K080595

2 510(k) Summary

DEC 0 5 2008

Submitter:	CellaVision AB Ideon Science Park SE-223 70 Lund Sweden
Contact Information:	C. G. Bundy Associates, Inc. 6470 Riverview Terrace Fridley, MN 55432
Submission Date:	February 27, 2008
Device Name and Classification:	CellaVision DM96 with the body fluid application 21 CFR 864.5220 and 21 CFR 864.5260 Class II medical devices.
Equivalent Device Identification:	CellaVision AB believes that DM96 with the additional body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and function. The additional intended use of body fluid is substantially equivalent to the Romanowsky stain manual light microscopic process for cell classification (21CFR 864.3600 Class I exempted from pre-market notification procedure)
Device Description:	The CellaVision DM96 with the body fluid application is a laboratory instrument used to perform differential analysis by locating, digitally storing and displaying cells in human body fluid preparations. The CellaVision DM96 with the body fluid application is a new intended use that follows the same process as the currently cleared DM96 with white blood cell differential, RBC characterization and platelet estimation (K033840).
Intended Use:	DM96 is an automated cell-locating device. 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. DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells

Comparison Table:

Comparative features of DM96 with Body Fluid application compared with the predicate device:

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
Intended use	Automated cell-locating device for cell-location and identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for cell-location and identification of blood smears, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood and body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood.
Sample preparation	Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including	*White blood cells:* The examiners usually locate/count white blood cells by moving according to the battlement track pattern on the smear and distinguish between classes of	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
	deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.	white blood cells.	deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.
Overview image	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.	The operator scans the slide to get an overview on parts of or the whole slide in different magnifications.	The device presents an overview image of a part of the slide. The image gives the operator possibilities to get an overview of the part in different magnifications.

Summary of Testing:
The CellaVision DM96 was cleared by the FDA in 2004. The intended use has been modified to include presentation of white blood cells on cytocentrifuged body fluid preparations.

Tests on cytocentrifuged body fluid preparations including specimen types such as cerebrospinal fluid, serous fluid and related fluids were conducted and successfully completed.
Tests were also conducted to validate performance including accuracy, precision and cell-location.

Conclusion:
Based on extensive performance testing including comparison to the predicate devices, it is the conclusion of CellaVision AB that DM96 with the body fluid application is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 5 2008

CELLAVISION AB
c/o Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432
ATTN: Constance G. Bundy

Re: k080595
Trade/Device Name: CELLAVISION DM96 with the Body Fluid Application
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ, JOY
Dated: November 17, 2008
Received: November 21, 2008

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

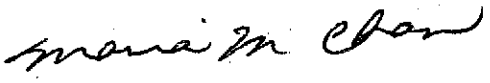
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080595

Device Name: CellaVision DM96 with the body fluid application

Indications For Use:

DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080595

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

March 19, 2010

Cellavision Ab
c/o Constance G Bundy
6740 Riverview Terrace
Minneapolis, MN 55432 US

Document No: k080595
Re: k080595
Received: March 3, 2008

Categorization Notification

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

If you have any questions regarding this complexity categorization, please contact Lea Carrington at 301-796-6164.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

ATTACHMENT

Document Number : k080595

Test System: CELLAVISION AB DM 96 (BODY FLUID APPLICATION)
Analyte : White Blood Cell Differential (WBC Diff)
Complexity : HIGH

CLIA Routing Slip

Document No : k080595

Re : k080595

Division: DIHD
Branch: HECB

Applicant: Cellavision Ab
Trade Name: Cellavision dm96 with the body fluid application

DMC Date Received: March 3, 2008
Division Date Received: March 6, 2008

Categorization Information

CLIA Reviewer: Paula Stewart [PCS]
Date Review Completed: December 2, 2008

Date Branch Concurred: March 12, 2010
Date Coordinator Concurred:
Effective Date: MAR 19 2010

Test Systems/Analytes/Grading

(See Attachment)

PCS 3/22

QC: gmB

ATTACHMENT

Document Number : k080595

Test System: CELLAVISION AB DM 96 (BODY FLUID APPLICATION)

(b)(4) Trade Secret Process - Product Specs

[redacted]

no PI in Image

K080595

2 510(k) Summary

DEC 0 5 2008

Submitter: CellaVision AB
Ideon Science Park
SE-223 70 Lund
Sweden

Contact Information: C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432

Submission Date: February 27, 2008

Device Name and Classification: CellaVision DM96 with the body fluid application

21 CFR 864.5220 and 21 CFR 864.5260 Class II medical devices.

Equivalent Device Identification: CellaVision AB believes that DM96 with the additional body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and function. The additional intended use of body fluid is substantially equivalent to the Romanowsky stain manual light microscopic process for cell classification (21CFR 864.3600 Class I exempted from pre-market notification procedure)

Device Description: The CellaVision DM96 with the body fluid application is a laboratory instrument used to perform differential analysis by locating, digitally storing and displaying cells in human body fluid preparations.

The CellaVision DM96 with the body fluid application is a new intended use that follows the same process as the currently cleared DM96 with white blood cell differential, RBC characterization and platelet estimation (K033840).

Intended Use: DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells

Comparison Table:

Comparative features of DM96 with Body Fluid application compared with the predicate device:

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
Intended use	Automated cell-locating device for cell-location and identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for cell-location and identification of blood smears, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood and body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood.
Sample preparation	Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including	*White blood cells:* The examiners usually locate/count white blood cells by moving according to the battlement track pattern on the smear and distinguish between classes of	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 12, 2008

510k Number: K080595
Product: CELLAVISION DM96 WITH THE BODY

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 28, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432
ATTN: CONSTANCE G. BUNDY

510(k) Number: K080595
Device: CELLAVISION DM96 WITH THE BODY FLUID APPLICATION

Extended Until: 24-JUL-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20850

March 04, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432
ATTN: CONSTANCE G. BUNDY

510(k) Number: K080595
Received: 03-MAR-2008
Product: CELLAVISION DM96 WITH THE BODY FLUID APPLICATION

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see www.fda.gov/cdrh/elecsub.html.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural questions, or want information on how to check on the status of your submission, please contact DSMICA at (240)276-3150 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

CellaVision AB
Lund, Sweden

K080595/H1

March 19, 2008

Office of In Vitro Diagnostic Devices (HFZ-440)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Rd.
Rockville, MD 20850

Re: 510(k) K080595 – Form FDA 3674, Certification of Compliance with Requirements of Clinical Trials.gov Data Bank

Please add the attached form to the above referenced 510(k) file.

Thank you.

Regards,

Constance G. Bundy

Constance G. Bundy, 510(k) Contact
C. G. Bundy Associates, Inc.
763-574-1976
Fax 763-571-2437
cgbundy@attglobal.net

2008 APR 24 A 1:03

E43

42

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
CellaVision AB

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
March 4, 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Ideon Science Park
SE-223 70
Lund, Sweden

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 011 46 46 286 4400
(Fax) 011 46 46 286 4470

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)
CellaVision DM96, Automated Cell-locating Device
21 CFR 864.5260; 21 CFR 864.5220, Class II

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K080595

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
None

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Constance G. Bundy

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Constance G. Bundy
(Title) Authorized Representative, 510(k) Contact

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
6470 Riverview Terrace
Fridley, MN 55432
USA

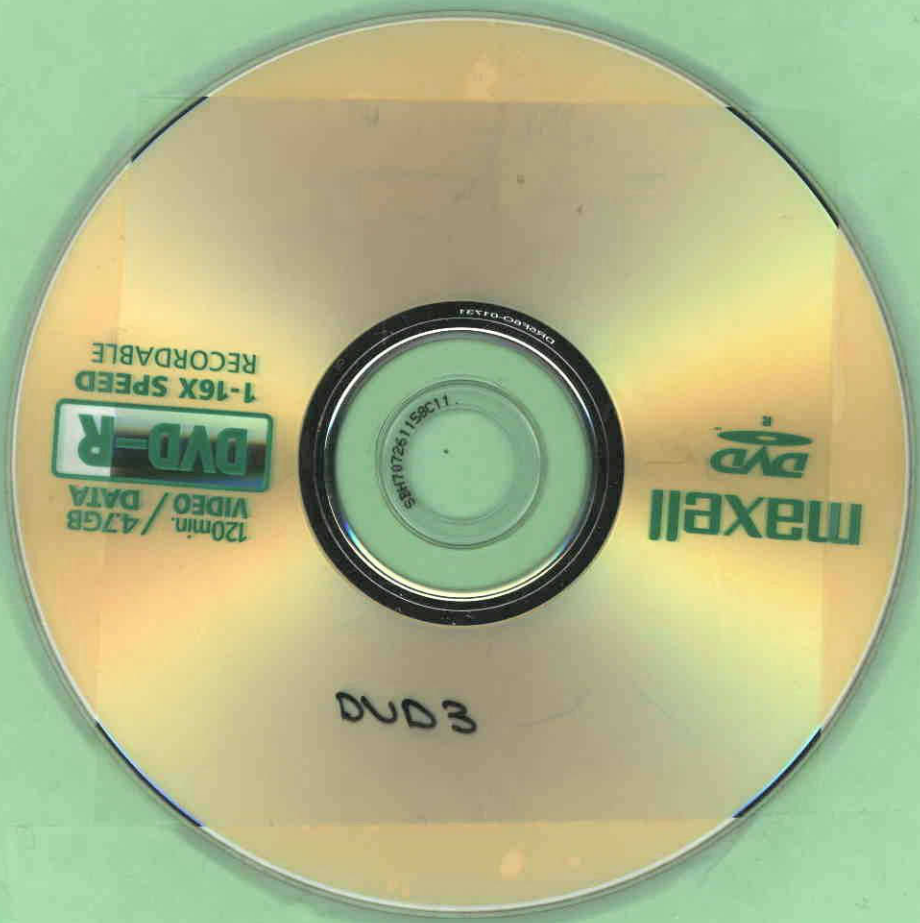
14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 763-574-1976
(Fax) 763-571-2437

15. DATE OF CERTIFICATION
3/18/08

CD-R
700 MB / 80 min
COMPACT
disc
Recordable
CD2

CD-R
700 MB / 80 min
COMPAC
disc
Recordable
CD 1

maxell
DVD
R
120min. VIDEO / 4.7GB DATA
DVD-R
1-16X SPEED
RECORDABLE
DVD3


maxell
DVD
R
120min. VIDEO / 4.7GB DATA
DVD-R
1-16X SPEED
RECORDABLE
DVD3

CellaVision AB
Lund, Sweden

K080595/: A2

July 2, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) K080595, DM96 – Response to Deficiencies

CellaVision AB is responding to deficiencies received by email April 23 and May 2, 2008. The response includes 3 DVDs. A listing of the contents of the DVDs is included in the response.

Should there be any questions regarding the responses, please contact Constance Bundy, Regulatory Consultant to CellaVision AB.

Sincerely,

Constance G. Bundy

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FDA CDRH DMC
JUL 07 2008
Received

K48

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(b)(4) Trade Secret Process - Product Specs

[redacted]

Revised Indications for Use page

Hazard Analysis Documents

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MEMORANDUM - electronic (email correspondence)

Date: April 23, 2008

From: Paula M. Stewart, Scientific Reviewer, OIVD, DIHB
Tel. No. 240-276-1317
E-mail: paula.stewart@fda.hhs.gov
Fax: 240-276-0663

Subject: K080595, DM96 with body fluid application
Request for Additional Information

To: CellaVision AB
C/o Constance G. Bundy
E-mail: cgbundy@attglobal.net
Tel: (763) 574-1976
Fax: (763) 571-2437

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Paula Stewart

MEMORANDUM - electronic (email correspondence)

Date: May 2, 2008

From: Paula M. Stewart, Scientific Reviewer, OIVD, DIHB
Tel. No. 240-276-1317
E-mail: paula.stewart@fda.hhs.gov
Fax: 240-276-0663

Subject: K080595, DM96 with body fluid application
Request for Additional Information - Software

To: CellaVision AB
C/o Constance G. Bundy
E-mail: cgbundy@attglobal.net
Tel: (763) 574-1976
Fax: (763) 571-2437

(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Paula Stewart

Indications for Use

510(k) Number (if known):

Device Name: CellaVision DM96 with the body fluid application

Indications For Use:

DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080595

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

(b)(4) Trade Secret Process - QA/Risk analysis

Content DVD 1

Answers to Memorandum, dated April 23, 2008.
Answers to Memorandum, dated May 2, 2008.

(b)(4) Trade Secret Process - Product Specs

[redacted]

Content DVD 2

Excel file with line data for the differential cell count computations.

(b)(4) Trade Secret Process - Product Specs [redacted]

[redacted]

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[redacted]

CLIA Routing Slip

Document No : k080595

Re : k080595

Division: DIHD
Branch: HECB

Applicant: Cellavision Ab
Trade Name: Cellavision dm96 with the body fluid application

DMC Date Received: March 3, 2008
Division Date Received: March 6, 2008

Categorization Information

CLIA Reviewer: Paula Stewart [PCS]
Date Review Completed: December 2, 2008

Date Branch Concurred:
Date Coordinator Concurred:
Effective Date:

Test Systems/Analytes/Grading

(See Attachment)

ATTACHMENT

Document Number : k080595

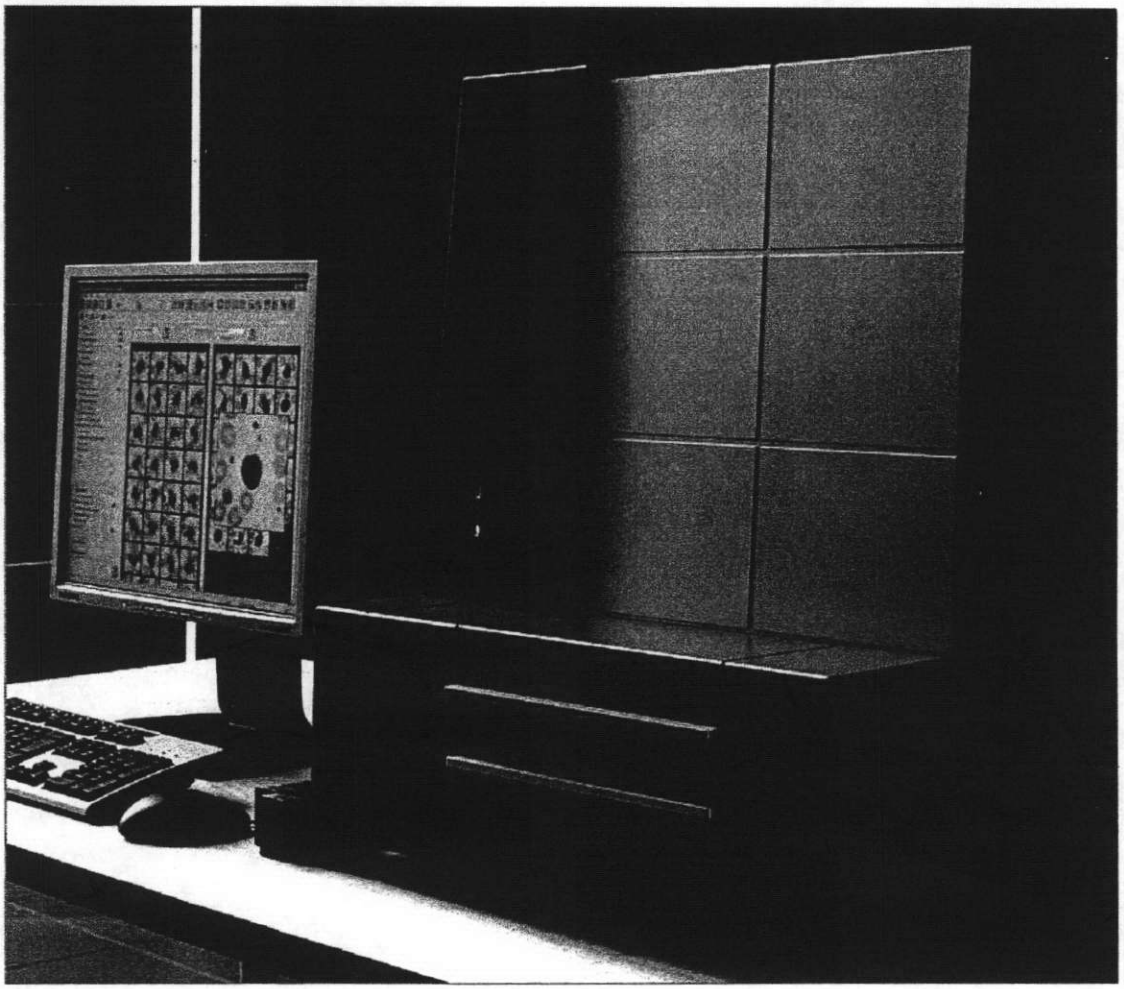
Test System: CELLAVISION AB DM 96 (BODY FLUID APPLICATION)

(b)(4) Trade Secret Process - Product Specs

[redacted]

CellaVision™ DM96

V 2.0



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CELLAVISION

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Preface

CellaVision™ is a trademark of CellaVision AB.

All other trademarks used in this document are property of their respective owners.

No part of this document or the products it describes may be reproduced or transmitted by any means or in any form without prior consent in writing from CellaVision AB.

U.S. patents no. 6268611 and 6341180. Swedish patent no. 517626 and 520829. 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).

Article No.PM-10034

Revision 2007-08-28

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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 DM96 (also referred to as the system), aiming for an efficient way to give you good understanding and knowledge of the system and its features. References are made to appendices providing additional information. Some self-explaining dialogs have been left out in the text.

Typographical conventions:

- Names of keys and on-screen objects with which you interact are presented in italics: e.g. click *PRINT*.

***Note!** This User's manual covers all applications (e.g. Peripheral Blood and Body Fluid applications) available for the CellaVision DM96 system. The applicability of some sections in this User's manual may therefore depend on the applications installed on the system. Contact your local distributor for more information.*

1.1.1 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.

Warning alerts appear in this manual as follows:

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

(Cont'd)

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(Cont'd)

Place the system on a steady table. Do not place it where it is exposed to bumps or vibrations, excessive temperature variations or direct sunlight. The system must be connected to grounded electrical sockets only. Authorized personnel should do the initial installation and reinstallation after moving the system. Do not install or run any software not supplied with the system. To maintain electromagnetic compatibility, use only original components. Spillage of fluid on the surfaces of the system may cause malfunctions or deterioration. Wipe off spilled fluids immediately with a soft tissue.

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.

The following symbols are found on the system:

Symbol	Explanation
	Indicates that the surface becomes hot and should not be touched with bare hands.
	Documentation needs to be consulted.
IVD	In vitro diagnostic medical device
40°C 10°C	Temperature limitation
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment
I	On (Supply).
○	Off (Supply).

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1.2 Intended Use of CellaVision DM96

CellaVision™ DM96 is an automated system intended for in-vitro diagnostic use.

CellaVision DM96:

- Scans whole or parts of a microscope slide;
- Automatically locates and presents images of cells on smears from various specimens;
- Is intended to be used by skilled operators.

1.2.1 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.

1.2.2 Body Fluid Application

The body fluid application (BF) 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.

1.3 General Description of CellaVision DM96

CellaVision DM96 consists of a slide feeder unit, 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 G — Slide Preparation Guidelines).

General Functionality of the System:

- Receives order information from and sends results to the LIS;
- 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.

1.3.1 Peripheral Blood Application

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 WBC.

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

(Cont'd)

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(Cont'd)

WBC Reclassification for Peripheral Blood
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: *Polychromasia, Hypochromasia, Anisocytosis, Microcytosis, Macrocytosis and Poikilocytosis.*

RBC characterization
The operator can characterize to *Target cells, Schistocytosis, Helmet cells, Sickle cells, Spherocytosis, Elliptocytosis, Ovalocytosis, Tear drop cells, Stomatocytosis, Acanthocytosis, Echinocytosis, 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 G — Slide Preparation Guidelines for recommended staining recipes).

1.3.2 Body Fluid Application

General Functionality

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

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other.* Cells pre-classified 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 pre-classified 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 WBC.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 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 G — Slide Preparation Guidelines for recommended staining recipes).

Limitations

A significant number of samples have not been evaluated for the following fluid types: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage. Therefore, they are not included in the statistical analysis.

1.3.3 CellaVision™ Remote Review

CellaVision™ Remote Review is an additional software to CellaVision™ DM96. The software gives remote users access to analyzed slides and the possibility to reclassify cells and sign slides from another location. A slide being verified on CellaVision DM96 can simultaneously be opened on a CellaVision Remote Review and vice versa. CellaVision™ Remote Review is intended to be used with the Peripheral Blood and the Body Fluid applications. See 9 CellaVision Remote Review — Multiple Users for more information.

1.4 Components and Mechanical Operation

1.4.1 Major Parts of the System

The system comprises the following major units:

- Computer system
- Slide scanning unit (SSU)
  - Motorized microscope
  - Digital color camera
  - Immersion oil unit
  - Slide feeder unit with barcode reader
  - Magazine feeder unit
  - Control unit
  - Casing

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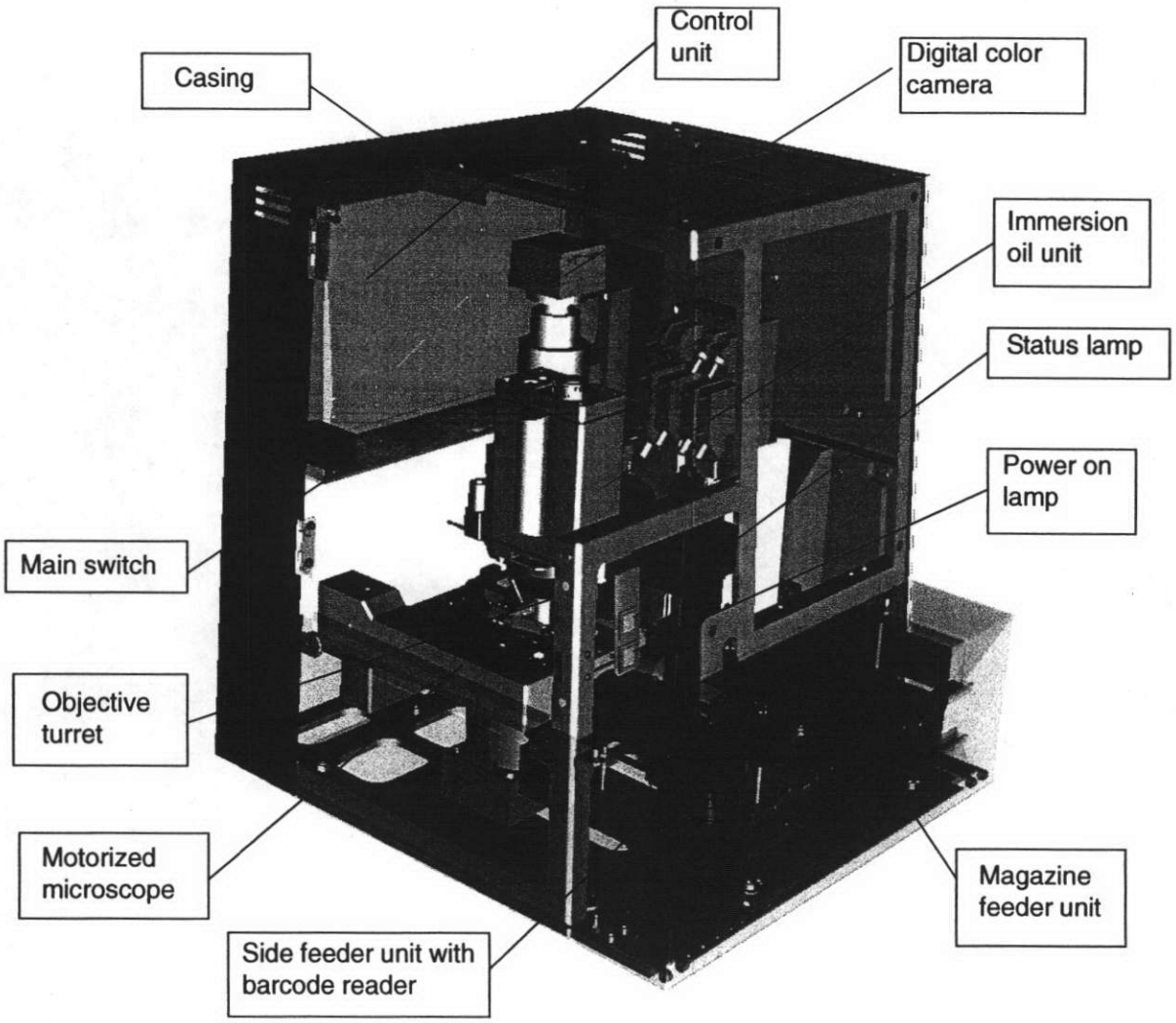
Slide Scanning Unit:



WARNING

Keep your fingers clear from the objective turret, otherwise personal injury may result.

WARNING

Do not remove the rear cover, dangerous voltages inside.

WARNING

The oil may cause sensitization by skin contact. We recommend using gloves.

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Motorized Microscope
The motorized microscope is a fixed-XY-stage upright light microscope with a moving objective focus. It has a motorized 5-position objective turret and a 100 W halogen illumination system. The microscope is motorized for fully automated positioning and focusing of the slide during process.

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. The canister capacity is about 500 ml. A sensor detects if the oil level is below 100 ml.

Slide Feeder Unit with Barcode Reader
The slide feeder transports slides from a magazine to the stage and back again after the slide has been processed. It is equipped with a barcode reader which scans the barcode of both the slide and the magazine. For maximum safety, the barcode of the slide is scanned both before and after processing. See Appendix A — System Specification for more information about barcodes.

Magazine
The magazine can be loaded with up to 12 slides (clipped/round corner slides).

Magazine Feeder Unit
The unit moves magazines from the conveyer to the slide feeder unit and from the slide feeder unit to the output drawer. It is equipped with a counter for the number of magazines in the conveyer and a sensor that warns if the output drawer is full.

Control Unit
The control unit controls motors, sensors, oil applying and illumination. It functions as a slave computer to the PC via an unshared 100 Mbit Ethernet connection.

Computer System
A PC system running Microsoft® Windows®XP and CellaVision DM software.

Casing
The casing comprises a metal cabinet including 5 hatches/drawers: main hatch, lamp hatch, input hatch, service hatch and output drawer.

WARNING

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

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2 Operating Procedures

2.1 Starting the System

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

Start the system as follows:

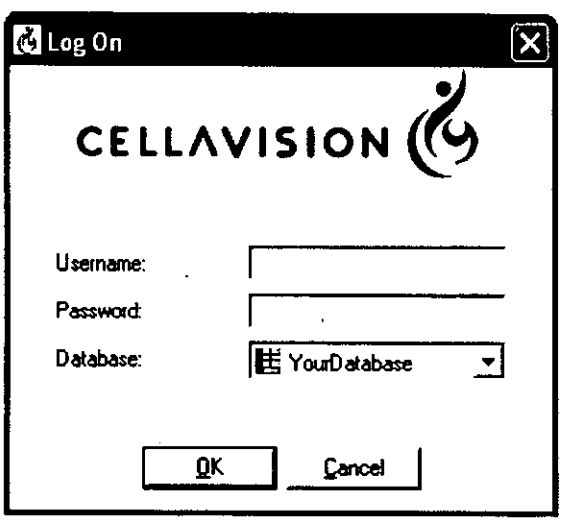
1. Switch on the slide scanning unit.
2. Switch on the system computer.
   Wait until the status lamp on the slide scanning unit is flashing or continuously lit (see picture in 1.4.1 Major Parts of the System).
3. In the *Log On* dialog, type username, password and select the desired database. The following icons indicate available database types:

   Processing database

   Export database

   Scan database

   CellaVision Competency Software database



4. Click *OK*.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CELLAVISION AB
c/o Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432
ATTN: Constance G. Bundy

DEC 0 5 2008

Re: k080595
Trade/Device Name: CELLAVISION DM96 with the Body Fluid Application
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ, JOY
Dated: November 17, 2008
Received: November 21, 2008

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080595

Device Name: CellaVision DM96 with the body fluid application

Indications For Use:

DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080595

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 21, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

510k Number: K080595

Product: CELLAVISION DM96 WITH THE BODY

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 12, 2008

510k Number: K080595
Product: CELLAVISION DM96 WITH THE BODY

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 09, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

510k Number: K080595

Product: CELLAVISION DM96 WITH THE BODY

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 28, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432
ATTN: CONSTANCE G. BUNDY

510(k) Number: K080595
Device: CELLAVISION DM96 WITH THE BODY FLUID APPLICATION

Extended Until: 24-JUL-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

CellaVision AB
Lund, Sweden

May 22, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) K080595, DM96 – Request for Extension of Time

(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Constance G. Bundy

FDA CDRH DMC

MAY 27 2008

Received

Constance G. Bundy
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432
763-574-1976
Fax: 763-571-2437
cgbundy@attglobal.net

C11
178

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 25, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432
ATTN: CONSTANCE G. BUNDY

510(k) Number: K080595
Product: CELLAVISION DM96 WITH THE BODY FLUID APPLICATION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20850

March 04, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MN 55432
ATTN: CONSTANCE G. BUNDY

510(k) Number: K080595
Received: 03-MAR-2008
Product: CELLAVISION DM96 WITH THE BODY FLUID APPLICATION

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see www.fda.gov/cdrh/elecsub.html.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural questions, or want information on how to check on the status of your submission, please contact DSMICA at (240)276-3150 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K080595

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CELLAVISION
6470 Riverview Terrace
Fridley MN 55432
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
NO DATA

2. CONTACT NAME
Constance Bundy

2.1 E-MAIL ADDRESS
cgbundy@attglobal.net

2.2 TELEPHONE NUMBER (include Area code)
7635741976

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) Trade Secret Process

Constance G. Bundy 24-Feb-2008

K27 HE II

193

510(k) Type: Traditional

Device Common Name: Automated Cell-locating Device

Submitter: CellaVision AB
Ideon Science Park
SE-223 70, Lund, Sweden

Contact: Constance G. Bundy
C. G. Bundy Associates, Inc.
6470 Riverview Terrace
Fridley, MN 55432
763-574-1976
Fax: 763-571-2437
cgbundy@attglobal.net

Confidentiality: This submission contains commercial and confidential trade secret information and we respectfully request maximum protection provided by the law.

Classification Regulation: 21 CFR 864.5260; 21 CFR 864.5220

Class: Class II

Panel: Hematology and Pathology Devices Panel (81)

Product Code: JOY; GKZ

Associated Documents: None

Basis for Submission: CellaVision AB is seeking clearance to expand the intended use of the CellaVision DM96 to include location and presentation of white blood cells in cytocentrifuged body fluids. The CellaVision DM96 with the peripheral blood application was cleared by the FDA in 2004 and holds the 510(k) number K033840.

Sincerely,

Constance G. Bundy

FDA CDRH DMC
MAR - 3 2008
Received

Design and Use of Device

Question	Yes	No
Is the device intended for prescription use?	☒	☐
Is the device intended for over-the-counter use?	☐	☒
Does the device contain components derived from a tissue or other biologic source?	☐	☒
Is the device provided sterile?	☐	☒
Is the device intended for single use?	☐	☒
Is the device a reprocessed single use device?	☐	☒
If yes, does this device require reprocessed validation data?	☐	☐
Does the device contain a drug?	☐	☒
Does the device contain a biologic?	☐	☒
Does the device use software?	☒	☐
Does the submission include clinical information?	☒	☐
Is the device implanted?	☐	☒

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Indications for Use

510(k) Number (if known): K080595

Device Name: CellaVision DM96 with the body fluid application

Indications For Use:

DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

2 510(k) Summary

Submitter:	CellaVision AB Ideon Science Park SE-223 70 Lund Sweden
Contact Information:	C. G. Bundy Associates, Inc. 6470 Riverview Terrace Fridley, MN 55432
Submission Date:	February 27, 2008
Device Name and Classification:	CellaVision DM96 with the body fluid application 21 CFR 864.5220 and 21 CFR 864.5260 Class II medical devices.
Equivalent Device Identification:	CellaVision AB believes that DM96 with the additional body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and function. The additional intended use of body fluid is substantially equivalent to the Romanowsky stain manual light microscopic process for cell classification (21CFR 864.3600 Class I exempted from pre-market notification procedure)
Device Description:	The CellaVision DM96 with the body fluid application is a laboratory instrument used to perform differential analysis by locating, digitally storing and displaying cells in human body fluid preparations. The CellaVision DM96 with the body fluid application is a new intended use that follows the same process as the currently cleared DM96 with white blood cell differential, RBC characterization and platelet estimation (K033840).
Intended Use:	DM96 is an automated cell-locating device. 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. DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells

Comparison Table:

Comparative features of DM96 with Body Fluid application compared with the predicate device:

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
Intended use	Automated cell-locating device for cell-location and identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for cell-location and identification of blood smears, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood and body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood.
Sample preparation	Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including	*White blood cells:* The examiners usually locate/count white blood cells by moving according to the battlement track pattern on the smear and distinguish between classes of	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
	deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.	white blood cells.	deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.
Overview image	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.	The operator scans the slide to get an overview on parts of or the whole slide in different magnifications.	The device presents an overview image of a part of the slide. The image gives the operator possibilities to get an overview of the part in different magnifications.

Summary of Testing:
The CellaVision DM96 was cleared by the FDA in 2004. The intended use has been modified to include presentation of white blood cells on cytocentrifuged body fluid preparations.

Tests on cytocentrifuged body fluid preparations including specimen types such as cerebrospinal fluid, serous fluid and related fluids were conducted and successfully completed.
Tests were also conducted to validate performance including accuracy, precision and cell-location.

Conclusion:
Based on extensive performance testing including comparison to the predicate devices, it is the conclusion of CellaVision AB that DM96 with the body fluid application is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

3 Truthful and Accuracy Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Quality Assurance Manager of CellaVision AB, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Hans-Inge Bengtsson
(Signature)

Hans-Inge Bengtsson
(Typed Name)

February 15, 2008
(Date)

K080595
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

4 Class III Summary and Certification

This section does not apply.

5 Financial Certification or Disclosure Statement

This section does not apply.

6 Declaration of Conformity and Summary Reports

This section does not apply.

7 Device Description – DM96 with the Body Fluid Application

7.1 Intended Use

DM96 is an automated cell-locating device.

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.

DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

7.2 General Description of CellaVision DM96

CellaVision DM96 consists of a slide feeder unit, an optical 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.

General functionality of the system:

- Receives order information from and sends results to the Laboratory Information System (LIS). This system is not part of the subject device.
- 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.
- Creates digital slides.

7.3 Body Fluid application

General functionality of the body fluid application:

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

CellaVision DM96 with the body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and functionality. The intended use of the body fluid application is substantially equivalent to the Romanowsky stain manual light microscopic method for cell classification.

The sample preparation is performed outside the device, by using a cytocentrifuge and a staining unit. The sample is cytocentrifuged onto a glass slide and stained with Romanowsky stain, according to recommended instructions in the User's Manual.

Twelve slides can be loaded into each magazine. The magazines used for the body fluid application are identified through the color and the barcode on it. The magazines are put onto a conveyer belt and are automatically transported to the slide scanning unit.

The analysis process consists of an overview image processing and a cell-location step. The body fluid overview image displays the entire sample area. 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. The cell-location step uses the optical unit and a camera taking images of the identified cells and transferring them to a computer system. The computer system preclassifies the images and stores the images of the located cells and the results in a database, and displays the images in an organized manner.

Using CellaVision Remote Review software enables the operator to remotely view and work with data collected, stored and processed by CellaVision DM software.

The results can be sent to the LIS and/or to a Windows XP compatible printer.

7.4 Database

All order information, results and images are stored in the database. The operator can search the database for analyses using the following variables:

- Ordering physician
- Patient ID
- Last name
- Exclusion comment
- WBC comment
- Order ID
- Signed by
- First name
- Order comment
- Patient comment
- System serial number
- Cell comment
- Any comment
- BF comment
- Cell class comment

7.5 White Blood Cell Classification

The system preclassifies to the following WBC classes:

- Neutrophils
- Eosinophils
- Lymphocytes
- Macrophages (including Monocytes)
- Other

Cells pre-classified 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 pre-classified with a low confidence level.

The system preclassifies to the following non-WBC classes:

- Smudge cells
- Artefacts.

Non-WBCs are reported as number of cells or objects /100 WBC.

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

DM96 allows the operator to identify and verify each cell according to cell class, either by confirming the suggested classification or by reclassifying the cell from one cell class to another. When the operator has examined all cells and reclassified the wrongly classified cells to their correct class, he/she shall approve the results by signing off the results with a user name and password. The system compels the operator to view all presented cells and objects before signing the analysis.

DM96 allows the operator to add morphological comments to each cell. A set of user-definable standard comments and free text comments can be used as morphological feature flags.

DM96 presents the results, verified by the operator, as absolute numbers and percentage (%) found for each cell class. Non-white blood cells results are presented as absolute numbers and numbers / 100 white blood cells.

The operator approves the results before the results are sent to the LIS or printed.

7.6 Description of an Analysis

A summary of the DM96 process is as follows:

1. Body fluid is cytocentrifuged and stained outside the device on standard rectangular glass slides by standardized staining methods and recipes recommended by CellaVision AB.

2. Each slide is coded with a barcode label on the frosted end of the glass slide.

3. Up to twelve slides are placed in a magazine.

4. The magazines are put onto the conveyer belt in the input drawer. Up to eight magazines can be loaded onto the conveyer belt at the same time.

5. DM96 identifies the barcode on the magazines and slides.

6. DM96 requests order information from the LIS using the slide barcode information. If DM96 cannot communicate with the LIS, the system defines type of analysis from the information given by the barcode on the magazine and the predefined analysis settings.

7. The analysis starts on a predefined analysis area on the slide which may vary depending on the type of cytocentrifuge used in the laboratory for preparation of the sample. The location of this area is determined during the installation of the system.

8. The slide scanning unit identifies the coordinates of possible nucleated cells starting from the center of this predefined area using the 10x objective.

9. The slide scanning unit uses the 10x objective to get an overview image of the predefined area. The 50x objective can also be used in order to achieve a higher magnification of the predefined area.

10. The slide scanning unit locates and identifies white blood cells on a slide using the identified coordinates, stores digital cell images (100x objective) and preclassifies the objects.

11. The located white blood cells are presented in an organized manner (per cell class) on a color monitor. The operator reviews the stored images and verifies the white blood cell classification either by accepting the suggested classification or by changing/correcting the classification. The operator has the possibility to review the overview image for any abnormalities.

12. At the completion of the procedure, the white blood cell classification results are presented as the number of cells found for each cell class and as the percentage (%) of the total number of white blood cells counted on the slide.

13. A summary of the white blood cell analysis is presented. The operator signs the slide result with user name and password.

14. The results can be sent to the LIS and/or be printed.

7.7 User Interface Description

During the analysis the operator uses four different views. The views are described below.

7.7.1 System control view

The *System Control View* shows the ongoing slide processing, gives an overview of the preclassification and presents a log of processed magazines.

7.7.2 Database view

Displays an overview of processed orders/slides. The operator can browse, search and load stored results and cell images.

7.7.3 Verification view

WBC tab

- Displays the results from the white blood cell differential count.
- Cell images are sorted in cell classes.
- The operator can view the cell classes in different galleries to facilitate comparison and reclassification.
- The operator can confirm or change suggested classification of counted cells.
- The operator can add comments.
- An individual cell can be studied in detail by adjusting the cell image in the following ways: zoom in/out, increase/decrease light and color. All values can be reset.
- Comparison can be made with reference cells.

Sign Slide tab

- Displays a result summary.
- The operator can sign the slide result.

Overview Tab

The body fluid overview image displays the entire sample area. The overview image can be used to find cells of interest and for getting an overall impression of the sample.

7.7.4 Report view

- Displays results from white blood cell differential counts
- The operator can merge multiple slide results from one patient sample.
- Slides can be included or excluded.
- Comments can be added.
- The completed sample order can be signed.

7.8 Technical Description

7.8.1 LIS

LIS stands for Laboratory Information System, and constitutes a central system common to several instruments for retrieving analysis order information and storing results. CellaVision™ DM software communicates with the LIS to retrieve information on how many cells to count, and what kinds of analyses should be performed on a slide. The operator can also send the results of the analysis back to the LIS. DM96 will only support communication according to the ASTM/CLSI standards LIS1-A and LIS2-A2.

7.8.2 Artificial Neural Networks – This section is confidential

7.8.2.1 Topology

(b)(4) Trade Secret Process - Product Specs

[redacted]

7.8.2.2 Features

(b)(4) Trade Secret Process - Product Specs

[redacted]

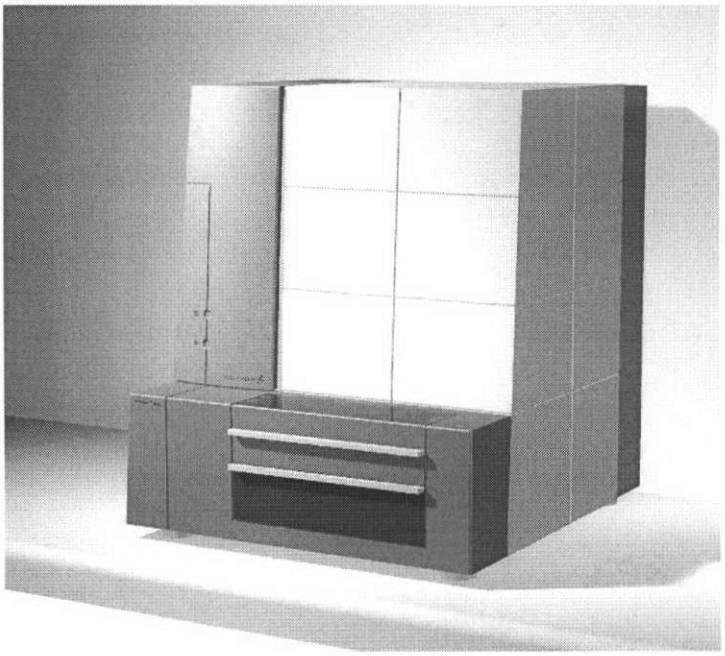
(b)(4) Trade Secret Process - Product Specs

[redacted]

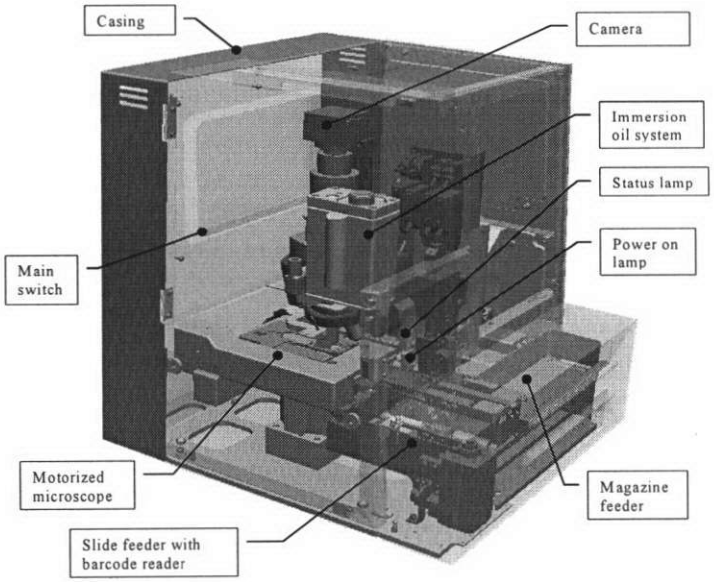
7.9 Hardware Description

The current CellaVision DM96 with the body fluid application is substantially equivalent with the 510(k) cleared DM96 with the peripheral blood application regarding technology and function. No changes were made to the hardware in order to incorporate the software supporting the new indication.

7.9.1 Image of the slide scanning unit



7.9.2 Functional view slide scanning unit



8 Device Specification

DESCRIPTION	DM96 SPECIFICATION
Parameters: White blood cell differential	See User's Manual, appendix B
Data input/output:	Input: Keyboard, color monitor, barcode reader, Ethernet port Output: Color monitor, high resolution printer, Ethernet port, Fire wire
Optional output:	RS232
Power requirements:	Voltage: 100 - 240VAC, current: 4 - 8 A
Physical:	**Slide Scanning Unit** Height: 62 cm Width: 53 cm Depth: 58 cm Weight: 60 kg
Operating temperature:	18°C – 31°C (64°F - 88°F)
Sound level:	Average 44 dBA Peak 59 dBA
Throughput:	Approximately 20 slides/h for orders containing only 10x overview images (6 mm analysis area). Approximately 6 slides/h for orders containing both 10x and 50 overview images (6 mm analysis area)
Performance	Cell-location: Average > 97%, Imprecision < 2%

9 Substantial Equivalence Discussion

Like the predicate device, DM96 with the body fluid application locates white blood cells, stores digital images of the cells and displays the images in an organized manner and suggests a cell class for each cell to aid operators in performing the differential count procedure. A competent operator is required to confirm or modify the suggested classification of each cell. It is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

Brief discussion of non-clinical factors supporting a determination of substantial equivalence:
The method requires a competent human examiner to review the microscopic images of the cells as does the predicate method and device. See the substantial equivalence comparisons below.

Brief discussion of clinical tests supporting a determination of substantial equivalence:
A clinical evaluation has been performed to confirm equivalence with the predicate method, the manual light microscopic process, for differentiation of white blood cells. The study has been performed according to a predefined protocol based upon the approved guideline, NCCLS EP9-A2. See Section 17 for details of and results from these tests.

Conclusions drawn from clinical tests:
The following information was obtained from the clinical tests:

- accuracy for cell-location
- accuracy for the verified classification for each cell class
- precision for the verified classification for each cell class

The results fulfilled the pre-defined requirements.

Comparative features of DM96 compared with the predicate devices:

Characteristic	**DM96 with Body Fluid Application**	**Manual light microscopic process**	**DM 96**
Intended use	Automated cell-locating device for cell-location and identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for cell-location and identification of blood smears, for in-vitro diagnostic use. Verification of results by skilled human operator.

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
Specimen type	Body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood and body fluids such as cerebrospinal fluid, serous fluid, bronchoalveolar lavage, and related fluids.	Peripheral blood.
Sample preparation	Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared by using a cytocentrifuge and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.	*White blood cells:* The examiners usually locate/count white blood cells by moving according to the battlement track pattern on the smear and distinguish between classes of white blood cells.	*White blood cells:* Cells are located/counted by moving according to the battlement track pattern. Cell images are analyzed using standard mathematical methods, including deterministic artificial neural networks (ANN's) trained to distinguish between classes of white blood cells. The cell images are pre-classified and the operator verifies the suggested classification by accepting or reclassifying.
Overview image	The device presents an overview image. The	The operator scans the slide to get an	The device presents an overview image of a

Characteristic	DM96 with Body Fluid Application	Manual light microscopic process	DM 96
	image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.	overview on parts of or the whole slide in different magnifications.	part of the slide. The image gives the operator possibilities to get an overview of the part in different magnifications.

10 Proposed Labeling

10.1 Labeling

Please refer to Appendix A, where you will find proposed labeling.

10.2 Instructions for Use

Please refer to Appendix B, where you will find the User's Manual.

11 Sterilization and Shelf Life

Not applicable. For in vitro diagnostic use only.

12 Biocompatibility

Not applicable. For in vitro diagnostic use only.

13 Software Including Risk Management

(b)(4) Trade Secret Process - Product Specs

[redacted]

Decision Process

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

13.2 Software Description

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

13.8 Validation, Verification and Testing

(b)(4) Trade Secret Process - Product Specs

[redacted]

14 EMC and Electrical Safety

The current CellaVision DM96 with the body fluid application is substantially equivalent with the 510(k) cleared DM96 with the peripheral blood application regarding technology and function. No significant changes were made to the hardware since the last EMC-test was performed (DANAK-198797). The EMC-report is included in Appendix E.

15 Performance Testing – Bench

15.1 Performance Testing

Tests were performed according to applicable parts of the FDA's Class II Special Controls Guidance Document - Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA – in order to ensure the safety, effectiveness, and compliance with product requirements for the CellaVision DM96 with the body fluid application.

15.2 Summary of Tests

The following tests were considered and, where applicable, successfully completed:

a) Evaluation of:
   - Accuracy (cell location and system)
   - System repeatability and precision
   - Performance characterization
   - Linearity
   - Carryover
   - Specimens

b) Inspections to verify that all design features are as intended and that all authorized design changes have been accomplished and recorded.

15.3 Tests

In this chapter follows a brief discussion and/or summary of tests conducted, including test methodology and pass-fail criteria.

15.3.1 Accuracy

15.3.1.1 Cell-location

15.3.1.1.1 Rationale

Evaluate and demonstrate the DM96 cell-location capability.

15.3.1.1.2 Test methodology

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

15.3.1.1.3 Pass-Fail Criteria

See table below.

(b)(4) Trade Secret Process - Product Specs

[redacted]

The test passed.

15.3.1.2 Accuracy - System

The characterization of the accuracy of the CellaVision DM96 with the body fluid application is presented in Section 17.

15.3.2 System Repeatability and Precision

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

16 Performance Testing – Animal

Not applicable

17 Performance Testing – Clinical

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

17.5 Conclusion

The accuracy evaluation was successful and shows that there were no systematic differences between the methods. For cell classes with r^2 values below 0.95 an evaluation was performed according to EP9-A2 and all those comparisons did pass. The short term imprecision results show that the methods are equivalent.

The overall results show that the methods are equivalent concerning all performance tests. The test passed.

18 List of standards

The following standards and guidelines were used in the design and testing of the CellaVision DM96.

1. Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA

2. Medical Devices – Application of risk management to medical devices, ISO 14971:2007

3. General Principles of Software Validation; Final Guidance for industry and FDA Staff, January 11, 2002.

4. Instructions for use for in vitro diagnostic instruments for professional use, EN 591:2001, European Standard.

5. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

6. In Vitro Diagnostic devices: Guidance for the Preparation of 510(k) Submissions, Food and Drug Administration, January 1997

7. Guidance for Industry, FDA Reviewer and Compliance on Off-The-Shelf Use in Medical Device, September 9, 1999

8. Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2 – 101: Particular requirements for in vitro diagnostic (IVD) medical equipment, EN 61010-2-101: 2002.

9. Evaluation of precision performance of quantitative measurement methods; Approved Guideline – Second edition, NCCLS Document EP5-A2.

10. Method comparison and bias estimation using patient samples; Approved guideline – Second edition, NCCLS Document EP9-A2.

11. Reference leukocyte (WBC) differential count (proportional) and evaluation of instrumental methods; Approved standard – Second edition, NCCLS Document H20-A2

12. Body fluid analysis for cellular composition; Approved guideline, CLSI Document H56-A.

13. Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 14, 2005.

Appendix A - Labels

The following examples of labels are included:

- Shipping Label (box label)
- Type Label (Affixed to the instrument)
- DVD Box labels
- DVD label

Note: All documents are signed and filed at CellaVision AB.

Appendix A – Shipping Label

CELLAVISION

Ideon Science Park SE-223 70 Lund Sweden

CellaVision™ DM96
- Cell Locating Device

Serial No: _____

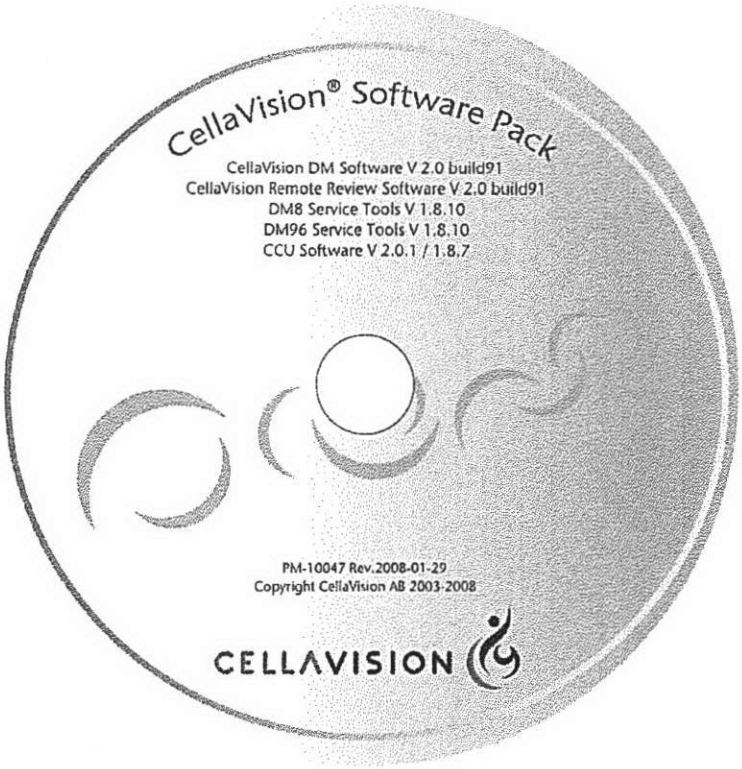
Model No: **XU-10020**

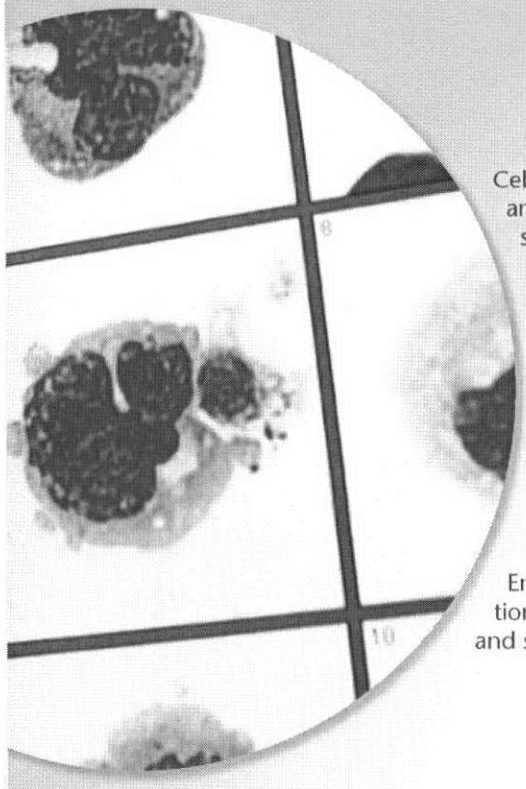
SW Ver: _____

IVD

CE

10°C 40°C


CellaVision® Software Pack
CellaVision DM Software V 2.0 build91
CellaVision Remote Review Software V 2.0 build91
DM8 Service Tools V 1.8.10
DM96 Service Tools V 1.8.10
CCU Software V 2.0.1 / 1.8.7
PM-10047 Rev.2008-01-29
Copyright CellaVision AB 2003-2008
CELLAVISION



CellaVision products offer automation and digitization of manual microscope examinations. The products automate the differential counts of cells in peripheral blood and body fluids, improving the efficiency and proficiency of the historically subjective differential review. Additionally, the advances of image analysis and network integration allow the cell image to become an integral part of the patient's record.

Enjoy your work. We welcome questions and your opinion on our products and services.

CELLAVISION

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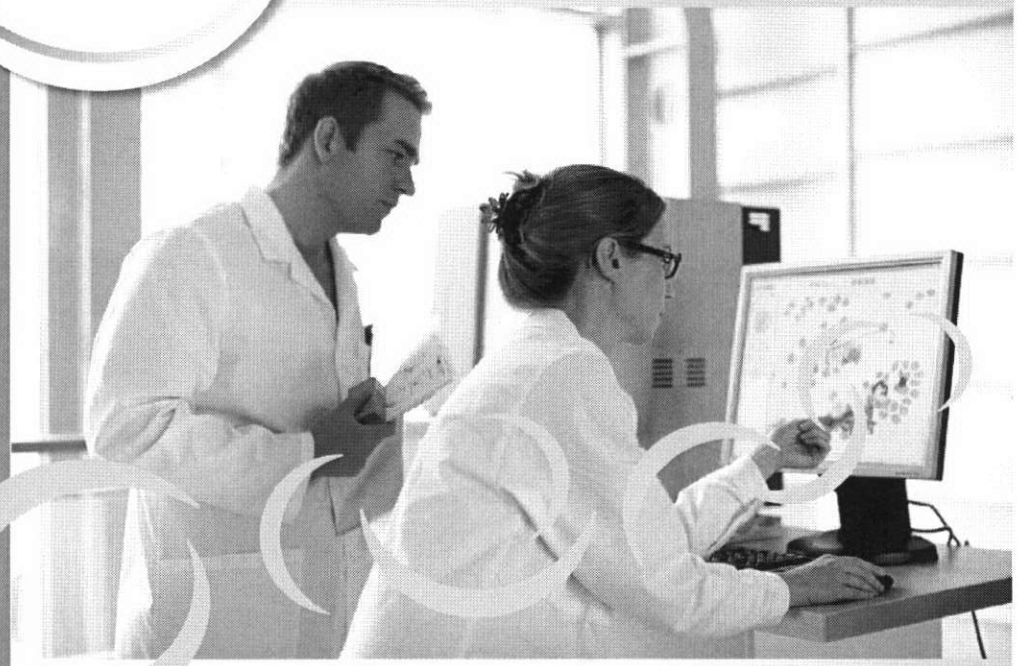
ph +46 46-286 44 00 • fax +46 46-286 44 70
info@cellavision.com • www.cellavision.com

CE IVD

PM.10250 2007-12-04

VISION

CellaVision® DM96



CELLAVISION

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CE CELLAVISION

Model No: XU-10020

Serial No:

100-240 VAC

50/60 Hz

2A-1A

Fuses: UL listed, T3.15A, 250 VAC ⚠

CellaVision AB
Ideon Science Park
SE-223 70 Lund, Sweden

C UL US LISTED
LABORATORY EQUIPMENT
22YH

RL-10031 2008-01-31

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Appendix B – User's Manual

Following document is included in this attachment

CellaVision DM 96 User's Manual

Note: All documents are signed and filed at CellaVision AB.

CellaVision™ DM96

V 2.0

USER'S MANUAL **English**

CELLAVISION

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Preface

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U.S. patents no. 6268611 and 6341180. Swedish patent no. 517626 and 520829. 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).

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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 DM96 (also referred to as the system), aiming for an efficient way to give you good understanding and knowledge of the system and its features. References are made to appendices providing additional information. Some self-explaining dialogs have been left out in the text.

Typographical conventions:

- Names of keys and on-screen objects with which you interact are presented in italics: e.g. click *PRINT*.

Note! *This User's manual covers all applications (e.g. Peripheral Blood and Body Fluid applications) available for the CellaVision DM96 system. The applicability of some sections in this User's manual may therefore depend on the applications installed on the system. Contact your local distributor for more information.*

1.1.1 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.

Warning alerts appear in this manual as follows:

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

(Cont'd)

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Place the system on a steady table. Do not place it where it is exposed to bumps or vibrations, excessive temperature variations or direct sunlight. The system must be connected to grounded electrical sockets only. Authorized personnel should do the initial installation and reinstallation after moving the system. Do not install or run any software not supplied with the system. To maintain electromagnetic compatibility, use only original components. Spillage of fluid on the surfaces of the system may cause malfunctions or deterioration. Wipe off spilled fluids immediately with a soft tissue.

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.

The following symbols are found on the system:

Symbol	Explanation
	Indicates that the surface becomes hot and should not be touched with bare hands.
	Documentation needs to be consulted.
IVD	In vitro diagnostic medical device
40°C 10°C	Temperature limitation
	This symbol is only valid in the European Community and indicates separate disposal of waste of electrical and electronic equipment
I	On (Supply).
○	Off (Supply).

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1.2 Intended Use of CellaVision DM96

CellaVision™ DM96 is an automated system intended for in-vitro diagnostic use.

CellaVision DM96:

- Scans whole or parts of a microscope slide;
- Automatically locates and presents images of cells on smears from various specimens;
- Is intended to be used by skilled operators.

1.2.1 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.

1.2.2 Body Fluid Application

The body fluid application (BF) 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.

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1.3 General Description of CellaVision DM96

CellaVision DM96 consists of a slide feeder unit, 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 G — Slide Preparation Guidelines).

General Functionality of the System:

- Receives order information from and sends results to the LIS;
- 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.

1.3.1 Peripheral Blood Application

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 WBC.

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

(Cont'd)

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(Cont'd)

WBC Reclassification for Peripheral Blood
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: *Polychromasia, Hypochromasia, Anisocytosis, Microcytosis, Macrocytosis and Poikilocytosis.*

RBC characterization
The operator can characterize to *Target cells, Schistocytosis, Helmet cells, Sickle cells, Spherocytosis, Elliptocytosis, Ovalocytosis, Tear drop cells, Stomatocytosis, Acanthocytosis, Echinocytosis, 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 G — Slide Preparation Guidelines for recommended staining recipes).

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1.3.2 Body Fluid Application

General Functionality

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

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other*. Cells pre-classified 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 pre-classified 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 WBC.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 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 G — Slide Preparation Guidelines for recommended staining recipes).

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1.3.2 Body Fluid Application

General Functionality

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

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other*. Cells pre-classified 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 pre-classified 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 WBC.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 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 G — Slide Preparation Guidelines for recommended staining recipes).

Limitations

A significant number of samples have not been evaluated for the following fluid types: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage. Therefore, they are not included in the statistical analysis.

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1.3.3 CellaVision™ Remote Review

CellaVision™ Remote Review is an additional software to CellaVision™ DM96. The software gives remote users access to analyzed slides and the possibility to reclassify cells and sign slides from another location. A slide being verified on CellaVision DM96 can simultaneously be opened on a CellaVision Remote Review and vice versa. CellaVision™ Remote Review is intended to be used with the Peripheral Blood and the Body Fluid applications. See 9 CellaVision Remote Review — Multiple Users for more information.

1.4 Components and Mechanical Operation

1.4.1 Major Parts of the System

The system comprises the following major units:

- Computer system
- Slide scanning unit (SSU)
  - Motorized microscope
  - Digital color camera
  - Immersion oil unit
  - Slide feeder unit with barcode reader
  - Magazine feeder unit
  - Control unit
  - Casing

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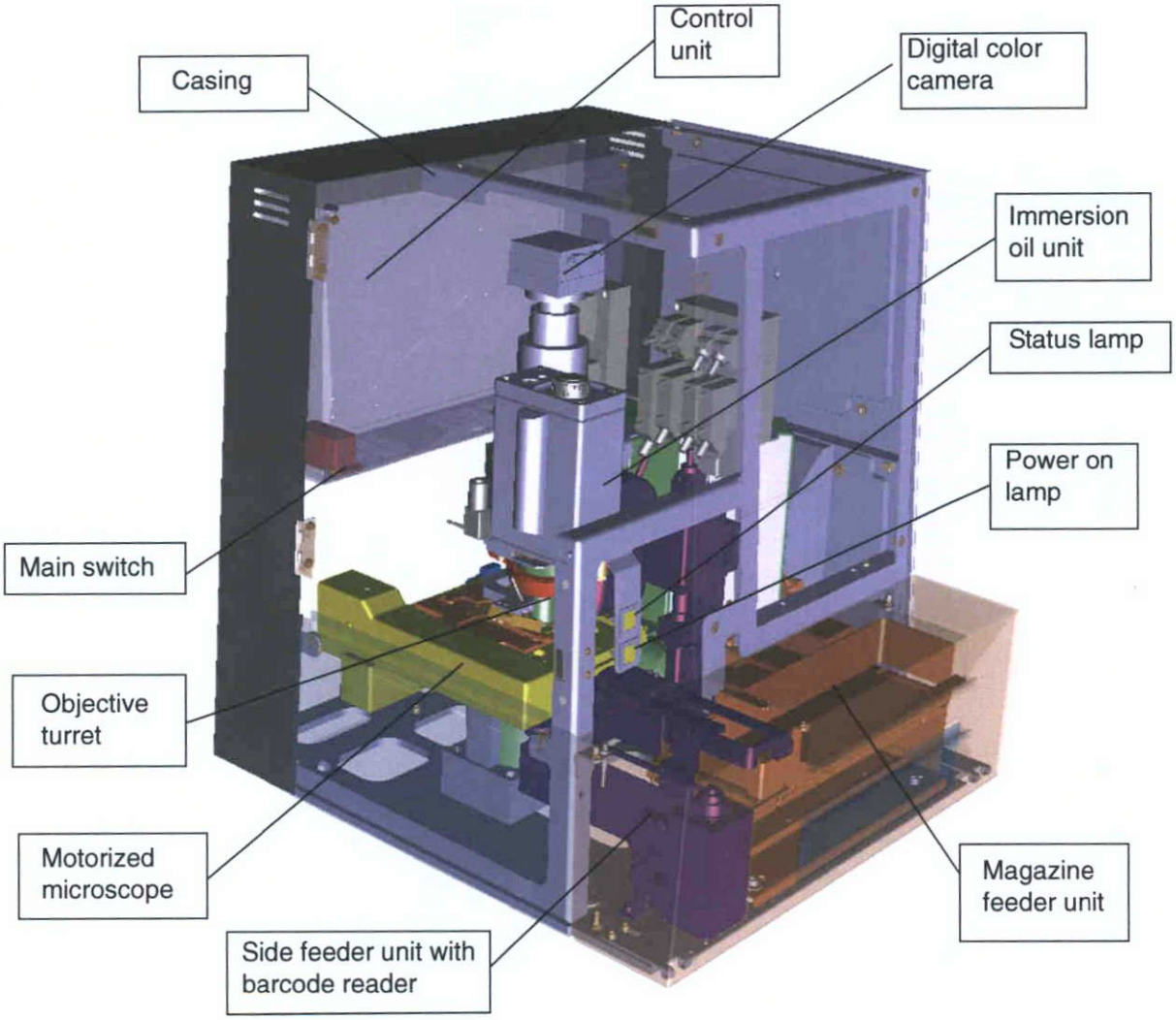
Slide Scanning Unit:



WARNING

Keep your fingers clear from the objective turret, otherwise personal injury may result.

WARNING

Do not remove the rear cover, dangerous voltages inside.

WARNING

The oil may cause sensitization by skin contact. We recommend using gloves.

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Motorized Microscope
The motorized microscope is a fixed-XY-stage upright light microscope with a moving objective focus. It has a motorized 5-position objective turret and a 100 W halogen illumination system. The microscope is motorized for fully automated positioning and focusing of the slide during process.

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. The canister capacity is about 500 ml. A sensor detects if the oil level is below 100 ml.

Slide Feeder Unit with Barcode Reader
The slide feeder transports slides from a magazine to the stage and back again after the slide has been processed. It is equipped with a barcode reader which scans the barcode of both the slide and the magazine. For maximum safety, the barcode of the slide is scanned both before and after processing. See Appendix A — System Specification for more information about barcodes.

Magazine
The magazine can be loaded with up to 12 slides (clipped/round corner slides).

Magazine Feeder Unit
The unit moves magazines from the conveyer to the slide feeder unit and from the slide feeder unit to the output drawer. It is equipped with a counter for the number of magazines in the conveyer and a sensor that warns if the output drawer is full.

Control Unit
The control unit controls motors, sensors, oil applying and illumination. It functions as a slave computer to the PC via an unshared 100 Mbit Ethernet connection.

Computer System
A PC system running Microsoft® Windows®XP and CellaVision DM software.

Casing
The casing comprises a metal cabinet including 5 hatches/drawers: main hatch, lamp hatch, input hatch, service hatch and output drawer.

WARNING

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

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2 Operating Procedures

2.1 Starting the System

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

Start the system as follows:

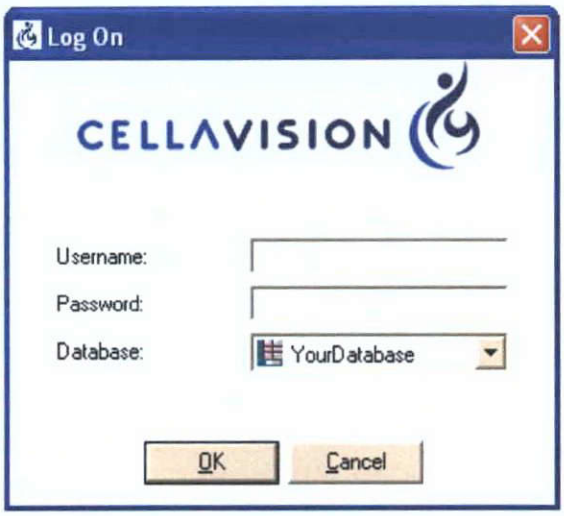
1. Switch on the slide scanning unit.
2. Switch on the system computer.
   Wait until the status lamp on the slide scanning unit is flashing or continuously lit (see picture in 1.4.1 Major Parts of the System).
3. In the *Log On* dialog, type username, password and select the desired database. The following icons indicate available database types:

   Processing database

   Export database

   Scan database

   CellaVision Competency Software database



4. Click *OK*.

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2.2 System Control View

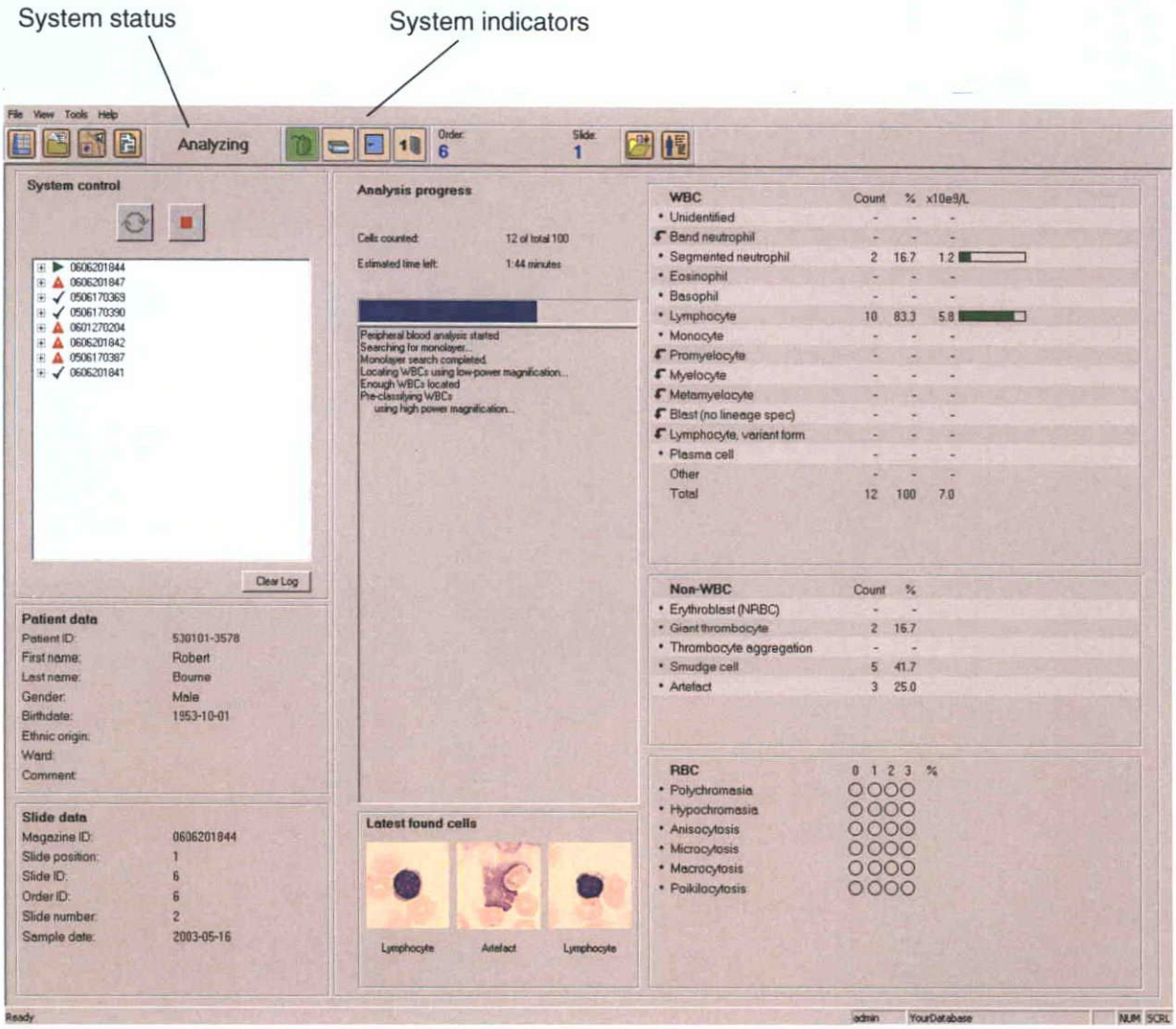
The *System Control View* shows the ongoing slide processing, gives an overview of the preclassification and presents a log of processed magazines. The layout of the *System Control View* depends on the type of application.

Click *System Control View* in the toolbar.

Information in Toolbar

System indicators show oil level, number of magazines 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.*



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2.3 Slides and Magazines

2.3.1 Barcodes

Important

Only slides labeled with barcodes can be processed. Use only barcode formats appropriate for the system (see Appendix A — System Specification).

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 solely of digits - a peripheral blood analysis will be performed.
- Blue magazines with barcodes consisting of the prefix 'BFS' followed by digits - a body fluid analysis will be performed.

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

Slide ID

The Slide ID is the barcode printed on the slide's label.

(Cont'd)

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(Cont'd)

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*.

2.4 Loading Slides into a Magazine

Load the slide into the magazine with the barcode upwards and towards the operator. 12 slides can be loaded into a magazine. The slide positions in the magazine are numbered 1-12 from the bottom up.

Caution

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

Note! *The same magazine can be used up to 100 times. When this limit is reached a warning is shown.*

Caution

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

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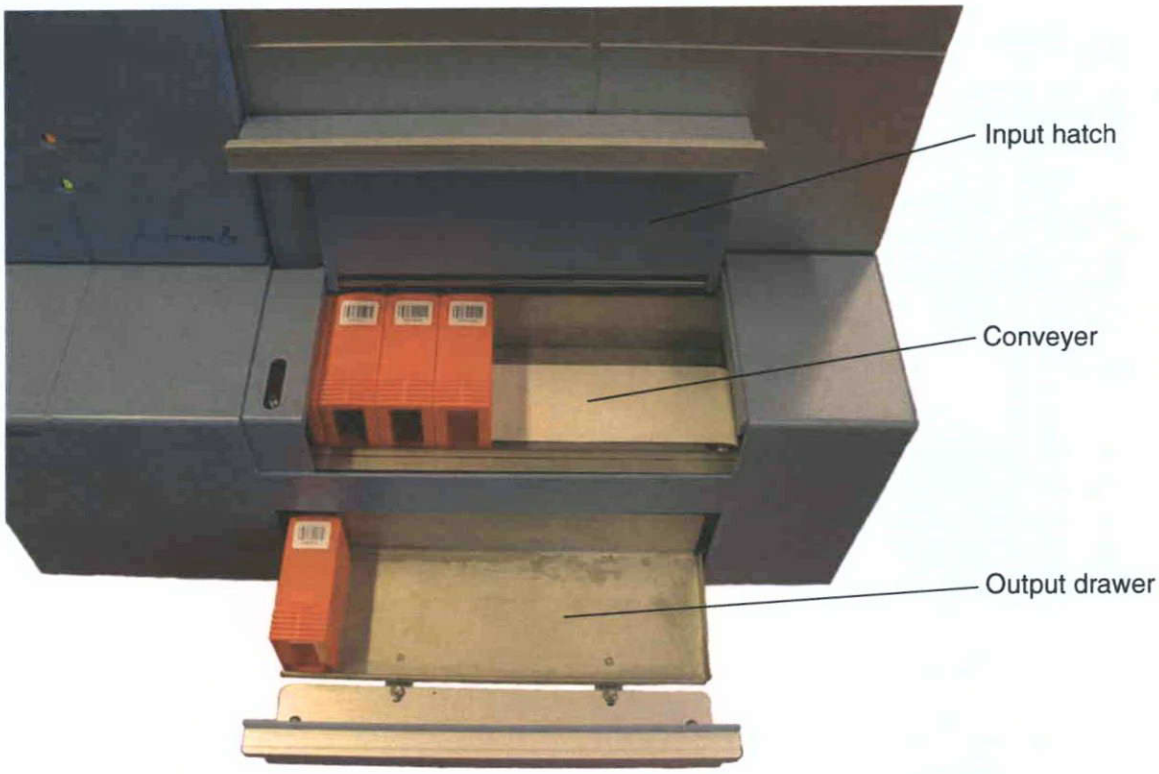
2.5 Processing Slides

2.5.1 Adding Magazines



Open the input hatch and put the magazines on the conveyer. The magazines must have the barcode turned upwards and the open end of the magazine inwards.

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

2.5.2 Starting the Slide Processing

Click on the *Start* button to start the slide processing. If you want the processing to start automatically when a magazine is inserted into the system, you can enable autostart in *Analysis Settings*. You still have to manually start the processing if the system has been stopped, restarted or if an error has occurred.

Start button

Autostart - Replaces the Start button.

Stop button

(Cont'd)

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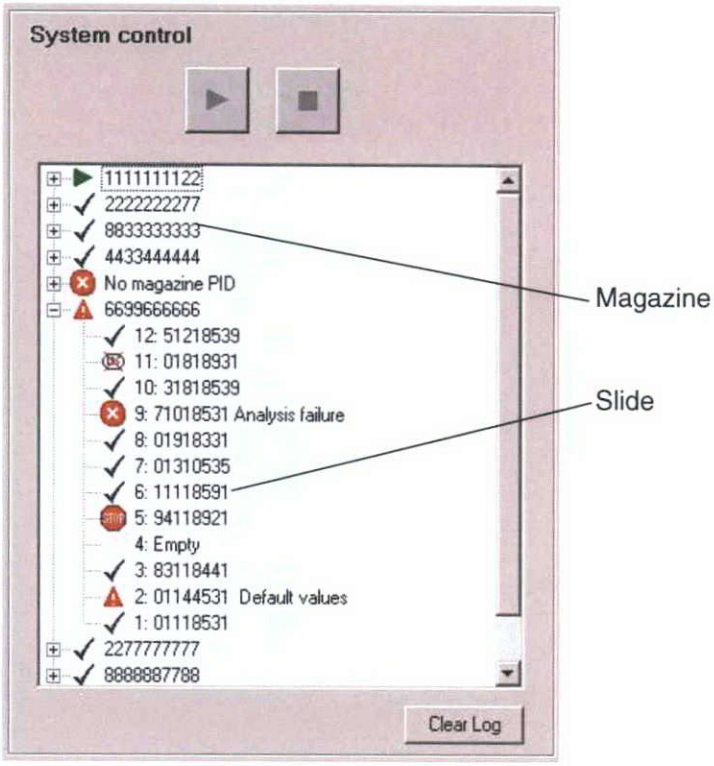
(Cont'd)

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



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

2.5.3 Magazine Status

The following information is available for each magazine:

Magazine status	Magazine ID (barcode).
⚠	012345678912

Magazine Status :

▶	Analyzing	
✓	Finished	The whole magazine is processed and all slides have status OK.
⚠	Warning	A slide with status Warning, Stopped, Failed or Cancelled exists in the magazine.
⊗	Failed	The magazine has no magazine ID.

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2.5.4 Slide Status

The following information is available for each slide:

Slide status	Slide position	Order/Slide ID (barcode)	Error/warning text
⚠	7	012345678912	Default values

Slide Status:

▶	Processing	
✓	OK	Slide processed with no warning or error.
⚠	Warning	Slide processed with a warning, see warning texts below. Results exist.
STOP	Stopped	Slide processing stopped by user. No results exist.
✖	Error	All ordered analyses failed, see error texts below. No results exist.
	Cancelled	The slide was cancelled in the LIS. Slide not processed.
Empty	Empty or no slide PID	Empty slide position in the magazine or no barcode on slide.

Warning Texts:

Default values	The order was not found in the LIS.
Incomplete analysis	The required number of WBCs were not found or one of the ordered analyses failed.

Error Texts:

Invalid slide PID	Invalid barcode on the slide.
Analysis failure	Slide processing failed.
Critical failure	A critical error occurred.

Slide Information Dialog

Double-click on a slide to open the Slide Information dialog. Additional information on the processed slide, e.g. the cause of an error, is displayed here.

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2.6 Ejecting Magazines

The magazine currently being processed can be ejected.

1. Click *Stop*. A *Stop/Continue* dialog appears.
2. Click *Stop*.
3. Select *Eject Magazine* in *Tools* menu. An *OK/Cancel* dialog appears.
4. Click *OK*. The magazine is ejected into the output drawer.

2.7 Handling of STAT Slides

1. Eject the magazine.
2. Load the STAT slide in slide position 1 in a magazine.
3. Open the input hatch and put the magazine to the left of the other magazines.

Note! *The leftmost magazine can be hard to pull out. Open and close the input hatch and the conveyor will move the magazines to the right.*

4. Click *Start*.

2.8 Shutting Down the System

Shut down the system as follows:

1. Eject any remaining magazine from the system.
2. Select *Exit* in the *File* menu.
3. Switch off the system computer.
4. Switch off the slide scanning unit.

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3 Verifying Processed Slides, Peripheral Blood

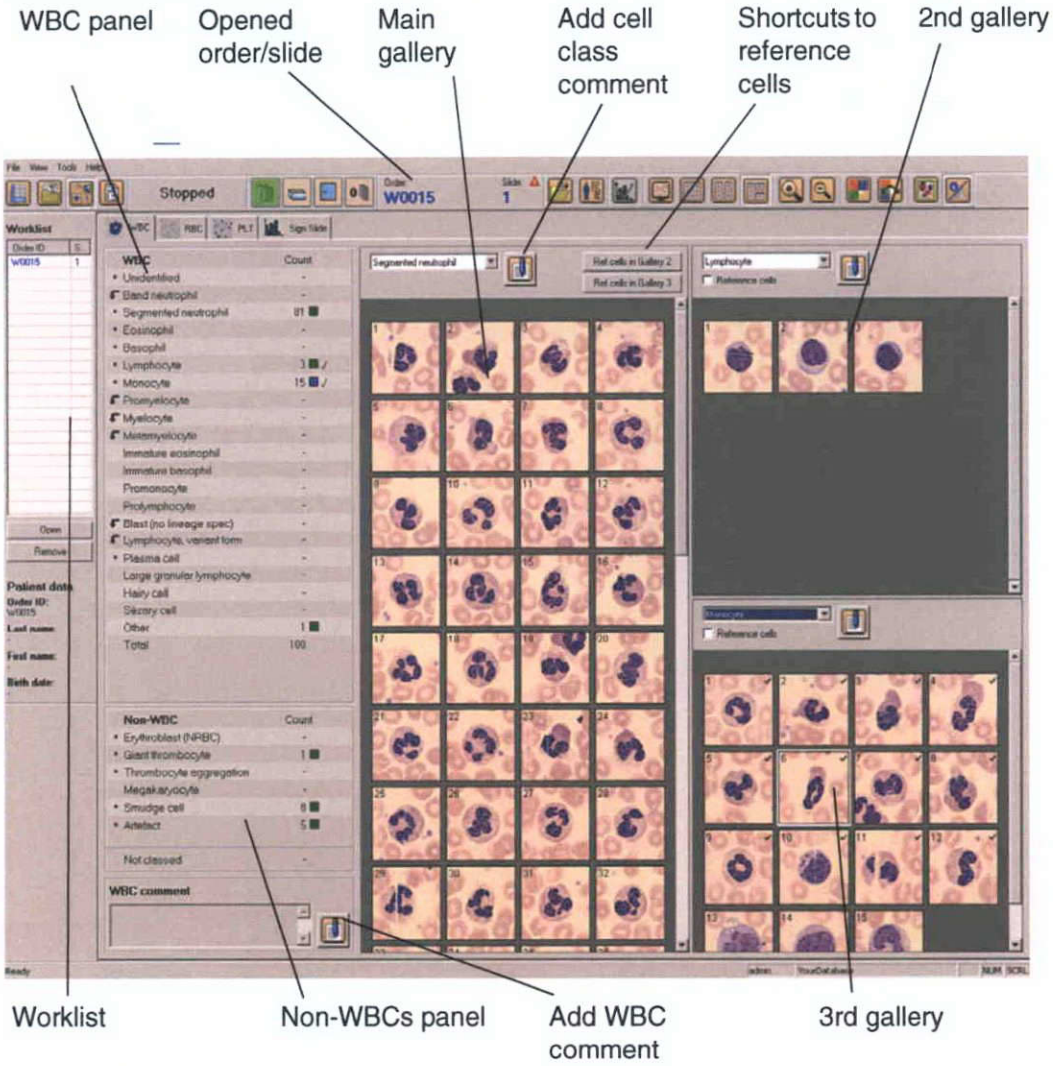
Opening an unsigned slide leads directly to the *Verification View*, where various tabs can be selected in order to review WBC, RBC and PLT and to Sign the Slide. To open a slide, see 6.1.3 Opening an Order/Slide.

Click *Verification View* in the toolbar.

***Note!** With DMConfiguration tool it is possible to add user defined WBC cell classes and RBC characteristics. To do this, contact your service personnel.*

3.1 White Blood Cell Classification

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



(Cont'd)

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(Cont'd)

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 or an arrow. In settings (see 10.4 Adjusting Reclassification Settings), you may choose to auto-forward preclassified WBCs to another cell class as follows:

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.*

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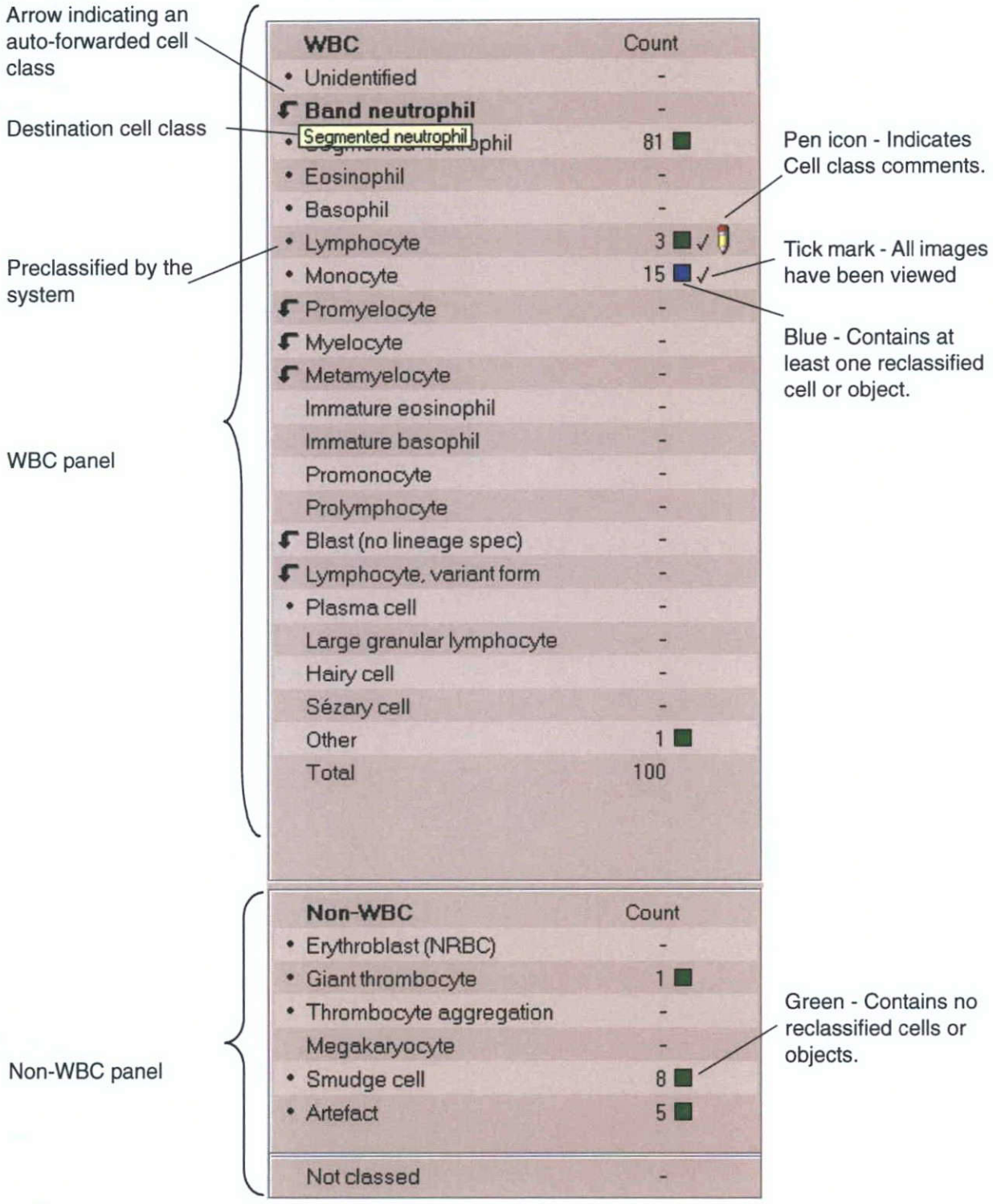
An arrow indicates an auto-forwarded cell class. Place the cursor over the arrow to see the destination cell class.



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3.1.1 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

Left- and right-clicking in the WBC and Non-WBCs panels also changes cell class in the main and the 2nd gallery, respectively. You can also select cell class in the drop-down list.

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 other show reference cells when checkbox Reference cells is activated. 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.

—— 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 program.

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 10.9 Adjusting Reference Cells Settings.

Note! *Reference cells are not available for body fluids.*

(Cont'd)

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(Cont'd)

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 3.4 Comments).

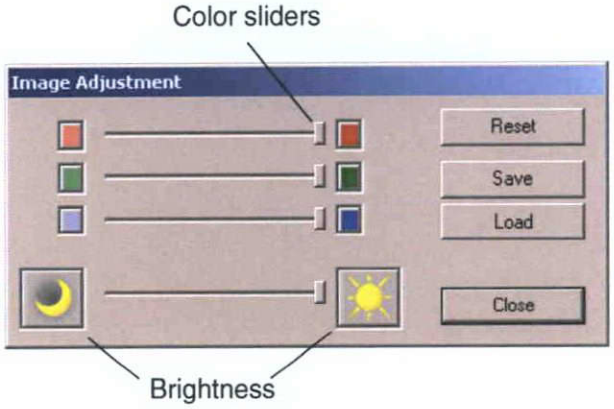
WBC Full Screen View
Click *WBC Full Screen View* to display all WBCs sorted by class.

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



Color sliders: Changes the color composition of the image.
Brightness: Adjusts the brightness of the image.
Reset: Restores original settings.
Save: Stores individual settings.
Load: Gets individual settings.

(Cont'd)

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(Cont'd)

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

Note! *You may also double-click on a WBC to enlarge it, and use the wheel button to zoom in/out.*

3.1.2 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.*

(Cont'd)

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(Cont'd)

Splitting Cells

If more than one cell is displayed in an image it can be difficult to determine which cell the system has actually identified. Click *Cell Marker* and a green square appears, marking the cell.

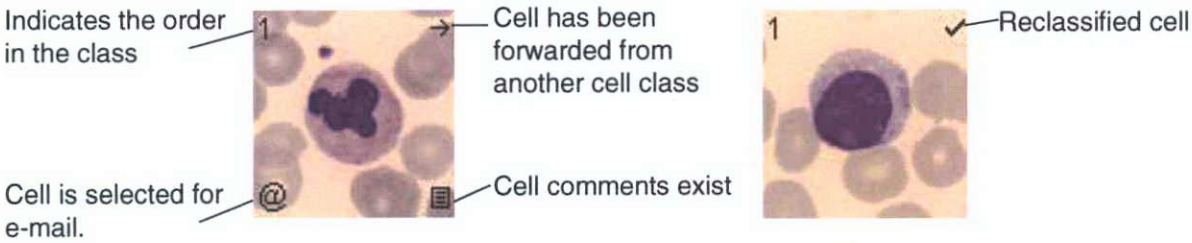
Cell Marker

Sometimes the system fails to separate WBCs and the green square will cover more than one cell. It is now possible to split cells using the right-click menu and select *Split cell*. A dialog appears explaining the procedure. Split cells are always moved to the bottom of the gallery. The green square is never changed for split cells. Instead, if you click on *Cell Marker*, a red cross marks the cell.

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

WBC Attributes

Each cell is associated with attributes.



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

WBC Attributes

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Right-click Menu

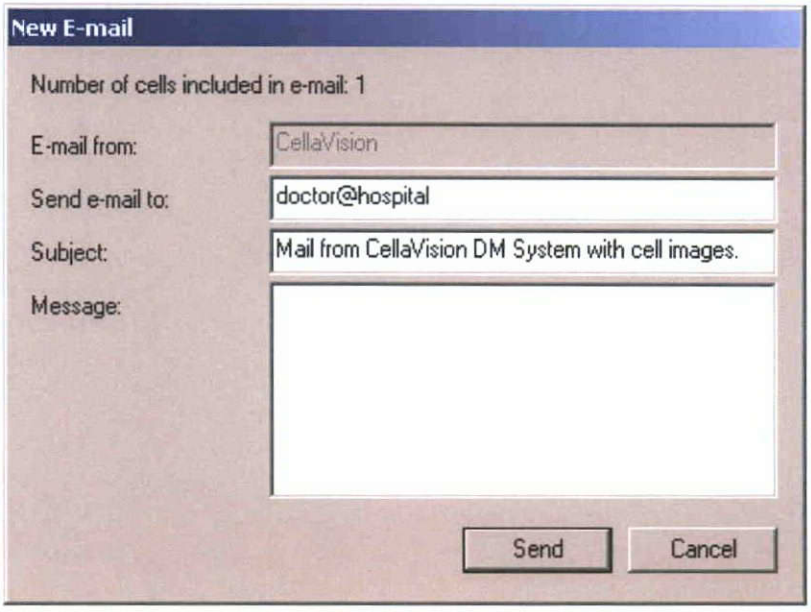
Right-click on a cell to set/view attributes. A menu appears, allowing the following options:

1. *View DM's 1st, 2nd and 3rd suggestions of classification.*
2. *Reclassify cell.*
3. *Add/view cell comments* (see 3.4 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.*

3.1.3 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.*

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3.1.4 Copying Images to Disk

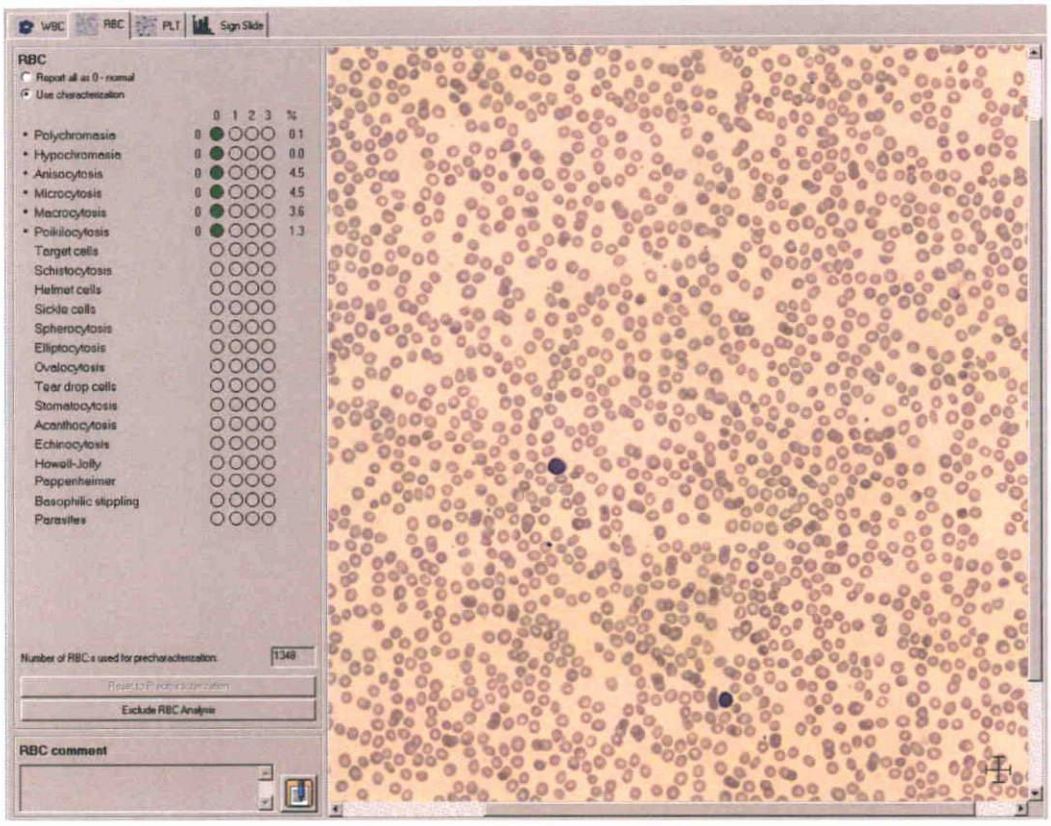
You may copy selected images to disk.

1. Select cells for copying.
2. In the right-click menu select *Copy images to disk…* and the *Copy images to disk* dialog appears.
3. Specify the destination path where you want the images to be saved.
4. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

3.2 Red Blood Cell Characterization

The RBC overview image corresponds to the area of 8 microscopic high power fields (HPF) (100x objective and a 22mm ocular). See 10.5 Adjusting RBC Precharacterization Settings.



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.

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(Cont'd)

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.

In the bottom right-hand corner of the RBC image there is a cross-shaped ruler that represents 14 µm across. As the image magnification is increased, numbers will appear at the ends of the ruler to indicate the scale in micrometers. 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.

The ruler will be placed back in the bottom right corner whenever the view is changed.

The ruler shape can be toggled between the default cross shape and a line shape by double-clicking on it. The shape will not change back to the cross when shifting views.

A thin window frame appears around the ruler when the mouse pointer is moved over it to indicate that the ruler can be moved or have its shape changed.

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3.2.1 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/out by moving the mouse pointer up/down.

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

Note! *You may also double-click in the RBC image to enlarge a limited area, and use the wheel button to zoom in/out.*

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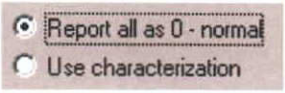
3.2.2 Characterizing Red Blood Cell Morphology

There are two ways to report the RBC result:



a) Report all as normal

1. Select radio button *Report all as 0 - Normal.*

b) Use characterization

1. Select radio button *Use characterization.*
2. 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.

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

3.2.3 Excluding the Red Blood Cell Analysis

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

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3.3 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 22mm ocular). The overview image is divided into 4, 9 or 16 sub-images (grid squares) as defined by the grid size. The grid size options are 2x2, 3x3 and 4x4. The 4x4 grid size gives the largest magnification of the image. There are as many entry fields as there are grid squares.

By clicking *Help Lines* in the toolbar, a grid of lines is drawn over the image to facilitate the counting of PLTs.

There are two ways, or modes to perform the PLT estimation. This is determined in PLT settings (see 10.6 Adjusting PLT Settings).

1. Counting PLTs in the overview image
2. Estimating the PLT concentration level

Note! *When a slide is opened for the first time, the slide gets mode according to the settings and the mode can then not be changed for that order. The system ensures that all slides in a multi-slide order have the same mode.*

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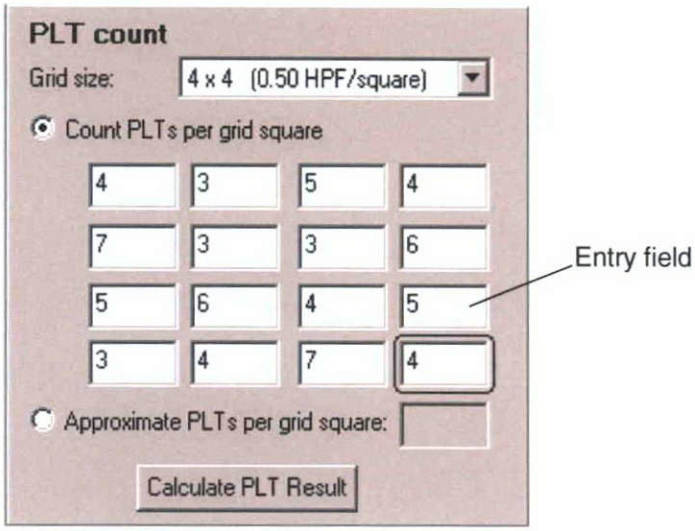
3.3.1 Counting Platelets in the Overview Image

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.



a) Counting PLTs per grid square

1. Select the *Count PLTs per grid square* radio button.
2. 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.

b) Specifying an approximate PLT count per grid square

1. Select the *Approximate PLTs per grid square* radio button.
2. Use the entry fields to view different grid squares.
3. Estimate the average PLT count per grid square and type this value in the field.

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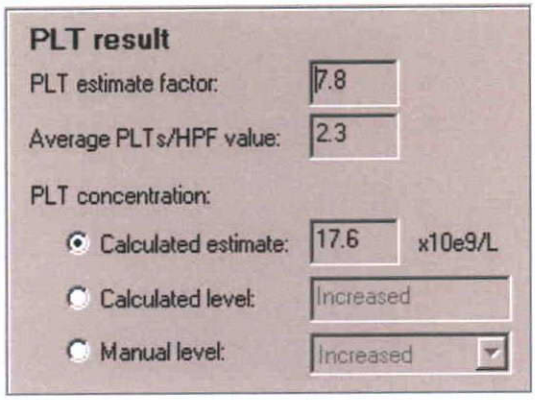
(Cont'd)

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 have to determine your own PLT estimate factor and enter it in PLT settings. By default, it is set to "0" (See Appendix F — Determining the Platelet Estimate Factor).

Note! *In the calculations, several decimals are used. The presented results are truncated to 1 decimal, which means that the results may seem incorrect.*

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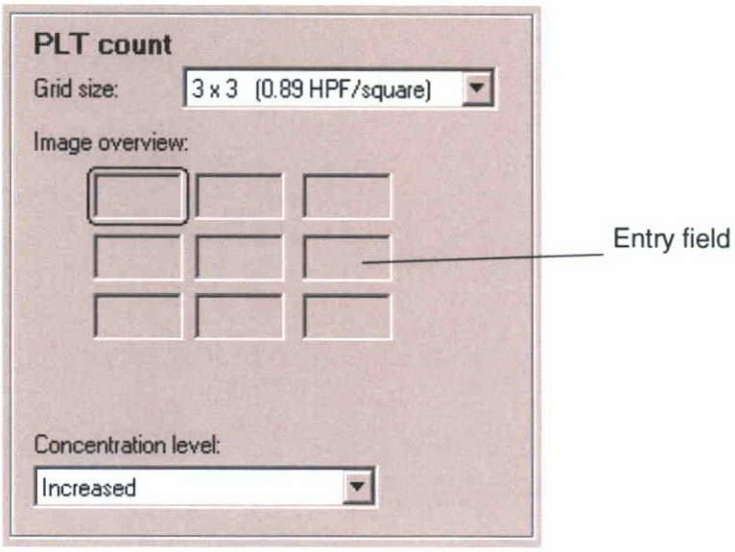
3.3.2 Estimating the Platelet Concentration Level

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

3.3.3 Excluding the Platelet Analysis

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

3.4 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 *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.*

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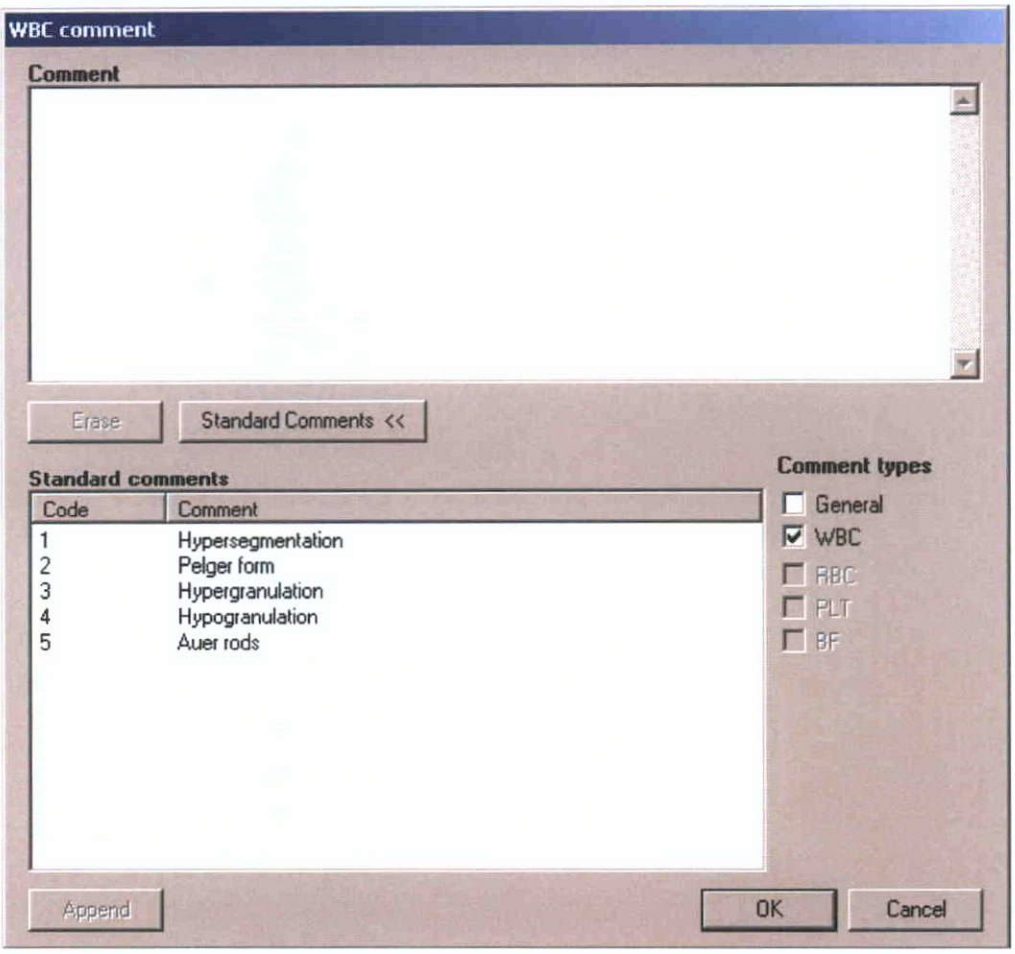
3.4.1 Adding Comments

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.

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



You may write/edit comments in the *Comment* box. Click *Standard Comments* to show/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*.

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(Cont'd)

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 10.8 Adjusting Standard Comments Settings.

To clear comments, click *Erase*.

3.5 Order Data

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

A dialog is shown containing information about the open order. If no data is received from the LIS it is possible to edit some of the information. The Order ID can only be edited if it starts with 'ER'.

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

If you can't generate barcode labels (printer is broken, out of printer ribbon, or out of labels) you can use pre-printed labels with the prefix 'ER' (available through your local dealer).

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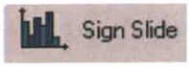
3.6 Signing a Slide

A summary of the WBC, RBC and PLT 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. Activate/deactivate the automatic options *Sign order when signing slide*, *Send to LIS* and *Print order*.
4. 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. Default values for the *Sign Slide* dialog are set in *Settings* under *Report/Sign*. The option to send results to the LIS is activated in *Analysis* in *settings*.

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

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3.6.1 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:

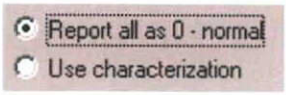
WBC

- All cell classes must have been viewed, i.e. there should be tick marks after each cell class.
- No WBCs 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 3.3 Estimating Platelets.

OR:

- Click *Exclude PLT Analysis*.

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4 Verifying Processed Slides, Body Fluids

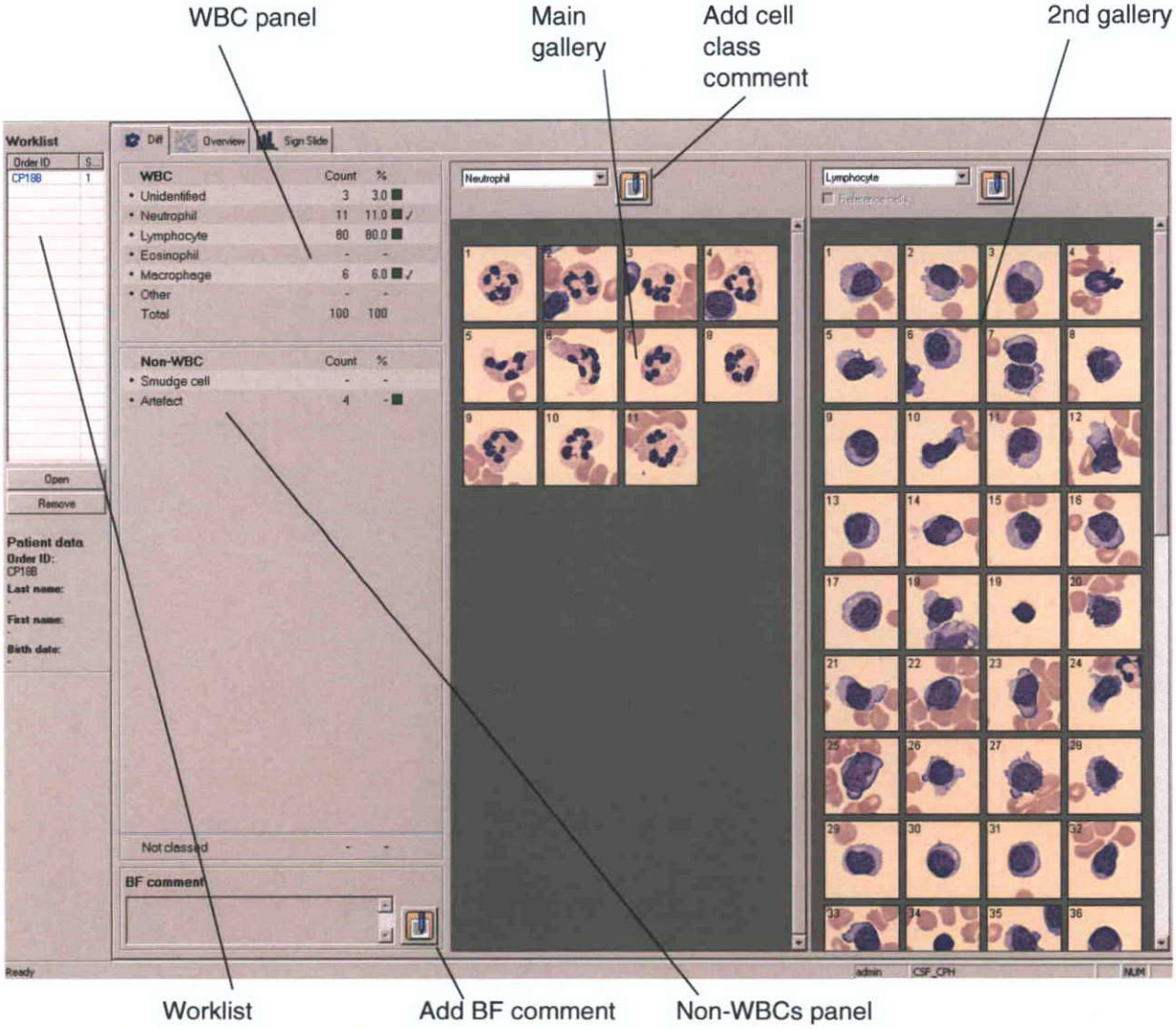
Opening an unsigned slide leads directly to the Verification View, where the tabs for *Overview*, *WBC* and *Sign Slide* are shown. To open a slide, see 6.1.3 Opening an Order/Slide.

Click *Verification View* in the toolbar.

Note! *With DMConfiguration tool it is possible to add user defined WBC cell classes and Non-WBC classes. To do this contact your service personnel.*

4.1 Body Fluids Differential

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



(Cont'd)

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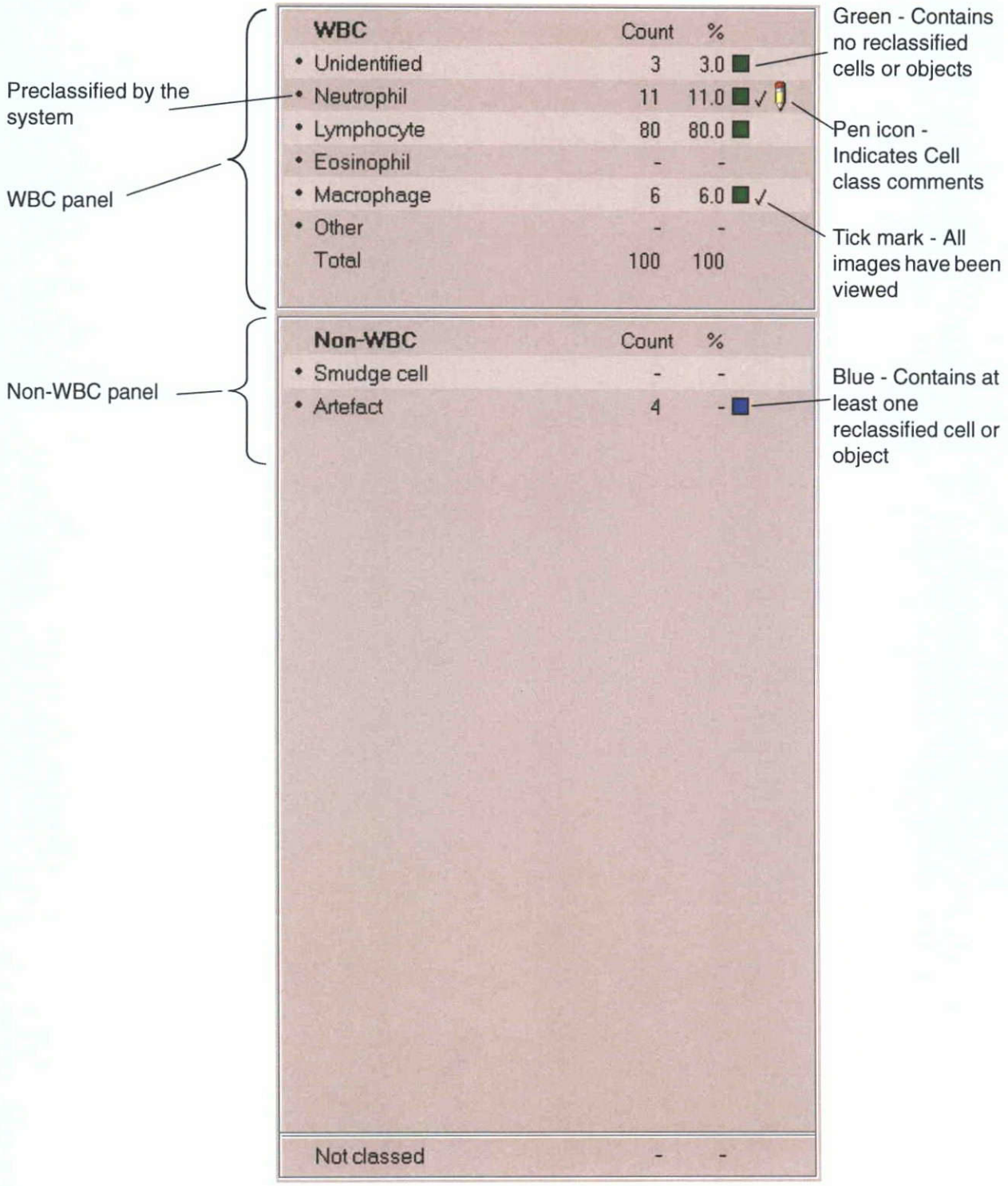
(Cont'd)

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.



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4.1.1 Customizing Views

To Customize views, see 3.1.1 Customizing Views.

4.1.2 Reclassifying Cells

To reclassify cells, see 3.1.2 Reclassifying White Blood Cells.

4.1.3 E-mail

To email cell images, see 3.1.3 E-mail.

4.1.4 Copying Images to Disk

To copy cell images, see 3.1.4 Copying Images to Disk.

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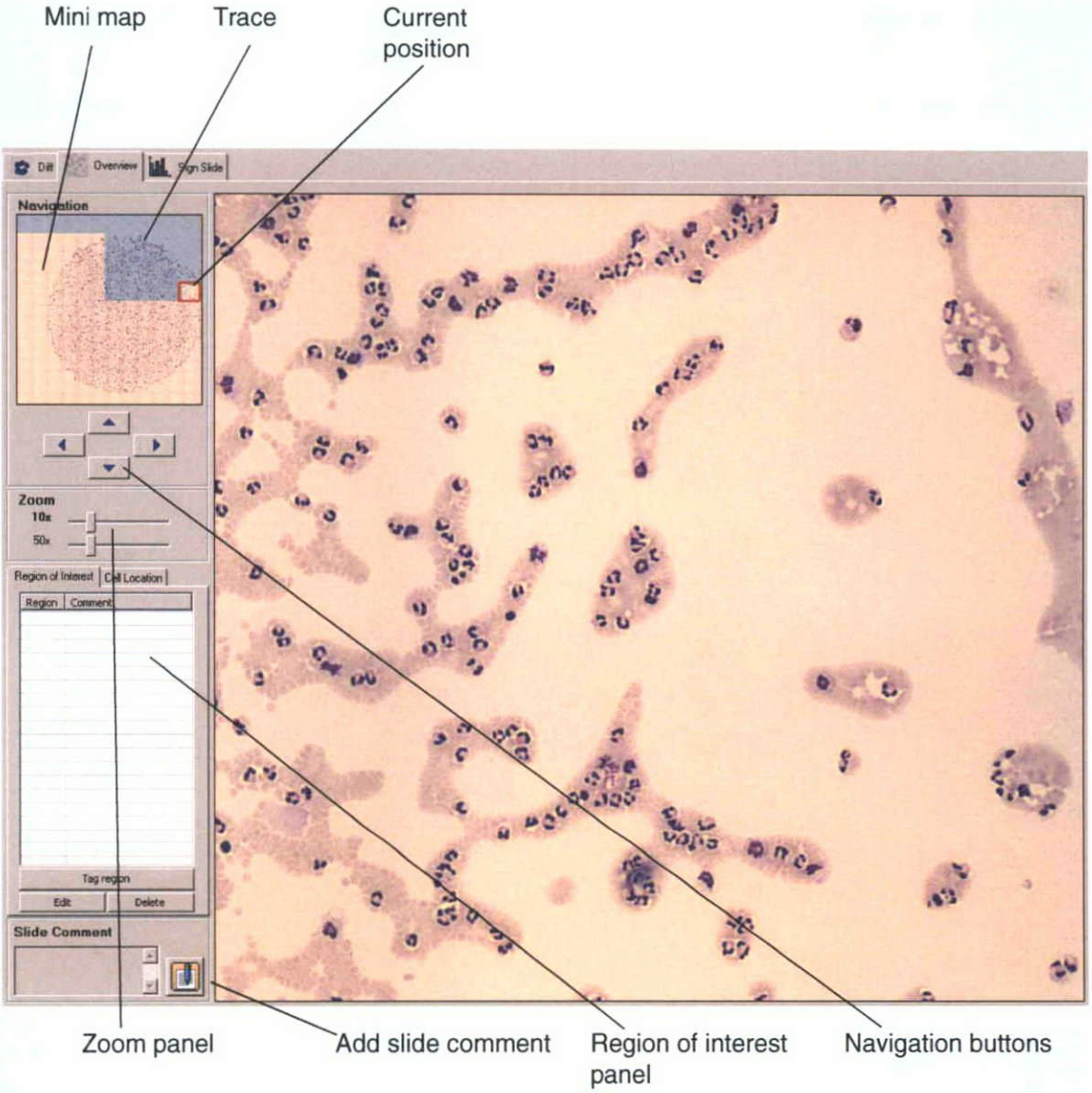
4.2 Body Fluids Overview Image

The body fluid overview image displays the entire sample area (see 10.13 Adjusting BF Analysis Area). 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 10.3 Adjusting Analysis Settings).



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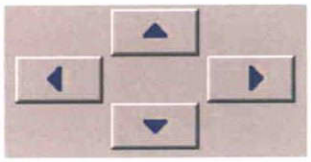
4.2.1 Navigating in the Overview Image

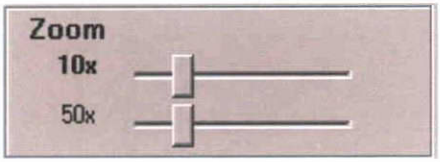
Navigate in the overview image by using the keyboard arrow buttons or the navigation buttons.



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.



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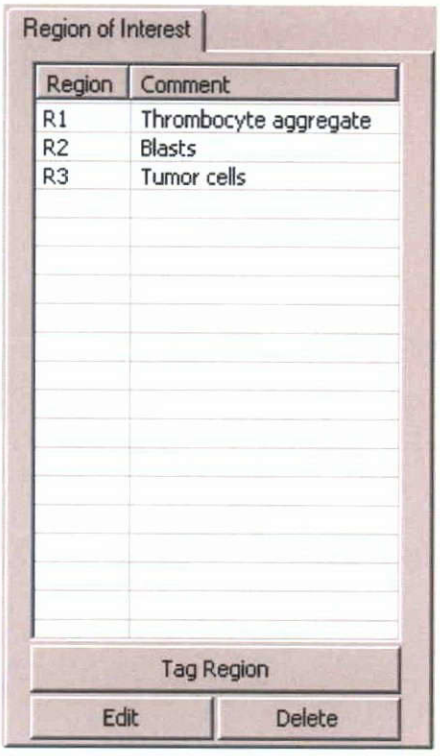
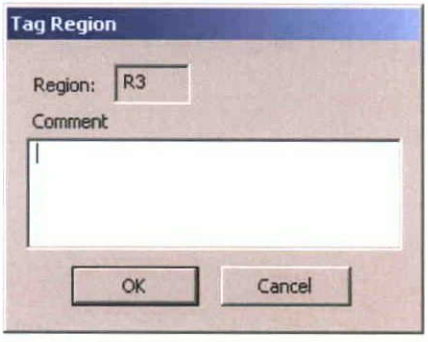
4.2.2 Tagging Regions of Interest

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.*



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4.2.3 Copying Regions of Interest to Disk

You can copy an individual region of interest image to disk.

1. Select a region of interest.
2. On the right-click menu select *Copy image to disk…* and the *Copy the image to disk* dialog appears.
3. Specify the destination path where you want the image to be saved.
4. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

4.3 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.*

4.3.1 Adding Comments

To add a comment, click *Comment*. For more details, see 3.4.1 Adding Comments.

Comments

4.4 Order Data

To view or edit the order data, see 3.5 Order Data.

4.5 Signing a Slide

The Body Fluid differential is presented in the *Sign slide* tab. To sign a slide, see 3.6 Signing a Slide.

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5 Reporting Results

See 10.7 Adjusting Report/Sign Settings for Report/Sign settings.

Click *Report View* in the toolbar.

In the *Report View* you compare the results of each slide in the order and you can exclude slides from the reported result. You sign the order, send order data to the LIS and cancel an order. You can also write a general comment on the order.

5.1 Merging Slides

In the *Slide Merge* tab you compile analysis results for the whole order based on one or several slides. You can also look at all comments associated with an order.

Result Panel

Result

	MT Order 120 (1)	MT Order 120 (2)	Reported Result
WBC			
Unidentified			
Band neutrophil	4.2%	[illegible]	4.2%
Segmented neutrophil	22.0%	[illegible]	22.0%
Eosinophil	15.3%	[illegible]	15.3%
Basophil	5.1%	[illegible]	5.1%
Lymphocyte	16.1%	[illegible]	16.1%
Monocyte	14.4%	[illegible]	14.4%
Promyelocyte			
Myelocyte	1.7%	[illegible]	1.7%
Metamyelocyte	3.4%	[illegible]	3.4%
Immature eosinophil	4.2%	[illegible]	4.2%
Immature basophil	5.1%	[illegible]	5.1%
Promonocyte		[illegible]	
Prolymphocyte		[illegible]	
Blast (no lineage spec)			
Lymphocyte, variant form			
Plasma cell	2.5%	[illegible]	2.5%
Large granular lymphocyte			
Hairy cell	1.7%	[illegible]	1.7%
Sézary cell	2.5%	[illegible]	2.5%
Other	1.7%	[illegible]	1.7%
Non-WBC			
Erythroblast (NRBC)	5.1%	[illegible]	5.1%
Giant thrombocyte		[illegible]	
Thrombocyte aggregation		[illegible]	
Megakaryocyte		[illegible]	
Smudge cell		[illegible]	
Artefact		[illegible]	
Not classed			

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.

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(Cont'd)

Including/Excluding Slides in/from the Reported Result

When a slide is signed, it is automatically included in the reported result. To include/exclude a slide, activate/deactivate the checkbox next to the Slide ID. When a slide is excluded, a dialog is shown where you may write a comment explaining the exclusion.

Note! *It is only possible to include signed slides.*

Note! *It is not possible to merge slides if one or more slides have a "confirm cell counter result" flag. The calculated result in the reported result column will be displayed incorrectly.*

Changing the Reported Result

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

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

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

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(Cont'd)

Comment Panel

Comment

	MT Order 120 (1)	MT Order 120 (2)
Exclusion comment		
WBC comment		
WBC cell class comments		
Unidentified		
Band neutrophil	Comment Comment to this cell class.	Comment to this cell class.
Segmented neutrophil		
Eosinophil	Comment to this cell class.	Comment to this cell class.
Basophil		Comment to this cell class.
Lymphocyte	Comment to this cell class.	Comment to this cell class.
Monocyte	Comment to this cell class.	Comment to this cell class.
Promyelocyte		
Myelocyte		
Metamyelocyte		
Immature eosinophil		
Immature basophil		Comment to this cell class.
Promonocyte		Comment to this cell class.
Prolymphocyte		
Blast (no lineage spec)		
Lymphocyte, variant form		
Plasma cell		
Large granular lymphocyte		
Hairy cell	Comment to this cell class.	
Sézary cell	Comment to this cell class.	
Other		
Non-WBC cell class comments		
Erythroblast (NRBC)		
Giant thrombocyte		
Thrombocyte aggregation		
Megakaryocyte		
Smudge cell		
Artefact		
Not classed		
RBC comment	Comment to this RBC.[admin]	
PLT comment	Comment to this PLT.[admin]	

Here you see all comments associated with the order. Only the beginning of the comment is shown in the table. Click on a comment to view the whole comment text. It is not possible to edit comments in this panel. All comments in the *Comment* panel will be included in the report.

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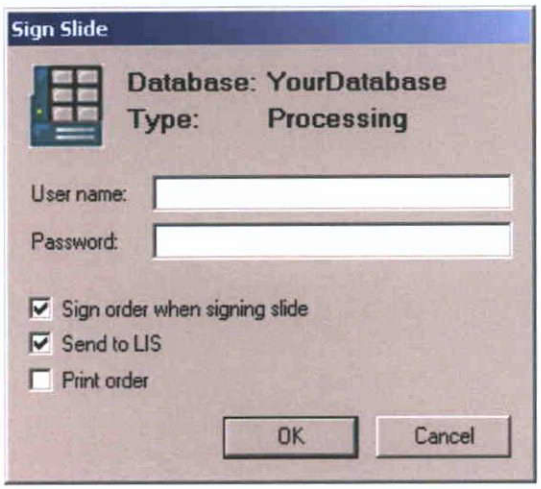
5.2 Report Preview

This tab contains a preview of the report. The format of the report is based on templates and these can be selected in *Settings* (see 10.7 Adjusting Report/Sign Settings).

5.3 Signing an Order (result)

1. Click *Sign Order.*



2. Type *Username* and *Password* (if not prefilled).
3. Select whether order shall be sent to the LIS and/or printed.
4. Click *OK.*

Note! *No order data can be changed after signing. Comments may still be added.*

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.*

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5.5 Canceling an Order

To cancel an order you sign the order with no included slides. When the order is sent to the LIS the order will be reported as cancelled.

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) .

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6 Database and Archiving Data

Click *Database View* in the toolbar.

Processed and pending orders are stored in the database. You can switch between the two types, using the tabs *Processed Orders* and *Pending Orders*.

6.1 Database — Processed Orders

You can search for and open processed orders and slides stored in the system. Orders are displayed according to the *Search criteria*. Select an order to display more information in the *Order data* panel. All slides belonging to the order are shown in the *Slide* list. Select a slide to display more information in the *Slide data* panel.

(Cont'd)

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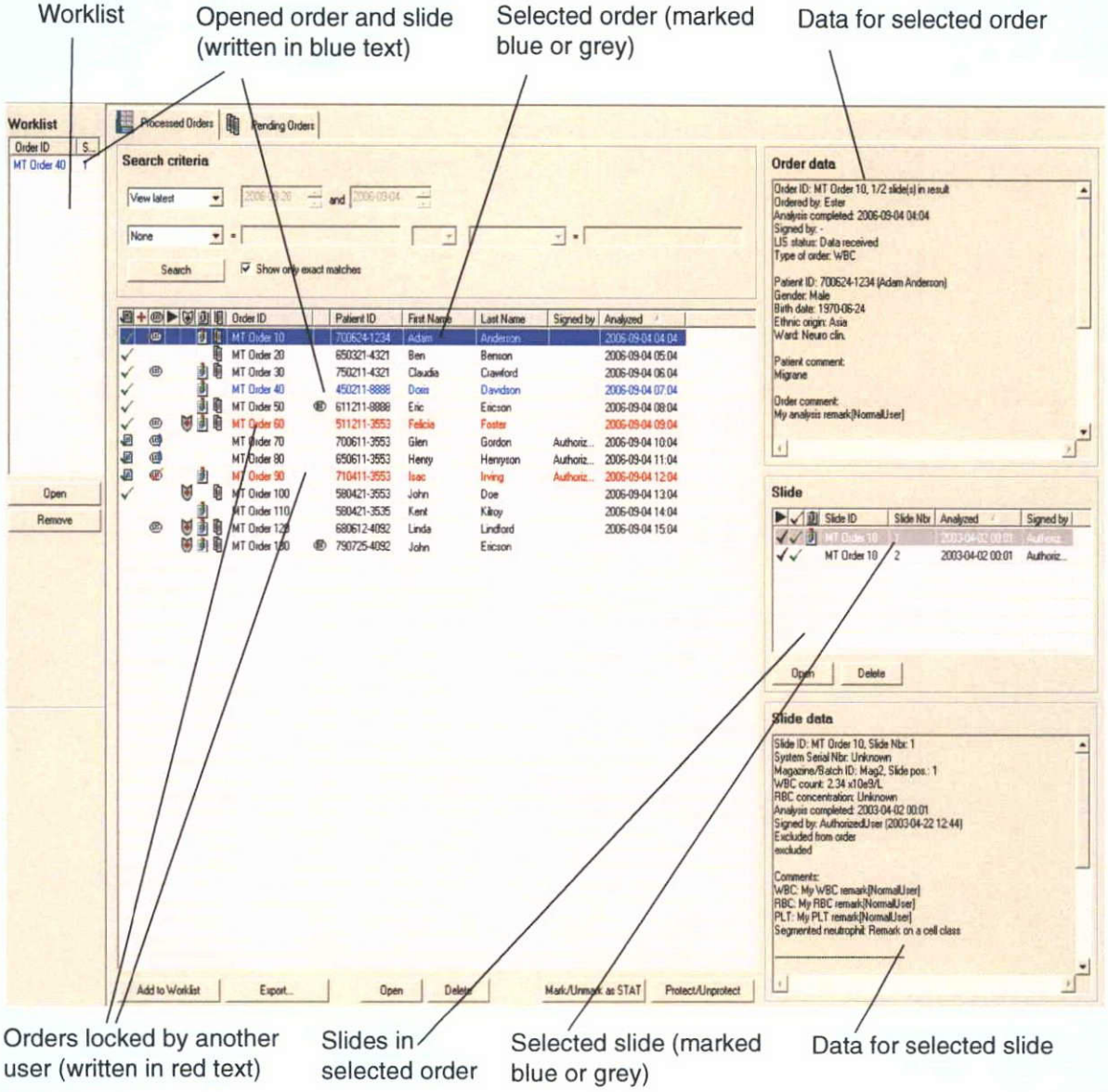
(Cont'd)



An open order and slide is always written in blue text. An order/slide opened by another operator on a CellaVision Remote Review/CellaVision DM is written in red text. In the *Order data* and *Slide data* panels, *Locked by* indicates who has opened the order/slide (the person logged on to Windows) and on which computer.

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6.1.1 Order List

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

							Order ID		Patient ID	First Name	Last Name	Signed by	Analyzed
✓		LIS					MT Order 10		700624-1234	Adam	Anderson		2006-09-04 04:04
✓							MT Order 20		650321-4321	Ben	Benson		2006-09-04 05:04
✓		LIS					MT Order 30		750211-4321	Claudia	Crawford		2006-09-04 06:04
✓							MT Order 40		450211-8888	Doris	Davidson		2006-09-04 07:04
✓							MT Order 50	BF	611211-8888	Eric	Ericson		2006-09-04 08:04
✓		LIS					MT Order 60		511211-3553	Felicia	Foster		2006-09-04 09:04
		LIS					MT Order 70		700611-3553	Glen	Gordon	Authoriz...	2006-09-04 10:04

Order status

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

STAT mark +

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

LIS status

Empty field	No data sent or received.
LIS	Data received.
	Waiting to send result.
	Result is sent.
	Result is sent, send failure.
	Result is successfully sent.

(Cont'd)

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(Cont'd)

Process status	▶
Empty field	All slides in the order have process status OK.
	Slide with process error in the order.
	Stopped slide in the order.
	Slide with process status in the order.

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.

Multi-slide status	
Empty field	One slide in order.
	More than one slide in order.
C	The order contains a cell counter confirmed result.

Order type	
Empty field	Peripheral blood order.
BF	Body fluid order.

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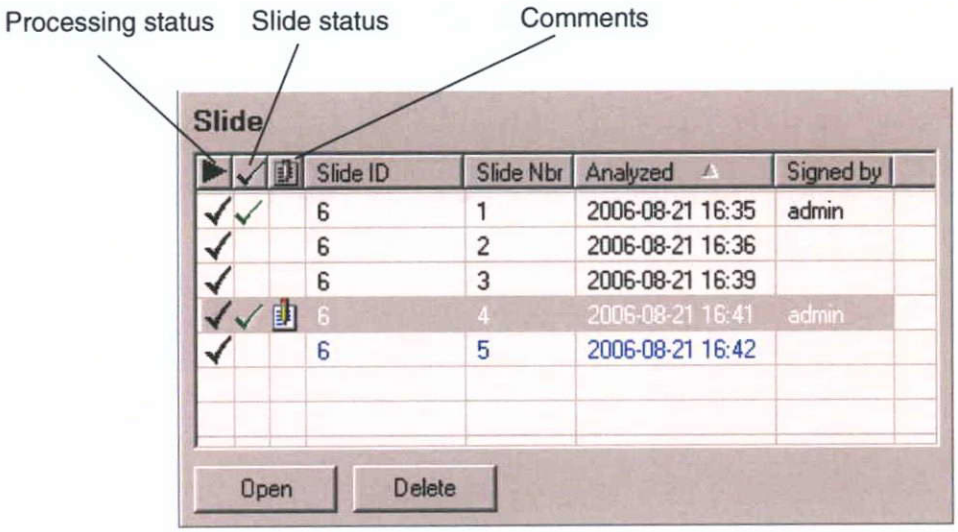
6.1.2 Slide List

Processing status



Process status ▶

✓	Slide processing OK.
STOP	Slide processing stopped. No result exists.
⚠	The required numbers of WBCs were not found, one of the ordered analyses failed, or the order was not found in the LIS, slide processed with default values.
✕	Processing error. No result exists.

Slide status ✓

Empty field	Not signed.
✓	Signed

Comments

Empty field	No comments.
	Comments exist.

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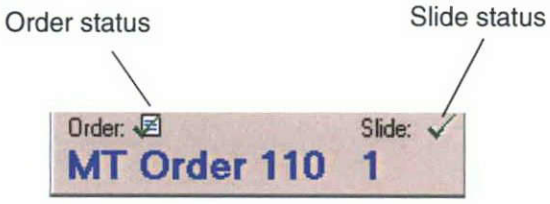
6.1.3 Opening an Order/Slide

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



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

You may close the order and the slide using a toolbar button.

Close Order and Slide

6.1.4 Protecting an Order

You may protect orders to prevent slides from being deleted or archived.

1. Select the order.
2. Click *Protect/Unprotect*.

You may select multiple orders using *Ctrl* or *Shift*.

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6.1.5 Searching for an Order/Slide

You select the orders to be displayed using the *Search criteria*. Here, you may specify date intervals for desired orders. Use "View latest" as a shortcut for orders less than one week old. You may also add search strings for patient data, order data and comments.

6.1.6 Deleting an Order/Slide

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

Note! *Signed slides cannot be deleted. However, deleting an order deletes all slides in the order, signed or not. Only Administrators can delete signed orders.*

6.1.7 Exporting Orders

You may export signed orders from the current database to another one.

An export database or a CellaVision Competency Software database must be created before exporting can start. This can be done in the database settings tab (see 10.1.1 Creating a New Database).

a) Exporting to an export database

1. Select one or several orders.
2. Click *Export*.
3. Select a database in the list.
4. Check *Delete orders after export* to perform an export (the order will be copied if unchecked).
5. Click *Export*.

b) Exporting to a CellaVision Competency Software database

1. Select one or several orders.
2. Click *Export*.
3. Select a database in the list.
4. Click *Export*. Orders will not be deleted and patient data will not be copied.

Restrictions:

- Only signed orders can be exported.
- Orders imported to an export database will always have a "protected" flag preventing them from being autodeleted (if autodelete is enabled).
- Only peripheral blood orders can be exported to CellaVision Competency Software databases.
- Orders residing in a Scan database cannot be exported.

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6.1.8 Copying Images to Disk

You can copy all images from selected orders to disk.

1. Select one or several orders.
2. On the right-click menu select *Copy images to disk…* and the *Copy images to disk* dialog appears.
3. Specify the destination path where you want the images to be saved.
4. Uncheck *WBC images* or *Overview images* (RBC/PLT images) to exclude this type of images.
5. Click *OK*.

Note! *The directory you specify in the destination path must exist.*

6.1.9 Printing Orders

You can print order data and data for all slides belonging to it. Select the *order/slide* and select *Print* in the *File* menu.

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

6.1.10 The Worklist

The Worklist facilitates an automatic workflow (see Appendix D — Recommended Workflow). The Worklist contains shortcuts to slides. It is also active in *Verification* view to simplify opening of new slides. Double-click on a slide, or click *Open* to open it. Click *Remove* to remove slides from the Worklist. When a slide is signed or closed, it is automatically removed.

Note! *Show/hide the Worklist by pressing Ctrl+w.*

Adding Slides to the Worklist

Slides may be added to the Worklist both manually and automatically.

A) Manually

1. Select one or more orders.
2. Click *Add to worklist*. All slides belonging to the order(s) are added.

B) Automatically

1. Slides are added when the system finishes processing them. This option is set in *Analysis* in *Settings*.
2. When you open an order, all slides belonging to it are added.

Note! *When the program is closed, the Worklist is emptied.*

Note! *BF slides are not automatically added to the worklist.*

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6.2 Database — Pending Orders

This tab 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 if you do not have a connection to the LIS.

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

Processed Orders | Pending Orders

+	Order ID		Patient ID	First Name	Last Name	Birth date	Nbr of cells	Sample Date	Ordering Physician
	MT Order 400		560421-2234	Michelle	Lawson	1956-04-21		2001-02-12	Dr Spock
	MT Order 390		680124-2334	Margret	Clark	1968-01-24		1997-10-30	Ester
	MT Order 380	BF	560121-2234	Eddie	Levinson	1956-01-21	125	2001-02-12	Dr Spock
	MT Order 370		680224-2334	Mike	Elson	1968-02-24	150	1994-10-30	Sister
	MT Order 360		480624-2234	Sid	Fernwiller	1948-06-24	200	1999-12-31	Ester
	MT Order 350		560421-2234	Clara	Spielberg	1956-04-21		2001-02-12	Dr Spock
	MT Order 340		680124-2334	Louise	Clark	1968-01-24		1997-10-30	Ester
	MT Order 330		560121-2234	Billy	Hutchinson	1956-01-21	100	2001-02-12	Dr Spock
	MT Order 320		680224-2334	Mike	Carlson	1968-02-24	100	1994-10-30	Sister
	MT Order 310		780624-2234	Nicky	Rooney	1978-06-24	100	1999-12-31	Ester

Add... Edit... Delete

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/edit* the Order Data.

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6.2.1 Pending Orders Dialog for Peripheral Blood

Order Data

Order ID*: MT Order 350

Type of order*

- [x] WBC Number of WBCs to count: 100
- [ ] RBC
- [ ] PLT
- [ ] STAT

WBC count (x10e9/L): 7.2

RBC conc.(x10e12/L):

Sample date: [x] 2001-02-12

Ordering physician:

(* required field)

Patient ID: 560421-2234

First name: Clara

Last name: Spielberg

Birth date: [ ] 1956-04-21

Gender: ○ Male ◉ Female

Ethnic origin:

Ward:

Patient comment

OK Cancel

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6.2.2 Pending Orders Dialog for Body Fluid

Order Data

Order ID*: MT Order 380

Type of order*

☑ Diff Number of WBCs to count: 125

☑ Overview

○ Overview 10x

◉ Overview 10x+50x

☐ STAT

WBC count (x10e6/L): 33.0

RBC conc.(x10e6/L): 10.0

Sample date: ☑ 2007-08-08

Ordering physician:

(* required field)

Patient ID: 560121-2234

First name: Eddie

Last name: Levinson

Birth date: ☑ 1956-01-21

Gender: ◉ Male ○ Female

Ethnic origin:

Ward:

Patient comment

Add Close

6.3 Archiving Data

Select *Tools/Archive* and the *Archiving Guide* will appear explaining the procedure. Make sure that a valid archiving media has been specified. This is done in the *Archiving* tab under *Settings* (see 10.11 Adjusting Archiving Settings).

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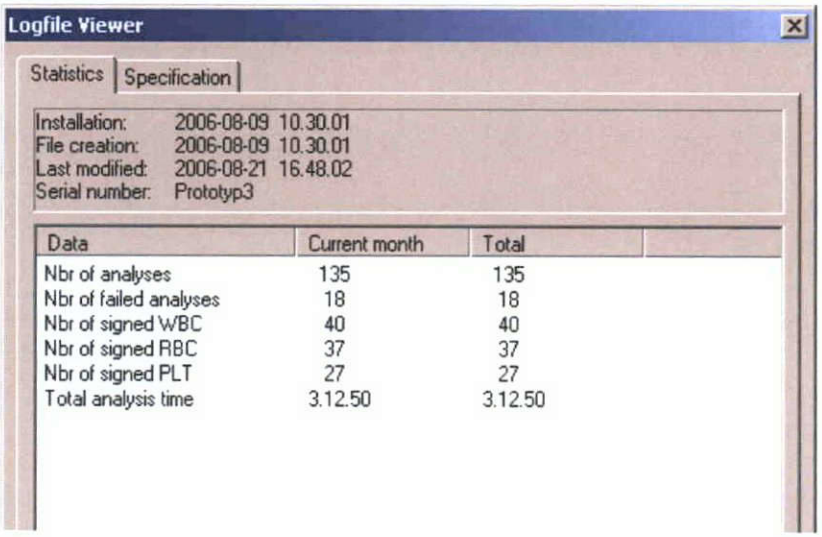
6.4 Usage Log

The system continuously saves data of processed slides and stores it in a Usage log. To view this log select *Tools/ View Log*. The log consists of two pages, *Statistics* and *Specification*.

6.4.1 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. The information can be selected for a specific month by entering *Year* and *Month* and clicking *Update*.

6.4.2 Specification

The *Specification* page is only accessible to Administrators. 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. You may specify the month the same way as described above.

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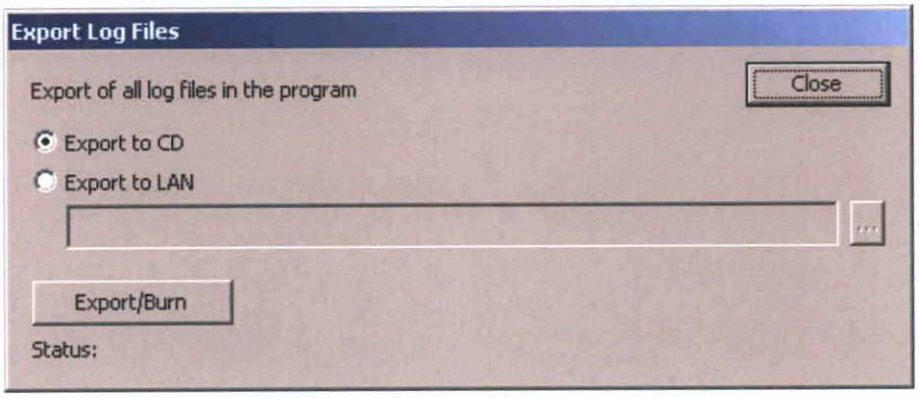
6.5 Export Log Files

It is possible to export all logging information from the system. If a system error occurs, the information is needed for trouble shooting. Select *Tools/ Export Log Files*. The log files can be burnt directly to a CD, or exported to the LAN (and then, for instance, attached to an e-mail).

***Note!** CellaVision DM must be idle during export. Otherwise, the export will not be complete.*



6.6 Backup and Recovery of the Database

It is important to backup the database quite 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. Two types of backup procedures are described below: System backup and Online backup.

The main advantage of an online backup is that the database is backed up while the system can remain operational. A disadvantage is that there must be enough disk space available to copy the complete database. If the disk space is limited, a system backup can be preferable. For a system backup, the database server must be stopped.

It is possible to configure the database so that no data will be lost in case of a hard disk crash, but it is more complicated and requires at least two hard disks with separate disk controllers. For more information about this, contact your distributor.

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6.6.1 System Backup

System backup is a simple file copy process performed from the operating system. The backup procedure must be performed by a Windows Administrator. Before the file copying can start the database server must be stopped. After the file copying, the database server must be restarted.

1. Start the program Mimer Administrator (*Start menu/All Programs/Mimer SQL Engine/Mimer Administrator*).
2. Right click on the database name in the *Local* tab, and select *Stop Server.* (Note that one column in the list specifies the home directory of the database).
3. Verify the database files (see 6.6.3 Verify Backup).
4. Use e.g. Windows Explorer to copy the files (*.dbf) in the database home directory to a backup location (normally tape or network drive).
5. Right-click on the database name again in the program Mimer Administrator and select *Start Server.*

6.6.2 Online Backup

An online backup is performed without stopping the database server. The backup procedure uses SQL system management statements and must be performed by a CellaVision DM software Administrator (but not necessarily a Windows Administrator).

First all data files (called databanks) in the database are backed up. Then the backup files are copied to a backup location (tape or network drive).

In the following example, the database is called mydatabase and it is backed up into a directory called c:\backupdir.

1. Start a command prompt (*Start menu/Run/cmd*).
2. At the prompt, type `bsql mydatabase` and press *Enter* to start the BSQL database tool.
3. Log on as Administrator (e.g. as 'admin').
4. At the prompt, type `START BACKUP;` and press *Enter* to start the backup procedure.
5. Type `CREATE BACKUP IN 'c:\backupdir\ciimg' FOR DATABANK ciimg;` and press *Enter.*
6. Type `CREATE BACKUP IN 'c:\backupdir\logdb' FOR DATABANK logdb;` and press *Enter.*

(Cont'd)

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7. Type `CREATE BACKUP IN 'c:\backupdir\sqldb' FOR DATABANK sqldb`; and press *Enter*.
8. Type `CREATE BACKUP IN 'c:\backupdir\sysdb9' FOR DATABANK sysdb`; and press *Enter*.
9. Type `CREATE BACKUP IN 'c:\backupdir\transdb' FOR DATABANK transdb`; and press *Enter*.
10. Type `COMMIT BACKUP`; and press *Enter* to complete the backup procedure.
11. Type `EXIT`; and press *Enter* to exit the BSQL tool.
12. Type `exit` and press *Enter* to close the command prompt.
13. Verify the backup files (see 6.6.3 Verify Backup).
14. Use e.g. Windows Explorer to copy the files in the backup directory to a backup location (normally tape or network drive).

The name of the backup files should be the same as the original database files. (Note that the filename for the databank SYSDB may differ).

Note! *A more advanced, but easier to use, backup script is available through CellaVision or your local distributor.*

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6.6.3 Verify Backup

The databank check (DBC) program should be run before archiving the backup copies of the databank files (e.g. copying them to tape or network) to verify the physical integrity of the databank files.

A report file is created each time the DBC program is run. In the following example, the report file is given the same name as the databank (but a different file extension).

1. Start a command prompt.
2. Type `dbc c:\backupdir\ciimg c:\backupdir\ciimg` and press *Enter.*
3. Type `dbc c:\backupdir\logdb c:\backupdir\logdb` and press *Enter.*
4. Type `dbc c:\backupdir\sqldb9 c:\backupdir\sqldb9` and press *Enter.*
5. Type `dbc c:\backupdir\sysdb c:\backupdir\sysdb` and press *Enter.*
6. Type `dbc c:\backupdir\transdb c:\backupdir\transdb` and press *Enter.*
7. Type `exit` and press *Enter* to close the command prompt.

If a databank file is corrupt in some way, 'Errors are logged' is shown. The errors are logged in the report file. Normally the message 'No errors found' is shown.

If the DBC program reports that a databank file is corrupt, the database backup procedure must be re-run.

6.6.4 Recovery

If the hard disk crashes or the database files become corrupt because of some other reason, an old backup can be used. Always use the most recent backup.

Note! *All data stored in the database since the last database backup will be lost in case of a hard disk crash. It is recommended to frequently backup the database.*

To restore a database from a backup, do as follows:

1. Stop the database server using Mimer Administrator if necessary. A program called Mimer Controller can also be used to stop (and start) the database server.
2. Copy all database files (*.dbf) from the backup location (c:\backupdir in the examples above) to the home directory (can be viewed in Mimer Administrator).
3. Restart the database server.

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7 Digital Slides

With CellaVision DM96 it is possible to create digital slides.

Important

The digitalized image generated provides a general overview of the prepared sample within the intended use of the CellaVision DM96 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 CellaVision DM. To create a Scan Database, see 10.1.1 Creating a New Database.

Log on to a Scan Database, see 2.1 Starting the System.

To customize your system, such as scan area and magnification, see 7.4 Customizing the System.

7.1.1 Slide and Magazine Requirements

Requirements for the slides used when scanning:

- Glass
- Size in mm: 75.0-76.0 x 25.0-26.0 x 0.9-1.2
- Ground edges
- Clipped or round corners
- Barcode labeled
- Frosted end

Note! *When using cover slips, make sure the scanning area is within the cover slip area.*

Note! *Coverslipped slides are supported as long as the total thickness of the slide is within the requirements.*

Note! *CellaVision DM96 analyzers with a serial number higher than 31216 or systems that have been upgraded with the Stage Upgrade Kit (CellaVision Part number XU-10043) support slides with the following dimensions (mm): 75.0-76.0 x 25.0-26.3 x 0.9-1.2*

Note! *Any type of CellaVision magazines can be used for a scan analysis.*

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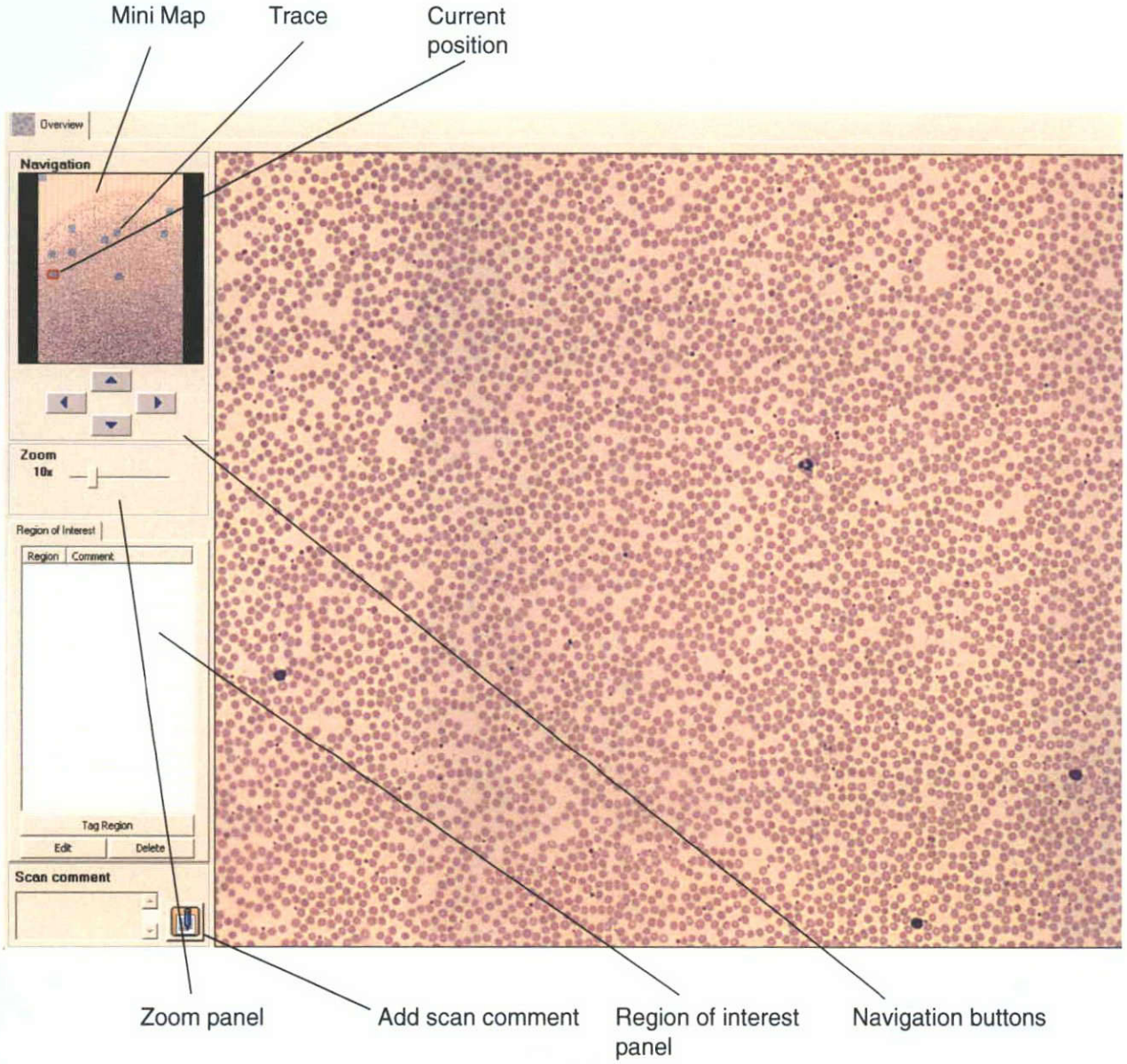
7.2 Scan Overview Image

Opening a scanned slide leads directly to the *Scan Verification View.* To open a slide, see 6.1.3 Opening an Order/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.



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.

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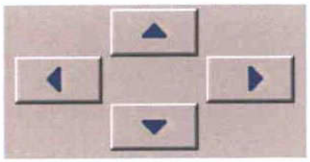
7.2.2 Navigating

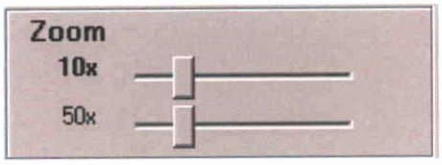
Move efficiently in the *Mini Map* by using the keyboard arrows or the *Navigation Buttons*.



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.



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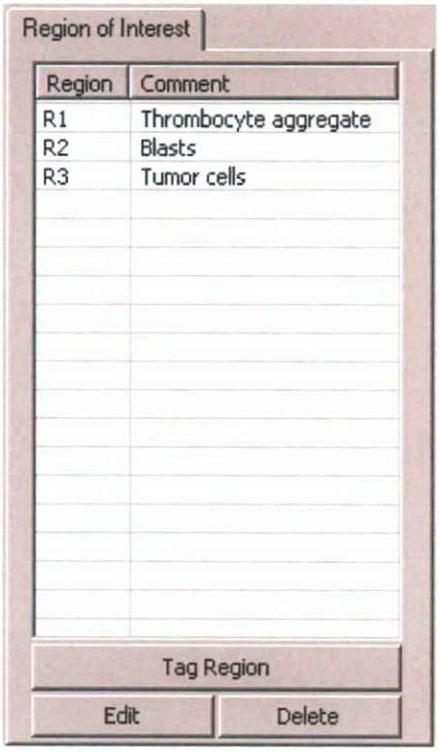
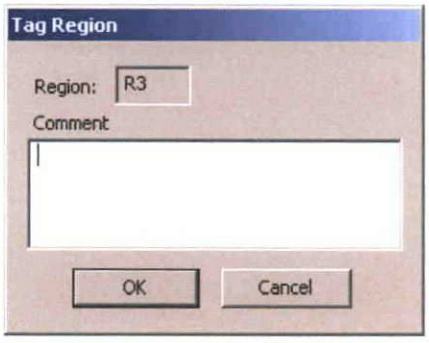
7.2.3 Tagging Regions of Interest

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.



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

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7.3 Database View

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

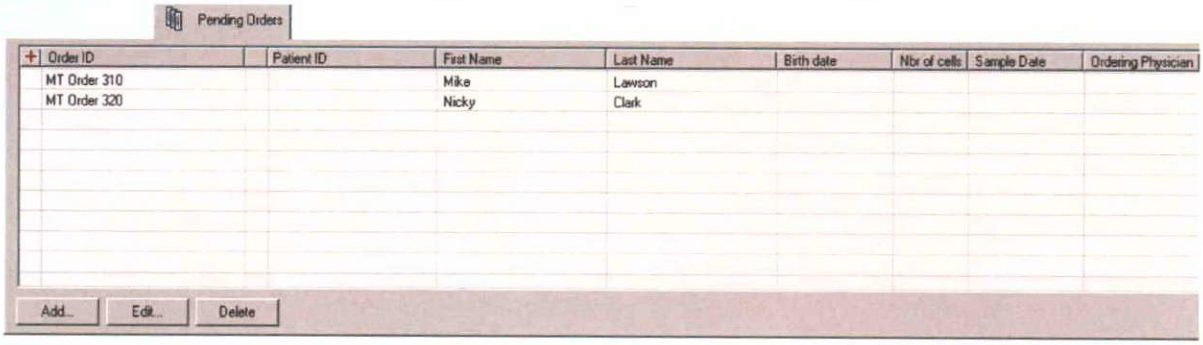
Click *Database View* in the toolbar.

7.3.1 Processed Orders

Scanned slides are automatically signed. For more details about Processed orders, see 6.1 Database — Processed Orders.

7.3.2 Pending Orders

A pending order has manually been added to the database and has not yet been processed. Pending Orders are useful when defining scan area for individual slides.



To add an order, click *Add.*

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

(Cont'd)

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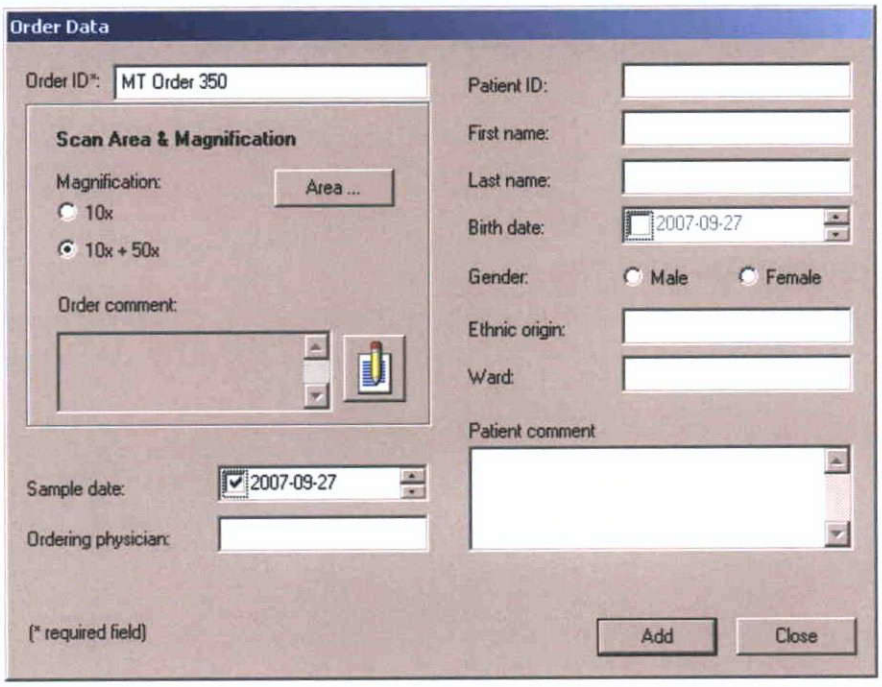
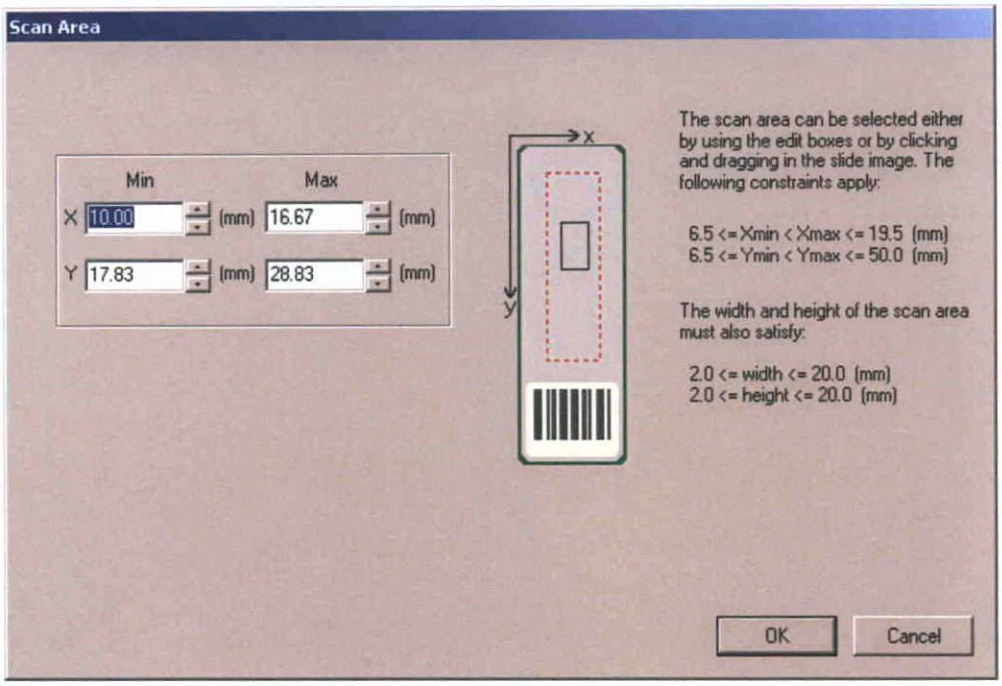
(Cont'd)



To define scan area for the slide, click *Area*. Define the area that you want to scan on this particular slide.



Note! *If no scan area is defined, the default scan area setting will be used.*

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7.4 Customizing the System

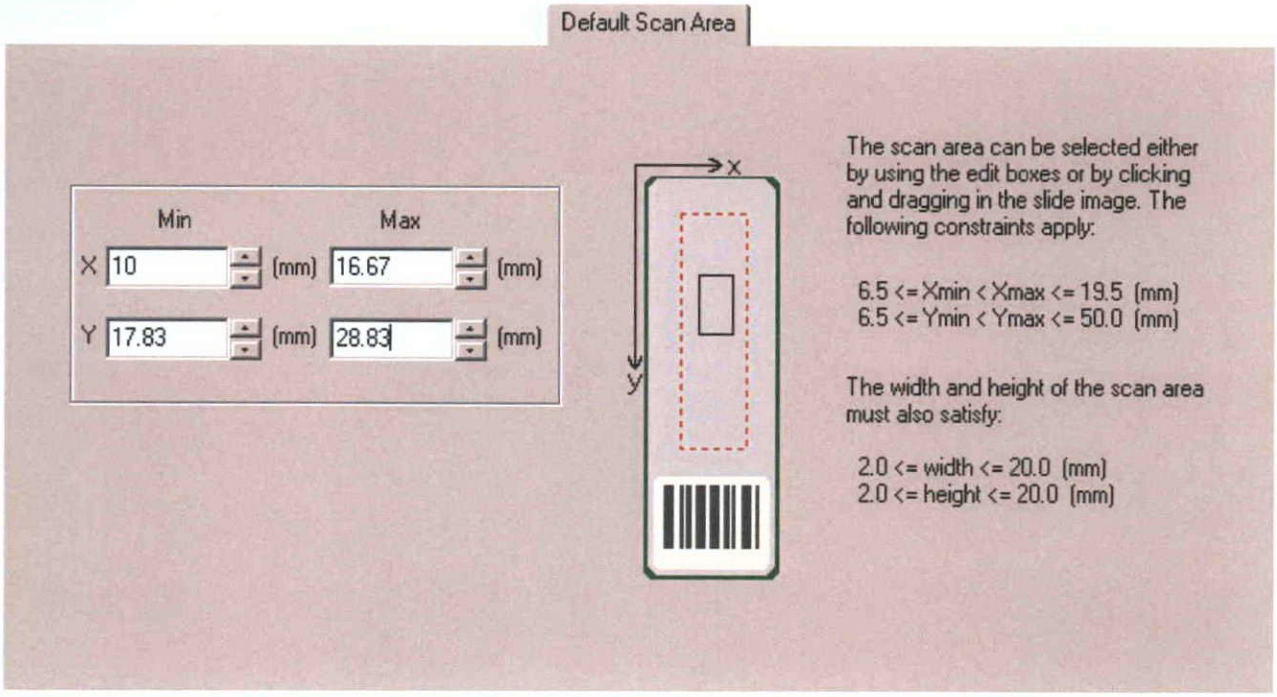
To customize the system, go to the *Tools* menu and select *Settings*.

7.4.1 Adjusting Database, Users and Language

To adjust the settings for database, users and language, see 10.1 Adjusting Database Settings, 10.2 Adjusting Users Settings and 10.12 Adjusting Language Settings.

7.4.2 Adjusting Default Scan Area

To adjust the default scan area, go to *Tools/Settings/Default Scan Area*.



To adjust the scan area settings for individual slides, click *Database View* and select *Pending Orders*. See 7.3.2 Pending Orders.

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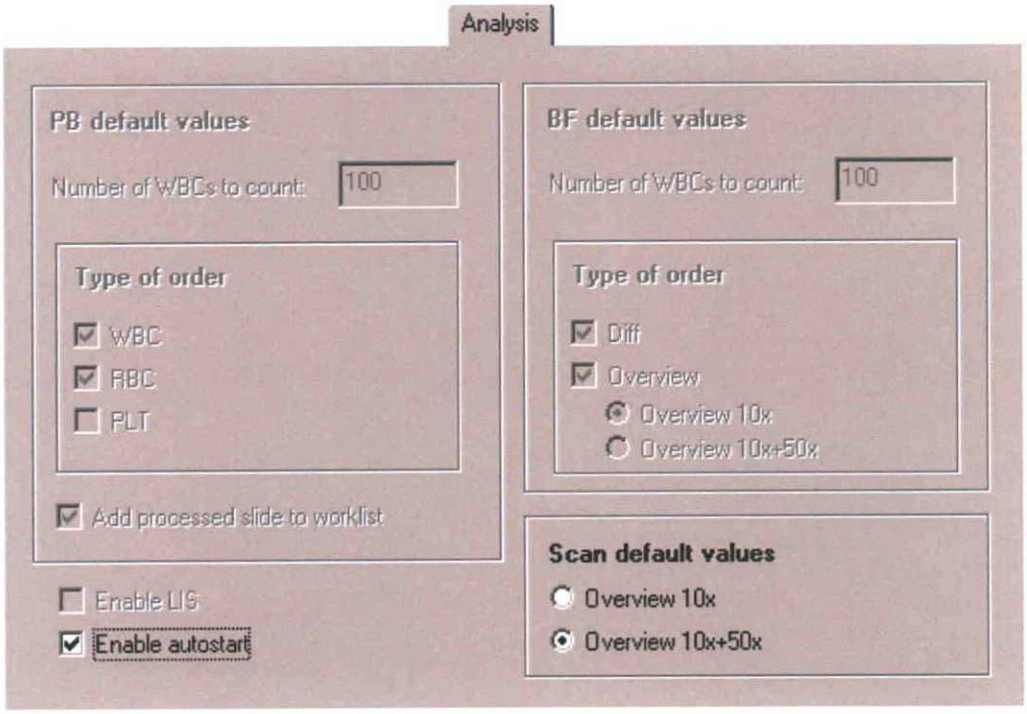
7.4.3 Adjusting Analysis

To adjust the default analysis settings, 10x or 10x and 50x magnification, go to *Tools/Settings/Analysis*.



To adjust the analysis settings for individual slides, click *Database View* and choose *Pending Orders*. See 7.3.2 Pending Orders.

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7.4.4 Adjusting Autodelete

It is not possible to archive the orders. All orders will be autodeleted after a specified number of days.

Autodelete Strategy

The autodelete strategy depends on your throughput and the need for saving images for future use. The autodelete settings are database specific, enabling each database to have its own autodelete strategy.

Delete all images:

All orders and images are permanently deleted when the time has expired.

Keep Region of interest images:

The orders are not deleted, but all images except the *Region of interest* and *Mini map* images are deleted when the time has expired.

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8 System Information

Information about your system is available from *Help/System Information*. The information presented depends on your system and installed software. Some of the following information is present in the 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.
- Licensed software.
- License expiry date.

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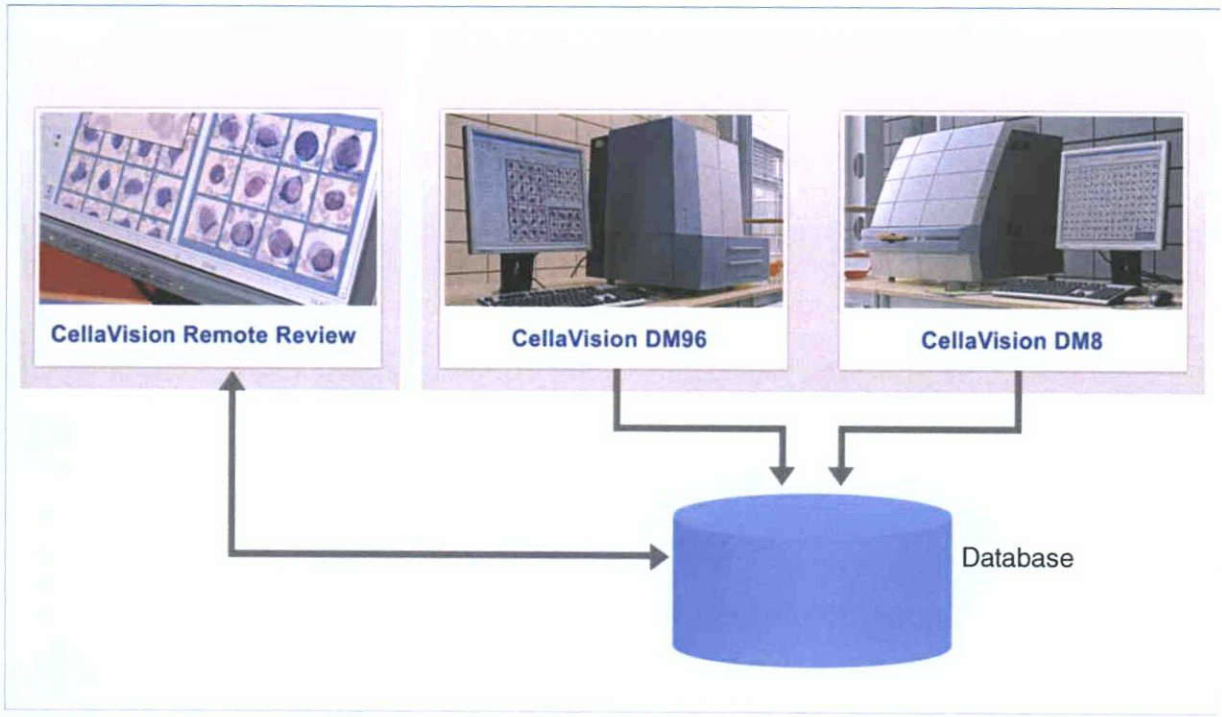
9 CellaVision Remote Review — Multiple Users

A CellaVision Remote Review has network access to a database containing data from slides processed by CellaVision DM.



The operating procedures in *Database View*, *Verification View* and *Report View* are the same for CellaVision Remote Review as CellaVision DM. It is not possible to process slides or archive data using CellaVision Remote Review.

9.1 Working with Orders/Slides

When opening an order/slide with CellaVision DM or a CellaVision Remote Review the order and the slide will be locked for other operators. In all other CellaVision Remote Review and CellaVision DMs connected to the database this is indicated with red color in *Order list* and *Slide list* in the *Database View* (see 6.1 Database — Processed Orders). A locked order/slide can be opened but not modified, i.e. no changes can be done in *Verification View* and *Report View*. In the *Order data* and *Slide data* panels, *Locked by* indicates who has opened the order/slide (the person logged on to Windows) and on which computer.

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10 Customizing the System

Settings are stored in either the system (or CellaVision Remote Review) or the database.

A setting that is stored in the system applies to that system only. Other systems connected to the same database as the system may have other values of the setting.

A setting that is stored in the database applies to all systems connected to the same database. If you change the setting, it will be changed for all systems connected to the database.

The following settings are stored in the database:

- Restricted user search options
- User settings
- Analysis default values
- Enable LIS
- Add processed slide to worklist
- WBC reclassification settings
- RBC precharacterization settings
- PLT settings
- Active report template
- Report template contents
- Default settings for sign dialogs
- Standard comments
- Custom reference cells
- Autodelete/Archiving settings

The following settings are stored in the system:

- Enable autostart
- Email settings
- Language
- Body fluid analysis area

Select *Tools*, followed by *Settings* and the appropriate tab to customize the system. Different users are allowed to edit different settings (see Appendix E — User Authorization Levels).

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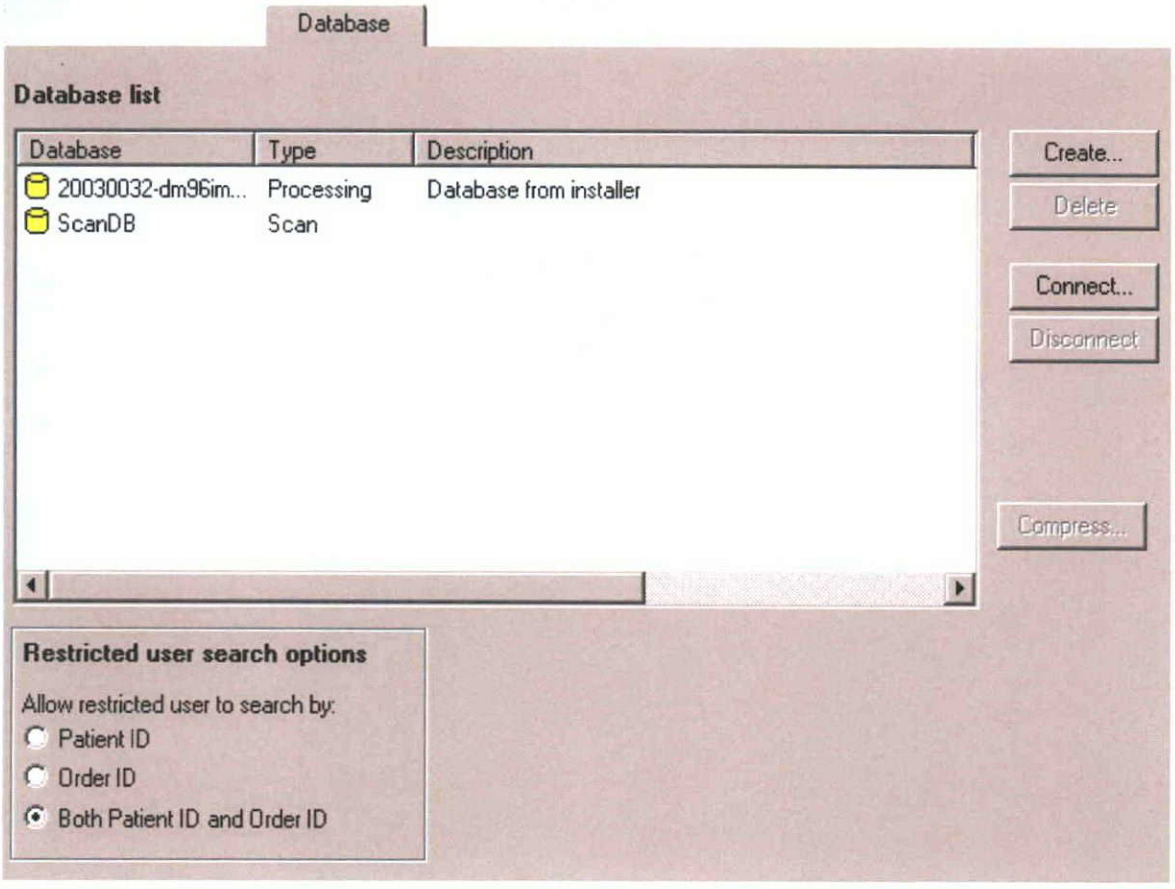
10.1 Adjusting Database Settings

Here you create new databases and new database connections. In the *Log On* dialog you select which database to use. It is also possible to compress an existing local database.



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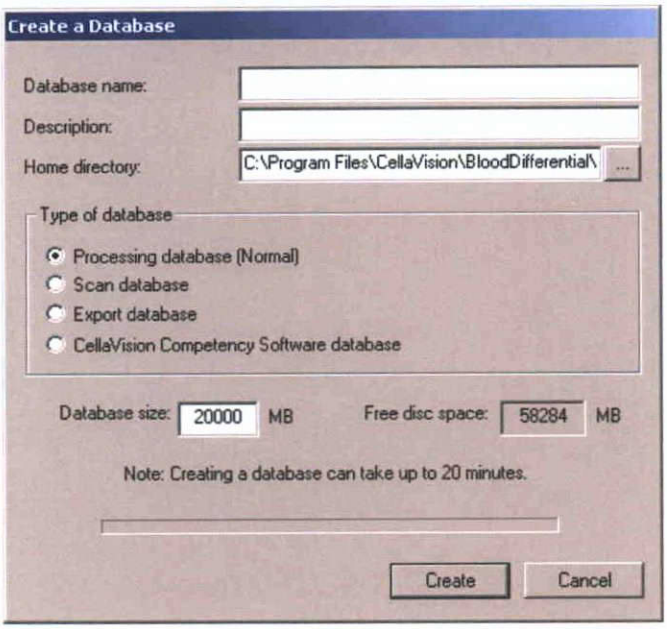
10.1.1 Creating a New Database

1. Click *Create*. A dialog appears, where you may enter *Database name*, *Description*, *Home directory* and *Database size*.
2. Select one of the following types of database:

- Processing database, a database for processing slides.
- Export database, a database that is used when you want to export orders from another database. This type cannot be used for processing slides.
- CellaVision Competency Software database, a database for use with CellaVision Competency Software. A CellaVision Competency Software database cannot be used for processing slides.
- Scan database, a database for scanned slides.

3. Click *Create*. A new folder with the chosen Database name will be created in the specified *Home directory*.



Creating a database requires that there is sufficient free disk space. A processing database requires 20 GB, a scan database requires 20 GB, an export database requires 1 GB and a CellaVision Competency Software database requires 100 MB.

Note! *Having many databases affects system performance negatively.*

Note! *A database can be created only on your local computer.*

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10.1.2 Deleting a Database

1. Select the database in the list.
2. Click *Delete*.

10.1.3 Creating a New Database Connection

1. Click *Connect*. A dialog appears where you may enter Database name, Description and Remote computer.
2. Click *OK*. A new connection will be shown in the list.

Note! *On the remote computer, select Help/System Information to find out the name of the computer.*

10.1.4 Deleting a Database Connection

1. Select the connection in the list.
2. Click *Disconnect*.

10.1.5 Compressing a Database

1. Select the database in the list.
2. Click *Compress*. A dialog appears.
3. Click *Compress database*.
4. Click *Close*.

A compressed database will occupy less space on the hard disk. The performance might also be improved.

Note! *It can take a long time to compress a database. If the database is >10 GB in size it can take some hours. The process requires free disk space twice the size of the database to be compressed.*

Note! *During compression, no client may be connected to the database! This means that you cannot compress the database you are currently logged on to.*

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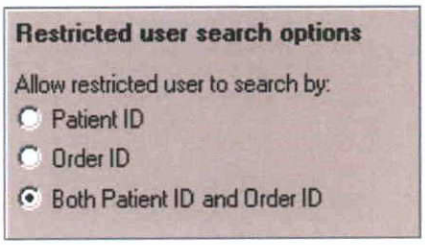
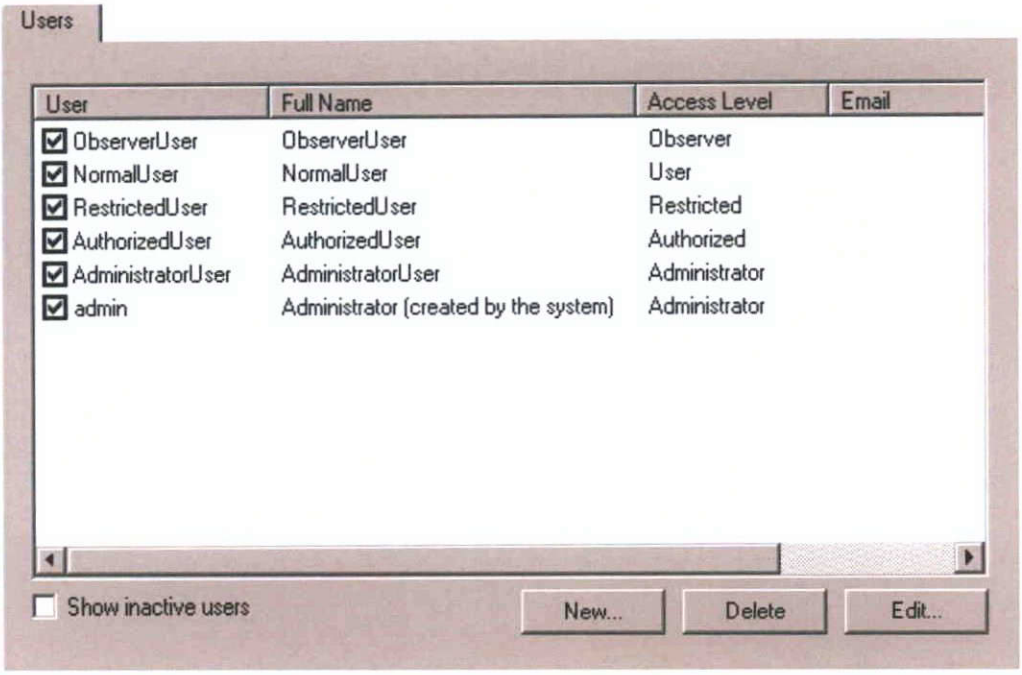
10.1.6 Setting User Restrictions

Here you set the available database search criteria for the Restricted user. Select the desired *Restricted user search options*.



10.2 Adjusting Users Settings



Show inactive users: Activate this checkbox if inactive users shall be shown in the list.
New: Add a new user (see dialog below).
Edit: Edit user information (see dialog below).
Delete: Delete selected users.

(Cont'd)

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(Cont'd)

There are 5 levels of user authorization:

Observer: Only allowed to view images and results.
User: Can reclassify and recharacterize WBC, RBC and PLT, but not sign slides.
Authorized: Same as User, but can sign slides and orders.
Restricted: Same as Authorized, but with restricted database access.
Administrator: Full access to the system.

The authorization level determines the different functions and features the operator can access (see Appendix E — User Authorization Levels).

User: Login name. The checkbox Account Active indicates if the account is active.
Full Name: Full name of the operator.
Access Level: Level of user authorization.
E-mail: The operator's e-mail address.

Note! *When you create a new user the username must be unique and start with a letter (a-z or A-Z). The following words are reserved: SYSTEM, SYSADM, SYS, SELECT, TABLE, USER,UPDATE, IF, IS.*

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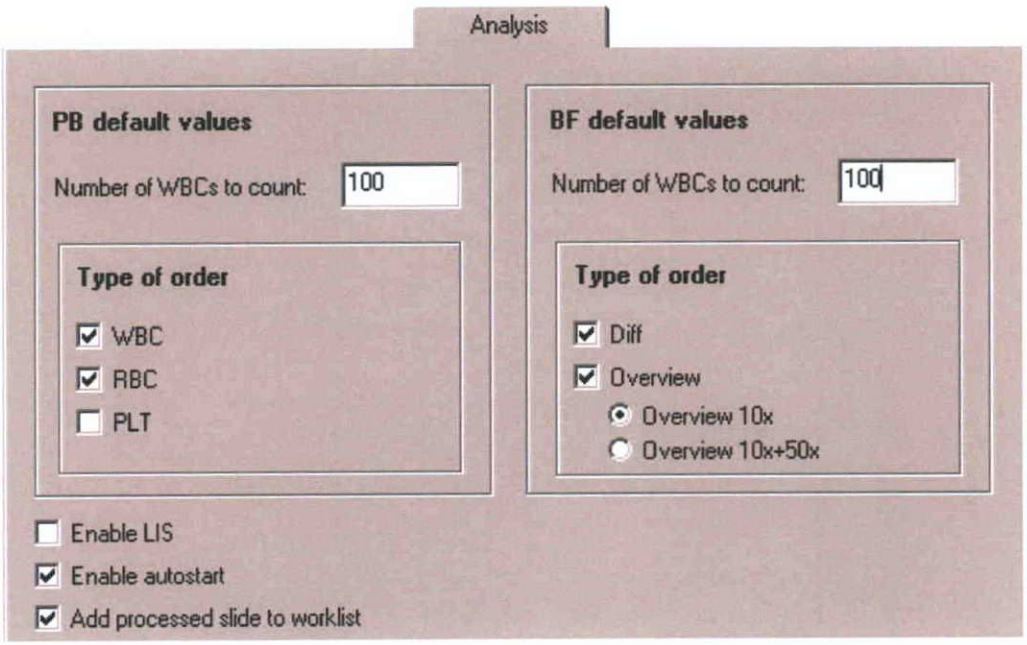
10.3 Adjusting Analysis Settings



Default values: These values are used if the order to analyze is not found in the database or in the LIS. Type of order is the analysis to perform.

Enable LIS: Activate this checkbox and restart the program if the LIS will be used.

Enable autostart: If this checkbox is activated the processing starts automatically when a magazine is loaded into the system.

Add processed slide to worklist: If this checkbox is activated, processed slides will automatically be added to the Worklist.

***Note!** BF slides are not automatically added to the worklist.*

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10.4 Adjusting Reclassification Settings

PB Reclassification

Forward preclassified cells

Forward cells from:

- ☐ Band neutrophil to Segmented neutrophil
- ☐ Metamyelocyte to Segmented neutrophil
- ☐ Lymphocyte, variant form to Lymphocyte
- ☐ Plasma cell to Lymphocyte
- ☐ Immature cells to Other

Note: The classes included in Immature cells are: Blast cell, Metamyelocyte, Myelocyte and Promyelocyte.

Forward preclassified cells: Select your forwarding criteria using the checkboxes.

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10.5 Adjusting RBC Precharacterization Settings

Here you adjust the percentage limits for the different levels of the morphology characteristics. It is also possible to disable the RBC precharacterization.

RBC Precharacterization

☐ Enable RBC precharacterization

RBC limits (%)

	1 (Slight)	2 (Moderate)	3 (Marked)		1 (Slight)	2 (Moderate)	3 (Marked)
Polychromasia:	1.5	2.5	3.5	Anisocytosis:	6	15	30
Hypochromasia:	6	15	30	Microcytosis:	6	15	30
Poikilocytosis:	2	6	15	Macrocytosis:	6	15	30

Anisocytosis sizes (micrometers)

Microcytosis <= 6.5 < Normal < 8.5 <= Macrocytosis

Reset RBC Limits and Anisocytosis size to their default values: Reset

Note. Default values according to "O'Connor, Barbara H, A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology, Lippincott Williams & Wilkins, (1984)"

Enable RBC precharacterization: Deactivate this checkbox if RBC precharacterization shall not be performed. Manual RBC characterization will still be possible.

RBC limits: The percentage limits used for RBC precharacterization. The default values are set according to O'Connor, Barbara H, A Color Atlas and Instruction Manual of Peripheral Blood Cell Morphology, Lippincott Williams & Wilkins, (1984).

Anisocytosis sizes: Set size limits for precharacterization of Anisocytosis.

Reset: Resets all RBC limits and Anisocytosis sizes to their default values.

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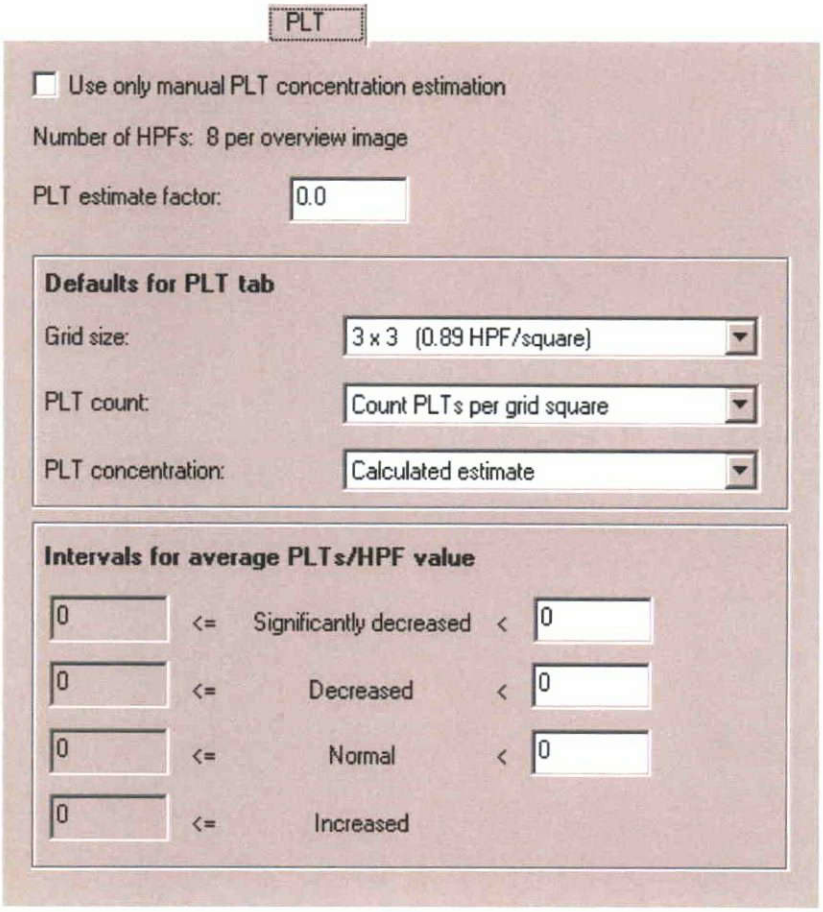
10.6 Adjusting PLT Settings

In the *PLT* tab you set the *PLT estimate factor* and the limits for the PLT concentration levels. You also set the default settings for the *grid size*, *PLT count* and *PLT concentration result*. It is also possible to enable the option to use manual PLT concentration estimation.



Use only manual PLT concentration estimation: When this checkbox is activated PLT estimation is done by estimating the concentration level to *Significantly decreased, Decreased, Normal* or *Increased*. No values for the PLT count can be entered and no calculation can be performed. This setting takes effect the very first time a slide is opened and can then not be changed for the order.

PLT estimate factor: See Appendix F — Determining the Platelet Estimate Factor for how to determine the PLT estimate factor.

Important

You have to determine your own PLT estimate factor. By default, it is set to "0".

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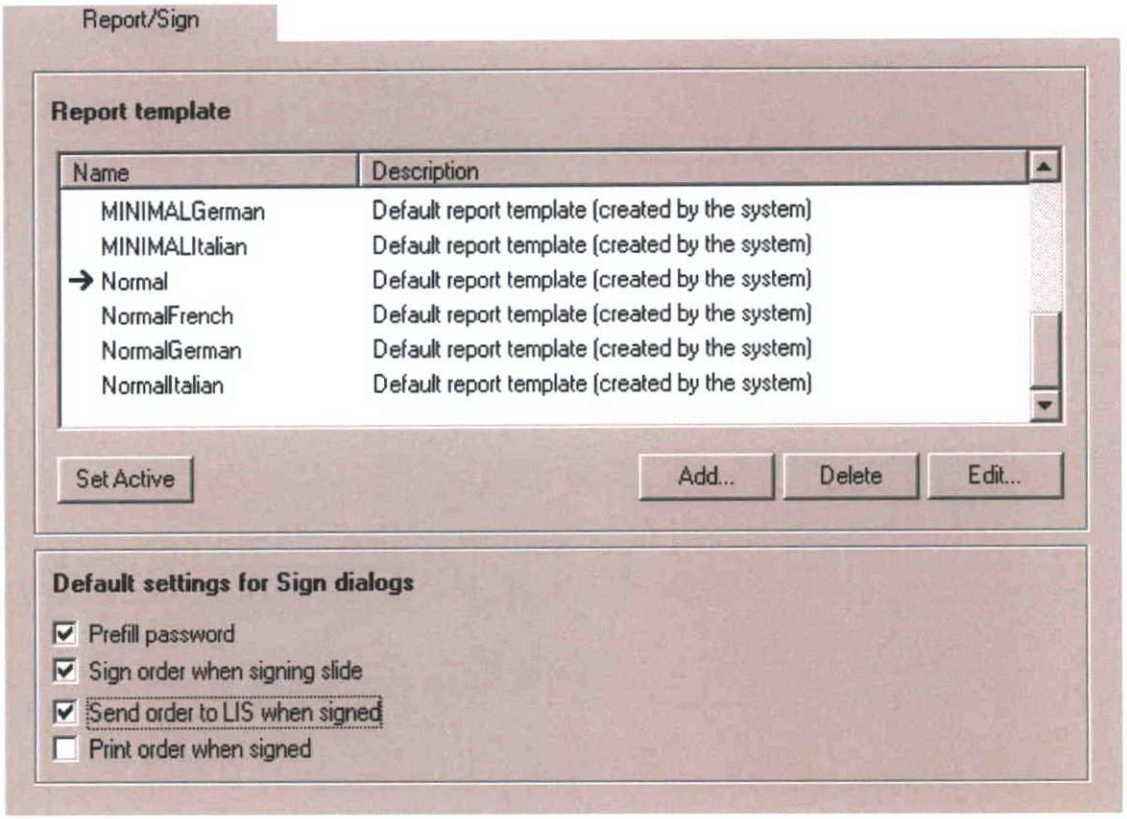
(Cont'd)

Defaults for PLT tab: Sets the default values for Grid size, PLT count and PLT concentration.

Intervals for average PLTs/HPF value: These intervals are used to calculate the PLT result Calculated level.

10.7 Adjusting Report/Sign Settings

In the *Report/Sign* tab you set the template to use in printed reports and the default settings for the signing dialogs.



Report: All available templates are displayed in the list. The currently used template is indicated with an arrow. To change which template to use, select a template in the list and click *Set Active*.

Default settings for Sign dialogs: Here you set the default values for the *Sign Slide* and *Sign Order* dialogs.

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10.8 Adjusting Standard Comments Settings

Standard Comments

Code	Comment	Comment Type
1	Hypersegmentation	WBC
2	Pelger form	WBC
3	Hypergranulation	WBC
4	Hypogranulation	WBC
5	Auer rods	WBC
6	Doehlie bodies	WBC
7	Pyknotic nucleus	WBC
8	Vacuolization	WBC
9	Cleft nuclei	WBC
10	General RBC slide comment	RBC
11	General slide comment	General

☐ Include code in comment
☑ Always show expanded

New... Delete Modify...

Include code in comment: If activated, the code is written together with the standard comment.

Always show expanded: If activated, the standard comments are visible by default when the comment dialog is opened.

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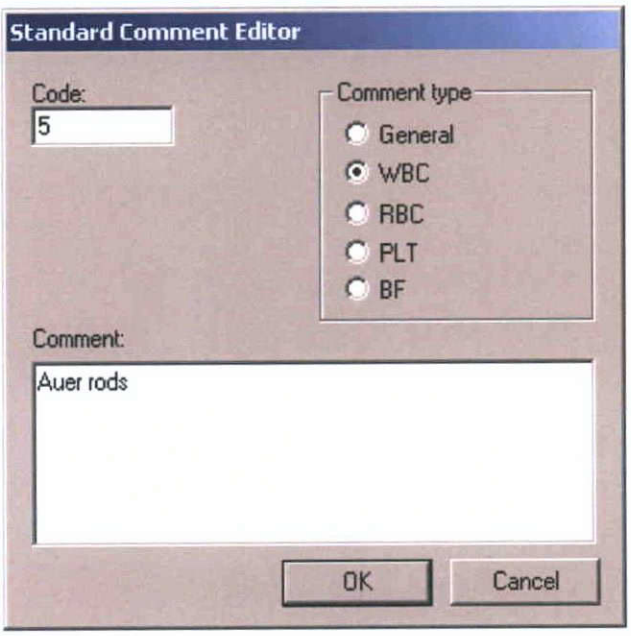
(Cont'd)

Adding a New Standard Comment

1. Click *New*.
2. The *Standard Comments Editor* appears.



3. *Enter Code, Comment type* and *Comment*. Standard comments of type WBC, RBC, PLT or BF will only be available in the respective tab. General comments are always accessible.
4. Click *OK*.

Deleting a Standard Comment

1. Select the standard comment in the list.
2. Click *Delete*.

Modifying a Standard Comment

1. Select the standard comment in the list.
2. Click *Modify* and the *Standard Comments Editor* appears.
3. Edit *Code*, *Comment type* and *Comment*.
4. Click *OK*.

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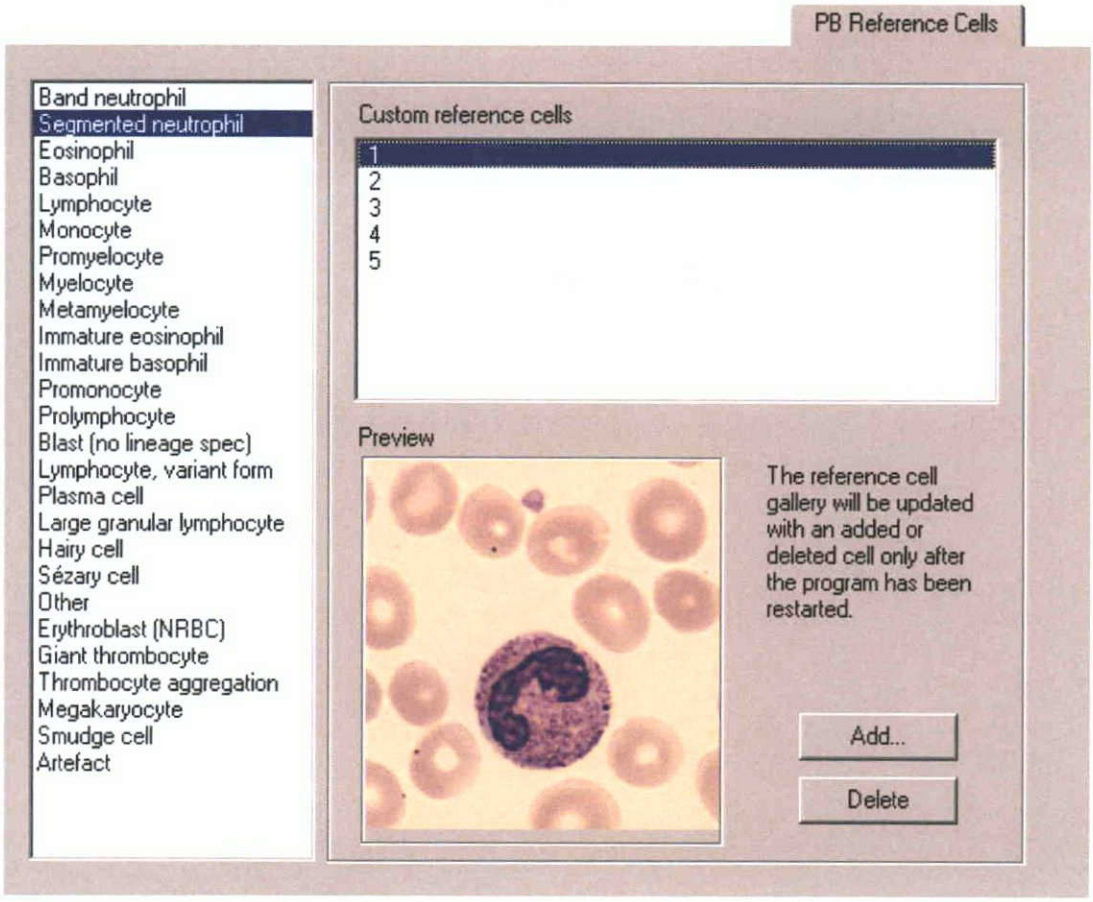
10.9 Adjusting Reference Cells Settings

Click on a cell class to see a list of all *Custom reference cells* belonging to it. Click on a specific cell to display it in the *Preview* window.



Click *Add* to add custom reference cells from disk. Valid file formats are JPEG (".jpg") and bitmap (".bmp"). All cell images will be stored in the JPEG format. You can also store cells from processed slides (see "Right-click Menu" in 3.1.2 Reclassifying White Blood Cells) as custom reference cells.

Click *Delete* to remove the selected custom reference cell.

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10.10 Adjusting E-mail Settings

Enter *Default recipient* of e-mail, specify *Mail server* and *E-mail from*, i.e. sender of e-mail.

10.11 Adjusting Archiving Settings

For storage safety reasons and limited hard disk capacity, it is recommended that you regularly archive the cell images or delete the orders. When you archive, the cell images and comments are transferred from the database to a CD or a hard disk. However, if you delete an order with archived images, you will not be able to access these images again.

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Archiving/Autodelete

Strategy

- (•) Archiving
- ( ) Autodelete

Warn when the following two conditions are met:

1) The number of signed orders exceeds 300

2) These orders are older than 30 days

Archiving media

- (•) Network path or local drive
- ( ) CD archiving

Path for archiving:

C:\Documents and Settings\CVUser\Des [Browse...]

Images to archive

Cell images

PB cell images	None	All	10 cells/class
Normal WBCs	( )	(•)	( )
Abnormal WBCs	( )	(•)	( )
Non-WBCs	( )	(•)	( )
BF cell images			
WBCs	( )	(•)	( )
Non-WBCs	( )	(•)	( )

PB overview images (RBC/PLT)

( ) None (•) All

BF overview images

Overview images

( ) None (•) 10x ( ) 10x+50x

Region of interest images

( ) None (•) All

Note! *Only images from signed slides can be archived.*

Orders Archiving Strategy

The archiving strategy depends on your daily throughput and the need for saving images for future use. The autodelete/archiving settings are database specific, enabling each database to have its own archiving strategy.

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(Cont'd)

1. Autodelete (*Autodelete instead of archive*, activated)

Warn when the following two conditions are met:

1) The number of signed orders exceeds 300

2) These orders are older than 30 days

All signed orders are permanently deleted when the time has expired. However, autodelete will not begin until the specified number of candidates has been reached.

Example: With the setting above, autodelete will not begin until there are 500 orders older than 30 days.

2. Archive images (*Autodelete instead of archive*, deactivated)

Keep locally at least: Specify the minimum number of days that images from signed slides shall be stored.

Warn when candidates reach: Specify the minimum number of non-archived signed orders at which the program shall prompt the user with a warning message

Archive Media

Select your archive media

- CD Archiving
- Network path or local drive

Archived Images

The images are divided into groups. Use the radio buttons to archive either a certain number of images from each cell class in a group, or all available images, or no images at all from a group.

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(Cont'd)

PB Cell images
Overview images: RBC and PLT

Normal cells:

Segmented neutrophils	Monocytes	Basophils
Lymphocytes	Eosinophils	

Abnormal cells:

Band neutrophils	Lymphocytes variant forms	Prolymphocytes
Promyelocytes	Plasma cells	Large granular lymphocytes
Myelocytes	Immature eosinophils	Hairy cells
Metamyelocytes	Immature basophils	Sézary cells
Blast cells	Promonocytes	User defined WBCs

Non-WBCs:

Other	Giant thrombocyte	Smudge cell
Not classed	Thrombocyte aggregation	Artefacts
Erythroblast (NRBC)	Megakaryocyte	User defined Non-WBCs

BF Cell images
Overview images: 10x overview images and 50x overview images.

Region of interest images: Regions of interest tagged by the user.

WBCs:

Neutrophils	Eosinophils	Lymphocytes
Macrophages	Other	User defined WBCs

Non-WBCs:

Smudge cell	Artefacts	User defined Non-WBCs

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Archiving Recommendations

It is recommended to keep the size of the database around 20 GB for optimal database performance.

Always combine archiving with a backup of the database (see 6.6.1 System Backup). The database contains the path to the archived images. If a hard disk crash occurs, it will not be possible to restore the archived images, unless a backup exists.

Note! *Select Compress Database to view the database size (see 10.1.5 Compressing a Database).*

Hard Disk Space Requirements Peripheral Blood

A processed slide with 100 WBCs collected will require about 5 MB of hard disk space. RBC and PLT use the same overview image and will require about 1 MB. A processed slide with 100 WBCs and RBC and/or PLT ordered will require about 6 MB of hard disk space.

Hard Disk Space Requirements Body Fluids

A processed slide with 100 WBCs collected will require about 5 MB of hard disk space. For an analysis area with a diameter of 6mm the10x overview images require about 15 MB and 50x overview images require about 130 MB. A processed slide with 100 WBCs, 10x and 50x overview images ordered will require about 150 MB of hard disk space (6 mm analysis area). Increasing the analysis area from 6 mm to 8 mm will require 78% more disk space for the overview images.

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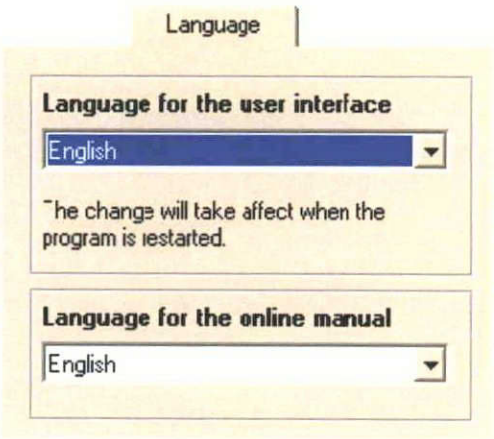
10.12 Adjusting Language Settings

In the *Language* tab you set language for the user interface and manual.



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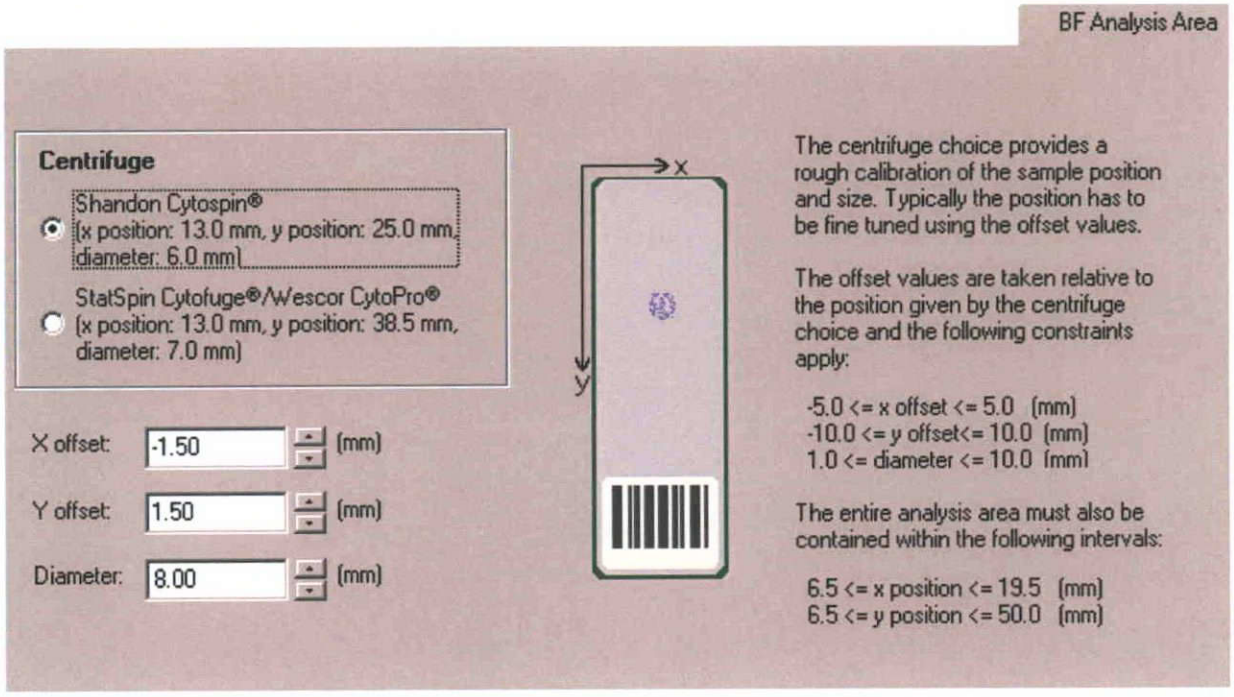
10.13 Adjusting BF Analysis Area

10.13.1 Centering the Analysis Area

Before using the system for the first time or when necessary, define the sample spot location. This is done in *Tools/Settings/BF Analysis Area*.



1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for *Centrifuge*.
2. Run an analysis of a Body Fluid slide with a representative sample spot location.
3. Go to the *Overview* tab. Use the *Navigation* display to establish whether the analysis area needs to be adjusted.
4. If further adjustments are needed, go to *Tools/Settings/BF Analysis Area* and adjust the *X-offset* and *Y-offset* settings (see example below).
5. Restart the program, delete the order and rerun the slide to verify your new settings.

Note! *It is important to delete the order before the slide is rerun. Otherwise the settings from the previous run will be used, which means that your changes to the analysis area settings will have no effect.*

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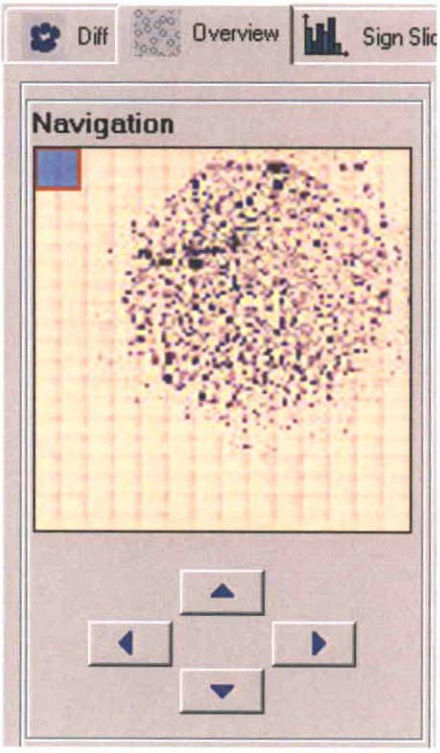
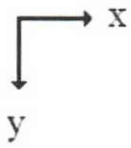
The *Diameter* setting was 8 mm in the example below. In order to center the analysis area on the sample spot, the analysis area needs to be offset by 1.5 mm in the positive x direction and 1.5 mm in the negative y direction.





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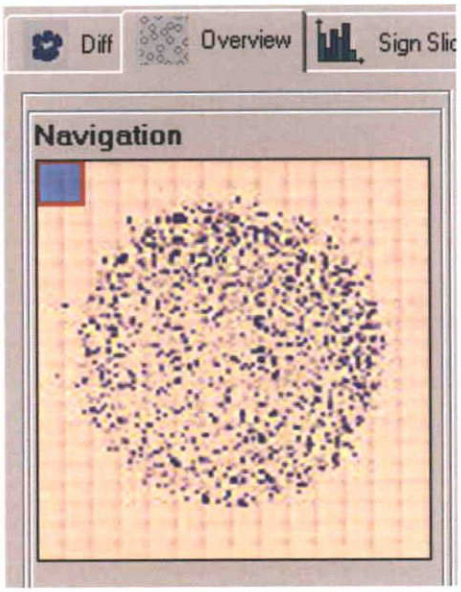
10.13.2 Adjusting the Size of the Analysis Area

To adjust the size of the analysis area, do as follows:

1. Go to *Tools/Settings/BF Analysis Area* and select the desired setting for Diameter.
2. Restart the program, delete the order and rerun the slide to verify your new setting.

As a rule of thumb, the analysis area diameter should be 1mm larger than the sample spot diameter. The slightly larger analysis area diameter will allow for variation in sample spot location between slides. The image below shows an example where the analysis area covers the sample spot well.



Take the last analysis performed and check how well the analysis area covers the sample spot. If the analysis area is too large or too small, go to *Tools/Settings/BF Analysis Area* and adjust the *Diameter* setting.

Note! *Increasing the Diameter setting will increase the processing time.*

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11 Quality Control

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 microscope objective. 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.

Cell Location Performance

The Cell location test is used to verify the slide preparation process and the system hardware. The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test, see Appendix H — Cell Location. Running the test once or twice a day is a recommended interval at the high-load laboratory.

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12 Maintenance

Caution

Be careful not to bend or put excessive force to any part of the system interior.

12.1 Daily Maintenance

1. Make sure there are no magazines in the system.
2. Shut down the system according to the instructions in this manual.
3. Open the main hatch.
4. Clean the XY stage from immersion oil with a lint-free soft cloth.
5. Close the main hatch.

12.2 Weekly Maintenance

12.2.1 Cleaning of Objectives

1. Make sure there are no magazines in the system.
2. Shut down the system according to the instructions in this manual.
3. Open the main hatch.
4. Clean the lens on all objectives by wiping them gently with lens paper. Always use a fresh lens paper to avoid oil contamination. To reach all lenses, carefully turn the objective turret.
5. Apply step 5-11 only on the high power wet objectives. Put a drop of isopropyl alcohol on a piece of crumbled lens paper. Do not use an excessive amount of solvent.
6. Wipe the objective once to remove most of the oil. Do not use a circular motion to clean lenses as this increases the risk of scratching the surface.
7. Take a new piece of lens paper and put a drop of lens cleaner in the middle.
8. Place the lens paper over the objective.
9. Use a cotton swab to gently hold the paper against the objective while you drag the lens paper away from the objective.

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(Cont'd)

10. The cotton swab should remain over the center of the objective and the lens paper under it should be wet. If the lens paper dries out then repeat starting on a wet (but non-oily) spot on the lens.
11. Repeat once from step 5.

Important

Make sure there is no oil on the low power (10x) dry objective.

Important

Cleaning with alcohol increases the risk of air bubbles on the objective, which affects the image quality for the first two slides. To avoid the problem, it is recommended to run two slides after weekly maintenance. Delete these slides immediately to avoid the risk of result mix-ups.

Caution

Avoid alcohol on the oil level indicator.

12.2.2 Slide Guides

Clean the slide guides carefully to remove any glass shards or particles. Apply one drop of stage oil at the two positions, marked by red dots in the image below.

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12.3 Preventive Maintenance

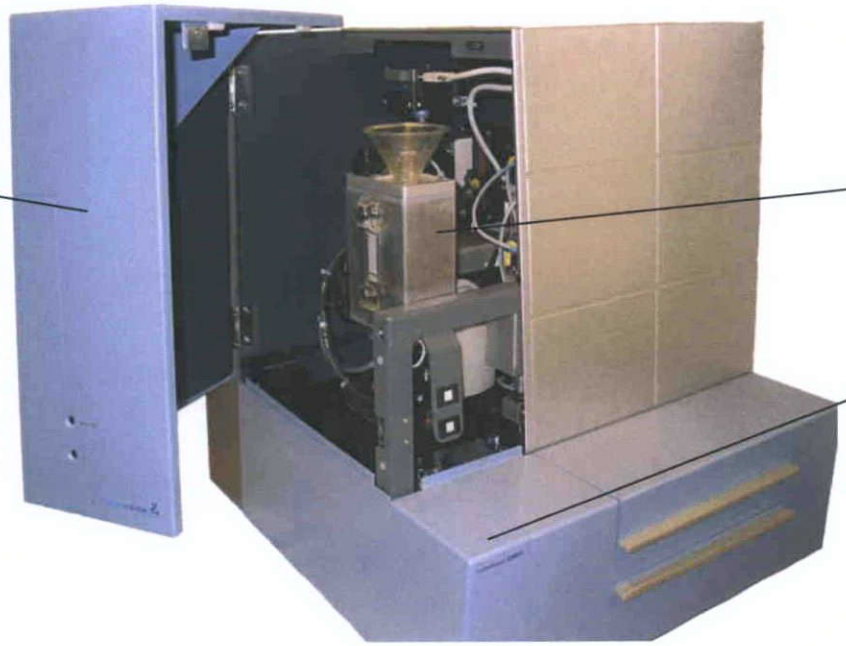
No preventive maintenance by the user is necessary. Preventive maintenance is to be performed by CellaVision authorized personnel.

12.4 Remedial Maintenance

12.4.1 Immersion Oil Refill

WARNING

The oil may cause sensitization by skin contact. We recommend using gloves.



1. Open the main hatch.
2. Remove the screw cork from the oil canister.

(Cont'd)

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(Cont'd)

3. Fill up with specified oil using a clean funnel. Do not fill up above the black line.We recommend not filling up more oil than will be used in 6 months. A full oil canister of 500ml corresponds to about 10000 slides.
4. Clean the system from immersion oil spillage with a lint-free soft cloth.
5. Refit the screw cork.
6. Close the main hatch.

Caution

Use only immersion oil recommended by CellaVision AB (see Appendix A — System Specification).

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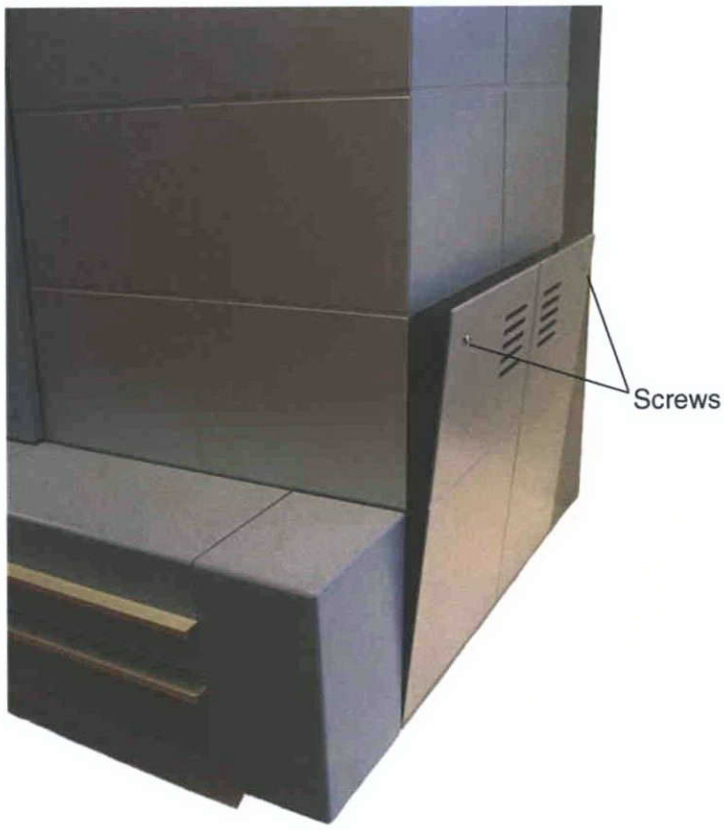
12.4.2 Bulb Exchange

WARNING

When you exchange a bulb, first switch off the SSU. Wait for the lamp housing and lamp bulb to cool before touching.



1. Loosen the 2 non-detachable screws, which hold the lamp hatch, about half a turn counter clockwise, using a 3 mm Allen key.
2. Remove the hatch by pulling it outwards and then upwards.

(Cont'd)

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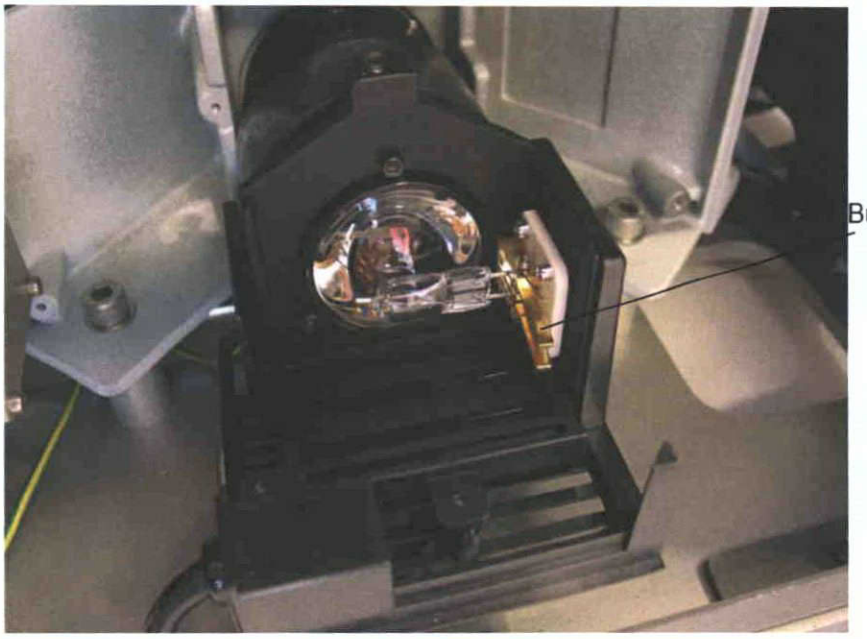
(Cont'd)

3. Loosen the non-detachable screw of the lamp house cover using a 3 mm Allen key.
4. Lift and remove the cover of the lamp house.



Caution

Do not touch the new bulb with bare hands. If fingerprints are made on the bulb, wipe it with a soft, lint-free cloth.

(Cont'd)

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(Cont'd)

5. Press the bulb clamping levers and gently withdraw the old bulb from the lamp housing.
6. Press the bulb clamping levers and fully insert the bulb pins into the pin holes.
7. Gently release the bulb clamping levers to their original position to secure the bulb.
8. Refit the lamp house cover.
9. Tighten the screw of the lamp house cover.
10. Refit the lamp hatch.
11. Tighten the screws of the lamp hatch.

12.5 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.

12.5.1 Controlling the Database Size

A large database will have lower performance (access time, database search time etc.) compared to a smaller database. The size of the database can be controlled by two methods:

1. Activate autodelete of orders.
2. Archive images onto CD-R/RW or LAN.

Recommendation:
Keep the size of the database below 20 GB. See 10.11 Adjusting Archiving Settings for more information.

Note! *Select Compress Database to view the database size (see* 10.1.5 Compressing a Database*).*

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13 Troubleshooting

13.1 Troubleshooting Steps

If a problem occurs, follow these steps:

1. Observe any unusual circumstances surrounding the problem.
2. Note any error messages displayed.
3. See 13.2 Troubleshooting Chart to find possible remedies.
4. If the problem persists, contact your distributor for assistance.

13.2 Troubleshooting Chart

13.2.1 General Startup Errors

Problem	Cause	Action
You try to start the program. Message box: The program has already been started and you cannot start another until the previous one is closed.	Previous program has not closed.	Make sure the program is closed. Wait 10 seconds and try again.
Message box: Could not log on to the system. Make sure you typed your username and password correctly.	Wrong username and/ or password.	Enter correct username and password. Note that passwords are case sensitive ("a" and "A" is not the same).
	Caps Lock is activated.	Deactivate Caps Lock.
Message box: Could not log on to the system. Network connection error!	The database server could not be reached.	If the database is stored on the system computer, restart the computer and the program. Otherwise, check the network connection and that the computer that stores the database is turned on.
Message box: Disk space exhausted.	The database is located on the C:\ drive.	Move the database to the E:\ drive.
Logging on to the system is slow.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database resides.
	The database is too large.	Keep the database size at the recommended level (see 12.5 Database Performance).
	The database files are fragmented.	Compress the database (see 10.1.5 Compressing a Database).

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13.2.2 Hardware Startup Errors

Problem	Cause	Action
In startup test: <LIS Communication Server ERROR: No contact could be established with remote LIS server!>	LIS cable is disconnected.	Make sure that the cable to the LIS is connected. Restart the program.
In startup test: Camera 1394 Communication Server. Could not initialize camera. Please check camera cable.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
In startup test: Instrument Communication Server. -SSU error. No connection with the CCU. ERROR: Initialization failed.	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Restart the system and program.
The yellow status lamp is not lit even 30s after power on.	The status lamp is not working.	Contact your local vendor's technical support.
The yellow status lamp is flashing but the startup test was successful.	The oil level is low.	Fill up the oil canister.
The yellow status lamp is flashing and the startup test fails on System Control Server.	One of the hatches is not closed.	Make sure all hatches are closed and restart the program.
	There was a jam.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, Contact your local vendor's technical support.
	The output drawer is full and there is a magazine waiting to be moved into the drawer.	Check that no magazine is positioned to the far right in the output drawer. Restart the SSU and the program.
The green power on lamp is never lit.	The power is out for the SSU.	Connect the power cable and try again.
	The power on lamp is not working,	Contact your local vendor's technical support.

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13.2.3 General Processing Problems

Problem	Cause	Action
Start is deactivated.	No magazines on the conveyer.	Add magazines (see 2.5.1 Adding Magazines).
	One or more hatches are open, indicated by:	Close all hatches. See Appendix C — Buttons and Indicators for Hatch Indicators.
	An error has occurred during slide processing.	Restart the SSU and the program.
Slide process does not start, even though Autostart is selected.	No magazines on the conveyer.	Add magazines (see 2.5.1 Adding Magazines).
	One or more hatches are open, indicated by:	Close all hatches. See Appendix C — Buttons and Indicators for Hatch Indicators.
	System status is Idle or Stopped.	Click Start.
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.
Slide status: Incomplete analysis Less than the ordered number of cells are collected.	Too small monolayer found.	Prepare the slides with longer blood films.
	Artefacts (staining precipitates) on the slide.	Make sure that the solutions are changed according to the recommendations in Appendix G.
	Dust on objectives.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
	High power cell images are not centered.	See the trouble shooting sections above.'
	Oil or dust on the low power objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
	The microscope lamp is defective.	Replace the lamp (see 12.4.2 Bulb Exchange).

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	System needs calibration or alignment.	Contact your local vendor's technical support.
Slide status: Incomplete analysis Could not find RBC monolayer	Oil on the slide.	Clean the oil off the slide and process it again.
Slide status: 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 G.
	Oil on the slide.	Clean the oil off the slide and process it again.
	Oil or dust on the low power objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance)
Slide status: Light error when using 10x/50x/100x magnification	Dirty objective.	Perform weekly maintenance on the specified objective (see 12.2 Weekly Maintenance)
	Too dark specimen.	Make sure that the slides are prepared according to the recommendations in Appendix G.
	Condenser is dirty	Clean condenser
	The microscope lamp is defective.	Replace the lamp (see 12.4.2 Bulb Exchange
High power images are not in focus.	Dust on the objective.	Perform weekly maintenance on the current objective (see 12.2 Weekly Maintenance
	Incorrect objective settings.	Contact your local vendor's technical support
Message box: Critical internal error.	Temporary software error.	Restart the SSU and the system computer.
Message box: An error occurred during oil dispensing. Check the oil level. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The oil canister is empty.	Refill oil canister.
	There are air bubbles in the oil hose.	Restart the SSU, run a slide. Repeat until there are no air bubbles in the oil hose.

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Seemingly normal slides get slide status: Empty or no slide PID.	The barcode reader is not connected.	Check the cabling of the barcode reader.
	No barcode found.	Check positioning and size of the barcode (see Appendix A — System Specification).
	The barcode could not be read due to bad print quality.	Clean the barcode printer head.
		Replace the printer ribbon on the barcode printer.
Message box: Critical error, no connection with the database.	Connection with the database has been lost.	Check network connection. Restart the system computer, or the computer on which the database resides.
Message box: Verify that the following hatches are closed:	At least the hatch specified in the message box is open.	Close all open hatches and click Retry.
Database access is slow.	The database server needs to be restarted.	Restart the system computer, or the computer on which the database resides.
	The database is too large.	Keep the database size at the recommended level (see 12.5 Database Performance).
	The database files are fragmented.	Compress the database (see 10.1.5 Compressing a Database.
Body fluid sample spot is not centered	Incorrect configuration of BF analysis area	Configure the BF analysis area settings (See 10.13 Adjusting BF Analysis Area).
	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 10.13 Adjusting BF Analysis Area).
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.

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13.2.4 Hardware Errors During Processing

Problem	Cause	Action
Message box: Critical jam error.	At least the motor specified in the message box reported a jam error.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	Magazine is broken, and fragments are blocking the slide.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Load the slides to a new magazine. Restart the SSU and the program. If error persists, contact your local vendor's technical support.
	The barcode could not be read after the slide was processed.	Wipe off oil from the barcode label.
Message box: Critical calibration error.	At least the motor specified in the message box reported a jam error.	Remove any magazines and slides (see 13.2.10 Slide Transport Jam). Restart the SSU and the program. If error persists, Contact your local vendor's technical support.
Message box: Critical temperature error.	Critical temperature in the SSU.	Shut down the SSU and contact your local vendor's technical support.
Message box: Critical communication error.	No connection between the SSU and the system computer.	Check the connection between the SSU and the system computer. Check power connection to the SSU. Restart the system and the program.
Message box: Magazine infeed error. Remove the magazine if it is stuck. Restart the system. If the problem persists, see troubleshooting section in the User's manual.	The magazine is stuck.	Remove the magazine (see 13.2.11 Magazine Transport Jam). Restart the SSU and the program.
Message box: Positioning failure when reading the slide barcode. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide is stuck or broken.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.

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Message box: Positioning error when moving the slide from the magazine into the slide holder. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide was stuck, broken or fell out during transport to the slide holder.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.
Message box: Positioning error when moving the slide from the slide holder into the magazine. Remove the slide if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The slide was stuck, broken or fell out during transport back into the magazine.	Remove the slide (see 13.2.10 Slide Transport Jam). Restart the SSU and the program.
Message box: Magazine eject error. Remove the magazine if it is stuck or broken. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The magazine is stuck.	Remove the magazine (see 13.2.11 Magazine Transport Jam). Restart the SSU and the program.
	Slides are not fully inserted into the magazine since it is worn out.	Push the slides back into the magazine. Restart the SSU and the program. Discard the worn out magazine.

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Message box: An error occurred when changing objectives. Make sure that nothing is preventing the objective rotation. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Some object prevents changing of objectives.	Remove the object that prevents changing of objectives. Rotate the objectives by hand to make sure that nothing is preventing the objective rotation. Restart the SSU and the program.
Message box: Positioning error occurred when calibrating the motors. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual. The error was reported for the following motors:	Something prevents motor movement during calibration of motors.	Remove the obstacle that prevents motor movement. Restart the SSU.
Message box: Temperature too high in the Control Unit. Shut down the system. Check that the air filter on the back of the SSU (slide scanning unit) not is dirty. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	The air filter is dirty.	Check that the air filter on the back of the SSU is not dirty.
	The fan in the control unit does not function.	The fan has to be exchanged.

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Message box: Communication error between the system computer and the SSU (slide scanning unit). Reconnect the network cable between the system computer and the SSU. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Network cable between the system computer and the SSU is disconnected.	Reconnect the network cable. Restart the SSU and the program.
	Network card in the SSU or system computer is broken.	The network card has to be exchanged.
Message box: This operation can not be performed at this time. The system must be restarted. If the problem persists, see troubleshooting section in the User's manual.	Communication error between SSU and system computer.	Restart the SSU and the program.
Message box: No camera found. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Message box: Camera initialization error. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.

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Message box: Connection with the camera lost. Check cable between the camera and the system computer. Restart the software. If the problem persists, see the troubleshooting section in the User's manual to solve this problem.	The camera cable is disconnected.	Make sure that the camera cable is connected to both the camera and the system computer. Restart the program.
Message box: The configuration of the Control unit is incorrect. Please contact support.	The Control unit has lost its configuration.	Contact your local vendor's technical support.
Message box: File system or registry error. Restart the system. If the error persists see troubleshooting section in the User's Manual.	The File system or registry is corrupt.	Reinstall the program.

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13.2.5 LIS Errors

Problem	Cause	Action
Slide status: 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.	Make sure that the cable to the LIS is connected.
LIS status:	The connection to the LIS has been broken.	Make sure that the cable to the LIS is connected. Results are automatically resent when connection is established.

13.2.6 Archiving Errors

Problem	Cause	Action
Message box: There was a general error when accessing the recorder. Check error logs.	If a problem occurred previously while trying to archive, it may be that the recorder has not been unlocked.	Restart the system computer and the program and try archiving again.
Message box: The chosen location for the temporary archive files used for burning does not have enough space. Free up space at the location and try again.	The volume or media chosen to store the temporary (when recording to CD) or actual archive does not have enough room left.	Contact your Administrator. Free up space for the temporary image. NOTE: When archiving to LAN or a hard drive on the computer, the archiving wizard requires at least 1 Gb. If CD recording is used, the archiving wizard requires 3 times the capacity of the CD in temporary working space (i.e. for a 650 Mb disc, 1950 Mb of free space is required).
Automatic deletion is enabled instead of archiving, and the deletion starts, but does not delete any or all of the older orders matching the criteria.	A database exception occurred, either due to an error in the database, or due to a transaction conflict when a CellaVision remote review opens an old order just as it is about to be deleted.	Try setting the limit on the number of orders matching the criteria for automatic deletion lower (zero) and let the program start the deletion again. You can also sort the orders in the database and try to delete them manually.

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13.2.7 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.
		Ensure 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 solutions.
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.
Nearly all boxes are far from the cells.	Stage or calibration error.	Contact your local vendor's technical support.
Too many missed cells.	Too high WBC count	Do not process slides with a WBC count that exceeds $100x10^9$/l.
	Poor staining.	Verify staining procedure.
Long processing time.	Low WBC count.	Prepare a new slide with a higher WBC count.
	Poor staining.	Verify staining procedure.

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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.
		Ensure 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 solutions.
Too few WBCs located.	Few WBCs in sample	Use a larger sample volume.
Nearly all boxes are far from the cells.	Stage or 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.

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13.2.8 Barcode Problems

Problem	Cause	Action
The barcode could not be read.	Blurry barcode, caused by immersion oil on the barcode.	Make sure the barcode is resistant to immersion oil.
		Print the barcode as defined in Appendix A — System Specification.
	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)
	Symbology contrast is too low.	Adjust the printer.
		Use slides with a white, smooth, frosted area.
	The barcode is damaged (barcode cells are missing).	Adjust the printer.
		Use slides with a white, smooth, frosted area.
Critical error in the database.	The Order ID contains more than 24 characters.	Do not use an Order ID with more than 24 characters.
Could not find the order in the LIS.	Leading spaces in the Order ID.	Remove leading spaces in the Order ID.
		Also see section 12.2.5 for LIS errors.

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13.2.9 Staining Problems

Problem	Cause	Action
The red cells 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 be increased.
	Overwashing.	The washing technique may 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 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 red cells, nuclei or eosinophilic granules.	Understaining.	The fixation and staining time may be increased.
	Overwashing.	The washing technique may be corrected so that it is adequate but not excessive.
The erythrocytes 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 be decreased (shorten the staining time) and the amount of buffer increased (increase the stain/buffer time).

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	Inadequate washing.	Increase the wash step.
	Too high an alkalinity of stain or buffer.	The pH of the buffer may be checked with a pH meter and readjusted to a lower pH.
	Thick blood smears.	Prepare a thinner blood smear.
Samples have dark areas of stain or other artefacts.	Drying is occurring during the period of staining.	Ensure the adequate drying of samples previous to staining.
	Unclean 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.
		Ensure that the stain has not exceeded the expiration date

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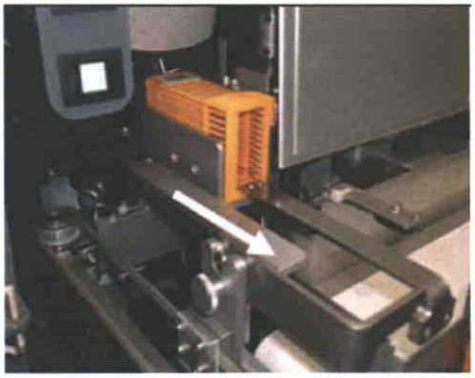
13.2.10 Slide Transport Jam

WARNING

Always turn the system mains off before interacting with the interior of the system.

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.Turn off the power to the SSU. 2.Open the Main hatch. 3.Open the Service hatch.
	4.Gently, pull the slide into the magazine by moving the QS arm straight back. If the slide does not move, lies loose or is broken, remove it by hand. 5.Gently pull the QS arm all the way in the direction indicated by the arrow. 6.Close all hatches and restart the system. The magazine will be ejected into the output drawer.

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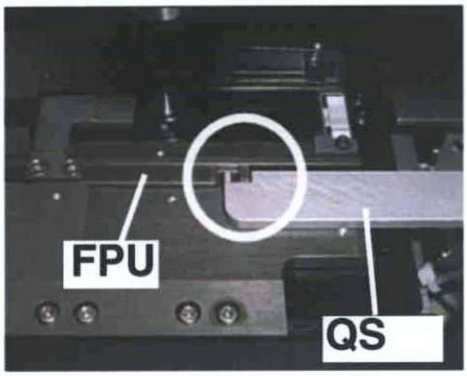
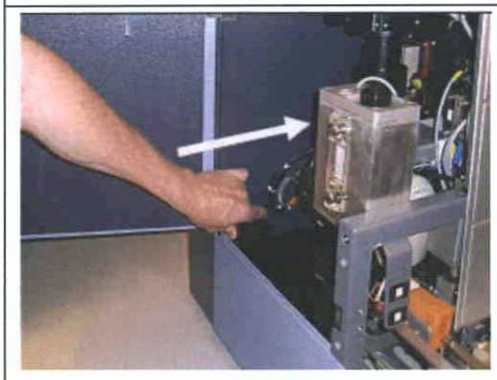
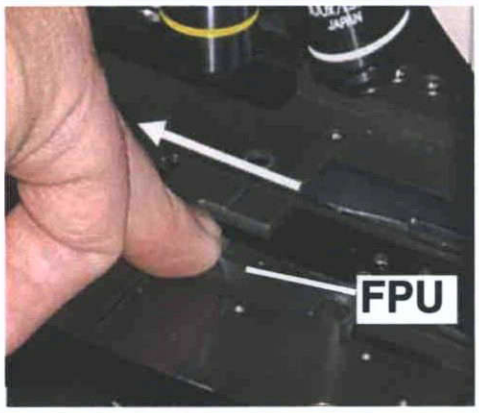
	If the jammed slide is on the XY-stage, move the immersion oil arm out of the way.

13.2.11 Magazine Transport Jam

	1.Turn off the power to the SSU. 2.Open the Main hatch. 3.Open the Service hatch. 4.Look on the stage. If the QS arm and the FPU are connected, as shown in the picture, proceed to step 5. Otherwise, proceed to step 6.
	5.Place your hand as shown in the picture. Push gently in the direction of the arrow until the FPU and the QS arm are disconnected.
	6.Gently slide the FPU fully onto the stage in the direction of the arrow.

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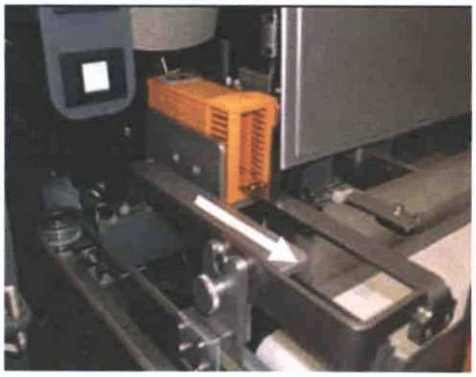	7.Gently pull the QS arm in the direction of the arrow until it stops.
	8.Move the lift down by turning the coupling to the drive screw.
	9.When the QS arm can clear the top of the magazine, stop turning the coupling and gently push the QS arm in the direction of the arrow until it is in contact with the magazine.
	10.Continue turning the coupling until, while looking through the Output Drawer, the magazine is level with the floor.

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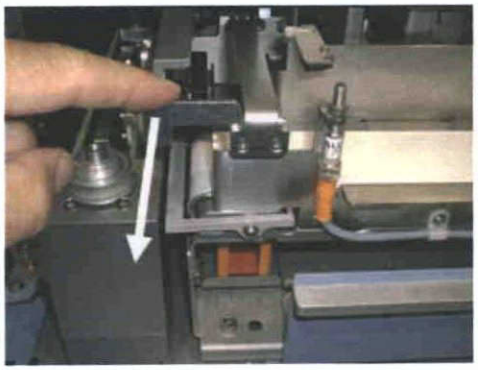
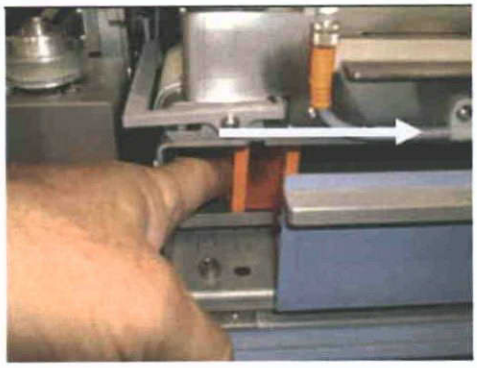
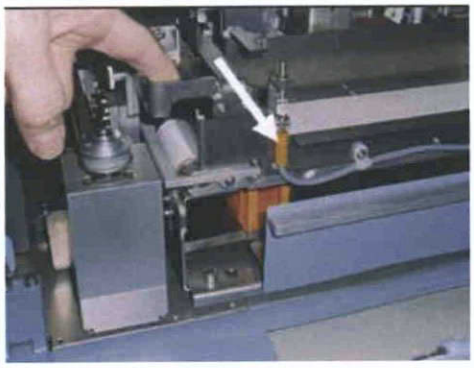
	11.Gently pull the QS arm in the direction indicated by the arrow until the magazine stops.
	12.Push the magazine onto the Output Drawer. 13.Open the Output Drawer and remove the magazine.
	14.Gently pull the QS arm in the direction of the arrow until it stops. 15.Close all the hatches and restart the system.

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Appendix A — System Specification

Climate Specification

CellaVision™ DM96 is designed to be safely operated at 18 °C to 31 °C (64 °F to 88 °F), at a maximum relative humidity of 90% with no condensation allowed, indoor use and altitudes up to 2000 m.

Physical Specification

Weight: 60 kg, excluding PC and monitor
Size (WxDxH): 53x58x62 cm, 20.9x23.6x24.8 inches

Electric Specification (monitor not included)

Voltage input: 100-240 VAC
Current input for the system computer: 6-3A
Current input for the slide scanning unit: 2-1A
Total current input for the system: 8-4 A
Voltage frequency: 50/60 Hz
Pollution degree: 2
Installation category: II
Over voltage category: II
Mains supply voltage fluctuations not to exceed ± 10 percent of the nominal voltage.

WARNING

Connect to ground sockets only.

WARNING

The mains supply cord and plug of the equipment shall comply with any national regulations.

WARNING

External computing devices connected to the communication connector (LAN) of the system have to comply with the standard UL 60950.

(Cont'd)

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(Cont'd)

Performance Specification Peripheral blood

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2 %.
Throughput: Approximately 30 slides/h for complete orders containing RBC, PLT and 100-cell WBC.

Results of short-term imprecision found in a clinical evaluation on 219 patient samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	4.7	Basophils	0.7
Band neutrophils	3.0	Lymphocytes	5.0
Eosinophils	1.2	Monocytes	2.0

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

Performance Specification Body Fluid

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2%.
Throughput: Approximately 20 slides/h for orders containing only 10x overview images (6 mm analysis area). Approximately 6 slides/h for orders containing both 10x and 50 overview images (6 mm analysis area).

Results of short-term imprecision found in a clinical evaluation on 116 samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Neutrophils	3.4	Macrophages	3.4
Eosinophils	0.7	Other	0.7
Lymphocytes	6.6		

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(Cont'd)

Performance Specification Peripheral blood
Average WBC cell-location and display of at least 97 % with a standard deviation less than 2 %.
Throughput: Approximately 30 slides/h for complete orders containing RBC, PLT and 100-cell WBC.

Results of short-term imprecision found in a clinical evaluation on 219 patient samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	4.7	Basophils	0.7
Band neutrophils	3.0	Lymphocytes	5.0
Eosinophils	1.2	Monocytes	2.0

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

Performance Specification Body Fluid

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2%.
Throughput: Approximately 20 slides/h for orders containing only 10x overview images (6 mm analysis area). Approximately 6 slides/h for orders containing both 10x and 50 overview images (6 mm analysis area).

Results of short-term imprecision found in a clinical evaluation on 156 samples, based on NCCLS standard H-20A*:

Cell class	SD (%)	Cell class	SD (%)
Neutrophils	3.4	Macrophages	6.3
Eosinophils	0.8	Other	2.2
Lymphocytes	6.0		

* The following fluid types were not included in the evaluation: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage.

Performance Specification Scan

Throughput data and disk space requirements for the scanned slides:

Analysis area size	Overview images	Processing time	Disk space
5x5 mm	10x	1 min	10 MB
5x5 mm	10x+50x	8 min	130 MB
10x10 mm	10x	2 min	45 MB
10x10 mm	10x+50x	30 min	500 MB

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

Materials Specification

Immersion oil: Trak 300™ Automated Differential System Immersion Oil. Refractive index 1.5150. Viscosity 300 cSt. PCB free. 500ml should be sufficient for approximately 10000 analyses.

Bulb: OSRAM XENOPHOT HLX 64625 FCR 12 V 100 W halogen.

CellaVision slide magazines.

Stain: May Grünwald Giemsa or Wright.

Slide requirements (mm): glass, 75.0-76.0 x 25.0-26.0 x 0.9-1.2, ground edges, clipped or round corners, frosted end.

Note! *CellaVision DM96 analyzers with a serial number higher than 31216 or systems that have been upgraded with the Stage Upgrade Kit (CellaVision Part number XU-10043) support slides with the following dimensions (mm): 75.0-76.0 x 25.0-26.3 x 0.9-1.2*

(Cont'd)

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(Cont'd)

Slide descriptions:

Clipped corners

Round corner

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

Caution

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

Caution

Using the magazines more than 100 times may damage the system.

Barcode

The system requires high quality barcode labels on the slides. Maximize the barcode width for best result.

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

Linear Barcode Scanner

The following barcode formats are accepted by the system:

UPC-A	Interleave 2 of 5	CODE 11
UPC-E	Industrial 25	China Postage
EAN-13	Matrix 25	MSI/PLESSEY
CODE 39	CODABAR/NW7	CODE 32
CODE 128	CODE 93	BC412

The minimum barcode resolution shall be 7 mil.

(Cont'd)

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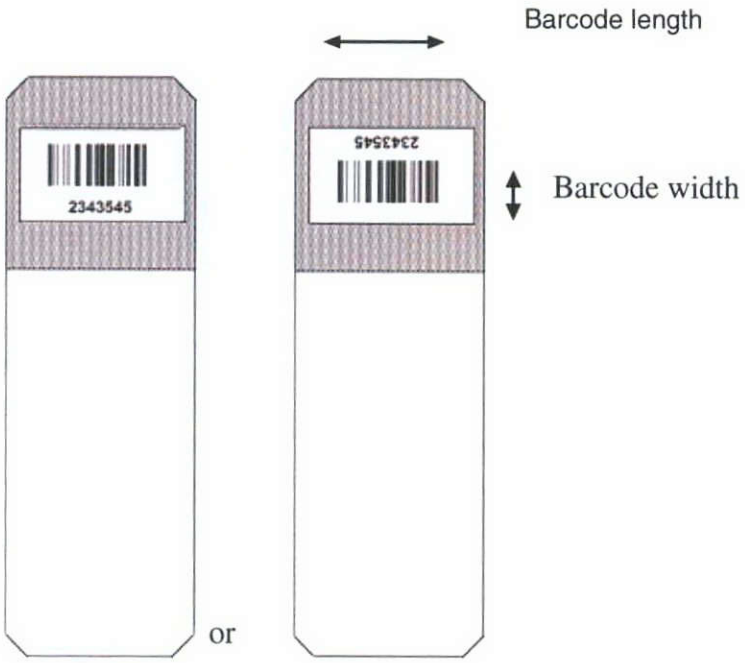
(Cont'd)

The label should be positioned as shown in the figure below. The edges of the label shall be at least 1 mm from the edges of the slide.

Note! *Avoid oil on the slide label.*



2D-D Barcode Scanner

The following barcode formats are accepted by the system:

Linear codes			
CODE 39	CODABAR/NW7	Code 128	Interleave 2 of 5
2D-D codes			
DataMatrix	QR		

(Cont'd)

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(Cont'd)

Requirements

Sample ID

When using either a DataMatrix or a QR code the only information allowed in the code is a sample ID (i.e. no other data), which may be at most 24 characters long but which may be padded with spaces (ASCII code 32). No leading spaces are allowed.

Print quality

The printed barcode shall be resistant to immersion oil and be printed with a high contrast ratio between background and the printed barcode. If the barcode is printed directly onto a slide, it must be printed on a white, smooth, frosted area of the slide.

Barcode size

The minimum supported barcode resolutions are listed in the table below.

Supported code resolution	
Code	**Cell size, mil**
QR	13
DataMatrix	9
Code 39	7
Code 128	7
Codabar/NW7	7
Interleave 2 of 5	7

(Cont'd)

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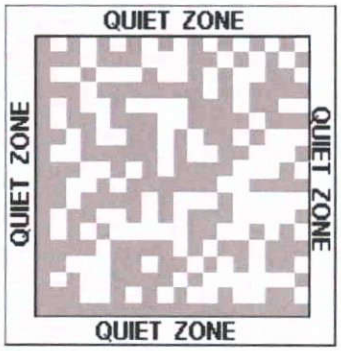
(Cont'd)

Quiet zone

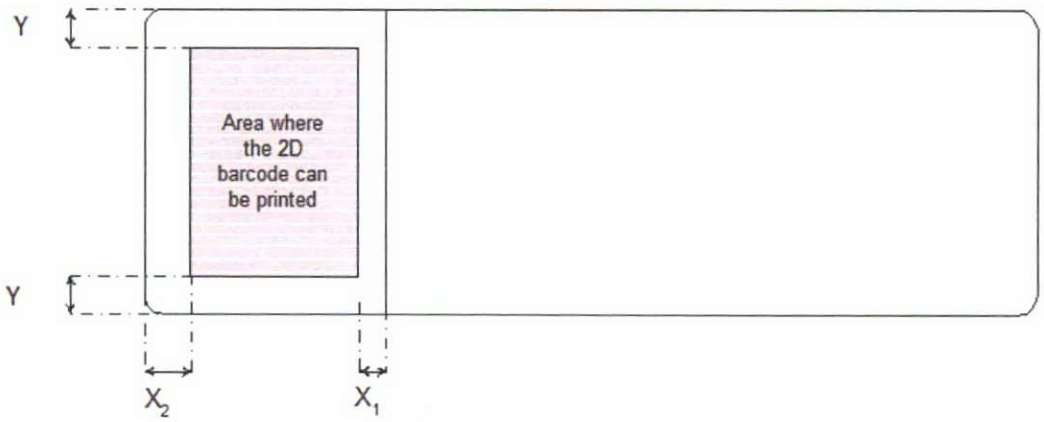
The recommended quiet zone is listed in the table below.

Symbology	**Vertical quiet zone, cells**		**Horizontal quiet zone, cells**	
	Top	Bottom	Top	Bottom
DataMatrix	1	1	1	1
QR	4	4	4	4



Barcode position

The barcode shall be positioned within the area as illustrated in the figure below.



Where

X1 > 2 mm; X2 > 6mm; Y > 4mm

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Firefighting Procedures

Fire and explosion hazard:

Flash point: >300°F / 149°C

Upper explosive limit: N/A

Lower explosive limit: N/A

Fire fighting media: Carbon dioxide, Foam, dry chemical, and waterfog.

Fire response procedures: Fire fighters must use self-contained breathing apparatus.

Unusual fire and explosion hazards: Containers should be kept cool in the event of fire.

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Appendix B — Storage and Handling

Storage

The system shall be stored within the following climate condition: 10 °C to 40 °C (50 °F to 104 °F), at a maximum relative humidity of 80% with no condensation allowed.

Transporting the System

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

Disposal Information

Magazines: As combustible plastics (PC + ABS).
The system: Please contact your distributor.

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Appendix C — Buttons and Indicators

If you place the mouse-pointer over the buttons or indicators, you can view tool tips in the Status bar (bottom left-hand corner).

Buttons

	CellaVision™ DM software	
	System Control View	F4
	Database View	F5
	Verification View	F6
	Report View	F7
	Close Order and Slide	
	Order Data	
	Help Lines	Enables help lines for PLT estimate.
	Confirm Cell Counter Results	
	Comments	
	WBC Full Screen View	
	WBC Galleries	
	Zoom Mode	
	Zoom In/Zoom Out	
	Scroll Mode	

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	Color/Brightness	Adjusts image color and brightness.
	Toggle Color/Brightness	Toggles between default color and lights settings and personal settings.
	Cell Marker	Shows/Hides square for cell identification.
	WBC Attributes	Shows/Hides WBC attributes.
	Entire RBC Image	Shows the entire RBC image.
	Start	
	Stop	

Indicators

	Autostart	Automatic start of slide processing.
	Oil Level Indicators	Indicates an empty oil canister.
		Indicates need for refilling of oil.
		Indicates a full oil canister.
	Output Drawer Indicators	Indicates room left in the output drawer.
		Indicates a full output drawer.
	Hatch Indicators	Indicates all hatches closed.
		Indicates an open hatch or oil immersion arm in wrong position.

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	Magazine Indicator	Indicates the number of magazines in the system except those in the output drawer.

Keyboard shortcuts

Ctrl+w	Show/hide Worklist.

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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.

Recommended Settings (see 10.7 Adjusting Report/Sign 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

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 slides - 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.

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Workflow Single Slides / Confirm Cell Counter Results

Go to *Database View* (Shift+F1).

↓

Select orders.

↓

Click *Add to worklist*.

↓

Double-click on the first slide in the Worklist.

↓

Verify WBC.

↓

Click *RBC* tab.
Perform RBC review.

↓

Click *PLT* tab.
Perform PLT review.

↓

Click *Sign Slide* tab.

↓

Sign the slide. The next slide in the Worklist.
will automatically be opened.

↓

When the last slide in the worklist has been signed,
the Database View automatically opens.

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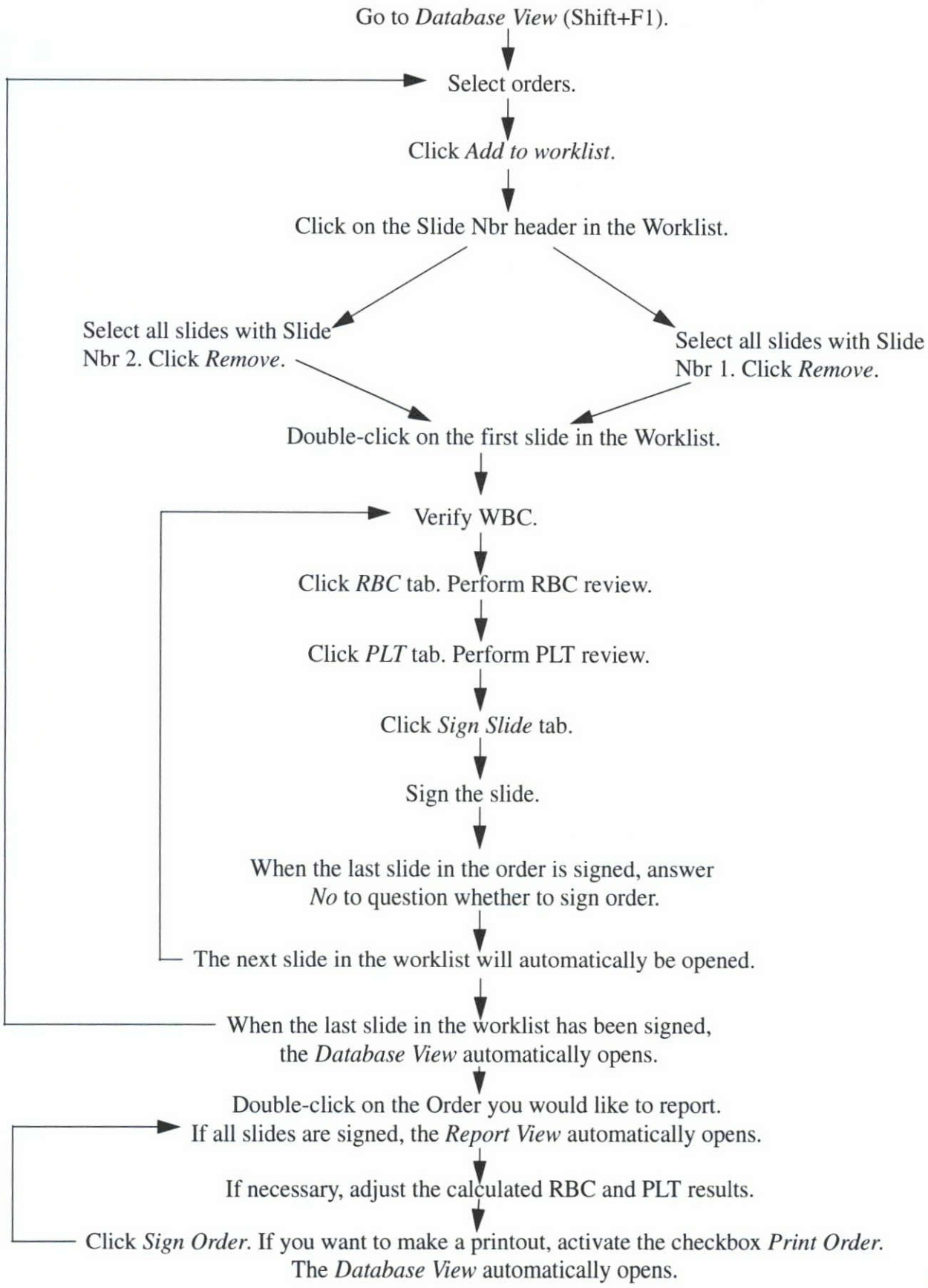
Workflow Duplicate Slides



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Appendix E — User Authorization Levels

	Action/Setting	Observer	User	Restricted	Authorized	Administrator
	Start slide processing		X		X	X
	Search in the database on Order ID and Patient ID	X	X	X	X	X
	Search in the database on other criteria	X	X		X	X
	Verify and comment WBC, RBC and PLT		X	X	X	X
	Edit Order data				X	X
	Add/edit pending orders		X	X	X	X
	Sign slides and reports			X	X	X
	Send results to the LIS			X	X	X
	Delete unsigned slides/ orders				X	X
	Delete signed orders					X
	Archive					X
	Export orders				X	X
	Protect order from archiving				X	X
	Send images with e-mail	X	X	X	X	X
	Export log files					X

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Database settings					X
Users settings					X
Analysis settings					
Default values Add processed slide to worklist				X	X
Enable LIS					X
Enable autostart					X
WBC reclassification settings					X
RBC precharacterization settings					X
PLT settings					
Use only manual PLT concentration estimation Defaults for PLT		X	X	X	X
PLT estimate factor Intervals for average PLTs/HPF					X
Report/Sign settings					X
Standard comments settings				X	X
Reference cells settings				X	X
E-mail settings					X
Archiving settings					X

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Appendix F — Determining the Platelet Estimate Factor

Follow the procedure below to determine the PLT estimate factor.

1. Perform automated PLT counts with a cell counter on 30 consecutive blood samples.
2. Prepare and stain one smear for each sample.
3. Perform PLT analyses on the system. Let the system calculate the average PLTs/HPF values for each sample.
4. Divide the cell counter PLT value by the system average PLTs/HPF value for each sample to get the conversion factors.
5. Add all 30 conversion factors and divide by 30 to get the PLT estimate factor.
6. Enter the PLT estimate factor in the *PLT* tab in *Settings*.

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Appendix G — Slide Preparation Guidelines

Slide Preparation for Peripheral Blood

WARNING

Always use protective gloves when in contact with blood.

Sample

Collect blood from a vein or by skin puncture in an EDTA sample tube (K2EDTA or K3EDTA, 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.

Preparing Blood Films

1. Mix the tube (20 complete inversions by hand) before preparation.
2. Use a clean dry microscope glass slide (see Appendix A — System Specification 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, ending in a squared or straight edge, without any grainy streaks, troughs, ridges, holes or bubbles. The blood film must be at least 30 mm in length, terminating 5- 15 mm from the edge.

(Cont'd)

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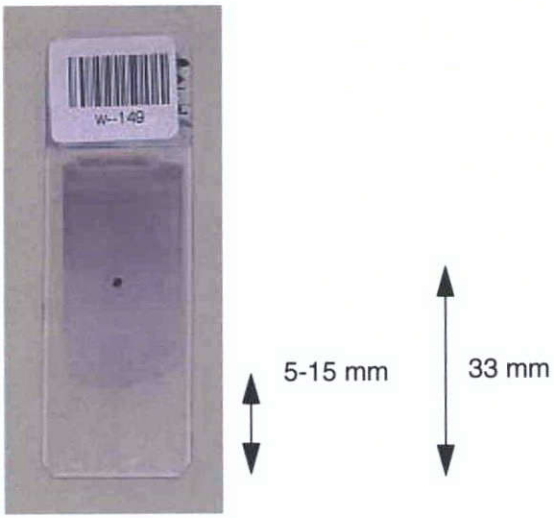
(Cont'd)

4. Dry the slide rapidly.
5. Stain the slide within one hour.



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

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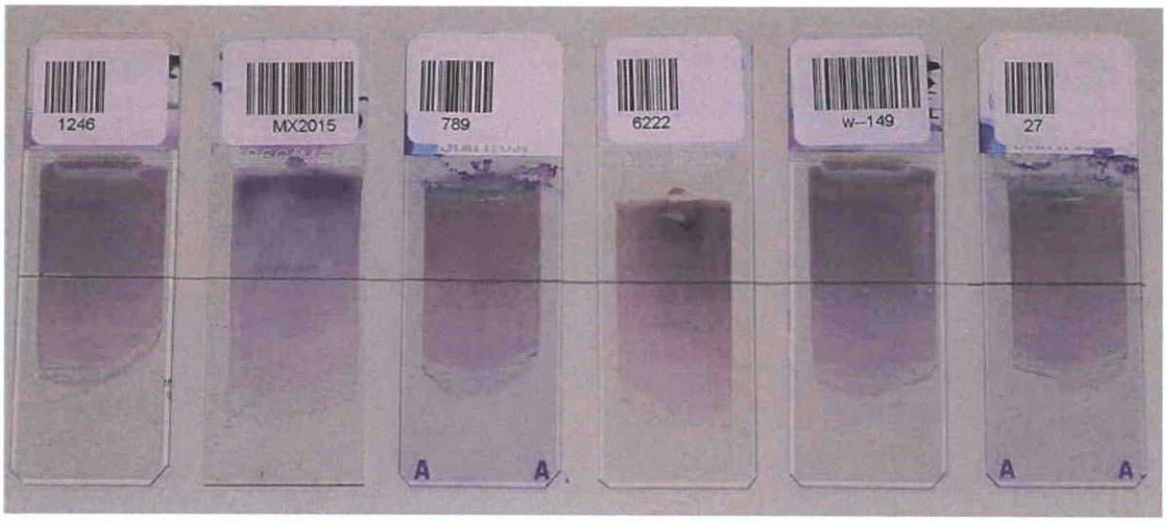
Example Smears

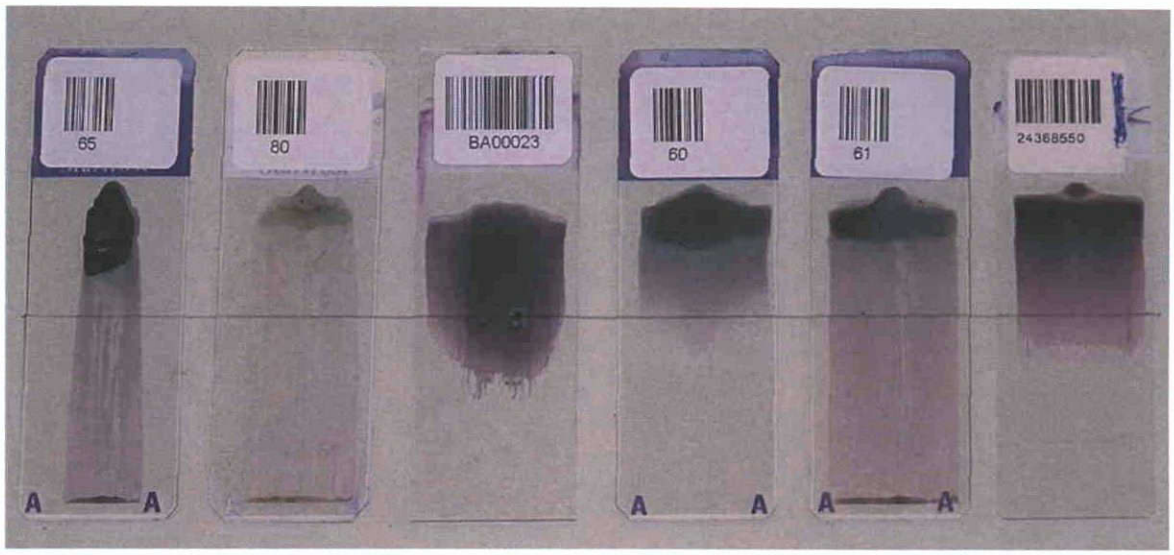
The line in the images indicates the analysis starting point.

Accepted



These slides are all prepared according to the specifications and will be accepted in the DM8/DM96.

Not Accepted



These slides are not prepared according the specifications and will not be accepted in the DM8/DM96

(Cont'd)

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(Cont'd)

Recommended Staining Recipes

CellaVision™ DM is optimized to analyze samples stained with May Grünwald Giemsa (MGG) stain and Wright stain. Dip the slides in the solutions according to one of the following recipes.

MGG Stain

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

Alternative 1

	Solution	Reaction time	Change solution
1	May Grünwald stock solution a	5 min	Twice a week
2	May Grünwald working solution b	15 min	Every day
3	Buffer working solution d	Quick rinsing	Every day
4	Giemsa working solution f	30 min	Every day
5	Buffer working solution d	Extensive rinsing	Every day

Alternative 2

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

(Cont'd)

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(Cont'd)

a	May Grünwald stain, stock solution:	Merck M1424 Eosin-methylenblue solution, modified for microscopy (contains methanol). Store at +15 °C to +25 °C.
b	May Grünwald working solution:	Dilute 1 part of May Grünwald stock solution with 1 part buffer work solution. Stable for 8 hours.
c	Buffer stock solutions 1 and 2:	1) 9.07g KH2PO4 (0.067M) ad 1000ml deionized water Store at +4 °C to +8 °C. 2) 9.45 g Na2HPO4 (0.067M) ad 1000ml deionized water Store at +4 °C to +8 °C.
d	Buffer working solution, pH 6.8	Combine 127 ml KH2PO4 stock solution with 123 ml Na2HPO4 stock solution ad 5000 ml deionized water. Adjust to pH 6.8. Store at +4 °C to +8 °C. Durable for a month at +4 °C.
e	Giemsa stain, stock solution:	Merck M9204 Azur-eosine-methylenblue solution for microscopy (contains methanol). Store at +15 °C to +25 °C. Durable for several months if kept in a dark bottle.
f	Giemsa working solution:	Dilute 1 part Giemsa stock solution with 19 parts buffer work solution. Stable for 8 hours.

(Cont'd)

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(Cont'd)

Wright Stain

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

Alternative 1: Sysmex SMS SP 100 slide stainer

	Solution	Reaction time
1	Wright stain	2 min
2	Wright stain diluted 1:10 with phosphate buffer pH 6.8	7 min
3	Rinse in deionized water	30 sec

Alternative 2: Beckman Coulter GENS slide stainer

	Solution	Reaction time
1	Methanol	30 sec
2	TruColor Wright stain	2 min 30 sec
3	TruColor Wright stain diluted 1:6 with phosphate buffer pH 7.2	6 min 30 sec
4	Rinse in phosphate buffer pH 7.2	1 min 15 sec
5	Rinse in deionized water	45 sec

Wright stain alternative 2 can also be used for manual dip method.

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Slide preparation for body fluid

WARNING

Always use protective gloves when in contact with Body Fluids.

Sample

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

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 both with a drop or two of bovine serum albumin (BSA), which promotes cell adhesion to the microscope slide, may be used as a diluent.

The recommendation is to have 5000-12000 cells in total on the slide

Note! *Cells are concentrated approximately 20-fold by cytocentrifugation, however the quantitative yield varies from 30-75%. 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. Body Fluid Analysis for Cellular Composition, CLSI, H56 A Vol 26, No 26)*

Use a clean dry microscope glass slide (see Appendix A — System Specification 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.*

Stain the slide using the same staining recipe as for peripheral blood samples. (See Recommended Staining Recipes for staining recommendations).

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Appendix H — Cell Location

Cell Location for Peripheral Blood

The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test. Running the test once or twice a day is a recommended interval at the high-load laboratory. The test establishes how many percent of the nucleated cells (i.e., WBC and NRBC) that are found on a slide.

The Cell Location tool may be accessed in the Tools menu.

Slide Requirements

Use a blood sample with a WBC count in the normal WBC range. To reduce processing time, a WBC count above $7x10^9$/l is recommended. If the system cannot locate at least 100 nucleated cells, the result will be discarded.

The percentage of non-nucleated cells (i.e., all other object that are not identified as being a WBC or NRBC cell, e.g. smudge cells) must not exceed 30% of the total number of objects.

The slides must have a barcode label, starting with the text "QC". All slides with this kind of label are automatically treated as cell location test slides. When the slide has been processed it will only be available in the Cell Location tool. Pre-printed QC labels are available from your local dealer.

Running a Cell Location Test

1. Select a slide that meets the requirements and put a QC label on it.
2. Put the slide in a magazine, place it in the DM and process the slide.
3. Go to the Cell Location tool when the slide has finished.
4. Select the new slide at the top of the slide list.
5. Go through all the images belonging to the slide and examine them for missed nucleated cells. Enter the number of missed cells, if any, in the input field for each image.
6. When all images have been examined the result will appear at the end. Check that it is within acceptable limits.

(Cont'd)

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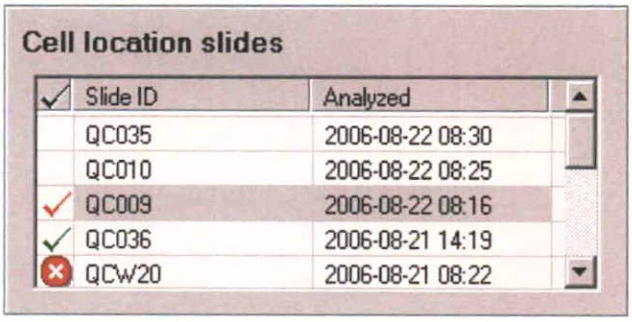
(Cont'd)

Examining a Cell Location Slide

Select the slide in question from the list of cell location slides.



Slide status	✓
Empty	Slide has no result (not all images have been examined).
✓	Slide has a result and no missed nucleated cells (all images have been examined).
✓	Slide has a result but contains missed nucleated cells (all images have been examined).
⊗	Slide error, probably due to a failure in slide processing (e.g., not enough nucleated cells were found).

Go through each image in the list of overview images and check if they contain any missed nucleated cells. Green boxes mark the nucleated cells and blue boxes mark other found objects that are not nucleated cells (e.g. artefacts). Missed nucleated cells are those cells not marked with a box in the image. Double-click in the overview image to magnify the area of interest.

Black boxes mark the number of cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.

Note! *On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.*

(Cont'd)

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(Cont'd)

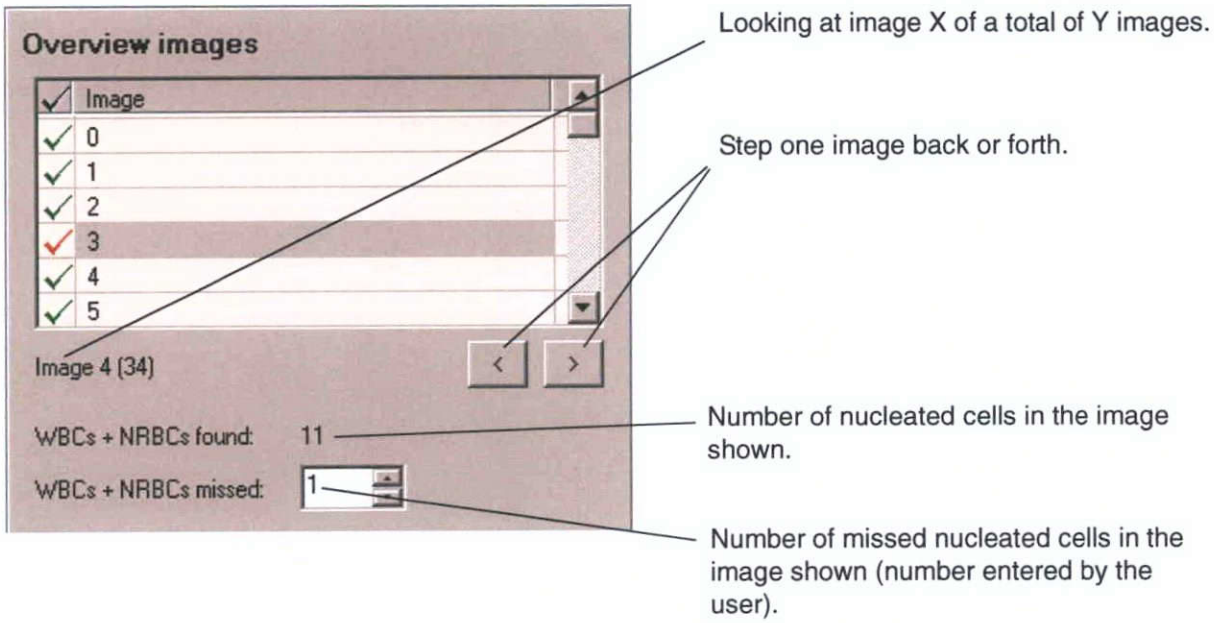

Image status	✓
Empty	Image has not been viewed.
✓	Image has been viewed and has no missed nucleated cells.
✓	Image has been viewed but contains missed nucleated cells.

The Result

When a slide has been examined a result is automatically calculated. The percentage indicates how many nucleated cells the system found including the manually added number of missed cells.

It is possible to adjust the total number of found nucleated cells, if it is determined that some found cells are neither WBC nor NRBC cells. For instance, if the system identifies 187 nucleated cells but the user thinks 3 of them do not fall under this category, he/she can enter 184 in the Manual correction field and this number will be used in the calculation.

(Cont'd)

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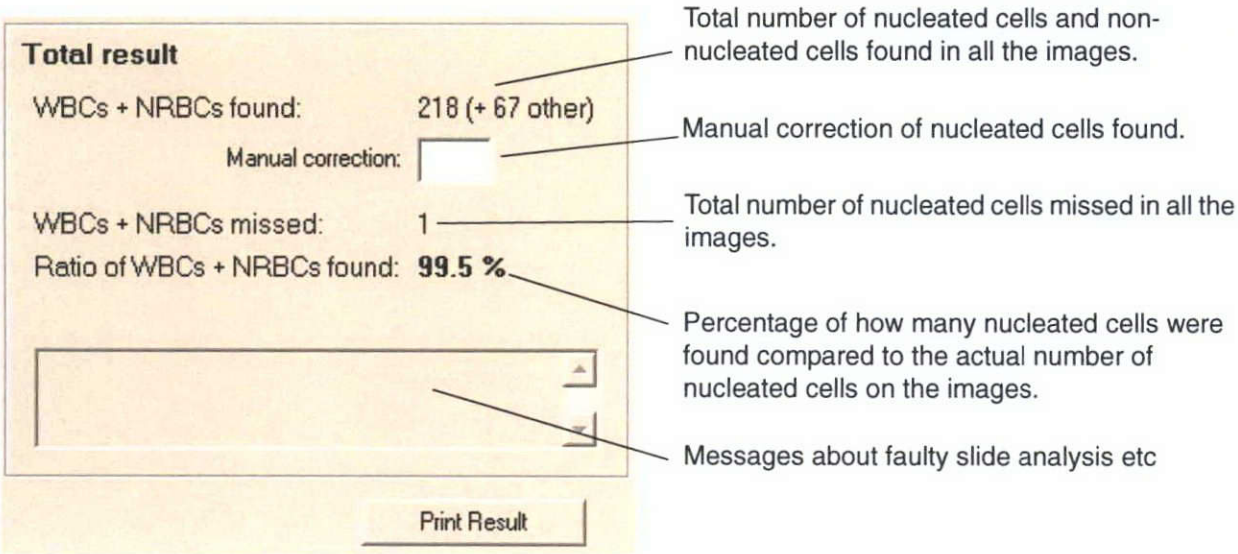
(Cont'd)



The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix A — System Specification.

If any of the requirements regarding the number of nucleated cells or non-nucleated cells are not fulfilled, an error message will be shown in the Total result panel.

The cell location results can be printed by clicking the *Print Result* button.

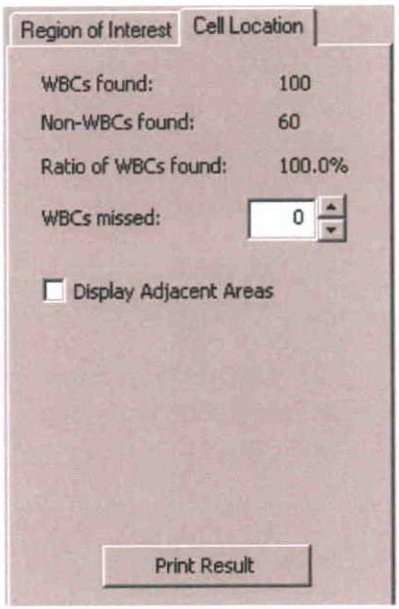
Deletion of Cell Location Slides

Slides older than five days are automatically deleted at program startup/logon.

4/2

Cell location for Body Fluids

The cell location performance shall be verified at regular intervals and after changes in staining procedure or staining solutions by running the Cell location test. It is also recommended to run cell location test for each new body fluid specimen analysed in the laboratory. For the definition of body fluid specimens see CLSI H56-A Body Fluid Analysis for Cellular Composition; Approved Guideline. Running the test once or twice a day is a recommended interval at the high-load laboratory. The test establishes how many percent of the nucleated cells that are found on a slide.



The Cell Location tool may be accessed by clicking on the cell location tab in the body fluid overview view. Cell location information is available for all BF slides.

Slide Requirements

Use a body fluid sample with a total number of WBCs less than 12000.

Running a Cell Location Test

1. Select a slide that meets the requirements and process it like a regular BF slide.
2. Open the slide and go to the Overview and select the Cell Location tab.
3. Navigate through the entire analysis area and look for missed nucleated cells. Enter the number of missed cells, if any, in the input field.
4. When the entire area has been viewed, check that the result it is within acceptable limits.

Note! *It is recommended that you order 10x+50x overview images for cell location slides.*

Note! *QC labels are not required for running cell location test on body fluid slides.*

(Cont'd)

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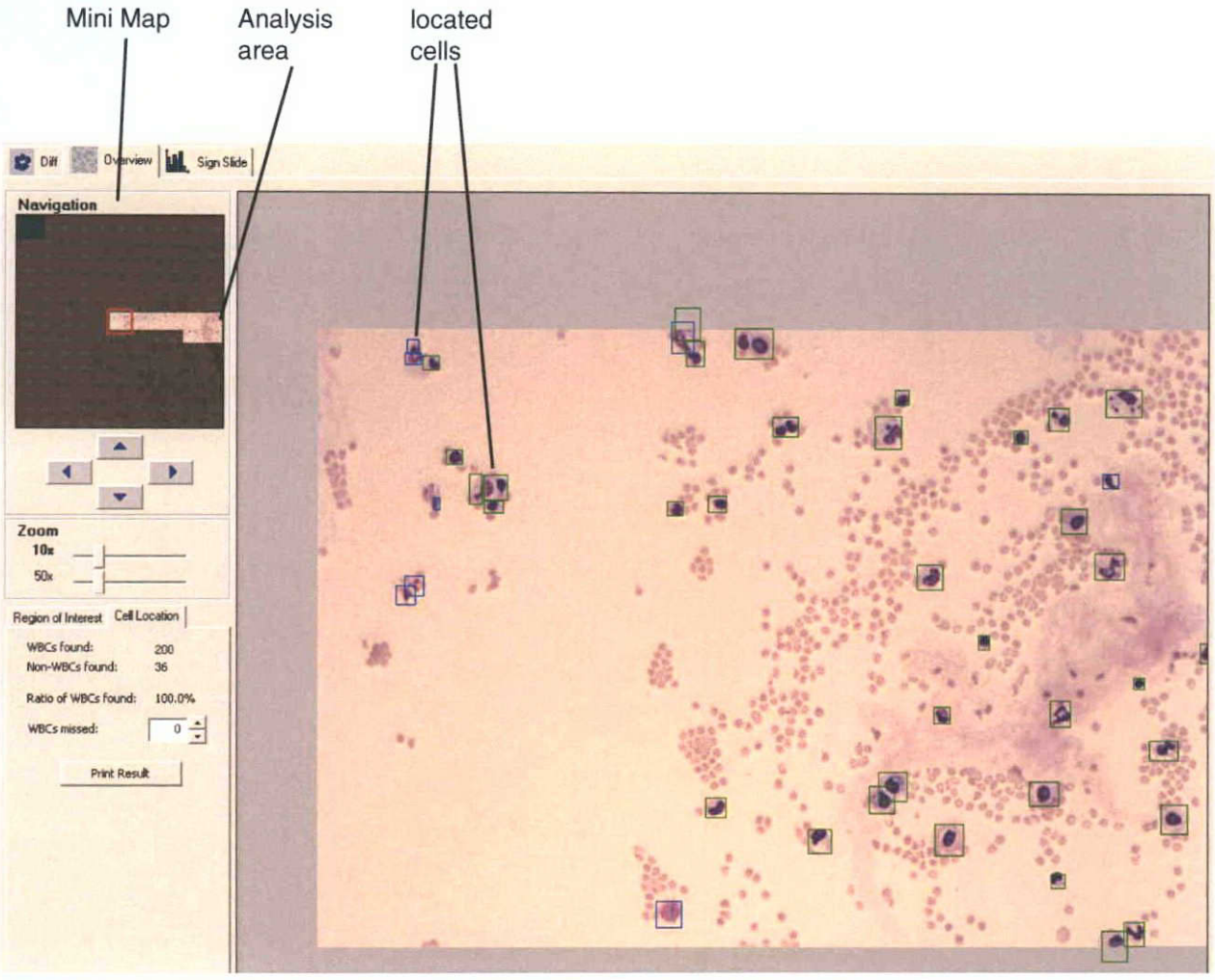
(Cont'd)

Examining a Cell Location Slide

Open the slide in question from the database view.



The analysis area used for collecting cells is represented by the bright part of the mini map.

Navigate through the analysis area and check if it contains any missed nucleated cells. Green boxes mark the nucleated cells and blue boxes mark other found objects that are not nucleated cells (e.g. artefacts). Missed nucleated cells are those cells not marked with a box in the image.

(Cont'd)

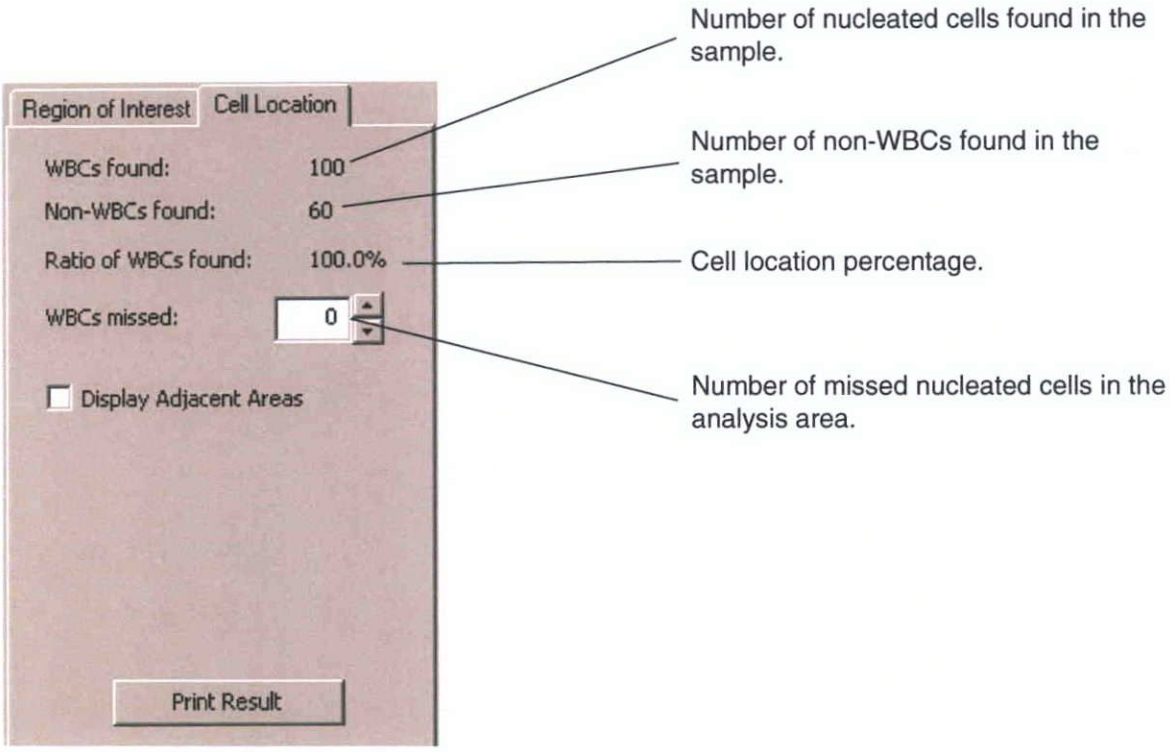
4/4

(Cont'd)

Black boxes mark the cells that were located but not needed for the test, indicating that the system has located enough cells for the test and is coming to an end.

***Note!** On screen, cell images are not always presented in the same order as the system is working. Cells marked with black boxes may occur in the middle of the test, not only towards the end.*

***Note!** The last collected cell will be marked with both a black and a green or blue box.*



The Result

The result is automatically calculated. The percentage indicates how many nucleated cells the system found including the manually added number of missed cells.

The result should be compared to the laboratory's own established limits. Performance characteristics when using standardized staining and smear preparation procedures are presented in Appendix A — System Specification.

The cell location results can be printed by clicking the *Print Result* button.

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Appendix I — Glossary

	Description
Analysis	Starts with the loading of slides and ends with the finished report.
Confirmation	The operator approves the preclassification.
Duplicate slide differential	Two different persons sign one slide each in the order. The average result is presented.
Grid square	Sub-images of a PLT overview.
In-vitro	Outside the living body; in an artificial environment.
LIS	Laboratory Information System
Magazine	A container transporting up to 12 slides in the system.
Magazine ID	The barcode no. on the magazine label for magazine identification.
MGG	May Grünwald Giemsa; a Romanowsky stain for blood smears.
Mini map	Overview image of 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 the operator cannot identify and wants to exclude from the differential count.
Operator	The person who works with the system.
Order	The name of the ordered analyses on the slides from the same sample.
Order ID	Order identifier. There can be several slides with the same Order ID but 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.
Patient ID	Unique number identifying the patient.
Pending order	An order manually added to the database, waiting to be processed.
PID	Positive Identifier. The barcode on the slide.
PLT	Platelet, thrombocyte
PLT estimate	Estimation of the PLT concentration.
PLT estimate factor	A predetermined factor to calculate the PLT estimate.
Precharacterization	The system suggests RBC morphology characteristics.
Preclassification	The system suggests WBC classification.
Processing slides	The sequence of events from when the magazines are put on the conveyer to when they are ejected to the output drawer.
Quick scans	Quickly scanned slides for cell counter verification. The results are not sent to the LIS.
RBC	Red blood cell, erythrocyte
Reclassification	The operator changes the preclassification.

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Reference cells	Cells with typical characteristics available in the 2nd and 3rd galleries.
Region of interest	Part of the BF 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	Finally confirming analysis results before locking and reporting them.
Slide ID	The barcode number on the slide (PID). Same as Order ID.
Slide number	A number that uniquely identifies slides within the same order.
Slide position	The position of a slide in the magazine.
Unidentified	Cells and objects which the system cannot preclassify.
Verification	The operator's review of WBC, RBC and PLT, e.g. reclassification and confirmation of WBCs.
WBC	White blood cell, leukocyte
Wright	A Romanowsky stain for blood smears.

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Appendix C - Requirements specifications and Design descriptions

Following documents are attached under this section:

Requirement document:
SEL-007 SRS

System design descriptions:
QCV-017 Terminology
SEL-501 SDD
SEL-502 SWDD DM Software Overview

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QUALITY ASSURANCE DOCUMENT

DOCUMENT: Standard Operating Procedure	REGISTRATION NO: QCV-017
TITLE: Terminology	PAGE: 1(12)
	REVISION NO: 02
	EFFECTIVE FROM (yyyy-mm-dd):

WRITTEN BY: ..... Magnus Johnsson, Project Manager	DATE (yyyy-mm-dd): .....
APPROVED BY: ..... Peter Wilson, Product Manager	DATE (yyyy-mm-dd): .....
APPROVED BY: ..... Christian Matson, R&D Director	DATE (yyyy-mm-dd): .....
APPROVED BY: ..... Hans-Inge Bengtsson, QA Manager	DATE (yyyy-mm-dd): .....

1 Introduction

1.1 Aim/purpose

This document defines and describes the terminology to be used in printed material documentation and GUI.

1.2 Scope

- Printed material produced by CellaVision AB (English)
- GUI for DiffMaster Octavia (English)
- GUI for CellaVision DM96 (English)

Exceptions from this document:

- CellaVision website
- CellAtlas
- Equator

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2 General Terminology and Language

Use American English (AE) instead of British English (BE):

For example use (AE):	**Instead of** (BE):
Analyze	Analyse
Anemia	Anaemia
Artifacts	Artefacts
Hematology	Haematology
Leukemia	Leukaemia
Leukocytes	Leucocytes
Tumor	Tumour

When referring to DiffMaster Octavia or CellaVision DM96:

Use	**Do not use**
Preclassification / suggestion	Classification
The *cell* has been reclassified	The *cell image* has been reclassified
The system *processes* a slide.	The system *analyzes* a slide.
The system	The instrument

3 Abbreviations

ANN	Artificial Neural Network
AST	Automatic Slide Transfer, see DM96 chapter 5
AMT	Automatic Magazine Transfer, see DM96 chapter 5
ASTM	American Society for Testing and Materials
BB	Black box
BD software	CellaVision Blood Differential software
CCU	CellaVision Control Unit = Black Box, see DM96 chapter 5
CSF	Cerebrospinal Fluid
DM96	CellaVision DM96
DPU	Drawer Pushing Unit, see DM96 chapter 5
FPU	Finger Pushing Unit, see DM96 chapter 5
GUI	Graphical User Interface
HPF	High Power Field
IOS	Immersion Oil System, see DM96 chapter 5
LIS	Laboratory Information System
MGG	May Grünwald Giemsa
NA	Numerical Aperture
PLT	Platelets, thrombocytes
PC	Personal Computer
PID	Positive Identification
RBC	Red Blood Cells, erythrocytes

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RTOS	Real Time Operating System
STAT	Short Turn Around Time, emergency sample
SSU	Slide Scanning Unit, see DM96 chapter 5
WBC	White Blood Cells, leukocytes
QS	Quer Shiebe, see DM96 chapter 5

3.1 Abbreviations of Laboratory Parameters

CBC	Complete Blood Count; includes RBC, WBC, Hb, PLT and usually MCH, MCV, MCHC and Hct.
Hb, Hgb (g/L)	Concentration of hemoglobin in red blood cells.
HCT, Hct (%)	Hematocrit, the percentile proportion of the red cells to the total volume of a centrifuged blood sample.
MCH (pg)	Mean (red) Cell Hemoglobin, Hb/Hct
MCHC (g/L)	Mean (red) Cell/Corpuscular Hemoglobin concentration, Hb/RBC
MCV (fl)	Mean (red) Cell/Corpuscular Volume, Hct/RBC
MGG	May-Grünwald Giemsa, a staining method for blood smears.
PLT, Plt ($x10^9$/L)	Platelets
RBC ($x10^{12}$/L)	Red blood cell / erythrocyte / Red Blood Cell count
RDW	Red cell Distribution Width, the area of distribution in size for red cells.
RETIC ($x10^9$/L)	Reticulocyte
WBC ($x10^9$/L)	White blood cell / leukocyte / White Blood Cell count

4 General Definitions

4.1 GUI cell class names

Non-WBCs	Cells and objects identified as not being white blood cells.
Not classed	Cells and objects the operator cannot identify and wants to exclude from the differential count.
Other	Cells that the operator identifies as white blood cells, but of a type other than those listed. Will be included in the differential count.
Unidentified	Cells and objects which the system cannot preclassify.

4.2 Slide preparation and staining

Blood smear	A thin blood film wedged and stained on a glass slide.
May Grünwald Giemsa	MGG; a Romanowsky staining method for blood smears.
Romanowsky stain	A family of staining methods for blood smears, including May-Grünwald-Giemsa and Wright.

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Specimen	A quantity of collected blood.
Sample	The representative part of a specimen used in the analysis.
Smear / blood film preparation	The procedure of removing a sample of blood from a collection tube and creating a monolayer on a glass slide. The preparation can also include staining of the smear.
Wright	A Romanowsky stain for blood smears.

4.3 Slide processing and review

Analysis	The procedure which starts when the operator loads the slides and ends when the operator signs the analysis. *Note! Has previously in some documents been used for the processing of slides.*
Confirmation	The operator approves the preclassification or precharacterization.
Duplicate slide differential	Two different persons sign one slide each in the order. The average result is presented by the system.
Grid square	Sub-images of a PLT overview.
High Power Field	HPF; an image of the blood smear corresponding to the ocular view of a microscope with 50x magnification.
Immersion oil	Oil used between the lens and slide to enhance optical resolution.
Laboratory Information System	LIS; a computerized information system which laboratory can use for managing patient records, analysis orders and results. The system can send/receive information to/from the LIS.
Multi-slide order	An order including more than one slide from one sample.
Operator	The person who works with the system.
Order	A set of data belonging to analyses ordered at the same time for one blood sample.
Order ID	Order identifier. There can be several slides with the same Order ID but different slide numbers.
Overview image	A large image assembled from several smaller images, where it is possible to characterize the red blood cell morphology or to estimate PLT concentration.
PLT estimate	Estimation of the PLT concentration in a blood sample.
PLT estimate factor	A predetermined factor to calculate the PLT estimate.
Precharacterization	A grade of a red blood cell morphology characteristic suggested by the system.
Preclassification	Classification of white blood cells suggested by the system.
Processing slides	The sequence of events from when the magazines are put on the conveyer to when they are ejected to the output drawer.
Reclassification	The operator changes the suggested classification.
Signing	The operator presses the sign button to end the verification procedure. He/she enters username and password.
Slide	A rectangular piece of glass for blood smears to be examined in a microscope.

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Verification	The operator's review of WBC, RBC and PLT, e.g. reclassification and confirmation of WBCs.
Quick scans	Quickly scanned slides for cell counter verification. The results are not sent to the LIS.

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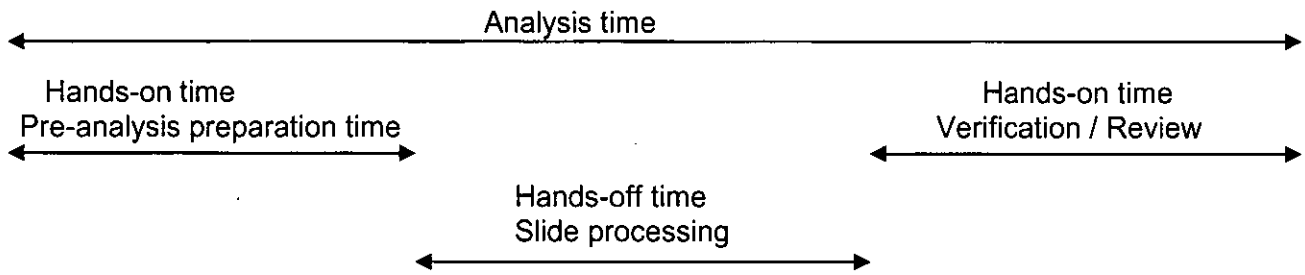
4.4 Time definitions



Analysis time	The effective time for the procedure that starts when the operator loads the slides and ends when the operator signs the analysis.
Hands off time	Walk-away time, when the system processes the slides without the need of the operator.
Hands on time	The time it takes for the operator to load the slides, start the slide processing, and to verify and sign the report.
Pre-analysis preparation time	The time it takes to load the slides holder, enter the patient data and apply the oil.
Verification / Review time	The time it takes for the operator to review the pre-classification, reclassify, verify and sign the report.
Throughput	The number of slides processed during a specified period of time.

4.5 Clinical evaluations

Abnormality	The definition differs depending on the situation. Samples can be classified as abnormal if the normal cell classes are present in levels outside the reference intervals or immature or abnormal cells exceeds established reference levels. Abnormal samples can also be defined as samples which are abnormal regarding distribution and flags in the cell counter analysis.
Accuracy	How obtained test values agree with an accepted reference measurement or "target value".
Clinical sensitivity	A test method's ability to obtain positive results in concordance with positive results obtained by the reference method.
Clinical specificity	A test method's ability to obtain negative results in concordance with negative results obtained by the reference method.
Precision	The closeness of reproducibility in replicate observations or tests.

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4.6 General lab terminology

Lab cell	A work station in a clinical lab where several instrument are connected to each other
Lines	A transfer system between several instruments on a clinical lab
Work cell	A workstation in a clinical lab where several instrument are connected to each other.

4.7 Specific Definitions for DiffMaster Octavia

Batch	The slides in one slide holder (up to 8).
Batch ID	The identification name or label of the batch.
Black box	BB; embedded computer controlling the system.
Computer system	PC + Cytologica
Cytologica	The software components handling GUI, hardware and image processing inside the PC in DiffMaster Octavia.
Order ID	The identification name or label for one order.
Review Station	A computer running Cytologica Review software.
Slide holder	A holder for up to 8 slides. The slides in one holder represents one batch.
Slide number	The identification number of a slide to uniquely identify slides within the same order.
System	DiffMaster Octavia

5 Specific Definitions for CellaVision DM96

Automatic Magazine Transfer	AMT; A hardware unit which transports a magazine from the conveyer to the AST.
Automatic Slide Transfer	AST; A hardware unit which transports a slide from a magazine onto the stage and back.
Batch	The slides in one magazine.
Batch ID	The barcode on the magazine = magazine ID.
Black box	BB; = CCU; embedded computer controlling the SSU.
CellaVision DM software	The software components handling GUI, hardware and image processing inside the PC in CellaVision DM96.
CellaVision Control Unit	CCU; Black Box; embedded computer controlling the SSU.
CellaVision DM96	DM96; SSU + computer system
CellaVision Remote Review software	The version of CellaVision Blood Differential software that cannot control the SSU but provides remote reviewing functionality by being able to connect to the DM96 database from another computer.
Computer system	PC + CellaVision Blood Differential software
Conveyor	Where the operator puts magazines to be processed.

Drawer Pushing Unit	DPU; pushes the magazine from AST into the output drawer.
Finger Pushing Unit	FPU; pushes and pulls slides in and out of magazines.
Grid square	Sub-images of a PLT overview.
Immersion Oil System.	The system that automatically applies immersion oil on the slides.
Lift	Transports magazines up to where slides can be pushed onto the stage or down to where magazines are kept after all slides have been analyzed.
Magazine	A container for up to 12 slides.
Magazine ID	The barcode on the magazine label for magazine identification = Batch ID.
Multi-slide order	An order including more than one slide from one sample.
Output drawer	Where magazines are kept after all slides have been processed.
Patient ID	Unique number identifying the patient.
Positive Identification	PID; barcode on the slide/magazine.
Review Station	A computer running CellaVision Remote Review software.
Slide ID	The barcode number on the slide (PID).
Slide number	A number that uniquely identifies slides within the same order.
Slide position	The position of a slide in the magazine.
System	CellaVision DM96
Slide Scanning Unit	SSU; the part of the system that processes magazines with slides. SSU consists of microscope, camera, IOS, slide feeder, magazine feeder unit, CCU and casing.
Stage	Where the slide is positioned while being processed.
Quer Shiebe	QS; the arm that pushes/pulls slides out and into a magazine. It also pushes/pulls magazines onto and off the lift.

6 Revision History

Rev	*CRN*	*Description of revision*	*Date of printout*
00	N/A	Document created	N/A
01	10298	Added DM96 terminology.	2003-12-04
02		Removed SEL-002 and replaced it with QCV-017. Added definition for CSF and transferred general lab terminology to QCV-017.	

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7 Distributionslista

Avdelning	Kopior	Datum/sign (år-mån-dag)	Retur/sign (år-mån-dag)
QA	1		
Marknad	1		
Utveckling	1		
Produktion	1		
Administration	1		

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Cirkulationslista

Jag har läst denna SOP och gjort mina kommentarer:

Namn	Datum (år-mån-dag)	Eventuella kommentarer inför nästa revision

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Appendix D - Risk Management

Following documents are attached under this section:

SEL-003 SRA
SEL-003-Appendix A – FMEcA
SEL-003-Appendix B – Function Blocks
SEL-003-Appendix C – Risk Chart

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(b)(4) Trade Secret Process - Risk Anaylsis

(b)(4) Trade Secret Process - Risk Anaylsis

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Appendix E - Test and validation studies

(b)(4) Trade Secret Process - Testing & Validation

[redacted]

(b)(4) Trade Secret Process - Testing & Validation

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Appendix F - Clinical Performance studies

Following documents are attached under this section:

(b)(4) Trade Secret Process - Performance Testing

[redacted]

(b)(4) Trade Secret Process - Performance Testing

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(b)(4) Trade Secret Process - Performance Testing

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name PAULA STEWART

Subject: 510(k) Number K080595/S2

To: The Record

Please list CTS decision code CS

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		X	
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	Class*	Product Code
21 CFR 864.5260		
21 CFR 864.5220	CLASS II	JOY,

(*If unclassified, see 510(k) Staff)

Additional Product Codes: GKZ

Review: [signature] (Branch Chief) [signature] (Branch Code) DHHD (Date) 12/2/08

Final Review: Maria M Chan (acting) (Division Director) 12/4/08 (Date)

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K080595

B. Purpose for Submission:

Expanded intended use

C. Manufacturer and Instrument Name:

CellaVision AB, CellaVision DM 96 with the body fluid application

D. Type of Test or Tests Performed:

White Blood Cells (differential), RBC characterization and Platelet estimation

E. System Descriptions:

1. Device Description:

CellaVision DM96 consist as of a slide feeder unit, an optical unit consisting of a microscope and camera (referred to as a slide scanning unit), a computer system contains the acquisition and classification software CellaVision DM software.

CellaVision DM96 with the body fluid application is substantially equivalent to the DM96 for peripheral blood regarding technology and functionality. The intended use of the body fluid application is substantially equivalent to the Romanowsky stain manual light microscopic method of cell classification.

The body fluid application functionality:

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

2. Principles of Operation:

Twelve slides can be loaded into each magazine. The magazine used for the body fluid application is identified through the color and the barcode on it.

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The magazines are put onto a conveyer belt and are automatically transported to the slide scanning unit. The analysis process consists of an overview image processing and a cell-location step. The body fluid overview image displays the entire sample area. 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. The cell-location step uses the optical unit and a camera taking images of the identified images and stores the images of the located cells and the results in a database, and displays the images in an organized manner.

3. Modes of Operation:

   The DM96 is an automated cell-locating device. The system also has Remote Review Station capability with network access to the main DM96 device.

4. Specimen Identification:

   Glass microscope slides are labeled with barcodes. Twelve slides fit into a barcoded labeled magazine.

5. Specimen Sampling and Handling:

   Body fluid is cytocentrifuged and stained outside the device on standard rectangular glass slides by standardized stained with Romanowsky stain.

6. Calibration:

   Not applicable.

7. Quality Control:

   The system performs self-tests during startup of the software, and at certain points during the operation of the system. Both hardware and software components are tested. The Cell location test is used to verify the slide preparation process and the system hardware. Running the test once or twice a day is a recommended interval at the high-load laboratory.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes __X____ or No_____

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F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5260, 21 CFR 864.5220

2. Classification:

   Class II

3 Product code:

   JOY, GKZ

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   DM96 is an automated cell-locating device.

   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.

   DM96 is intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells.

2. Special Conditions for Use Statement(s):

   Not applicable.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   CellaVision DM96, K033840
   Manual Light Microscope (Romanowsky stain process), Class I

2. Comparison with Predicate Device:

Similarities			
Item	DM96 with Body Fluid Application	Manual light microscope process	DM96
Intended Use	Automated cell-locating device for identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Manual method for cell-location and identification of blood smears and cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.	Automated cell-locating device for identification of cytocentrifuged body fluids, for in-vitro diagnostic use. Verification of results by skilled human operator.
Specimen type	Body fluids such as cerebrospinal and, serous fluid. Peripheral blood	Peripheral blood and body fluids.	Peripheral blood
Sample preparation	Body fluid samples are prepared by using a cytocentrifuged and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood. Body fluid samples are prepared using a cytocentrifuged and stained with Romanowsky stain.	Romanowsky stained blood film on glass slides of peripheral blood.
Analysis technique	White blood cells: Cells are located/counted by moving according to the battlement track pattern. Cells images are analyzed using standard mathematical methods. The cell images are pre-classified and the operator verifies the classification.	White blood cells: The examiners usually located/counted by moving according to the battlement track pattern on the smear and distinguish between classes of white blood cells.	White blood cells: Cells are located/counted by moving according to the battlement track pattern. Cells images are analyzed using standard mathematical methods. The cell images are pre-classified and the operator verifies the classification.
Overview image	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.	The operator scans the slide to get an overview on parts of or the whole slide in different magnifications.	The device presents an overview image. The image gives the operator possibilities to get an overview on parts of or the whole slide in different magnifications.

I. Special Control/Guidance Document Referenced (if applicable):

EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples*, Approved Standard-Second Edition, NCCLS
EP5A *Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline*, NCCLS
H20-A *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrument Methods, Approved Standard*, NCCLS
H56-A *Body Fluid Analysis for cellular composition; Approved guideline, CLSI*

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

A mixture of 156 samples (87 CSF and 69 BF) was identified according to EP9A-2 from two sites. All samples were initially analyzed on a cell counter or counted in a hemocytometer to get the leukocyte concentration. From each sample two cytocentrifuged smears were prepared. 200-cell differential counts were performed (400 cells/sample) with both methods and analyzed. The same examiners analyzed the same slides. The accuracy was tested through scatter-plots for each cell class.

Samples included in the study.

Defined as in study	Type	number
CSF	CSF	89
Serous	Peritoneal fluid	24
Serous	Pleural fluid	46

Results for all samples included are as follows:

Cell Class	Accuracy	95% CI Slope	n
Neutrophils	y= 1.0166x - 0.0030 r^2= 0.9903	1.0006 - 1.0326	156
Lymphocytes	y= 1.9840x - 0.0011 r^2= 0.9788	0.9609 - 1.0070	156
Macrophages	y= 0.9554x - 0.0113 r^2= 0.9648	0.9264 - 0.9845	156
Eosinophils	y= 1.1352x - 0.0018 r^2= 0.9737	1.1055 - 1.1649	156
Other cells	y= 1.0808x - 0.0019 r^2= 0.9566	1.0442 - 1.1174	156

Cells pre-classified as Basophils, Lymphoma cells, Atypical lymphocytes, Blasts and Tumor cells are automatically are forwarded to the cell class *Other.*

b. *Precision/Reproducibility*:

Short-term imprecision is equivalent for the test and reference method.

Short term imprecision results found on clinical evaluation on 156 samples

Cell Class	Test Method	Reference Method
	SD%	SD%
Neutrophils	3.4	3.6
Lymphocytes	0.8	1.0
Macrophages	6.0	6.1
Eosinophils	6.3	6.1
Other cells	2.2	1.6

c. *Linearity*:

Not applicable.

d. *Carryover*:

Not applicable

e. *Interfering Substances*:

Not applicable.

2. Other Supportive Instrument Performance Data Not Covered Above:

Not applicable.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

M. Other Supportive Device and Instrument Information:

Not applicable.

N. Administrative Information:

1. Applicant Contact Information:

   a. *Name of applicant:*

   CellaVision AB

   b. *Mailing address:*

   Ideon Science Park
   SE-223 70 Lund, Sweden

   c. *Phone #:*

   763-574-1976

   d. *Fax #:*

   763-571-2437

   e. *E-mail address (optional)*:

   cgbundy@attglobal.net

   f. *Contact:*

   Constance G. Bundy

2. Review Documentation:
   03/03/08 – Date received by DMC
   03/03/08 – Date received in DIHD
   03/03/08 – Date assigned
   03/05/08 – Date received by reviewer
   04/09/08 – Requested stats consult
   04/22/08 – Received stats consult
   04/23/08 – Placed on hold for requested additional information (included performance studies)
   05/02/08 – Requested additional information (software)
   07/25/08 – Requested additional information
   11/06/08 – Placed on hold for additional information request

11/24/08 – Received additional information
12/02/08 – SE decision

3. Substantial Equivalence Discussion:

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

a. *Explain how the new indication differs from the predicate device's indication:*

Not applicable.

b. *Explain why there is or is not a new effect or safety or effectiveness issue:*

Not applicable.

c. *Describe the new technological characteristics:*

Not applicable.

d. *Explain how new characteristics could or could not affect safety or effectiveness:*

Not applicable.

e. *Explain how descriptive characteristics are not precise enough:*

Not applicable.

f. *Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:*

Not applicable.

g. *Explain why existing scientific methods can not be used:*

Not applicable.

h. *Explain what performance data is needed:*

Performance data such as accuracy and precision are necessary to determine equivalence.

i. *Explain how the performance data demonstrates that the device is or is not substantially equivalent:*

The performance data and software documentation demonstrate equivalence.

O. Reviewer Name and Signature:

Paula M. Stewart
CDRH/OIVD/DIHD

Stewart, Paula M

From: C. G. Bundy [cgbundy@attglobal.net]
Sent: Monday, November 17, 2008 10:08 AM
To: Stewart, Paula M
Cc: Hans-Inge Bengtsson
Subject: K080595
Attachments: (b)(4) Trade Secret Process - Product Specs [redacted] c

Paula, (b)(4) Trade Secret Process - Product Specs [redacted]
Connie

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Stewart, Paula M

From: Dawson, John M*
Sent: Monday, November 17, 2008 11:42 AM
To: Stewart, Paula M
Cc: Russek-Cohen, Estelle
Subject: RE: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted]

John

From: Stewart, Paula M
Sent: Monday, November 17, 2008 11:02 AM
To: Dawson, John M*
Subject: FW: K080595

Hi John,
(b)(4) Trade Secret Process - Product Specs [redacted].

Thanks,
Paula

From: C. G. Bundy [mailto:cgbundy@attglobal.net]
Sent: Monday, November 17, 2008 10:08 AM
To: Stewart, Paula M
Cc: Hans-Inge Bengtsson
Subject: K080595

Paula (b)(4) Trade Secret Process - Product Specs [redacted]
Connie

16

Stewart, Paula M

From: C. G. Bundy [cgbundy@attglobal.net]
Sent: Monday, November 10, 2008 8:48 AM
To: Stewart, Paula M
Subject: Re: K080595/S001 CellaVision DM96

Paula, (b)(4) Trade Secret Process - Product Specs [redacted].
Connie

----- Original Message -----
From: Stewart, Paula M
To: cgbundy@attglobal.net
Sent: Thursday, November 06, 2008 9:18 PM
Subject: K080595/S001 CellaVision DM96

Dear Connie,

(b)(4) Trade Secret Process - Product Specs [redacted]

Best Regards,

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety
Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

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Stewart, Paula M

From: Dawson, John M*
Sent: Sunday, October 26, 2008 1:39 PM
To: Stewart, Paula M
Cc: Russek-Cohen, Estelle
Subject: K080595 CellaVision DM96
Attachments: (b)(4) Trade Secret Process - Product Specs [redacted]

Paula [redacted] (b)(4) Trade Secret Process - Product Specs [redacted]"?

From: Stewart, Paula M
Sent: Thursday, October 23, 2008 2:21 PM
To: Dawson, John M*
Subject: FW: K080595 CellaVision DM96

Hi John,
(b)(4) Trade Secret Process - Product Specs [redacted]

Thanks,
Paula.

From: C. G. Bundy [mailto:cgbundy@attglobal.net]
Sent: Tuesday, October 07, 2008 9:19 AM
To: Stewart, Paula M
Subject: Re: K080595 CellaVision DM96

Dear Paula, (b)(4) Trade Secret Process - Product Specs [redacted] (k)!
Regards, Connie Bundy

> ----- Original Message -----
> **From:** Stewart, Paula M
> **To:** cgbundy@attglobal.net
> **Cc:** Bautista, Josephine

18

Sent: Friday, September 26, 2008 10:52 AM
Subject: K080595 CellaVision DM96

Dear Ms. Bundy,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety
Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

Stewart, Paula M

From: C. G. Bundy [cgbundy@attglobal.net]
Sent: Tuesday, October 07, 2008 9:19 AM
To: Stewart, Paula M
Subject: Re: K080595 CellaVision DM96
Attachments: (b)(4) Trade Secret Process - Product Specs [redacted]

Dear Paula, (b)(4) Trade Secret Process - Product Specs [redacted] (k)!
Regards, Connie Bundy

----- Original Message -----
From: Stewart, Paula M
To: cgbundy@attglobal.net
Cc: Bautista, Josephine
Sent: Friday, September 26, 2008 10:52 AM
Subject: K080595 CellaVision DM96

Dear Ms. Bundy,
(b)(4) Trade Secret Process - Product Specs [redacted]

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety

20

Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

Memorandum

Center for Devices and Radiological Health
Public Health Service
Food and Drug Administration

Date: September 25, 2008

To the file: K080595/S1

Subject: DM96 with body fluid application

From: Paula M. Stewart

Participant: Constance Bundy, Regulatory Consultant

Company: CellaVision AB, Lund Sweden

(b)(4) Trade Secret Process - Product Specs

[redacted]

Stewart, Paula M

To: cgbundy@attglobal.net
Cc: Bautista, Josephine
Subject: K080595 CellaVision DM96

Dear Ms. Bundy,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety
Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

Stewart, Paula M

From: Stewart, Paula M
Sent: Friday, September 19, 2008 9:55 AM
To: 'C. G. Bundy'
Subject: RE: K080595

Hi Connie,

(b)(4) Trade Secret Process - Product Specs [redacted]

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety
Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

From: C. G. Bundy [mailto:cgbundy@attglobal.net]
Sent: Thursday, September 11, 2008 6:48 AM
To: Stewart, Paula M
Cc: Hans-Inge Bengtsson
Subject: Fw: K080595

(b)(4) Trade Secret Process - [redacted]
Connie
----- Original Message -----
From: C. G. Bundy
To: Paula Stewart
Sent: Tuesday, September 02, 2008 7:35 AM
Subject: Fw: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted] e, Connie Bundy
----- Original Message -----
From: C. G. Bundy
To: Paula Stewart
Cc: Hans-Inge Bengtsson
Sent: Wednesday, August 13, 2008 7:23 AM
Subject: K080595

Paula([redacted]
b
)
(
Thank you, Connie Bundy

24

Stewart, Paula M

From: C. G. Bundy [cgbundy@attglobal.net]
Sent: Thursday, September 11, 2008 6:48 AM
To: Stewart, Paula M
Cc: Hans-Inge Bengtsson
Subject: Fw: K080595
Attachments: (b)(4) Trade Secret Process - Product S

(b)(4) Trade Secret Process - Product S
Connie
----- Original Message -----
From: C. G. Bundy
To: Paula Stewart
Sent: Tuesday, September 02, 2008 7:35 AM
Subject: Fw: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted], Connie Bundy
----- Original Message -----
From: C. G. Bundy
To: Paula Stewart
Cc: Hans-Inge Bengtsson
Sent: Wednesday, August 13, 2008 7:23 AM
Subject: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted].
Thank you, Connie Bundy

25

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Stewart, Paula M

From: Stewart, Paula M
Sent: Tuesday, September 02, 2008 10:03 AM
To: 'C. G. Bundy'
Subject: RE: K080595

Hi Connie,

(b)(4) Trade Secret Process - Product Specs [redacted]

Regards,
Paula

From: C. G. Bundy [mailto:cgbundy@attglobal.net]
Sent: Tuesday, September 02, 2008 8:36 AM
To: Stewart, Paula M
Subject: Fw: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted] Connie Bundy
----- Original Message -----
From: C. G. Bundy
To: Paula Stewart
Cc: Hans-Inge Bengtsson
Sent: Wednesday, August 13, 2008 7:23 AM
Subject: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted]
Thank you, Connie Bundy

28

Stewart, Paula M

From: Stewart, Paula M
Sent: Friday, July 25, 2008 4:43 PM
To: 'cgbundy@attglobal.net'
Subject: K080595/S001, DM96 with body fluid application

Attachments: (b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

29

MEMORANDUM FOR PAULA STEWART, SCIENTIFIC REVIEWER, OIVD/DIHD

THROUGH, ESTELLE RUSSEK-COHEN, Ph.D.,
TEAM LEADER, DIAGNOSTIC DEVICES BRANCH

July 23, 2008

FROM: John M. Dawson, Contract Mathematical Statistician

SUBJECT: DM96 Automated Analyzer by CellaVisionAB (K080595), February 15, 2008

(b)(4) Trade Secret [redacted] w.

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Stewart, Paula M

From: Dawson, John M*
Sent: Friday, May 23, 2008 1:35 PM
To: Stewart, Paula M
Cc: Russek-Cohen, Estelle
Subject: RE: K080595 - CellaVision

(b)(4) Trade Secret Process - Product Specs

[redacted]

From: Stewart, Paula M
Sent: Friday, May 23, 2008 11:46 AM
To: Dawson, John M*
Subject: K080595 - CellaVision

Hi John,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thanks,

Paula

36

Stewart, Paula M

From: Brindza, Larry J.
Sent: Friday, May 23, 2008 3:14 PM
To: Stewart, Paula M
Subject: RE: K080595- Cella Vision

Hi Paula,

(b)(4) Trade Secret Process - Product Specs

Larry

From: Stewart, Paula M
Sent: Friday, May 23, 2008 12:06 PM
To: Brindza, Larry J.
Subject: K080595- Cella Vision

Hi Larry,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thanks,

37

Stewart, Paula M

From: C. G. Bundy [cgbundy@attglobal.net]
Sent: Thursday, May 15, 2008 1:10 PM
To: Stewart, Paula M
Subject: K080595

Paula, (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

Connie Bundy

38

Stewart, Paula M

From: Bautista, Josephine
Sent: Wednesday, April 16, 2008 10:25 PM
To: Dawson, John M*; Russek-Cohen, Estelle; Stewart, Paula M
Subject: Re: review of cellavision AB

(b)(4) Trade Secret Process - Product Specs [redacted]

----- Original Message -----
From: Dawson, John M*
To: Bautista, Josephine; Russek-Cohen, Estelle; Stewart, Paula M
Sent: Wed Apr 16 21:10:57 2008
Subject: RE: review of cellavision AB

(b)(4) Trade Secret Process - Product Specs [redacted]

From: Bautista, Josephine
Sent: Wednesday, April 16, 2008 6:34 PM
To: Russek-Cohen, Estelle; Stewart, Paula M
Cc: Dawson, John M*
Subject: RE: review of cellavision AB

(b)(4) Trade Secret Process - Product Specs [redacted]

Thanks,
Josie

From: Russek-Cohen, Estelle
Sent: Wednesday, April 16, 2008 12:01 PM
To: Stewart, Paula M
Cc: Dawson, John M*; Bautista, Josephine
Subject: review of cellavision AB

(b)(4) Trade Secret Process - Product Specs [redacted]

Estelle Russek-Cohen, Ph.D.
Team Leader and Mathematical Statistician
Diagnostics Branch (DXDB)
Division of Biostatistics HFZ-550
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville MD 20850

Estelle.Russek-Cohen@fda.hhs.gov
Phone 240-276-3043
Fax 240-276-3131
Division phone number 240-276-3133

Stewart, Paula M

From: Dawson, John M*
Sent: Tuesday, April 15, 2008 9:24 AM
To: Bautista, Josephine; Russek-Cohen, Estelle; Stewart, Paula M
Subject: RE: cellavision AB

(b)(4) Trade Secret Process - Product Specs [redacted]

From: Bautista, Josephine
Sent: Monday, April 14, 2008 8:02 PM
To: Russek-Cohen, Estelle; Stewart, Paula M
Cc: Dawson, John M*
Subject: RE: cellavision AB

Hi Estelle,

(b)(4) Trade Secret Process - Product Specs [redacted]

Thanks,
Josie

From: Russek-Cohen, Estelle
Sent: Monday, April 14, 2008 2:50 PM
To: Stewart, Paula M; Bautista, Josephine
Cc: Dawson, John M*
Subject: cellavision AB

HI Paula and Josie:

(b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade
S t

Estelle Russek-Cohen, Ph.D.
Team Leader and Mathematical Statistician
Diagnostics Branch (DXDB)
Division of Biostatistics HFZ-550
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville MD 20850

Estelle.Russek-Cohen@fda.hhs.gov
Phone 240-276-3043
Fax 240-276-3131
Division phone number 240-276-3133

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name PAULA STEWART

Subject: 510(k) Number K080595/S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Stewart, Paula M

From: Stewart, Paula M
Sent: Thursday, November 06, 2008 3:19 PM
To: 'cgbundy@attglobal.net'
Subject: K080595/S001 CellaVision DM96

Attachments: (b)(4) Trade Secret Process - Product Specs

Dear Connie,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Best Regards,

Paula M. Stewart
Office of In Vitro Diagnostic Device Evaluation and Safety
Division of Hematology and Immunology Devices
paula.stewart@fda.hhs.gov
Office (240) 276-1317
Fax (240) 276-0663

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Paula Stewart

Subject: 510(k) Number K080595

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

Rev. 5/30/07

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			
3. Does this device type require a PMA by regulation? (Please see management.)			
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			
5. a. Did the firm request expedited review? (See management.)			
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			

TRANSMISSION VERIFICATION REPORT

TIME : 03/06/2008 11:39
NAME : 3A
FAX : 2402760663
TEL : 2402760493
SER.# : BROM5J392370

DATE,TIME	03/06 11:37
FAX NO./NAME	917635712437
DURATION	00:02:15
PAGE(S)	05
RESULT	OK
MODE	STANDARD ECM

763-571-243

K080595

FDA

Center for Devices and Radiological Health
CDRH

Office of In Vitro Diagnostic Device Evaluation & Safety
Center for Devices and Radiological Health
Food & Drug Administration
2098 Gaither Road, HFZ-440
Rockville, Maryland 20850

Office Director's # 240-276-0484 *Chemistry & Toxicology Division # 240-276-0443*
Microbiology Division # 240-276-0496 *Immunology & Hematology Division # 240-276-0493*

FAX # 240-276-0652 or 240-276-0663

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763-571-2439

K080595

FDA

Office of In Vitro Diagnostic Device Evaluation & Safety
Center for Devices and Radiological Health
Food & Drug Administration
2098 Gaither Road, HFZ-440
Rockville, Maryland 20850

Office Director's # 240-276-0484 *Chemistry & Toxicology Division # 240-276-0443*
Microbiology Division # 240-276-0496 *Immunology & Hematology Division # 240-276-0493*

FAX # 240-276-0652 or 240-276-0663

"THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you."

To: Constance Bundy
c/o CellaVision AB

From: JOAN McCLAIN-BENNETT

Total Pages: 4/+ COVER

Comments: K080595 - Automated Cell-locating Device

Additional required form.

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Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the Public Health Service Act (PHS Act) by adding section 402(j) (42 U.S.C. 282(j)). The new provisions require additional information to be submitted to the clinical trials data bank (ClinicalTrials.gov), including expanded information on clinical trials and information on the results of clinical trials.

One new FDAAA provision, 42 U.S.C. 282(j)(5)(B), requires that a certification (see form below) accompany human drug, biological, and device product submissions made to FDA. At the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (21 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. For the Center of Devices and Radiological Health, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, and premarket notifications (510(k)) require certification. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

FDAAA requires that the certifications be submitted to FDA beginning no later than **December 26, 2007.**

Links

The following links may be helpful:

- Link to the published Federal Register Notice:

http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm (txt)

http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.pdf (pdf)

- Link to the certification form:

http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf

- Link to FDAAA, Public Law 110-85:

http://www.fda.gov/oc/initiatives/HR3580.pdf

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank

(42 U.S.C. § 282(j))

(For submission with any application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

Form Approved:
Expiration Date:
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

3. ADDRESS (*Number, Street, State, and Zip Code*)

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)
(T)
(F)

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(*Attach extra pages as necessary*)

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ BLA ☐ PMA ☐ HDE ☐ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*If number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. AS APPLICABLE, CHECK ONLY ONE OF THE FOLLOWING BOXES AND PROVIDE ANY REQUIRED INFORMATION
(*See instructions for additional information and explanation*)

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, are not applicable because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, are not applicable to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, are applicable to any or all of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) APPLICABLE TO THE CLINICAL TRIAL(S) REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES IS(ARE) AS FOLLOWS
(*Include all NCT numbers - attach extra pages as necessary*)

NCT Number(s)

The undersigned declares that this is an accurate and complete submission of information. I verify under penalty of perjury that the foregoing is true and correct. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11
13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)*	14. TELEPHONE AND FAX NUMBER (*Include Area Code*) (T) (F)
15. DATE OF CERTIFICATION	

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Instructions for Completion of Form Number 3674

Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany any application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520 (m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

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1. Name of Sponsor/Applicant/Submitter - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date - This is the date of the application/submission which the certification accompanies.

3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. For Drugs/Biologics - Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. Type of Application/Submission - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. IND/NDA/BLA/PMA/HDE/510(k)/PDP/Other Number - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. Certification - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. The National Clinical Trial (NCT) numbers obtained from www.ClinicalTrials.gov for each clinical trial included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies also must be provided if Box C in 9 (Certification) is checked. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of clinical trials included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative - The person signing the certification must sign in this field.

12. - Name and Title of Person Who Signed in #11. - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. & 14. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

MEMORANDUM - electronic (email correspondence)

Date: April 23, 2008

From: Paula M. Stewart, Scientific Reviewer, OIVD, DIHB
Tel. No. 240-276-1317
E-mail: paula.stewart@fda.hhs.gov
Fax: 240-276-0663

Subject: K080595, DM96 with body fluid application
Request for Additional Information

To: CellaVision AB
C/o Constance G. Bundy
E-mail: cgbundy@attglobal.net
Tel: (763) 574-1976
Fax: (763) 571-2437

(b)(4) Trade Secret Process - Product Specs

[redacted]

A. **Performance Studies**

(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Paula Stewart

MEMORANDUM FOR PAULA STEWART, SCIENTIFIC REVIEWER, OIVD/DIHD

THROUGH, ESTELLE RUSSEK-COHEN, Ph.D.,
TEAM LEADER, DIAGNOSTIC DEVICES BRANCH

April 16, 2008

FROM: John M. Dawson, Contract Mathematical Statistician

SUBJECT: DM96 Automated Analyzer by CellaVisionAB (K080595), February 15, 2008

(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

October 09, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

510k Number: K080595

Product: CELLAVISION DM96 WITH THE BODY

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

CellaVision AB
Lund, Sweden

K080595/S1

October 6, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) K080595, DM96 – Response to Deficiencies

CellaVision AB is responding to deficiencies received by email July 25, 2008.

Should there be any questions regarding the responses, please contact Constance Bundy, Regulatory Consultant to CellaVision AB.

Please note new address for contact.

FDA CDRH DMC

OCT - 9 2008

Received

Sincerely,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432
763-574-1976
Fax: 763-571-2437
cgbundy@attglobal.net

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A. **Performance Studies**

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(b)(4) Trade Secret Process - Product Specs

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ATTACHMENT A

1.3.2 Body Fluid Application

General Functionality

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

Preclassification for Body Fluid

The system preclassifies the following WBC classes: *Neutrophils, Eosinophils, Lymphocytes, Macrophages (including Monocytes)* and *Other.* Cells pre-classified 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 pre-classified 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 WBC.

WBC Reclassification for Body Fluid

Besides the cell classes mentioned above, the operator can reclassify cells into the following cell classes: *Not classed* and 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 G — Slide Preparation Guidelines for recommended staining recipes).

Limitations

A significant number of samples have not been evaluated for the following fluid types: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage. Therefore, they are not included in the statistical analysis.

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(Cont'd)

Performance Specification Peripheral blood

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2 %.
Throughput: Approximately 30 slides/h for complete orders containing RBC, PLT and 100-cell WBC.

Results of short-term imprecision found in a clinical evaluation on 219 patient samples, based on NCCLS standard H-20A:

Cell class	SD (%)	Cell class	SD (%)
Segmented neutrophils	4.7	Basophils	0.7
Band neutrophils	3.0	Lymphocytes	5.0
Eosinophils	1.2	Monocytes	2.0

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

Performance Specification Body Fluid

Average WBC cell-location and display of at least 97 % with a standard deviation less than 2%.
Throughput: Approximately 20 slides/h for orders containing only 10x overview images (6 mm analysis area). Approximately 6 slides/h for orders containing both 10x and 50 overview images (6 mm analysis area).

Results of short-term imprecision found in a clinical evaluation on 156 samples, based on NCCLS standard H-20A*:

Cell class	SD (%)	Cell class	SD (%)
Neutrophils	3.4	Macrophages	6.3
Eosinophils	0.8	Other	2.2
Lymphocytes	6.0		

* The following fluid types were not included in the evaluation: pericardial, abdominal, drain, CAPD and bronchoalveolar lavage.

ATTACHMENT B

(b)(4) Trade Secret Process - Clinical Testing

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 21, 2008

CELLAVISION AB
C/O C.G. BUNDY ASSOCIATES, INC.
6740 RIVERVIEW TERRACE
MINNEAPOLIS, MINNESOTA 55432
UNITED STATES
ATTN: CONSTANCE G. BUNDY

510k Number: K080595

Product: CELLAVISION DM96 WITH THE BODY

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K080595/S2

CellaVision AB
Lund, Sweden

FDA CDRH DMC
NOV 21 2008
Received

November 17, 2008

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) K080595, DM96 – [redacted]

CellaVision AB is responding to deficiencies received by email November 6, 2008. The response is being submitted in duplicate as required.

Should there be any questions regarding the responses, please contact Constance Bundy, Regulatory Consultant to CellaVision AB.

Please note new address for contact.

Sincerely,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432
763-574-1976
Fax: 763-571-2437
cgbundy@attglobal.net

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