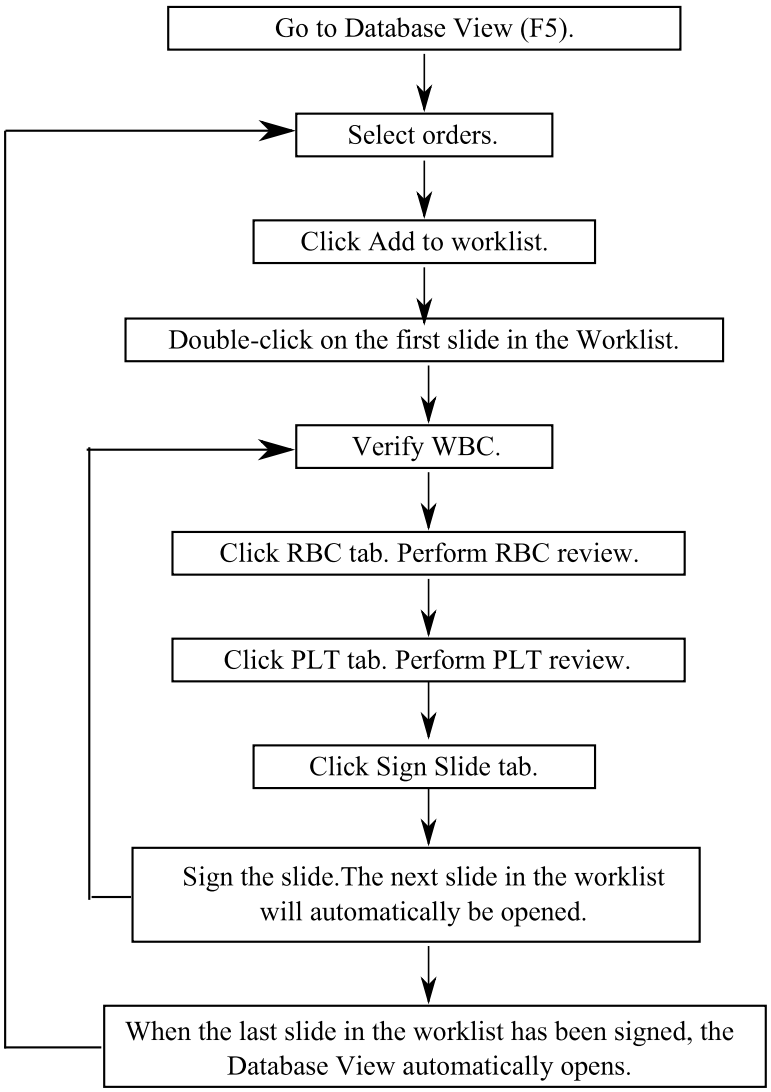
   Pre-fill password: Enabled

   Sign order when signing the slide: Disabled

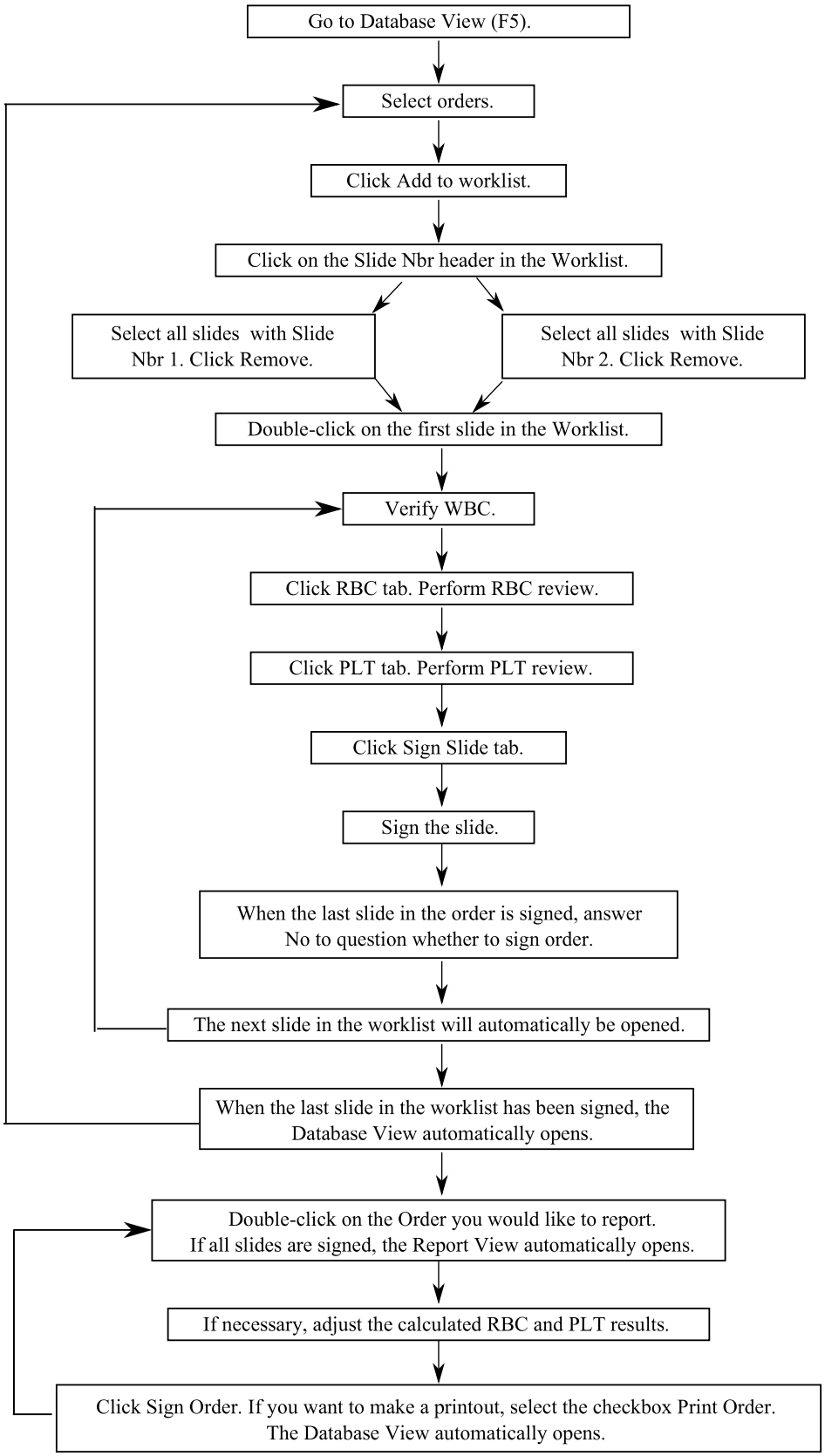
   Send order to LIS when signed: Enabled

   Review the cells in the WBC Galleries.

D.2 Workflow for single slides and confirm cell counter results



D.3 Workflow for duplicate slides



Appendix E - User access levels

Slide processing and verification	Observer	User	Restricted	Authorized	Administrator	Service
Start slide processing		●		●	●	●
Verify WBC preclassification		●	●	●	●	●
Verify RBC precharacterization		●	●	●	●	●
Estimate platelets		●	●	●	●	●
Add comments		●	●	●	●	●
Add comments to signed slides		●	●	●	●	●
Confirm cell counter results		●	●	●	●	●
Sign slides and orders			●	●	●	●
Send results to the LIS			●	●	●	●
Send images via e-mail	●	●	●	●	●	●
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				●	●	●
Add RBC example cells				●	●	●

Database	Observer	User	Restricted	Authorized	Administrator	Service
Find orders by order ID	●	●	●[4]	●	●	●
Find orders by patient ID	●	●	●[4]	●	●	
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				●	●	●
Delete signed orders					●	●
Export orders				●	●	●
Change the order ID on orders in an export database				●	●	
Mark an order for Transfer Tool		●		●	●	●
Change the order ID on orders that begin with “ER”				●	●	

4. Depending on settings.

Maintenance	Observer	User	Restricted	Authorized	Administrator	Service
Export log files	●	●	●	●	●	●
Perform a cell location test				●	●	●
Prime the oil		●		●	●	●
Move gripper to service position		●		●	●	●

Analysis settings	Observer	User	Restricted	Authorized	Administrator	Service
Change the default processing settings				●	●	●
Change the reclassifications settings					●	●
Change the report settings					●	●
Change the standard comments				●	●	●
Enable RBC precharacterization					●	●
Change the RBC grading and size limits					●	●
Change the aspect ratio of the RBC analysis area					●	●
Change which RBC morphology groups to use					●	●
Change the default processing settings for BF				●	●	●
Change the default BF analysis area					●	●
Change the intervals for the PLT concentration levels					●	●
Set the PLT estimate factor					●	●
Set up the system for manual PLT concentration estimation		●	●	●	●	●
Change the default scan area		●		●	●	●

General settings	Observer	User	Restricted	Authorized	Administrator	Service
Change e-mail 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					●	●

Appendix F - Slide preparation guidelines

F.1 Slide preparation for peripheral blood

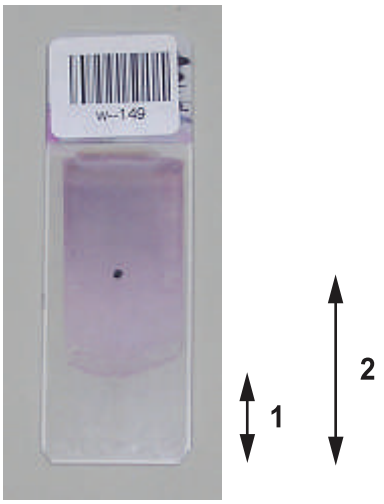
> **Warning!**
>
> Always use protective gloves when in contact with blood.

F.1.1 Sample

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). Mix the sample carefully with the anticoagulant. Store the tube at room temperature. Prepare the blood films within four hours of blood collection.

F.1.2 Preparing blood films

1. Mix the tube (20 complete inversions by hand) before preparation.
2. Use a clean dry microscope glass slide (see A.3.3 Slides for required slide types). Note that glass slides may lose their wetability on exposure to air, resulting in a poor smear.
3. Use the wedge technique performed manually or by a mechanical spreader. Manual wedge technique: Place a drop of blood near the labeled end of the slide. Narrow a spreader slide with polished edges at a 30- to 45-degree angle to the smear slide. Allow the blood to spread almost over the entire width of the slide. Then rapidly and smoothly push the spreader slide to the opposite end of the slide. There should be a gradual transition in thickness, without any grainy streaks, troughs, ridges, holes or bubbles. The blood film must be at least 30 mm in length, terminating 5 to 15 mm from the edge.
4. Dry the slide rapidly.
5. Stain the slide within one hour.



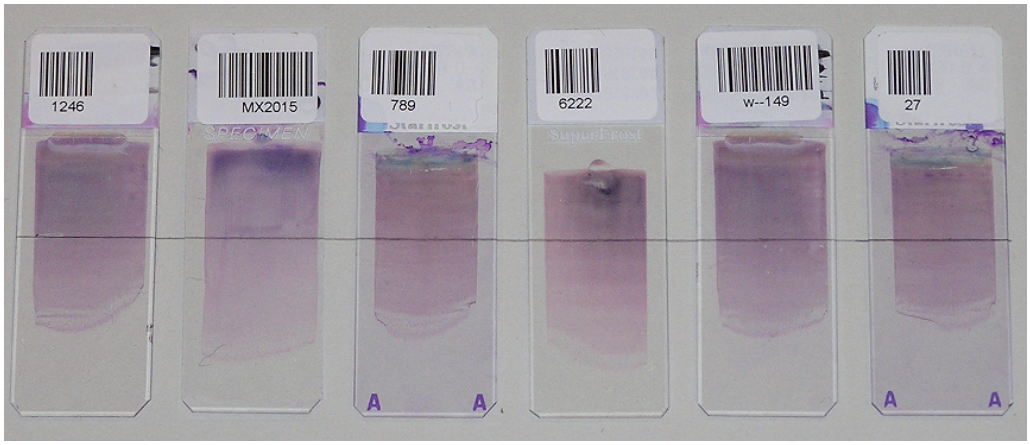
1. 5 to 15 mm
2. 33 mm

The dot in the image indicates the analysis starting point. The analysis proceeds from the starting point towards the thinner part of the smear.

F.2 Example smears

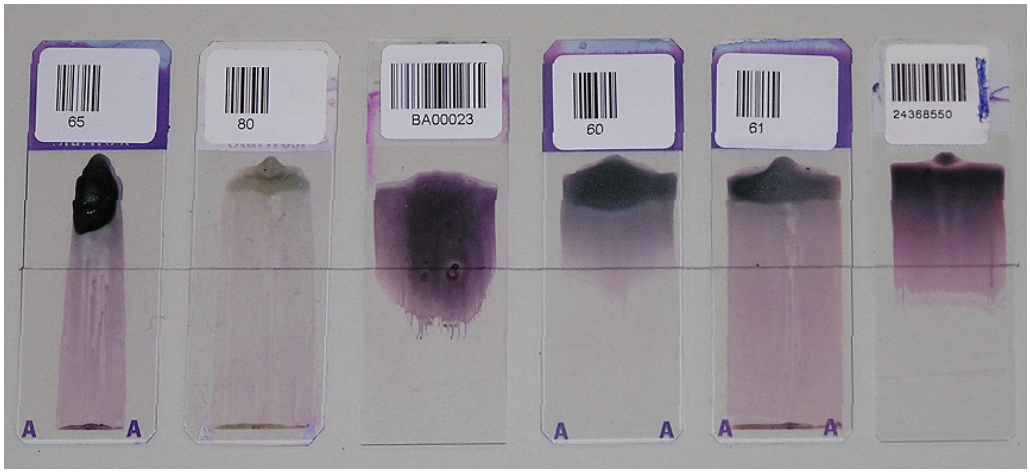
The line in the images indicates the analysis starting point.

Example 1 Accepted slides



These slides are all prepared according to the specifications.

Example 2 Not accepted slides



These slides are not prepared according to the specifications and should not be analyzed in the CellaVision® DM9600.

F.3 Recommended staining recipes

CellaVision® DM9600 is optimized to analyze samples stained with May Grünwald Giemsa (MGG) stain, Wright stain and Wright-Giemsa stain.

The staining recipes are only suggestions and may need to be adjusted according to the results of the Cell location test and level of preclassification accuracy that is achieved.

Contact the reagents provider for more information about recommended staining recipes when using a manual dip method.

Contact the vendor for recommending staining recipes when using a slide maker stainer.

Note:
Differences in staining results can be caused by alterations in pH, reagents etc. Local adjustments may be needed to achieve best results. Be aware of pH variations in water.

F.3.1 MGG stain

	Solution	Reaction time	Change solution
1	May Grünwald stock solution a	5 minutes	Twice a week
2	Buffer working solution c	Quick rinsing	Every day
3	Giemsa working solution e	10 minutes	Every day
4	Buffer working solution c	Extensive rinsing	Every day

a	May Grünwald stain, stock solution:	Eosin-methylenblue solution, modified for microscopy (contains methanol). Store at +15 ºC to +25 ºC.
b	Buffer stock solutions 1 and 2:	1) 9.07 g KH_2PO_4 (0.067M) ad 1 000 mL deionized water Store at +4 ºC to +8 ºC. 2) 9.45 g Na_2HPO_4 (0.067M) ad 1 000 mL deionized water Store at +4 ºC to +8 ºC.
c	Buffer working solution, pH 6.8	Combine 127 mL KH_2PO_4 stock solution with 123 mL Na_2HPO_4 stock solution ad 5 000 mL deionized water. Adjust to pH 6.8. Store at +4 ºC to +8 ºC. Durable for a month at +4 ºC.
d	Giemsa stain, stock solution:	Azur-eosine-methylenblue solution for microscopy (contains methanol). Store at +15 ºC to +25 ºC. Durable for several months if kept in a dark bottle.
e	Giemsa working solution:	Dilute 1 part Giemsa stock solution with 19 parts buffer work solution. Stable for 8 hours.

F.3.2 Wright stain

	Solution	Reaction time
1	Methanol	30 s
2	Wright stain	3 min.
3	Wright stain diluted 1:6 with buffer pH 7.15	6 min.
4	Rinse in pH adjusted distilled water	2 min. 30 s Reuse the water 5 times only
5	Dry	5 min.

F.3.3 Wright-Giemsa stain

	Solution	Reaction time
1	Methanol	30 s
2	Wright-Giemsa stain	3 min.
3	Wright-Giemsa stain diluted 1:10 with phosphate buffer pH 7.2	6 min.
4	Rinse in pH adjusted distilled water	1 min.
5	Rinse in pH adjusted distilled water	1 min.
6	Dry	4 min.

F.4 Slide preparation for body fluids

> **Warning!**
>
> Always use protective gloves when in contact with Body Fluids.

F.4.1 Sample

Quantitative assessment of cell counts and preparation of slides should be performed within 2 hours of collection.

F.4.2 Preparing the sample

Count the WBC and RBC concentration of the fluid. For best results, dilute samples with high cell density.

Buffered saline or standard tissue culture media may be used as a diluent.

For CSF always add a drop of 30% albumin which promotes cell adhesion to the microscopy slide.

The recommendation is to have 5 000 to 12 000 cells in total on the slide

Note:
Cells are concentrated approximately 20-fold by cytocentrifugation, however the quantitative yield varies from 30% to 75%. The speed and time of centrifugation, the amount of sample in the chamber and the filter paper absorbance are factors that can influence both the cell yield and morphology. (ref. CLSI document H56-A—Body Fluid Analysis for cellular Composition; Approved Guideline. Vol 26, No 26)

Use a clean dry microscope glass slide (see A.3.3 Slides for required slide types). Centrifuge the sample according to the manufacturer's recommendation. Dry the slide rapidly.

Note:
Do not use slides with cover slip.

F.4.3 Staining

Stain the slide using the same staining recipe as for peripheral blood samples. (See F.3 Recommended staining recipes for staining recommendations).

Appendix G - Glossary

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

Anisocytosis. Variation in size among red blood cells.

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 operator chooses to confirm cell counter results, only a confirmation flag for that result is sent to the LIS.

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

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.

In-vitro. Outside the living body; in an artificial environment.

LIS. Laboratory Information System.

Magazine ID. The barcode printed on the magazine label for magazine identification.

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.

Non-WBCs. Cells and objects identified as not being WBCs.

Not classed. Cells and objects that the operator cannot identify and wants to exclude from the differential count.

Operator. The person who works with the system.

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

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

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. Refers to the barcode on the slide or on the magazine.

PLT. Platelet, thrombocyte.

PLT estimate. Estimation of the PLT concentration.

PLT estimate factor. A predetermined factor to calculate the PLT estimate.

Poikilocytosis. Presence of abnormally shaped red blood cells.

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

Preclassification. 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.

RBC. Red blood cell, erythrocyte.

Reclassification. The operator changes the preclassification.

Reference cells. A collection of white blood cells with typical characteristics, available in the peripheral blood application.

Region of interest. A section of the body fluid or scan overview image tagged by the operator.

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

Signing. 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.

Slide position. The position of a slide in a magazine.

SSU. Slide scanning unit.

Unidentified. Cells and objects which the system cannot preclassify.

Verification. The operator's review of WBC, RBC and PLT, for example reclassification and confirmation of WBCs.

WBC. White blood cell, leukocyte.

Wright. A Romanowsky stain for blood smears.

Wright-Giemsa. A Romanowsky stain for blood smears.

Index

N

O

P

R

S

T

U

V

W

CE

CELLAVISION

CellaVision AB·Ideon Science Park·SE-223 70 Lund, Sweden
Phone +46 (0) 46 286 44 00·Fax +46 (0) 46 286 44 70
info@cellavision.com·www.cellavision.com

PM-10830-01 2015-07-10