NucleoCounter® NC-200™

Instrument User's Guide

P/N 991-0203

Revision 1.3
Caution!
This equipment must be operated as described in this User’s Guide and documents referred to herein. Please read the entire guide and referred documents before attempting to use this unit. Please pay attention to that gloves or protective clothing are not worn on the illustrations/pictures shown in this User’s Guide. However, ChemoMetec A/S does recommend that the user wear suitable protective clothing etc.

Contacting support
Technical information including product literature, answers to questions regarding the operation of the NucleoCounter® NC-200™ not covered in this document and referred documents is available through the following:

- For e-mail support, send questions to NucleoCounter® NC-200™ Technical Support on the address Support@chemometec.com
- Check out the FAQ section under support at www.chemometec.com
- To speak with a Technical Support Specialist, call (+45) 48 13 10 20.

Please note the NucleoCounter® NC-200™ serial number and have it available when contacting ChemoMetec A/S for support. The NucleoCounter® NC-200™ serial number is found on the label affixed to the bottom of the instrument. The version number of the NucleoView NC-200™ software shall also be noted, this can be found on the Help – About menu item in the NucleoView NC-200™ software.

Sales and ordering information
For sales assistance with NucleoCounter® NC-200™ or the NucleoView NC-200™ software, to place an order for a NucleoCounter® NC-200™ or consumables, call (+45) 48 13 10 20, fax (+45) 48 13 10 21, or send e-mail to Sales@chemometec.com

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ChemoMetec A/S reserves the right to make changes in the product design without reservation and without notification to its users.

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Declaration of Conformity

Name of product: NucleoCounter® NC-200™
Type: Flexible Cell Counter
Other identifying data: Part no. 900-0201

We declare under our sole responsibility that the products, to which this declaration relates, are in conformity with the Council Directives on the approximation of the laws of the EEC Member States relating to the following:

Directives
- Low Voltage Directive (2006/95/EC) LVD
- Machinery Directive (2006/42/EC) MD

Standards
- EN 61326-1:2006 Electrical equipment for laboratory use
- EN 61000-3-2: 2006 Limits for harmonic current emissions
- EN 61000-3-3: 1995 +A1 +A2: 2005 Limitation of voltage changes, voltage fluctuations and flicker

Standards
- EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use

Standards
- EN 12100-1: 2003 Safety of machinery; Basic concepts, general principles for design — Part 1
- EN 12100-2: 2003 Safety of machinery; Basic concepts, general principles for design — Part 2:
- EN ISO 14121-1:2007 Safety of machinery; risk assessment

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Date: 2011-July-1st

Signed: [Signature]

Name: Sarah R. Rasmussen
Position: QA/QC Manager

Name and address of manufacturer:

ChemoMetec A/S
Gydevang 43
DK-3450 Allerod
DENMARK
www.chemometec.com
Correct Disposal of This Product
(Waste Electrical & Electronic Equipment) - Europe only

This marking shown on the product or its literature, indicates that it should not be disposed together with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

This information is listed in “Appendix B: WEEE directive information in more EU languages”.

Introduction and intended use

The NucleoCounter® NC-200™ is a compact cell-counter intended to be used for precise cell counting within the life-science and pharmaceutical markets. The NucleoCounter® NC-200™ system is intended for research use only, not for diagnostic use. The NucleoCounter® NC-200™ uses disposable cassettes from ChemoMetec A/S.

The NucleoCounter® NC-200™ is a highly advanced cell counter based on fluorescence microscopy using CMOS camera technology with low magnification and advanced image analysis. Different properties of the individual cells can be analyzed with the 3 integrated light sources (365nm, 500nm and dark field) and with 2 emission bands. Spatial position is maintained from filter to filter enabling direct comparison of the different parameters detected or quantified on each individual cell. The low magnification (x1.3) guarantees a high analysis volume and thus ensures a high statistical performance.

Specially designed sample illumination ensures homogeneous illumination at the complete measuring area and thereby accurate quantification of fluorescence signal is achieved. Since no tubes, valves, hoses etc. are present the instrument is virtually service and maintenance free.

The NucleoCounter® NC-200™ is improved in relation to NucleoCounter® NC-100 and shares some of the strong features with the NucleoCounter® NC-3000. In normal viability analysis the sample volume is as high as 1.4 µl and the ability to detect cells in clusters is also available.

The NucleoCounter® NC-200™ part number at ChemoMetec A/S is 900-0201.
Warnings and precautions

Whenever the \(\text{⚠️}\) symbol appears on the NucleoCounter® NC-200™ instrument, it indicates that the manual must be consulted for precautions and warnings.

Power and cables

Use the shielded USB cable supplied with the NucleoCounter® NC-200™ to ensure that appropriate EMI classification is maintained for the intended environment.

⚠️ The USB interface connector of the NucleoCounter® NC-200™ must only be connected to SELV circuits. External computing devices connected to the USB interface connector of the NucleoCounter® NC-200™ have to comply with the standards, UL 1950 and IEC/EN 60950.

<table>
<thead>
<tr>
<th>Pin no.</th>
<th>Name</th>
<th>Maximum Voltage level</th>
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<tbody>
<tr>
<td>1</td>
<td>+5V</td>
<td>+5 VDC</td>
</tr>
<tr>
<td>2</td>
<td>D-</td>
<td>+3.5 VDC</td>
</tr>
<tr>
<td>3</td>
<td>D+</td>
<td>+3.5 VDC</td>
</tr>
<tr>
<td>4</td>
<td>DGND</td>
<td>0 VDC</td>
</tr>
<tr>
<td>Metal enclosure</td>
<td>Shield (connected to DGND)</td>
<td>0 VDC</td>
</tr>
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Table 1 Description of the NucleoCounter® USB interface connector

NucleoCounter® NC-200™ is powered by an external 24VDC power supply. For safe use, please follow the instructions for connecting the power supply.

⚠️ The NucleoCounter® NC-200™ shall only be used with an external power supply purchased at ChemoMetec A/S.

⚠️ The detachable DC power supply cord set and appliance inlet of the external power supply are considered as the disconnecting device.

⚠️ The mains supply cord and plug of the external power supply shall comply with any national regulations.

⚠️ The user should be made aware of that, if the NucleoCounter® NC-200™ and the external power supply are used in a manner not specified by the manufacturer, the

---

1 In normal operation mode (refers to Pin no 4)
Warnings and precautions

protection provided by the NucleoCounter® NC-200™ and the external power supply may be impaired.

Electromagnetic interference

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution! Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Cassettes, Reagents, Solutions and Dispensers

With respect to use and handling of cassettes, reagents, solutions and dispensers, please refer to appropriate package inserts for these items.

Caution! When using a bottle-top dispenser: To protect against accidental splashes, protective clothing, eye protection and gloves must be worn when using potentially hazardous liquids.

General

Any biological specimen should be handled, as if it is capable of transmitting infectious disease and disposed of with proper precautions according with federal, state and local regulations.

Avoid specimen contact with skin or mucous membranes.

Never pipette by mouth.

Avoid cross contamination of the samples when preparing the samples. This can compromise the quality of the results.
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1 Inspection, Unpacking and Installation of Equipment

Upon receiving the order from ChemoMetec A/S, the box or boxes should be carefully inspected for any damage that may have occurred during shipping. Any damage must be reported to the carrier and to ChemoMetec A/S immediately.

Unpack the order, saving the packing materials for possible later use.

Verify that the ChemoMetec packing list received refers to the correct and ordered materials, and that nothing is missing.

If any part of the order was damaged during shipping, is missing, or fails to operate, please contact ChemoMetec A/S.

The document supplied with the instrument:

- NucleoCounter_NC_200_IQ.pdf

This document describes in details how to inspect, unpack and install the NucleoCounter® NC-200™ instrument and the NucleoView NC-200™ software. This IQ will also ensure that the instruments basic functions respond correctly.

1.1 Operation of the NucleoCounter® NC-200™.

Before starting to use the NucleoCounter® NC-200™, it is important to refer to the following document:

- NucleoCounter_NC_200_IQ.pdf

This document presents a procedure which, upon successful completion, will assure that the advanced functions of the instrument are executed correctly.

Once the IQ and the OQ are finalized successfully, actual operation with the NucleoCounter® NC-200™ can begin.

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2 This document is present on the USB Flash drive in the DATA folder supplied with the instrument
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2 Cell counting with the NucleoCounter® NC-200™

The NucleoCounter® NC-200™ is a bi-color fluorescent cell-counting instrument. The NucleoCounter® has the advantage that only short training time is required before the user can run highly advanced cell counting protocols. The instrument itself is calibration free. The individual calibration parameter for a cassette will be read and used by the instrument during analysis.

The complete list of protocols is shown in the document; Protocol list for the NucleoCounter® NC-200™. This covers protocols such as:

- Count of Aggregated Cells Assay
- Viability and Cell Count – Aggregated Cells Assay
- Viability and Cell Count Assay

New protocols will be developed on an on-going basis and the updated list can be seen at the web site: www.chemometec.com

2.1 The NucleoCounter® NC-200™ instrument

The NucleoCounter® NC-200™ is shown in the figure below.
2.1.1 **Fluorescence microscope**

The NucleoCounter® NC-200™ is a fluorescent microscope with a magnification of approximately x1.3. It is equipped with 3 light sources (2 for fluorescent use and one for dark-field analysis). It has a dual-band emission filter.

At present only Via1-Cassette is used the NucleoCounter® NC-200™.

A number of different protocols can be run on the NucleoCounter® NC-200™. All of them are documented in application notes describing the procedure to be used for the protocol. The basis of all these protocols is to provide the operator with a simple set-up to perform an extremely advanced analysis in a very easy and flexible manner so that all personnel can be trained in a very short time.

The NucleoCounter® NC-200™ runs together with the NucleoView NC-200™ software, which can be installed on a PC having Windows 7 or 8 operating systems and USB 2.0 ports. See the Help Menu in the NucleoView NC-200™ software and the “Install_Guide” file on the supplied USB Flash drive for the list of PC Specifications.

2.1.2 **The Cassette fixture.**

The cassette fixture holds the cassette during analysis in the instrument. Refer to section “7.1 Cleaning” for guidelines on how to clean this fixture if required. A stepper motor moves the cassette piston after the RUN button has been activated.

2.1.3 **The RUN Key and LED indicator.**

On the front of the NucleoCounter® NC-200™ there is a RUN button. Activating this will run the last performed type of analysis on the instrument. In this way it is easy to perform a number of identical analyses in a routine manner.

On the rear of the instrument, a USB data connection (rev 2.0 or higher), a DC Power Connection and a DC fuse holder can be found. Please take care of these areas and keep them free of liquids and foreign objects at all times.
2.2 The Cassette

Figure 2 The Via1-Cassette. Here fluorescent dyes AO (Acridine Orange) and DAPI (4',6-diamidino-2-phenylindole) are immobilized in the first part of the flow system.

2.2.1 Loading the Cassette

The cassette is loaded by gently pressing the white piston down to the top of the cassette, which creates a partial vacuum in the flow system. The tip of the cassette must be immersed into a sample mixture when pressing the piston, resulting in sample being loaded into the flow system. Approximately 60µl is loaded into the flow system filling the first part of the channel in the cassette. The liquid is transferred to the measurement chamber when the cassette is inserted in the NucleoCounter® NC-200™ instrument and an analysis is initiated. Please note that approximately 100 µl in a normal micro centrifuge tube is recommended to reduce the risk of air being loaded into the system.

Figure 3 Loading of the Cassette
The cassettes to be used with NucleoCounter® NC-200™ are highly specialized devices, which hold the key to several of the unique features of the NucleoCounter® NC-200™ concept. For instance in the Via1-Cassette the fluorescent dyes AO (Acridine Orange) and DAPI (4',6-diamidino-2-phenylindole) are immobilized inside the flow channels of the disposable cassette. When the cassette has been loaded with approximately 60 µl of sample mixture, the dyes are dissolved and mixed with the sample, staining the cells.

After being placed in the NucleoCounter® NC-200™, the stained mixture is automatically transferred to the measurement chamber, where the fluorescent image is recorded. In a cassette the measurement volume is as large as 1.4 µl.

After analysis the sample and dyes are contained inside the cassette, which can be safely discarded. This offers a unique and safe sample handling and disposal.

As the Via1-Cassette (and all other cassettes) contains the entire flow system as well as measurement chamber, neither cleaning nor maintenance of the NucleoCounter® NC-200™ instrument itself is needed.

2.2.2 Sample volume

During production, a calibration parameter for every cassette is found, which specifies the precise depth or thickness of the measurement chamber of the device. The calibration parameter is used by the instrument during analysis and the volume analyzed is determined by multiplying the imaged area with the depth of the measurement area. The imaged area is only dependent on the optics of the instrument. Therefore, the area is constant and specific for each instrument.

The calibration parameter is printed on every single cassette as a dot code describing actual thickness of the measurement chamber of the cassette.

2.2.3 Cassette handling

The image analysis method of the NucleoView NC-200™ offers considerable stability, when eliminating non-cellular objects from the image, including scratches and smears on the cassette windows, and thus producing valid results even under extreme conditions. On the other hand, the quality of the cell count is best assured by keeping the windows of the cassette as clean as possible.

Caution! Be careful when attempting to wipe off the surface of the cassette, in an attempt to remove any foreign object, since the plastic material of the cassette can be scratched. In section 5.2 “Analysis with the cassettes” see how to place and remove the cassette.
3 Key, LED indicator and PC control

3.1 Interactive Controls

The figure above shows the front of the NucleoCounter® NC-200™. Two operational areas are present:

- Lid with cassette fixture behind
- Run button and a Tri color status LED indicator

The lid is located in the first area where the sample, contained in a cassette is placed. When the lid is opened, a cassette can be placed in the fixture. The other area is where the Run button and LED indicator are placed. Once a protocol has been selected in the software (see detailed description in the NucleoView NC-200™ Help), an analysis using this protocol can be performed by activating the Run button.

The LED indicator shows the status of the instrument.

- Green - the NucleoCounter® NC-200™ is ready for next operation.
- Red - the NucleoCounter® NC-200™ is busy.
- Orange - the NucleoCounter® NC-200™ is not in connection with the NucleoView NC-200™ software.
4 Start-up

4.1 Power on, power off

On the rear of the instrument, two plugs and one fuse holder are located. When seen from the rear the USB 2.0 port is to the left and the fuse holder and DC Power Plug is at the right. The NucleoCounter® NC-200™ is powered by a 24VDC external power supply. To connect the power supply to the NucleoCounter®, connect it to the DC Power Plug (see Figure 5), and plug the mains power cord of the power supply into a wall outlet.

Figure 5. Rear side of the NucleoCounter® NC-200™

The NucleoCounter® NC-200™ is turned “On” once the wall outlet is “On”. To power it “Off”, either remove the DC Power Plug or turn the wall outlet “Off”.

Figure 6 USB 2.0

Figure 7 DC Power Plug
4.1.1 Starting up

The NucleoCounter® NC-200™ is connected to a PC by inserting the respective plugs of a USB cable into the instrument and the PC.

Once the NucleoView NC-200™ program is launched the stepping motor for the piston actuator performs a homing procedure in order to assure correct positioning of the actuator.

After this initialization, the status indicator on the front will turn green and the NucleoCounter® NC-200™ is ready for operation.
5 Operation of the NucleoCounter®

5.1 Ready mode

Once the NucleoCounter® NC-200™ and the NucleoView NC-200™ software are ready, analysis can begin. In the NucleoView NC-200™ software, the browse menu can be used to select the protocol to be performed. Once selected, the run button on the front of the instrument (see Figure 4) or the run button in the software can be used to execute the analysis.

![Figure 8 NucleoView NC-200™](image)

5.2 Analysis with the cassettes

To analyze with a cassette:

1. Load the cassette with an appropriate sample according to the protocol used
2. Place the cassette into the cassette fixture and close the lid
3. Press the Run button.

After analysis the cassette is removed from the fixture and disposed of as biological waste according to national or regional laws or regulations regarding the nature of the mixture it contains.

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Footnote: Before this action the correct protocol has to be selected in the NucleoView NC-200™ software.
5.2.1 Actuator movements

When a cassette is analyzed after Run is pressed, the piston actuator will move the piston rod down through the cylinder of the cassette. Hereby, the sample material is transported to the cassette measurement chamber. The form and dimensions of the flow channels facilitate effective mixing of the sample. Sensors monitor sample flow. When the sample has been correctly loaded into the measurement chamber, the piston is stopped.

5.3 Result presentation

Depending on the type of analysis performed the result will be presented on the PC within a few seconds and the fluorescent image(s) will be stored on the hard disk. Typical process time is less than a minute for viability analysis using one Via-1 Cassette.

5.4 Protection of the optical system

The lid covers the fixture. This lid is designed to protect the area from dust and other potential contaminants, and to keep external light from interfering with the fluorescent image recording. The lid is mounted with a magnetic hinge.

Unless inserting or removing a cassette or cleaning the fixture, the lid should be closed at all times to protect the optical system of the NucleoCounter® NC-200™.
6 NucleoView NC-200™

The NucleoView NC-200™ software controls the NucleoCounter® NC-200™ instrument and image analysis of the recorded images. The program is installed on a Windows PC (Windows 7 or 8). Several options for data presentation are available in the NucleoView NC-200™ software. The main results of the analysis are presented directly on the user interface of the software. An extended result table is available in the result tab. Choosing files in the browse window directly on the user interface will display the results of the selected file.

Figure 11 A typical analysis with overlay function enabled
The events registered as cells can (when enabled in the protocol) be inspected by launching the Protocol Adaption Editor in the Tools menu and selecting to show events included in the count prior to running an analysis. This will launch a plot manager that shows a scatter plot with a gate that encloses the events recorded as cells. Furthermore, two histograms will be displayed showing the intensity and area of the events in the picture.

![Scatter plot and histograms](image.png)

**Figure 12** The Plot Manager showing a scatter plot and two histograms

A USB Flash drive supplied with the instrument contains the software, drivers, instrument specific data etc. On the same USB Flash drive you can also find the NucleoView NC-200™ User’s Guide. Run the file “Install_Guide” and follow the directions to the NucleoView NC-200™ User’s Guide. Once the program is installed the NucleoView NC-200™ User’s Guide can be displayed by following the directions: Menu – Help – Software Users Guide.

Refer to the NucleoView NC-200™ User’s Guide for additional information.
7 Maintenance of NucleoCounter® NC-200™

7.1 Cleaning

7.1.1 Instrument enclosure.
Depending on the environment in which the NucleoCounter® NC-200™ is operated, it is suggested that regular cleaning of the enclosure is carried out. When cleaning the enclosure it is recommended to use a soft moist cloth and gently wipe the surface. Any contamination, which does not come off immediately, should be rubbed gently with a cloth wetted with mild detergent. Never use organic solvents or aggressive detergents to clean the exterior of the NucleoCounter® NC-200™ as this might damage the surface. Cleaning of the enclosure on a daily basis can be performed by using a mild detergent.

7.1.2 Cassette fixture
When cleaning the cassette fixture, great care must be taken against introducing any liquid or dust into the NucleoCounter® NC-200™. Any liquid that enters the interior of the NucleoCounter® NC-200™ can damage the optical parts and thus compromise the quality of the cell counts.

The black surface of the cassette fixture is anodized aluminum and can therefore be wiped off with a clean, dry and dust free cloth that reduces fiber contamination of the cassette fixture.

An object on the surface of an optical component can influence the collected image. A contaminant will normally be visible as a faint object in the image. In case the contamination is on the cassette it will not be visible, when a new cassette is analyzed. If the contamination is present on every image taken, it is most likely that other optical parts are contaminated. In this case contact ChemoMetec A/S. An example of a relatively large contamination is given in Figure 13.

![An image showing a contamination of the optical system, visible as a white cloudy phenomenon in the upper right hand corner.](image)

The presence of a contaminant (e.g. dust particles) will normally not influence the counting of cells. The NucleoCounter® NC-200™ will distinguish between cells and contaminants, since a cell generally is significantly smaller than contaminants.
7.1.3 Spill of liquid

If liquid has been spilled on the instrument it can contaminate elements of the optical system. This contamination can show up in the image in several ways and have many causes but a common feature is that it cannot be removed by the use of compressed air.

Even though such phenomena are clearly visible on the image it only rarely affects the results of the NucleoCounter® NC-200™. Since it is possible to damage the optical system while attempting to clean the system, it is recommended that ChemoMetec A/S should be consulted before the user attempts such cleaning.

7.2 Decontamination

In case decontamination of the NucleoCounter® NC-200™ is required, please contact ChemoMetec A/S before taking action.
8 PC- maintenance, Error messages and Power-on failure

8.1 Required hard disk space for data storage.
The CM files stored on the hard disk can vary from 6MB to 30MB. Therefore it is important from time to time to check whether enough free space is present on the hard disk. ChemoMetec recommends a minimum of 10GBs free space on the hard disk.

It is recommended to make a periodic archiving of CM files to external storage. Those archived CM files can then be removed from the hard disk of the PC.

The periodic archiving can be made on either the creation date of the CM file, or when the free disk space is below a certain amount, or when the disk space used for CM files exceeds a certain amount. Contact the local IT Administrator in order to get information about procedures for external data storing.

A good example of the archiving procedure could be based upon:

- CM files older than 3 months are archived
- CM files uses more than 50GBs of disk space, archive the oldest CM files until less than 20GB is used
- When less than 10 GBs free space, archive the oldest CM files until less than 20GB is used.

Refer to the NucleoView NC-200™ User’s Guide for additional information.

8.2 Error messages
Under certain conditions the NucleoView NC-200™ software will display error messages during operation. Corrective actions can be found in the Help section of the NucleoView NC-200™ software, but if they do not correct the errors, contact ChemoMetec A/S or the local distributor.

8.3 Power-on failure
If the NucleoCounter® NC-200™ cannot be turned on, please verify that the power supply is connected to the NucleoCounter® NC-200™ and a working mains plug.

If the NucleoCounter® NC-200™ still does not turn on, inspect and/or replace the fuse as described below.

The fuse holder is located at the rear side above the power plug, see Figure 14.
Disconnect the power supply from the NucleoCounter®. Then remove the fuse holder using a screwdriver as indicated in Figure 14 (turn counter clockwise). Inspect the fuse. If it needs replacement use one as described by ChemoMetec A/S.

If the NucleoCounter® NC-200™ does not turn on after replacement of the fuse, or if the fuse was not broken, please contact ChemoMetec A/S or the local distributor for further instructions.
9 Technical specifications

9.1 The NucleoCounter® NC-200™

Optics
Lens with x1.3 magnification, 1/2.″ CMOS

Sample device
NC-200™ Cassettes,

Excitation (nm)
2 LED light sources with peaks at 365 nm, 505 nm and dark field light

Emission (nm)
A single dual-band emission filter: 410-460 nm and 540-650 nm

Sample consumption
60 μl

Analyzed volume
1.4 μl sample

Optimal Range
5 x 10⁴ - 1 x 10⁷ cells/ml

Cell types
Mammalian cells.

PC Platform
Microsoft Windows 7 or 8 32/64 bit, At least one USB 2.0 port must be available, Screen minimum 1024 x 768, At least 2 GB RAM and 10GB free disc space,

Analysis time
Typical 15-60 seconds

Data presentation
Images, tables, histograms, scatter plot

Weight and Dimensions
4.5 kg, H 26 cm, W 38 cm, D 22 cm.

Supply Voltage
24 VDC (100-240V~ 50-60Hz)

Power Consumption
7/20W (Ready mode/peak)

Operation and storage conditions
Maximum relative humidity 80 percent for temperatures up to 31°C decreasing linearly to 65 percent relative humidity at maximum 35°C; minimum temperature 15°C.

9.2 Sample medias

Storage and stability
Refer to package insert for the appropriate sample media type.
9.3 EU standards

The NucleoCounter® NC-200™ complies with EU standards as follows.

Directives

Low Voltage Directive (2006/95/EC) LVD
Machinery Directive (2006/42/EC) MD

Standards

EMC: EN 61326-1:2006 Electrical equipment for laboratory use
EN 61000-3-2: 2006 Limits for harmonic current emissions
EN 61000-3-3: 1995 +A1 +A2: 2005 Limitation of voltage changes, voltage fluctuations and flicker

LVD: EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use

MD: EN 12100-1: 2003 Safety of machinery; Basic concepts, general principles for design — Part 1
EN 12100-2: 2003 Safety of machinery; Basic concepts, general principles for design — Part 2:
EN ISO 14121-1:2007 Safety of machinery; risk assessment

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
10 Equipment and Accessories

On www.chemometec.com an updated list of Equipment and Accessories for the NucleoCounter® NC-200™ are available.
Appendix A: Description of changes from latest revision

This chapter describes changes from latest revision of this User’s guide.

A.1 New:

- N/A

A.2 Changes:

- Front Page
  - Revision 1.3

- Page iii
  - Revision 1.3
  - May 2014

- Cell counting with the NucleoCounter® NC-200™ (Page 6)
  - The NucleoCounter® NC-200™ runs together with the NucleoView NC-200™ software, which can be installed on a PC having Windows 7 or 8 operating systems and USB 2.0 ports.

- NucleoView NC-200™ (Page 15)
  - The NucleoView NC-200™ software controls the NucleoCounter® NC-200™ instrument and image analysis of the recorded images. The program is installed on a Windows PC (Windows 7 or 8).

- Technical Specifications (Page 21)
  - Microsoft Windows 7 or 8 32/64 bit, At least one USB 2.0 port must be available, Screen minimum 1024 x 768, At least 2 GB RAM and 10GB free disc space.

A.3 Removed:

- N/A
Appendix B: WEEE directive information in more EU languages

United Kingdom: Correct Disposal of This Product
(Waste Electrical & Electronic Equipment) - Europe only

This marking shown on the product or its literature, indicates that it should not be disposed together with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

Sweden: Korrekt avfallettering av produkten
(elektriska och elektroniska produkter) - Endast för Europa

Denna markering på produkten och i manualen anger att den inte bör sorteras tillsammans med annat hušhållsavfall när dess livstid är över. Till förebyggande av skada på miljö och hälsa bör produkten hanteras separat för ändamålsenlig återvinning av dess beståndsdelar.

Företagsanvändare bör kontakta leverantören samt verifiera angivna villkor i köpkontraktet. Produkten bör inte hanteras tillsammans med annat kommersiellt avfall.

Slovenia: Ustrezno odstranjevanje tega izdelka
(odpadna električna in elektronska oprema) - Samo Evropa

Oznaka na izdelku ali spremljevalni dokumentaciji pomeni, da ga na koncu uporabe ne smete odstranjevati skupaj z drugimi gospodinjskimi odpadki. Da bi preprečili morebitno tveganje za okolje ali zdravje človeka zaradi nenadzorovanega odstranjevanja odpadkov, izdelek ločite od drugih vrst odpadkov in ga odgovorno reciklirate ter tako spodbudite trajnostno ponovno uporabo materialnih virov.

Podjetja naj pokličejo dobavitelja in preverijo pogoje nabavne pogodbe. Tega izdelka pri odstranjevanju ne smete mešati z drugimi gospodarskimi odpadki.

Slovakia: Správna likvidácia tohto výrobku
(Elektrotechnický a elektronický odpad) - Platí len pre Európu

Toto označenie na výrobku alebo v sprievodnej brožúre hovorí, že po skončení jeho životnosti by nemal byť likvidovaný s ostatným odpadom. Prípadnému poškodeniu životného prostredia alebo ľudského zdravia môžete predísť tým, že budete taketo typy výrobkov oddeľovať od ostatného odpadu a vrátiť ich na recykláciu.

Priemyselni používateľia by mali kontaktovať svojho dodávateľa a preveriť si podmienky kúpnej zmluvy. Tento výrobok by nemal byť likvidovaný spolu s ostatným priamyselným odpadom.

Portugal: Eliminação Correcta Deste Produto
(Resíduo de Equipamentos Eléctricos e Electrónicos) - Apenas na Europa

Esta marca, apresentada no produto ou na sua literatura indica que ele não deverá ser eliminado juntamente com os resíduos domésticos indiferenciados no final do seu período de vida útil. Para impedir danos ao ambiente e à saúde humana causados pela eliminação incontrolada de resíduos deverá separar este equipamento de outros tipos de resíduos e reciclar-lo de forma responsável, para promover uma reutilização sustentável dos recursos materiais.

Os utilizadores profissionais deverão contactar o seu fornecedor e consultar os termos e condições do contrato de compra. Este produto não deverá ser misturado com outros resíduos comerciais para eliminação.

Poland: Prawidłowe usuwanie produktu
(zużyty sprzętu elektryczny i elektroniczny) - Tylko obszar Europy

Oznaczenie umieszczone na produkcie lub w odnoszących się do niego tekstach wskazuje, że produktu po upływie okresu użytkowania nie należy usuwać z innymi odpadami pochodzącymi z gospodarstw domowych. Aby uniknąć szkodliwego wpływu na środowisko naturalne i zdrowie ludzi wszelki niekontrolowany usuwanie odpadów, prosimy o oddzielenie produktu od innego typu odpadów oraz odpowiedzialny recykling w celu promowania ponownego użycia zasobów materialnych jako stałej praktyki.

Użytkownicy w firmach powinni skontaktować się ze swoim dostawcą i sprawdzić warunki umowy zakupu. Produktu nie należy usuwać razem z innymi odpadami komercyjnymi.
Correcte verwijdering van dit product
(elektrisch & elektronisch afvalapparatuur) - Alleen Europa

Dit merkteken op het product of het bijbehorende informatiemateriaal duidt erop dat het niet moet worden afgehandeld met andere huishoudelijke afval. Het moet worden overgedragen aan uw lokale afvalverwerker.

Producers are required to collect back at the end of their useful lives this type of electrical and electronic equipment.

Onbehoud van de andere wijzigingen. Sokrates 2014.
Appendix B: WEEE directive information in more EU languages

Finland
Tämän tuotteen turvallinen hävittäminen
(elektroniikka ja sähkölaitteet) - Vain Eurooppa

Ohjain merkitsee tuotetta tai tuotteen ohjelmistopohjassa olevaa merkintää, että tämä tuotetta ei tule hävittää kotitalousjätteen mukana sen elinkauden päästyttyä. Hallittamattomasti jätteenkäsittelyystä ympäristölle ja kansasainsen terveydelle aiheutuvien vahinkojen välttämiseksi tuote tulee käsitellä muista jätteistä erillään. Jäte on hyvä kierrettää raaka-aineiksi kestävän ympäristökehityksen taka.

Yrityskäyttäjien tulisi ottaa yhteyttä tavaranomistajaan ja selvitää hankintasopimuksen ehdot. Tätä tuotetta ei tule hävittää muun kaupallisestä jätteen seena.

Estonia
Olge viis toote kasutustes kõrvaldamiseks
(elektriliste ja elektrooniliste seadmete jäätmed) - Ainult Eurooppa

Selline tähistus tootel või selle dokumentidel näib, et toodet ei tohi kasutusajal lõppemisel kõrvaldata koos muude olmejäätmetega. Selleks, et vältida jätmete kontrollimatu kõrvaldamise seotud võimaliku kahju tekitamist keskkonna või inimeste tervele ning edendada materaalsete vahendite säätstävaid taaskasutusjäätmet, eraldage toode muudest jäätmetest ja suunake taasringlusse.

Firmad peaksid võtma ühendust tarnija ning kontrollima ostulepingu tingimusi ja sättete. Toodet ei tohi panna muude hävitamiseks mõeldud kaubandusjätmete hulka.

Spain
Eliminación correcta de este producto
(material eléctrico y electrónico de descarte) - Europa solamente

La presencia de esta marca en el producto o en el material informativo que lo acompaña, indica que al finalizar su vida útil no deberá eliminarse junto con otros residuos domésticos. Para evitar los posibles daños al medio ambiente o a la salud humana que representa la eliminación incontrolada de residuos, separe este producto de otros tipos de residuos y recíклélo correctamente para promover la reutilización sostenible de recursos materiales.

Los usuarios comerciales pueden contactar con su proveedor y consultar las condiciones del contrato de compra. Este producto no debe eliminarse mezclado con otros residuos comerciales.

Greece
Σωστή Διάθεση αυτού του Προϊόντος
(Απορρίµµατα Ηλεκτρικού & Ηλεκτρονικού Εξοπλισµού) - Μόνον για την Ευρώπη

Τα σήµατα που εμφανίζονται πάνω στο προϊόν ή στα εγχειρίδια που το συνοδεύουν, υποδηλώνουν ότι δεν θα πρέπει να ρίπτεται μαζί με τα υπόλοιπα οικιακά απορρίµµατα µετά το τέλος του κύκλου ζωής του. Προκειµένου να αποφευχθούν ενδεχόµενες βλαβερές συνέπειες στο περιβάλλον ή την υγεία εξαιτίας της ανεξέλεγκτης διάθεσης απορρίµµάτων, σας παρακαλούµε να το διαχωρίσετε από άλλους τύπους απορρίµµατα και να το ανακυκλώσετε, ώστε να βοηθήσετε στην βιώσιµη επαναχρησιµοποίηση των υλικών πόρων.

Οι επιχειρήσεις ιδιοκτήτες θα πρέπει να έλθουν σε επαφή µε τον προμηθευτή τους και να ελέγξουν τους άροι και τις προϋποθέσεις του συµβολαίου για την χρήση αυτών των υλικών πόρων.

Οι πολίτες θα πρέπει να έλθουν σε επαφή µε τον προμηθευτή τους και να ελέγξουν τους άροι και τις προϋποθέσεις του συµβολαίου για την χρήση αυτών των υλικών πόρων.

Germany
Korrekte Entsorgung dieses Produkts
(Elektronikmüll) - Nur Europa

Anzuwenden in den Ländern der Europäischen Union und anderen europäischen Ländern mit einem separaten Sammelsystem (Die Kennzeichnung auf dem Produkt bzw. auf der dazugehörigen Literatur gibt an, dass es nach seiner Lebensdauer nicht zusammen mit dem normalen Haushaltsmüll entsorgt werden darf. Entsorgen Sie dieses Produkt getrennt von anderen Abfällen, um die Umwelt bzw. der menschlichen Gesundheit nicht durch unkontrollierte Müllbeseitigung zu schaden. Recyceln Sie das Gerät, um die nachhaltige Wiederverwertung von stofflichen Ressourcen zu fördern.)

Gewerbliche Nutzer sollten sich an ihren Lieferanten wenden und die Bedingungen des Verkaufsvertrags konsultieren. Dieses Produkt darf nicht zusammen mit anderen Gewerbemüll entsorgt werden.

Denmark
Korrekt affaldsbortskaffelse af dette produkt
(elektrisk & elektronisk udstyr) - Kon Europa

Mærket på dette produkt eller i den medfølgende dokumentation betyder, at produktet ikke må bortskaffes sammen med almindeligt husholdningsaffald efter endt levetid. For at undgå skadelige miljø- eller sundhedsretningsvirkninger på grund af ukontrolleret affaldsbortskaffelse skal dette produkt bortskaffes sørskilt fra andet affald og indleveres behørigt til fremsæt for bæredygtig materialegenvinding.

Erhvervsbrugere bedes kontakte leverandøren og læse betingelserne og vilkårene i købekontrakten. Dette produkt bør ikke bortskaffes sammen med andet erhvervsaffald.

Czechoslovakia
Správná likvidace tohoto produktu
(Znièení elektrického a elektronického zaøízení) - Pouze Europa

Tato znaèka zobrazená na produktu nebo v dokumentaci znamená, že by neměl být pouøíván s jinými domácími zaøízeními po skonèení jeho funkcí. Aby se zabránilo možnému zneèívání životního prostøedí nebo zrání člověka díky nekontrolovanému znièení, odèle je proøim od ostatních typů odpadù a recyklujte je zpøodnì opûtového vyuøitì hmotných zdrojù.

Obchodníci by měli kontaktovat své dodavatele a zkontrolovat všechny podmínky koupì. Tento výrobek by se neměl míchat s jinými komerčními produkty, urèenymi k likvidaci.
The information contained herein is to the best of our knowledge accurate and complete. However cell species and cell environments may vary in property. Therefore systematic and/or random deviation between estimates obtained by the NucleoCounter® and other cell counting methods may occur. As such, nothing contained or stated herein including results obtained from use of the NucleoCounter® or NucleoCassette™ shall be construed to imply any warranty or guarantee. ChemoMetec A/S and affiliated companies shall not be held liable for damages and customers shall indemnify ChemoMetec A/S and affiliated companies against liability flowing from use of potentially inaccurate data generated by the NucleoCounter®. It is recommended that all results obtained with the NucleoCounter® are validated against appropriate reference methods and/or traditional laboratory methods at regular intervals.