

Hemolyzer® 5 NG (closed mode)



User Manual



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Foreword

Thank you for choosing the Analyticon Hemolyzer 5 NG automated hematology analyzer.

We believe that this instrument will definitely help you in your daily laboratory routine.

Welcome to the Analyticon family...

This user manual refers to the following product:

Article number	Product name
REF: HE5100	Hemolyzer 5 NG (closed mode)



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Address: Papírgyár u. 58-59,
H1038, Budapest, Hungary
www.normadiagnostika.com



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Introduction

Hemolyzer 5 NG is a small, 60 tests/hour forward laser scatter and impedance-based IVD hematology analyzer for small to medium sized laboratory use, performing 5-population analysis of whole blood samples.

Hemolyzer 5 NG is easy to use, uses low amounts of reagent for determining 27 hematology parameters.

Hemolyzer 5 NG's small footprint allows operating in space-constrained environment.

Who should read this manual

This manual is written for operators of the analyzer describing the structure of the analyzer, daily routine and basic maintenance required to keep the analyzer in good working condition to ensure reliable and dependable operation.

Symbols used in the manual

This Operator's manual uses symbols listed below to indicate hazards in connection with operating the analyzer. These symbols are used wherever such hazards arise during operation or handling of the analyzer.

Symbol	Meaning
	WARNING Risk of personal injury
	BIOHAZARD Risk of biological infection, contamination
	LASER RADIATION Risk of exposure to laser radiation

Intended Use

Hemolyzer 5 NG is a 60 tests/hour laser scattering and impedance-based IVD hematology analyzer for laboratory use, using specific reagents, performing 5-part differential analysis of 27 hematology parameters of anti-coagulated human whole blood samples introduced in closed vials.

Results are available in less than a minute after initiating the measurement process.

Disclaimer

The manufacturer reserves the right to:

- modify the contents of this manual without prior notice,
- change technology applied within the analyzer without prior notice,
- change technical specifications without prior notice.

The manufacturer does not warrant this manual to be 100% free of unintentional errors.

Please note that this Manual may be revised without prior notification. The Manufacturer reserves the right to change the specifications of the product and/or the contents of this manual as deemed necessary, without prior notice.

Pictures included in this manual may differ from the actual delivered product.

Performance and reliability are never influenced by minor visual differences between this manual and the actual product.

Symbols on the outside of the analyzer

Symbol	Meaning
	WARNING Risk of personal injury
	BIOHAZARD Risk of biological infection, contamination
	LASER RADIATION Class 1 laser product
	CE mark
	for In Vitro Diagnostic use
	Address of manufacturer
	Serial number
	Waste of electrical and electronic equipment

Technical contact

Hemolyzer 5 NG is a precise and accurate laboratory instrument. Its built-in safety measures guarantee safe and reliable operation. Being a complex device, there is limited access to internal structures provided to the end user.

Hemolyzer 5 NG is a Class 1 laser device, the embedded laser source is not exposed to the user or service personnel. Under no circumstances should the operator attempt to open or remove the outer cover of the analyzer, as this may influence reliable operation and might fool built-in safety measures and can invalidate warranty.

There are no user serviceable parts inside this analyzer. Adjustments of internal structures and repairs of these structures should only be performed by qualified service personnel.

Your local dealer is always ready to help you in case of malfunction. The contact of your local dealer is available on the insert of this Manual.

Analyticon will be doing its best to resolve your problems either directly or indirectly with the help of its local representative.

Warranty

Your Hemolyzer 5 NG comes with a one-year manufacturer's warranty against workmanship defects. Warranty claims must be made through your local representative.

Your supplier will only be able to repair and warrant operation of the analyzer as per its specifications if all service actions are performed by qualified service personnel, and the Warranty Label is intact.

Warranty is void if any of the below can be identified, or inoperability, malfunction can be traced back to any of the events listed below:

- broken warranty seal;
- intentional damage and/or modification to the analyzer;
- improper use, use against instructions in this manual, against intended use;
- damage from intentional activities overriding built-in safety logic;
- natural disaster;
- uncertified power supply, or unapproved peripheral has been connected to the analyzer;
- disassembly, repair attempt performed by unauthorized staff;
- damage rooted back to unreported shipping and/or installation induced activities.

The manufacturer does not recommend and support modifying the operating software of this hematology analyzer. The analyzer can log and track modifications to the operating software.

- If the End User required or performed installation of any software product not controlled by the manufacturer and would afterwards experience erroneous or unreliable operation of the analyzer, or would experience erroneous results, then the manufacturer cannot accept any complaints about operation, reliability or performance.

Exclusions to warranty

Items listed below are not covered by warranty unless they were found damaged upon arrival to the End User. In such cases, proper complaint must be filed along with a complaint registered with the forwarder/Distributor company:

- Batteries, external power cable
- Plastic cover elements (including transparent display cover)
- External reagent tubes
- Labels, printed material
- Internal piercing needle

Measurement technology

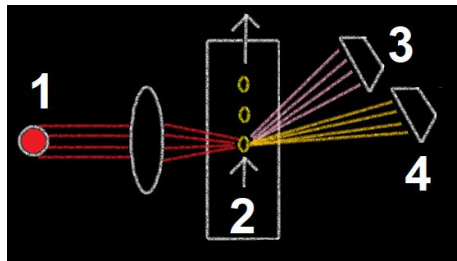
Hemolyzer 5 NG uses flow cytometry and volumetric impedance method to provide 27 hematology parameters from 38µl of whole human blood samples. The measurement cycle time is 60 seconds yielding 60 tests/hour throughput.

Laser-based cell counting

Flow cytometry is a technology that simultaneously measures and then analyzes multiple physical characteristics of single cells, as they flow in a fluid stream (2) through a beam of laser light (1). The properties measured include a particle's relative size and relative granularity.

These characteristics are determined using an optical-to-electronic coupling system that records how the cell scatters incident laser light in different angles.

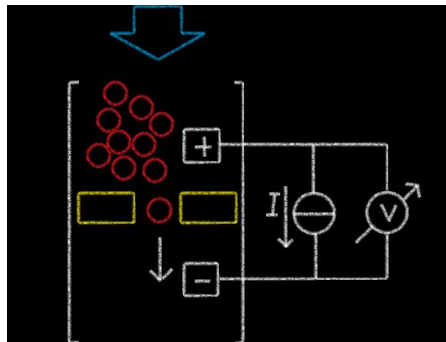
Low angle (1-5°) scattered light (3) is proportional to the cell's volume as it is scattered from the surface of cell membrane; while high angle (8-18°) scattered light (4) is proportional to the cell's internal complexity as it is scattered from the intra-cellular granules and nucleus.



Impedance-based cell counting

Cells found in a blood sample have various sizes. The volume of these cells can be measured electronically.

A known direct electric current (I) is driven through a small opening (aperture – yellow on figure) with 70µm of diameter separating two liquid compartments containing diluent, that conducts electricity. An injector pushes through (blue arrow) the diluted blood sample from one side of the aperture to the other side.



When there is only diluent in the aperture, a certain electric resistance can be measured due to the conductive characteristic of the diluent.

Blood cells do not conduct direct current. When a cell (red circle above) passes through the aperture (yellow) then the resistance of the liquid will increase for the moment the cell passes the aperture. The change of resistance is proportional to the volume of the cell in the aperture. The bigger the change, the bigger the cell passing through the aperture.

Hemoglobin measurement method

Determination of HGB is based on absorption of light of the hemolyzed blood sample.

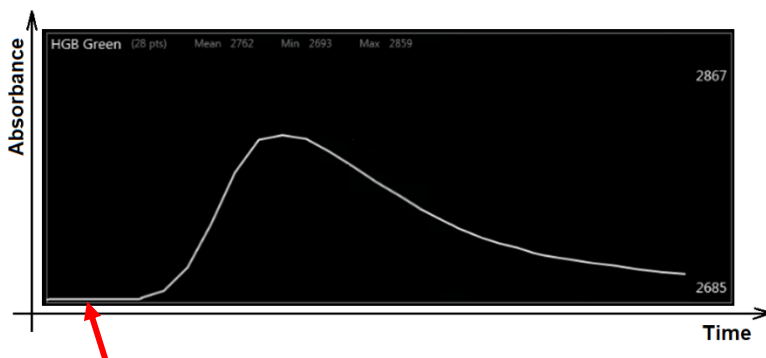
The analyzer separates two identical blood sample portions, one of them is used to measure RBC/PLT, the other one is used to measure WBC/HGB.

The WBC/HGB sample portion is transferred directly to a tubing filled with lyse reagent, then moved by the Lyse injector into the heater module for temperature-controlled hemolysis of RBCs.

After that, the lysed sample is pushed through the HGB head, and from the HGB head it gets to the laser flow-cytometer head. The WBC/HGB measurement process takes 15 seconds. The HGB head records HGB absorbance at every half a second while the laser head detects cells continuously.

Concentration of HGB absorbance detected by the HGB head changes in time, similarly to a kinetic photometric measurement.

The following HGB absorbance curve is obtained during HGB measurement:



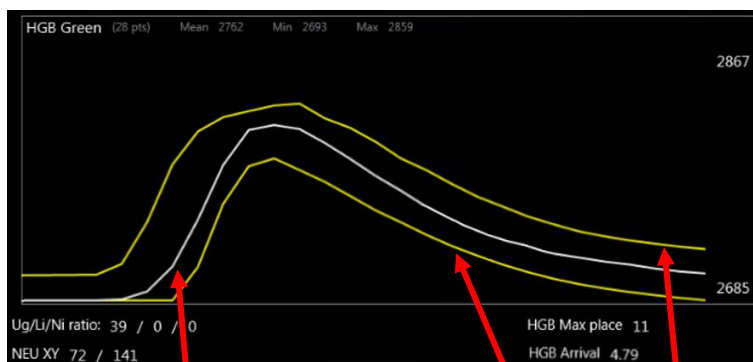
At the beginning of the HGB measurement there is no sample in the HGB head – this part is considered as HGB baseline or HGB blank – representing zero HGB concentration.

HGB baseline is different for each analyzer, it is 2685 in this case.

HGB value is calculated by integrating the area between the baseline and the absorbance curve.

HGB absorbance curve is normalized, its height is always the same.

In technical view, the HGB reference range is displayed by two yellow lines. These lines are generated by storing a previous HGB curve as reference.



HGB absorbance curve measured

Reference range of HGB curve

If the HGB curve is out of the yellow boundaries, then **HGB Baseline error** or **Unstable HGB** flag will appear along with the HGB result. This can be caused by bubbles. Check Technical flags section on **page 69** to solve such problems.

To achieve a stable HGB value, there must be at least 3 zero absorbance points detected at the beginning of the HGB measurement. **HGB arrival** is calculated to determine at which measurement point a HGB absorbance different from the baseline was detected. To have a valid HGB result, this value should be between 3.5 and 5.8.

HGB value measured requires correction caused by white blood cells that scatter light and increase HGB absorbance.

HGB correction for WBC interference

The analyzer SW uses the formula below to compensate increased HGB value caused by WBCs:

$$\text{HGB} = \text{HGB} - \text{WBC}/11, \text{ where HGB unit is g/l, and WBC unit is } 10^9/\text{L}.$$

For extremely high WBC count, where $\text{WBC} > 100 \text{ G/L}$, the linear correction described above is not accurate. In such cases, to measure more precise HGB result, it is recommended to rerun the sample prediluted in 1:1 ratio.

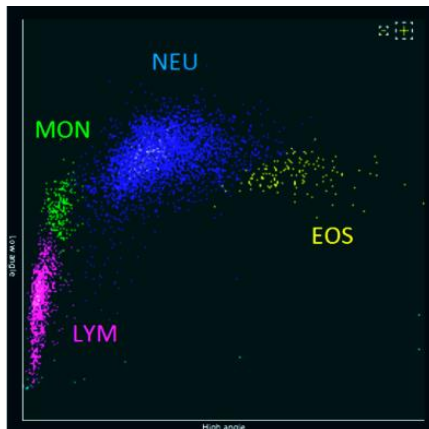
Interpreting scattergram

Hemolyzer 5 NG presents scattergrams on its screen, in printed or in electronic format. Cells scatter light when they pass through the laser beam.

The level of light scattering in the low angle (forward) direction is proportional to cell size. Cells also include granules, compartmented nuclei and other organelles. This leads to side scattering of light.

Light scattering into high angle depends on cell structure (e.g. granularity).

The populations are marked with colors.



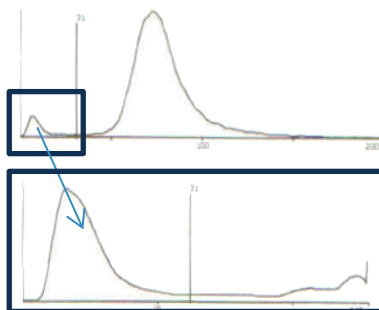
Interpreting histograms

Hemolyzer 5 NG presents histograms on its screen, in printed or in electronic format.

RBC and PLT histograms are related in such a way that the front of the RBC histogram is magnified, and repeated as the PLT histogram.

The horizontal axis represents cell volume in fL (femtoliter: 10^{-15} L) unit.

The vertical line (discriminator) separating PLT and RBC regions are present on both histograms. The discriminator is placed automatically by the analyzer SW.



Hematology parameters

Parameter	Explanation	Typical units
WBC	White blood cell count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
LYM	Lymphocyte count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
MON	Monocyte count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
NEU	Neutrophil count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
EOS	Eosinophil count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
BAS	Basophil count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
LYM%	Lymphocyte percentage (of WBC)	%
MON%	Monocyte percentage (of WBC)	%
NEU%	Neutrophil percentage (of WBC)	%
EOS%	Eosinophil percentage (of WBC)	%
BAS%	Basophil percentage (of WBC)	%
RBC	Red blood cell count	$10^6/\mu\text{L}$ & $10^{12}/\text{L}$
HGB	Hemoglobin	g/dL, g/L, mmol/L
HCT	Hematocrit	%, L/L
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular HGB	pg, fmol
MCHC	Mean Corpuscular HGB Concentration	g/dL, g/L, mmol/L
RDWsd/cv	Red blood cell distribution width	fL/%
PLT	Platelet (thrombocyte) count	$10^3/\mu\text{L}$ & $10^9/\text{L}$
MPV	Mean Platelet Volume	fL
PCT	Plateletcrit/thrombocrit	%
PDWsd/cv	Platelet cell distribution width	fL/%
PLC-R%	Platelet Large Cell Ratio; The ratio of PLT's with volume above 12fl versus total PLT count	%
PLC-C	Platelet Large Cell Count of PLT's with volume above 12fl	$10^3/\mu\text{L}$ & $10^9/\text{L}$
NLR	Neutrophil to Lymphocyte ratio (For details see page 149)	-

5-part differentiation of White Blood Cells

Five-part white blood cell differential counts (so-called diffs), performed during flow cytometry counting of blood cells, can accurately classify lymphocytes, monocytes, neutrophils, eosinophils and basophils with an error rate not exceeding that of conventional diffs. The differential count is made on diluted and hemolyzed specimens; hemolyzing is performed to break down RBC membranes, form stable HGB complex and shrink WBC cells. Normal RBC's have no nucleus; only WBC cells remain in the solution. The size (volume) and complexity of various WBCs are detected by the analyzer to classify cells.

The measurement process

The analyzer is able to process anticoagulated whole human blood samples in closed sample vials. Closed tube mode is only available with certain vial types. The analyzer will only run a vial that has the cap on. Vials without caps are not processed.

The sample vial with the cap is lowered into the sample rotor that turns the vial upside down to allow small sample volume aspiration. The vial is pushed onto a fixed metal sampling needle and is pierced in the upside-down position. The fixed needle is equipped with a washing head to clean the needle's external and internal surfaces.

The sampling system takes a total of 38µl of blood, 2 x 1.4µl of which is processed for the measurements. After sampling, the sample vial is returned to and ejected in the top position of the vial holder. The ceramic shear valve guarantees precise sampling volumes.

One of the 1.4µl blood samples is mixed with a lyse reagent. The temperature of the mixture is controlled. This mixture is then driven through the WBC measurement head. The lysed WBC solution prior to entering the measuring flow cell passes through an absorption measurement window and is measured for HGB content at 560nm wavelength. The lysed WBC solution is then focused using a combination of a 100 µm orifice and a double hydrodynamic focusing system and is led through a perpendicular red (660 nm wavelength) laser beam. The detector tube and amplifier collect scattered data about each individual passing cell during the 15 seconds of measurement.

The second 1.4µl processed blood sample is moved into the mix chamber using diluent, creating a dilution of approximately 1:1000. This mix dilution is then pushed through a 70 µm aperture with the help of a sheathing fluid, creating an overall dilution of 1:20000.

The electrical signal of each individual cell is measured (through stainless steel and platinum electrodes and is collected for 8 seconds) for RBC and PLT counts.

As a final step, the system drains the measuring elements and is ready to take the consecutive sample.

Supported blood collection vials

Hemolyzer 5 NG can process human whole blood samples from closed K-EDTA sample vials.

The analyzer supports the following closed sample vials:

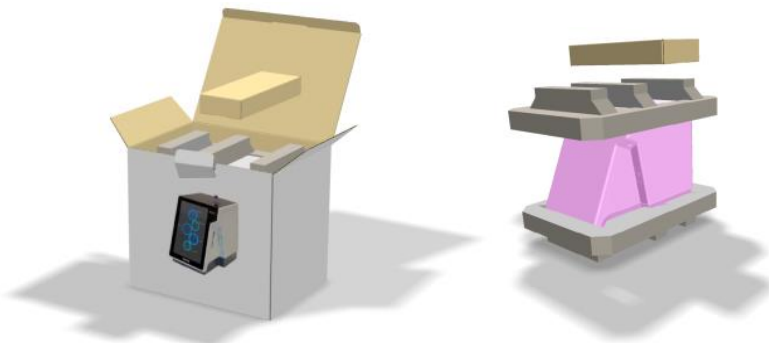
Type, Manufacturer	Minimum sample volume
BD Vacutainer (Ø13x75mm) or compatible	400µL
Greiner Vacuette (Ø13x75mm) or compatible	400µL
BD MAP vials or compatible	250µL

Please consult the instructions for use of relevant primary sample vial types.

	WARNING Vials with rubber stoppers (caps) are designed for a limited number of penetrations with a needle. Using a closed vial more than 5 times without removing it from the sample rotor poses a risk of damaging the rubber cap and causing liquid damage or clogging in the analyzer.
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Package contents

Hemolyzer 5 NG comes in a double cardboard packaging. The outer box provides protection against shipping damage to the analyzer's internal box.



The internal box contains the analyzer and its accessories inside protective foams. The analyzer comes with a protective film covering the scratch resistant screen cover.

Upon arrival, carefully check the contents of the package and look for visible damages, even on the outer packaging box. File any obvious damage through the shipping company to be eligible for compensation and support from your local dealer and from the manufacturer.

Packing list:

- Analyzer outer packaging box
- Accessories box
 - o Power supply; Power cord
- Reagent tubing set
 - o Black cap cleaning vials
- Documents and Guides
 - o Quick Reference Guide
 - o Reagent connector Guide
 - o Installation Report
- Shipping foams (top, bottom)
- Analyzer packaging bag
- Hemolyzer 5 NG analyzer

Accessories

- external power supply
SYS1443-6512-T3 or SYS1548-6512-T3
- grounded power cord matching your standard power outlets

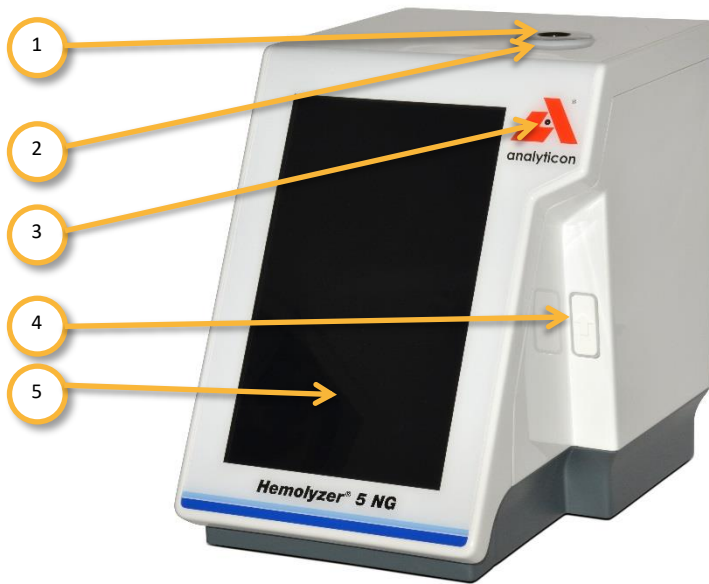


- reagent pickup tube set in a plastic bag:
 - reagent connector
 - tubing
 - caps for various reagent setup
 - draining tube kit
 - black cap cleaning vials
 - Reagent Connector Guide



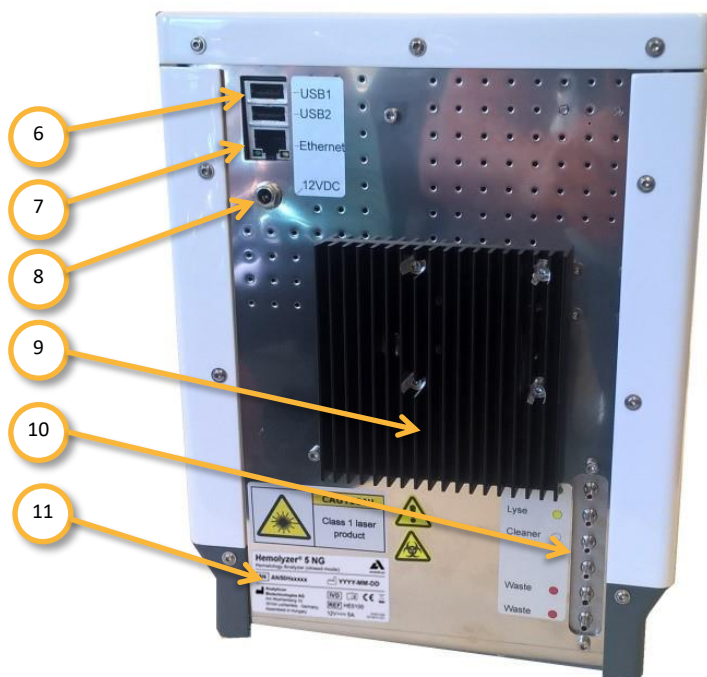
Always use original accessories and cables. Non-approved electronic accessories may damage the system and can result in electric shock.

Identifying parts of the analyzer



Front and right side of Hemolyzer 5 NG

1. Sample vial with cap
2. Status indicator ring
3. Front camera (in the middle of character O)
4. POWER/START button
5. Display with touch screen



Back of Hemolyzer 5 NG

6. USB connectors
7. RJ45 (network) connector
8. DC power inlet
9. Radiator of internal temperature control module
10. Reagent connectors
11. ID label of analyzer with S/N and electrical data

Installing the analyzer

	Hemolyzer 5 NG is a precise and accurate hematology analyzer. Incorrect handling or accidental falling of the analyzer may damage parts inside and could influence performance.
	To avoid overheating of the device, avoid installation in confined space. If the system detects overheating, safety functions will disable operation. Ambient temperature being above 30°C (86°F) for an extended time may cause the system over-heat.

1. Carefully remove Hemolyzer 5 NG from the shipping carton. Look for signs of damage, such as cracks on the outer covers or loose/missing screws. If you find such signs, please file a complaint to the shipping company to be eligible for compensation and support from your local dealer and from the manufacturer. Make sure you can find all the accessories listed in the packing list.
2. Prior to powering on Hemolyzer 5 NG, allow the analyzer to reach room temperature to avoid dew condensation. Sudden temperature changes may cause dew to condensate on colder internal structures and can lead to damage of electronic components.
3. Place the analyzer on a desktop bench and find a nearby **grounded power outlet**. Please avoid power extension cords, use direct connection to the power outlet. Always use the power supply packaged along with the analyzer.
4. Connect the power supply to the socket on the rear plate of the analyzer.
5. Connect the power cord to the power outlet.
6. Remove the protective foil from the analyzer's front.

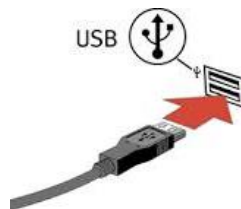
	Attention If you experience any error, like smoke, immediately disconnect the power cord from the power outlet. Use a fire extinguisher if necessary.
---	---

User serviceable parts

	Attention There are no user serviceable parts inside the analyzer. Please do not attempt to open or disassemble the analyzer to avoid electric shock or injury and will void the warranty
	Attention There is a Class 1 visible laser (660nm) source enclosed inside the analyzer. Hemolyzer 5 NG has internal safety locks to protect even unintentional exposure to laser light. Do not open the measurement head or permanent eye damage could occur. Exposure to direct laser radiation must be avoided.
	Attention Only qualified service personnel may perform adjustment and repair procedures related to internal components.

Connecting peripheral devices

Hemolyzer 5 NG offers 2 USB sockets for connecting external peripheral devices. To expand USB connectivity options, you can connect any standard USB HUBs.



Keyboard (optional)

Hemolyzer 5 NG supports connecting external USB keyboards that can facilitate data entry. The keyboard can be connected any time.

Mouse (optional)

Hemolyzer 5 NG supports connecting a USB mouse. The mouse can be connected any time. If a mouse is connected, the touch screen remains operating, yet a small arrow cursor will be displayed to track the movement of the mouse.

Bar code scanner (optional)

You can connect a USB bar code scanner.

USB flash drive (optional)

You can connect a USB flash drive to save reports, archive settings and database content. The USB flash drive is also suitable to review and import data stored externally.

USB Wi-Fi Dongle (optional)

The device offers connectivity options to wireless networks (sending measurement reports via email). Network settings must be revised. The analyzer software supports a limited number of Wi-Fi dongles.



Attention

It is not guaranteed that any random Wi-Fi dongle will work with the analyzer.

Supported models:

- AmbiCom WL250N-USB (Chipset: Ralink RT3070)
- EnGenius EUB9707 USB WiFi adapter
- LM Technologies – LM006

Network (“Ethernet”)

Connect the cable (not included) from the computer network to Hemolyzer 5 NG’s RJ45 socket. Network settings must be revised.



Reagent pack

The Analyticon Hemolyzer 5 NG reagent pack provides sufficient reagent to run a specified number of tests with the analyzer. The pack contains all necessary reagents. Waste must be collected in a separate container.

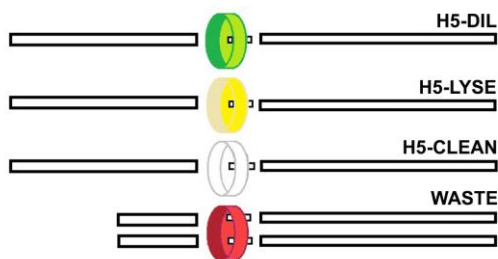
The reagent pack is a single use consumable. For connection, follow the Reagent Pack’s instructions for use.





Hematology reagent waste must be considered biohazard material. Always follow local regulations regarding disposal of used consumables, and reagent.

Assemble the reagent bottle caps following the sketch below:



Each tube is equipped with a label indicating which bottle to connect it to. The caps match the standard Hemolyzer 5 NG reagent bottles.



Attention

For best results and performance, place the reagents to the same level (on the same desk) as the analyzer.

Analyzer packaging material

Retain the packaging for future use and storage.

Power

External power supply

Hemolyzer 5 NG can only be used with the supplied external power supply. The power supply generates 12 VDC required for operation of the analyzer.

The power supply can operate between 100-240 VAC @ 50-60Hz. No setting is required for input voltage selection.

The power supply has standard input and output connectors.

Upon connecting the power supply, Hemolyzer 5 NG is in low power consumption mode and ready for operation.



Always use a grounded power outlet to avoid the risk of an electric shock, and to ensure reliable operation.

An unearthed power outlet may make the analyzer sensitive to external electrical interferences and may impair operation.

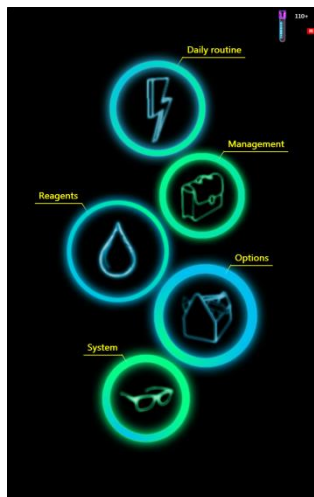
Power button

It is located on the right side of the beveled front panel. When the external power supply is connected both to the analyzer and to the mains outlet, the analyzer can be turned on by pushing the power button.



Power on

The single push of the START button will power on the electronics and Hemolyzer 5 NG will display the welcome screen and the main menu automatically.



When Hemolyzer 5 NG is turning on, the screen remains dark for a short time, only backlight illumination can be seen at the edges of the screen. This is normal.

Power off

Hemolyzer 5 NG is a sensitive device with liquids inside. A simple power off might leave the system in a state that can represent potential risk to moving components and liquids inside.

Therefore Hemolyzer 5 NG has a programmed power off sequence. It is recommended to always follow the programmed power off sequence to avoid unreliable operation of the structures inside the analyzer.

Hemolyzer 5 NG can be turned off by tapping the local menu button and initiating Shutdown in the menu. To power off the analyzer, select "Shutdown". The automatic process will start, and the analyzer is safely powered off within 2-3 minutes. Do not interrupt this sequence.



It is strongly recommended to power off the analyzer every day, at the end of the daily routine. This will save electricity and ensures that the analyzer operates reliably on a day to day basis.

Emergency power off

If necessary, Hemolyzer 5 NG can be powered off by holding the power button for 4 seconds. This method skips the preprogrammed Shutdown.

	Performing an emergency power off can leave the analyzer in an undetermined state. Not operating the analyzer after emergency power off can result in malfunction. Please contact your maintenance personnel to avoid damage to internal components.
---	--

To completely and immediately power down Hemolyzer 5 NG, remove the power cord plug from the mains outlet or the power connector from the back of the analyzer.

Handling reagents

Hemolyzer 5 NG operates with special reagents. The reagents have been carefully designed to meet the requirements of the analyzer. Hemolyzer 5 NG's quality assurance system requires the use of these special reagents. Hemolyzer 5 NG recognizes and accepts genuine reagents only. Reagents are sensitive substances and as such require careful handling.

Precautions about reagents

Reagents are considered chemicals and do arrive along with respective package inserts. MSDS are available on request. Always follow instructions of the reagents concerning reagent handling.

	It is recommended to wear protective gloves when installing and replacing reagents to avoid contaminating reagent tubes immersed into the reagent bottles.
	Always rinse reagent tubes at first installation using clean water to avoid contamination of reagents. After rinsing, wipe the outside of the tubes to be immersed using clean, lint-free tissues.

Reagent characteristics

Hemolyzer 5 NG's original reagents do not contain any environmentally hazardous substances.

Blood samples

Hemolyzer 5 NG can process anti-coagulated whole blood human samples.

Proper handling of a hematology sample is of key importance for accurate, dependable and reproducible results. Blood is a living tissue composed of cellular structures suspended in liquid plasma. The cellular structures are composed of cell membranes with liquid and intracellular structures inside. Hematology analyzers are designed to detect, calculate and classify these cellular bodies and their content. As the cells are actually alive in the meaning of active chemical interaction with their environment, keeping them close to their ideal environmental conditions is important for correct analysis. Blood samples intended to be analyzed for hematology purposes are sensitive to temperature, anticoagulant quantity and quality, and mechanical effects.

Follow the guidelines below for optimal sample handling.

Taking the sample

Collect venous blood using (preferably K2- or K3-EDTA-prefilled vacutainer; 1.5 – 2.2mg/ml) anticoagulant collection tube.



An EDTA quantity below or above the recommended ratio will cause false or no results due to improper chemical treatment of blood cells.

Rapidly and thoroughly mix the blood with the anticoagulant; do NOT shake the vial for mixing. The anticoagulant requires approximately 15 minutes for taking its required effect on the sample. Running the sample within the reaction time of the anticoagulant may result in false cell counts and improper differential results.

Transporting and storing samples

For best results, blood samples must be run within 8 hours from venipuncture if stored at room temperature.

- Samples should be stored upright on room temperature for not more than 12 hours.
- If samples need to be transported after collection, provide a cooled environment (2-8°C).
- Hematology blood samples must not freeze. Avoid direct contact of sample containers and cooling agent (cold surface, ice pack, etc.).
- Samples can be stored refrigerated (between 2-8°C) for not more than 24 hours prior to analysis.

Sample age

To get the best WBC differential results, samples should be analyzed between **30 minutes and 8 hours** after blood taking. This time period **can be extended up to 24 hours**, if samples are kept refrigerated **between 2-8°C**.

- If a sample is kept refrigerated, remove it from the fridge, and let it rest at room temperature for at least 15 minutes before analysis. Measuring cold sample may affect WBC differential results.

Analyzing samples beyond 24 hours after taking is not recommended.

See changes in WBC scattergram and degradation of results for a sample measured after 24 hours below.

A sample measured 6 hours after taking

Observe clear separation of scattergram and WBC populations.

No flags, no * at results.



The same sample measured after 24 hours (stored refrigerated)

Observe how the scattergram becomes less definite, Abnormal Diff flag appears, all Diff parameters are marked by *, WBC count is reduced.

In worse case, WBC differential results might not be displayed at all.



Preparation for analysis

- **Do not place samples on rockers/homogenizers, because it may negatively affect WBC differential results.**
- Sample temperature must be between 15-28°C. Lower temperatures will interfere with homogenization, higher temperature may induce faster degradation of cells.
- Samples must reach room temperature in a natural manner. Do not heat or directly warm the vials not even by holding them in your palm.
- Samples must not be mixed while cold. Doing so may physically damage the cells. Let the vials stand in their holder for 15 minutes before running them on the analyzer.

Proper Sample Mixing prior to run

Samples must be homogenized prior to analysis. It can happen manually or automatically by the Autoloader if connected to Hemolyzer 5 NG.

For proper manual sample mixing make **5 inversions** of the vial.

Follow the steps below:

1. Tilt the tube carefully **looking for clots** in the sample – if clot found refuse the sample from analysis.
2. Invert the tube: turn it upside down, allow the blood flow over completely (1-2 seconds), then turn it back.
3. Repeat tube inversion another 4 times (all together 5 times).
4. Run the sample immediately.
5. If you want to rerun a sample within a few minutes, invert the sample tube just once, and initiate sampling.

	Do not shake or drop the vial, this will form bubbles inside. Do not apply vortex mixing.
	Do not place samples on rockers/homogenizers, because it may negatively affect WBC differential results.
	When using the Autoloader, samples must not be manually mixed. Samples however must be inspected for clots.

Important factors for sample handling:

1. Running too fresh samples – taken in **half an hour** – may falsely trigger diagnostic flags. Wait 30 minutes before analysis.
2. **Analyzing a sample without homogenization will result in an incorrect report.** The analyzer has no sensor to detect lack of homogenization.
3. **Do not use an automatic sample mixer/rocker**, since it applies mechanical stress to the cells continuously which may negatively affect WBC differential results. For the same reason, **do not invert the sample tube more than 6 times.**

Vigorous mechanical mixing weakens cell membrane, especially NEU cells are sensitive to mechanical mixing.

During analysis, the cells are exposed to high mechanical stress and pressure – the cells flow in the laser head at high speed, and some of them may fall apart before reaching the optical detector if the cell membrane is not strong enough.

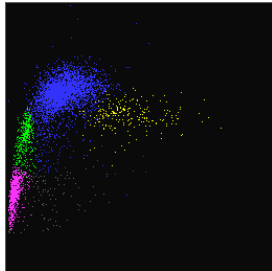
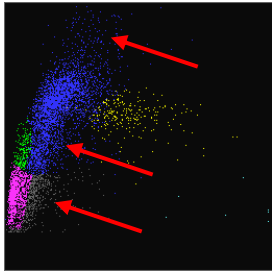
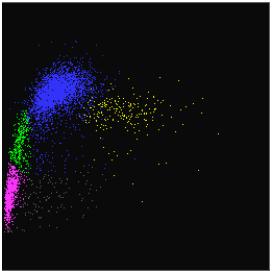
As a result, WBC scattergram will look less separated – see scattergrams below – and conditions of DIFF interpretation will be worse. In such case “Abnormal Diff flag” may be triggered.

- Leave the sample rest 20-30 minutes without mixing, and rerun sample after proper homogenization.

Cell membranes regenerate and better WBC differential results can be obtained. See the third scattergram below of a sample rerun after 30 minutes of rest.

4. **Doing less than 4 inversions may leave the sample in a non-homogenous state.**
5. If a sample is kept refrigerated let it rest at room temperature for at least for **15 minutes** before analysis. Measuring cold sample will affect WBC differential results.

Effect of excess mechanical mixing on WBC scattergram and after 30 minutes rest:

WBC scattergram of a sample mixed 5 times	WBC scattergram of the same sample mixed 10 times	WBC scattergram of the same sample after 30 minutes rest
		
Clear separation of WBC populations on scattergram, with very low number of grey dots in non-WBC region.	NEU population is skewed vertically, some damaged NEU cells appear near LYM, some of them near MON, and above NEU as well. The SW algorithm tries to give the best interpretation and DIFF results – see blue coloring of the skewed NEU population. Note: grey dots near LYM will not be interpreted as WBCs.	As cell membranes regenerated while sample relaxed, WBC scattergram obtained is very similar to the first run, with clear separation of WBC populations.

Bubbles in sample

If bubbles are present in a sample, the amount of actual sample processed by the analyzer may be less than required, then the analyzer may falsely report incorrect values.

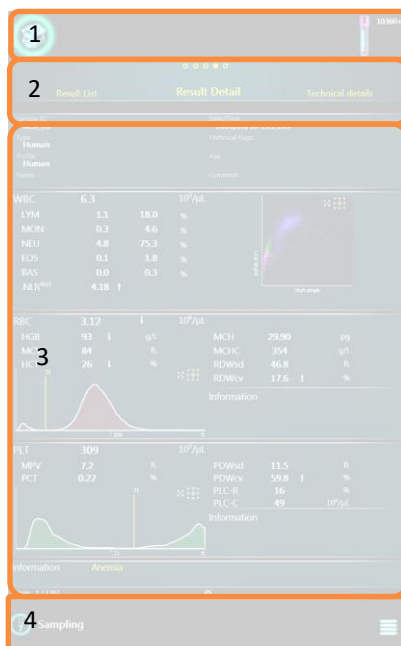
- Such sample should relax for 10 minutes before analyzing it.

Menu system

The screen area

Hemolyzer 5 NG's information display screen is divided into four areas:

1. Status bar
Displays active menu and instrument status
2. Page count area
(when left-right swipe is available)
3. Main information
Displays further functions available related to displayed data
4. Quick links



Menu tree

Daily routine	Sampling	Run FastBlank, closed vial samples (including QC samples and calibrator)
	Results	Database functions

Management	Maintenance	Prime & Drain, Cleaning, General
	Service	Service personnel Only

Reagents	Pack	Pack usage
	Individual reagents	Individual reagents usage

Options	System settings	Date/Time / E-mail / Printout / Printout Format / Network Printing / Customization / Profiles / LIS
	Customize	Appearance / Languages / Units /

System	History	Operation log
	About	System info / Hardware information / SW upgrade / Database

Gestures

Hemolyzer 5 NG's touch screen user interface allows operating the analyzer with light taps and swipe actions listed below.



Taps (quick touch and release over a certain point)



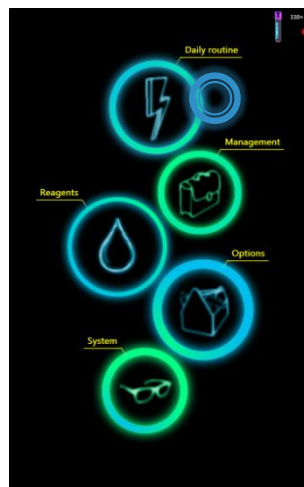
Swipe (quickly moving your finger along the screen without lifting your finger)

All actions (touch and release) are acknowledged by a small circular symbol appearing at the point where the user tapped the screen, and an audible "tick" is heard if sound was enabled.

Using the above basic actions, Hemolyzer 5 NG can interpret various combined actions, so-called gestures.

Tap

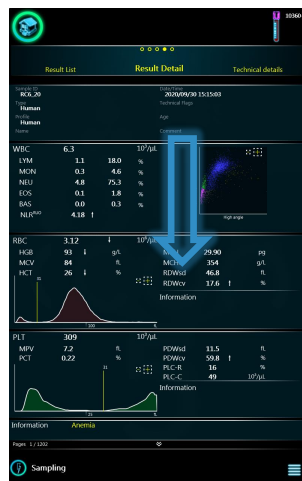
Touching (tapping) an active area (icon, data input field) will activate the corresponding function or open a sub-menu. For data input fields, an on-screen keyboard is displayed at the top or bottom quarter of the screen depending on the position of the data input field.



Swipe

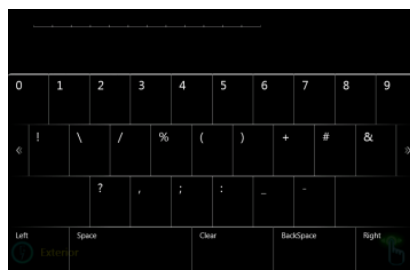
Hemolyzer 5 NG can display data that spans over several screens (pages). Such pages are indicated with small circles in the center near the top half of the screen.

To switch (scroll) between such screens, you need to perform a sweeping gesture by lightly touching the screen at any point of the screen showing data, and quickly sweep your finger in the direction of the intended scrolling action (up, down, left, right). The screen will be scrolled in the requested direction.



On-screen keyboard

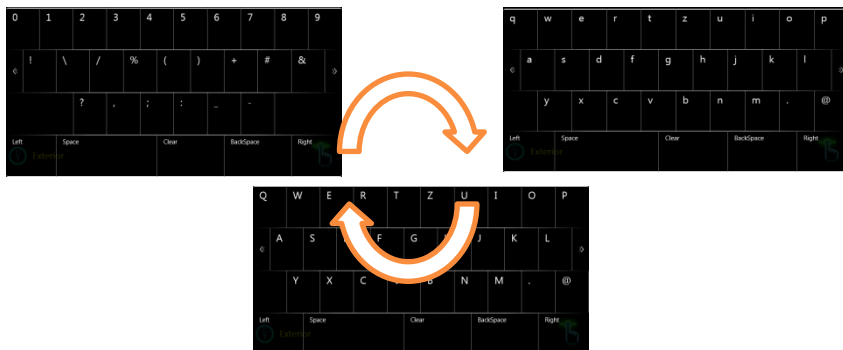
When you select to enter data, an on-screen keyboard will be displayed at the top or the bottom quarter of the screen. The position of the keyboard depends on the position of the data input field to avoid covering the field with the keyboard.



Data input

Alphanumeric input

Input fields are marked with an underscore. Tapping into any field allows editing data. The on-screen keyboard will be displayed either in the top or in the bottom quarter of the screen to make sure that the input field remains visible. The cursor is indicated by a light underscore below the character.



The on-screen keyboard allows changing symbols entered by changing the keys. The keyboard can be changed by swiping left or right to reveal capital letters, small letters and symbols.

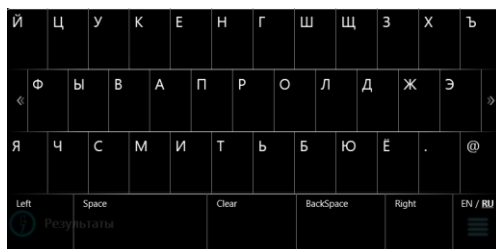
SPACE adds a space at the cursor.

CLEAR deletes the **entire** field.

BACKSPACE erases the character left of the cursor.

Russian layout

The keyboard can be accessed by setting the software's language to Russian, then choosing between "EN/RU" options on the bottom right corner of the On-screen keyboard.



External keyboard

If an external keyboard is connected to Hemolyzer 5 NG, then keystrokes from the external keyboard can be used to enter data into input fields. Keyboard layout is always US 101.

Barcode input

If an external barcode scanner is connected, then the read ID will be entered as Sample ID for the consecutive measurement.

This function is only active if the measurement function is activated. Barcode scanner data will not be interpreted as data for any other field.

To input barcodes:

- Make sure the analyzer is in measurement mode (ready to start)
- Scan the barcode with the handheld scanner

When a barcode has been recognized and interpreted, the bar-code will be entered into the Sample ID input field.

Numeric input

Some data fields may require modification on a larger scale. For this purpose, Hemolyzer 5 NG offers another intuitive setting method.

Sampling type		Auto Calibration			Manual Calibration		
	WBC	---	--	-	+	++	+++
	7.70 10 ³ /μL						
	RBC	---	--	-	+	++	+++
	4.83 10 ⁶ /μL						

Symbols ---, -- and – buttons will have decreasing effect on first, second and the third digit, respectively.

Symbols +, ++ and +++ buttons will have increasing effect on first, second and the third digit, respectively.

Description of icons displayed

	[Daily routine] Access measurement mode and results
	[Management] Access point of maintenance functions
	[Reagents] Reagent menu
	[Options] Settings
	[System] System administration utilities
	[Home] Back to the Main menu
	[WiFi] Wi-Fi network available
	[ETH] Wired network available
	[PrinterThermal] Thermal Printer connected
	[PrinterPCL] PCL5, PCL6, Host Based (ZJS) Printer connected
	[Printer] Unknown printer connected
	[Loading...] The analyzer is busy
	[QuestionMark] Measurement mode selection
	[Gift] New results are available
	[Vial] Available measurements of the installed reagent system
 E-mail	[E-mail] Send selected records in an e-mail
 TSF	[TSF] Save records into TXT file (Tab Separated File)

	[PDF] Save selected results into PDF file
	[LIS] Send results to LIS
	[Uncheck] Check/uncheck selected elements.
	[Drop] Discard elements
	[Reset/Load] Reset to original or default values/ Load data from external USB drive
	[Accept] Confirm and accept elements
	[Print] Print selected records
	[Eject] Remove vial from sampling rotor
	[Read] Read (scan) QR code
	[SelectionStart] Activates multi-selection
	[SameDay] Selects records of a specific date
	[SameSampleID] Selects records of a specific SampleID
	[CV] Calculate CV of selected results
	[Jump] Jumps to given date in records database
	[LoadW] Load wallpaper from USB mass storage device
	[SaveRAW] Save raw measurement data to USB mass storage device
	[ShutDown] Initiates shutdown sequence
	[ClosePage] Closes local menu

	[Calibrate] Loads mean of parameters as calibration target (selected records)
	[LoadProfiles] Load Profiles from USB mass storage device
	[SaveProfiles] Save Profiles to USB mass storage device
	[ResetMainToDefault] Reset Main Profiles to factory defaults
	[Full] External waste container is full. Tap for details.
	[Reset used reag.] If waste container limit is set, tap on this icon after draining the waste container
	[Menu] Access local menu
	[Results/technical view/Local menu] Set HGB absorbance curve of the actual database record as HGB reference
	[Results/technical view/Local menu] Clear HGB reference, reset to default
	ER mode selector button
	To exit ER mode (password protected)
	[Calendar Icon] Present if cleaning is recommended
	[Hide Cleaning] Ignore cleaning
	[Reagent pack replacement] Reagent pack replacement wizard
	[Check smear] smear examination of the blood sample is recommended

Setup

Hemolyzer 5 NG comes preprogrammed with the operating software, and has most its options set to standard values, values that suits most laboratories.

However, you can customize these settings to make Hemolyzer 5 NG fit into your daily routine even better. Here is a brief list of options that you are recommended to adjust or verify to make the use of the analyzer simple and convenient.

Initial setup

Below is a recommended sequence of settings so that you can start using the analyzer easily:

- choose a language for your analyzer
- practice gestures used on the screen
- set time and date
- set up your Laboratory information and measurement units
- set up your network and connectivity (email) (if available)

You can skip each stage; you can leave the setup wizard at any time. You can also (re)run the wizard at any time later.

Settings – Customize

Appearance

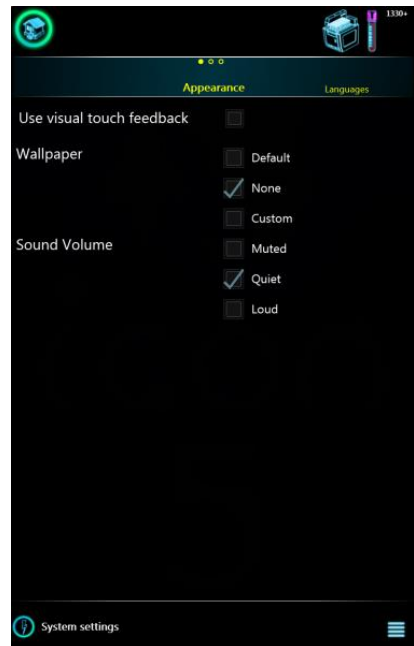
[Page 1]

You can disable the visual feedback of touchscreen gestures.

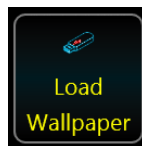
You can enable/disable audible touch feedback.

You can change the background image.

To use Custom wallpaper, use “Custom” setting, and load your wallpaper by accessing local menu and tapping the “Load Wallpaper” icon.



The wallpaper file must reside on a USB memory device, named "CustomWallpaper.png". Resolution must be **800 x 1280 pixels**. Do not use clear white or clear yellow images: this will impair screen readability.

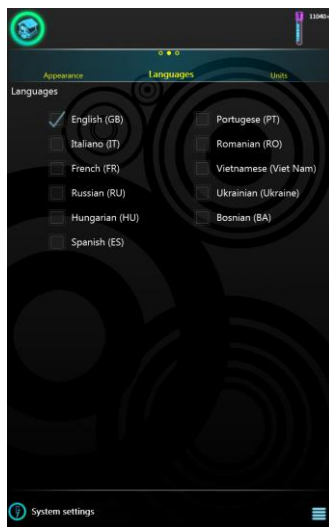


Hemolyzer 5 NG will confirm the new wallpaper file or will display an error message if the image is not of the right size, format, or it cannot be found in the root folder of the USB memory device.

Languages

[Page 2]

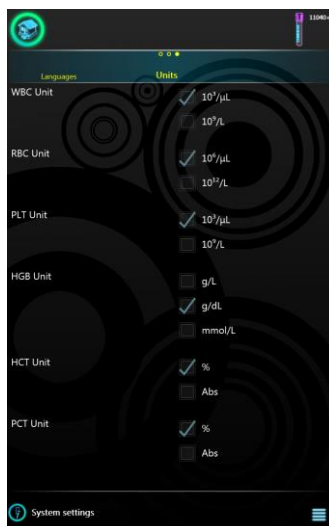
Language of the user interface can be changed. Changes have an immediate effect.



Units

[Page 3]

It also allows changing measurement units for parameters WBC, RBC, PLT, HGB, HCT and PCT.



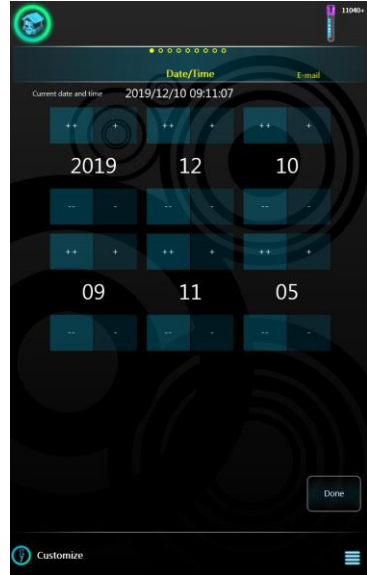
Functionality

This menu allows setting operation related parameters.

Date and time

[Page 1]

This menu allows changing the current date and time by pressing Done button.



E-mail settings

[Page 2]

This screen provides fields to set e-mail account parameters used for reporting:

- "Email to": Default "To:" address
- Sender e-mail address ("From:")
- "From:" email account password

It is necessary to define SMTP settings (default provider is Google because of compatibility issues).

For details, please consult your email provider. Gmail may require enabling "less secure apps" to allow the device to manage emails.

Some examples:

- Yahoo: smtp.mail.yahoo.com; 465 port; SSL
- Google: smtp.gmail.com; 465 port; SSL
- Office365: smtp.office365.com; 587 port; STARTTLS



You can choose to automatically generate and email the report in PDF format. Test your e-mail settings by tapping the “Test E-mail settings” button.

Network preferences

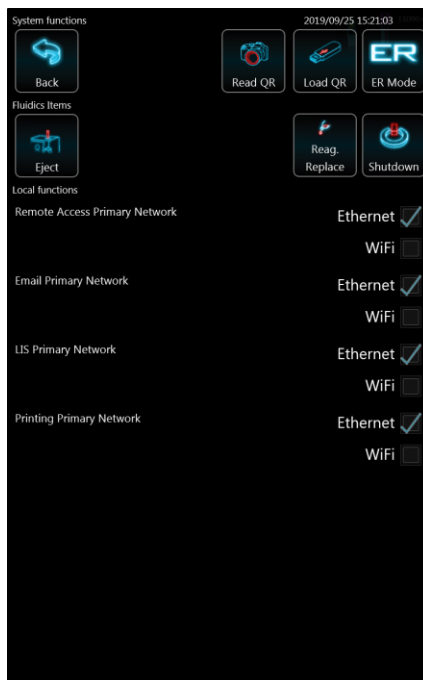
Hemolyzer 5 NG allows connection to networks over Wi-Fi or cable. Some processes may fail if they start communication over the wrong interface.

Tap the **Local Menu** on **Email settings page** to access Network preferences setting.

You can choose which interface (WiFi/Ethernet) to use for various activities:

- Remote Access
- Email transmission
- LIS transmission
- Network printing

Preferences can only be applied if both wired and wireless networks are available.



Printout Settings

[Page 3]

You can define some standard messages or comments to be included in a report generated by the analyzer.

Enter a header composed of 5 lines to be printed on all reports. These five lines can be left, center or right aligned.

Enabling “AutoPrint” will make Hemolyzer 5 NG print reports immediately upon completion of the measurement. (Requires connection of a printer or network printer)

It is possible to use A4 size paper with preprinted header. The preprinted header may be maximum 9 rows high.

Defining printout signature(s) will make Hemolyzer 5 NG print line(s) with the defined value(s) on the bottom of page. (Signature’s visibility on A4 formats depends on corresponding setting.)

You can force Hemolyzer 5 NG to use ESC/POS language for unrecognized printers.



WARNING

Forcing an incorrect language to a printer may result in scrambled printouts, and empty pages, even one single symbol per page!

Printout Format

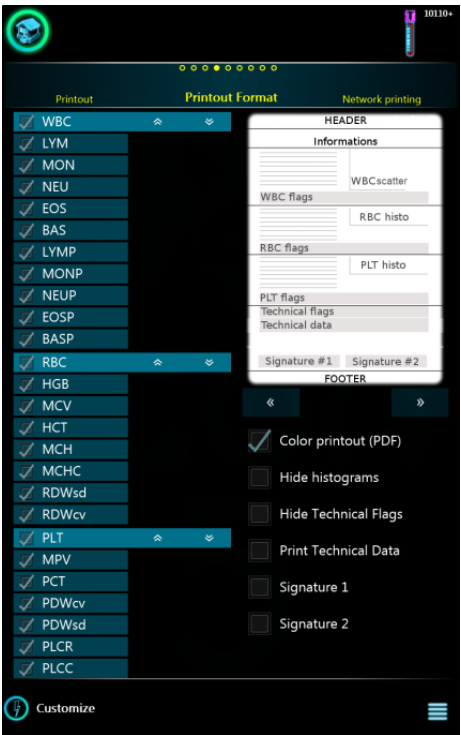
[Page 4]

You can choose between 3 different printout formats.

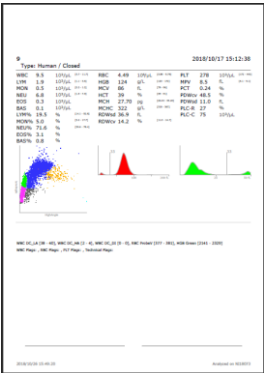
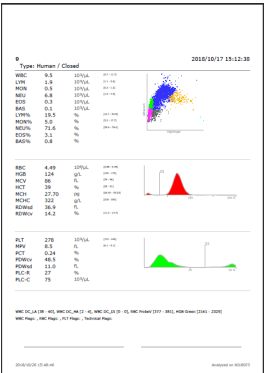
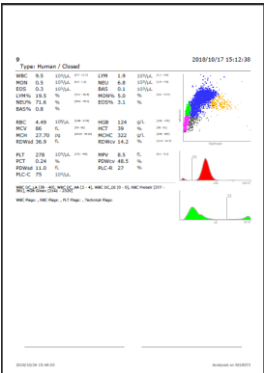
You can select which parameters you want to appear on the printout, and the order of appearance can also be customized.

Note: parameters cannot be moved within parameter groups. Parameter groups are separated by horizontal lines.

You can also choose whether you want the A4 reports to be colored or not, hide histograms, hide technical flags, print the technical data and show or not the signatures on the printout.



Color output is available for PDF, color printing depends on printer and its driver capabilities (PCL6).



Network Printing

[Page 5]

It is possible to use a **network printer** as a default printer – define the IP address and Port (consult your system administrator or printer manual for details) of the printer.

Select PCL5, PCL6 or Host Based (ZJS) language. Only these languages are available for network printing.

When all settings are made, you can print a Test page to verify the setup.



WARNING

Forcing an incorrect language to a printer may result in scrambled printouts, and empty pages, even one single symbol per page!
An incompatible printer may not even react to wrong messages, this way you get no feedback about the incompatibility.

It is possible to use Print server (PrintServer software is available from Analyticon) as a default printer. For more information, consult your distributor.

“PrintServer” allows the analyzer to use a remote PC (running Windows) and its connected printer to print reports.

You need to define the IP address and Port (consult your system administrator) of the PC running the Print Server.

When all settings are made, you can print a Test page to verify the setup.

Customization

[Page 6]

Defining Comment 1-3 values will change header of comment fields on printouts and user interface as well.

QC parameters: QC charts include only 11 parameters (WBC, LYM%, MON%, NEU%, EO%, BAS%, RBC, HGB, MCV, PLT, MPV) if short QC parameters mode is selected.

Used reagent limit: you can define the volume (in Liters) of the external container collecting waste liquids. When the free volume drops below 0.3L, there will be a Full container symbol in the upper right corner of the screen. If you set 0 as volume, Hemolyzer 5 NG will not display a warning at all.

Auto shutdown: The analyzer will automatically shut down at the selected time – expressed in integer hours, 24hrs format. E.g. 5 = 5:00am, 17 = 5:00pm.

You can choose to automatically generate and save a PDF report. This function requires connection of a USB mass storage device.

Enabling QC measurement warning allows the system to pop up a message about QC measurement importance after every daily startup.

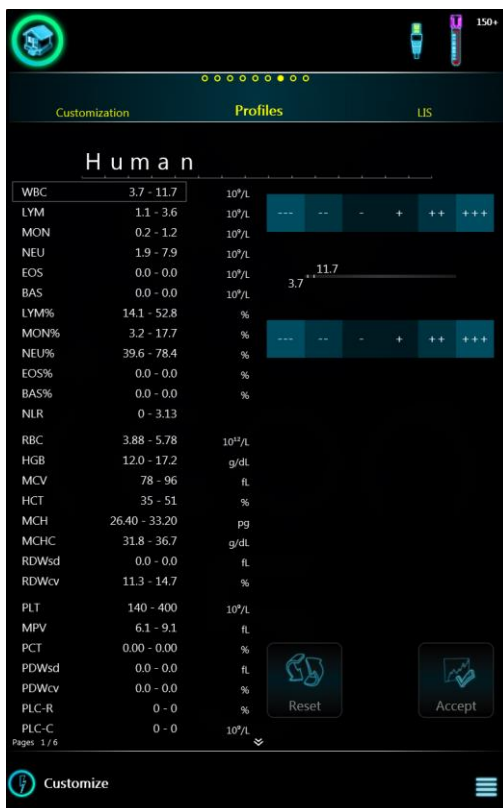
Profiles

[Page 7]

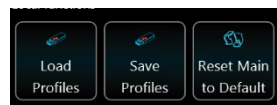
Minimum and maximum values of normal ranges can be set for each measured parameter (NLR^{RUO} lower range is fixed to 0.0). Measured values will be verified against these limits.

Hemolyzer 5 NG offers 7 profiles (Human, Male, Female, Profile 4-7). Swap between profiles by swiping up/down.

All limits can be changed. You can define custom names for Profile 4-7.



To backup/restore or reset to default predefined Profiles tap the Local Menu button.



- **Save Profiles** will save ALL profile normal ranges to the connected USB storage device.
- **Load Profiles** will load and overwrite ALL profile normal ranges from the connected USB storage device. There is no UNDO.
- **Reset MAIN to Default** will reset all Predefined (Human, Male, Female) to factory defaults. It will not change user defined profiles and their normal ranges

LIS - Laboratory information system

[Page 8]

Hemolyzer 5 NG is capable of transmitting reports using HL7 v2.5 protocol to a host computer.

This page allows setting HL7 server IP address along with the communication port and timeout value in seconds.

Automatic transmission of results can be enabled.

By enabling “Repeat Sample ID as Patient ID” the transmitting report will contain standard HL7 PID field which includes the sample identification string.

Keeping HL7 connection open after transmission can be enabled.

HL7 message format is depends on selected version. For more information requests for HL7 transmission protocol document.

You can receive worklists (sample information) in advance. To allow reception, define a receiver port and enable reception. The server must send sample data to the analyzer’s IP address (actual IP address can be checked by tapping the network symbol in the top row of the screen).

This page also allows setting up Remote Management parameters. For details, please contact your service personnel.

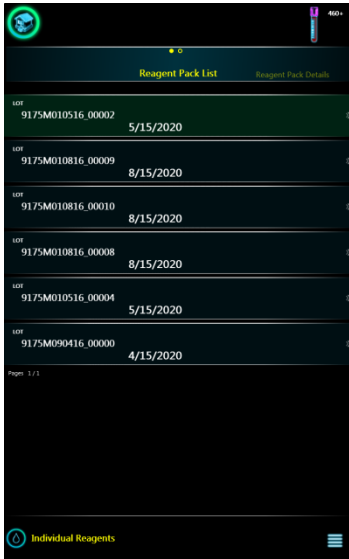
With LIS resend option you can set when the software should resend unsent LIS messages (in every 1/4/24 hours or never).

Setting up reagents

Hemolyzer 5 NG requires reagents to run. Connected reagents can be managed from the Reagents menu. Reagents menu has two separate branches: one for reagent packs, and one for individual (“Bulk”) reagents.

Reagent Pack

A list of reagent packs will be displayed. The active (currently used) pack will have a green background. Inactive packs have no coloring, expired or empty packs will have a dark red background.



Reagent Pack List		Reagent Pack Details
LOT	9175M010516_00002	5/15/2020
LOT	9175M010816_00009	8/15/2020
LOT	9175M010816_00010	8/15/2020
LOT	9175M010816_00008	8/15/2020
LOT	9175M010516_00004	5/15/2020
LOT	9175M090416_00000	4/15/2020

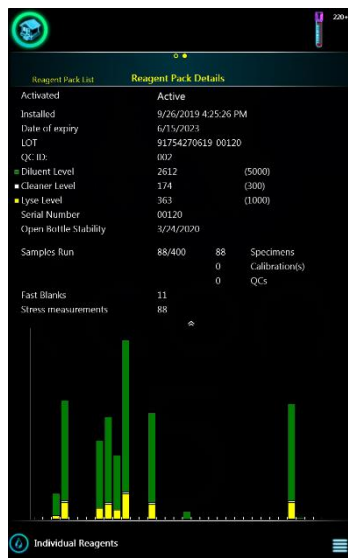
Page: 1 / 1

Individual Reagents

Swiping left on a row will bring up detailed information about the pack: LOT number, expiration, part (ordering) number, and level of the pack with consumption data, open bottle stability data (based on installation date) and usage statistics.

Activation and deactivation of reagents is possible through the local menu. Tap the Deactivate icon to stop using a pack. Tap the Activate icon to start using a pack.

Disabling a pack will not delete it from the reagent database.



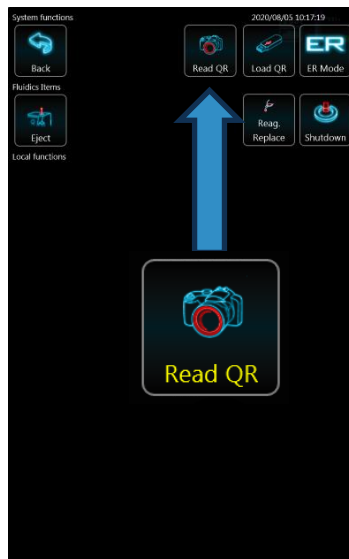
To add reagent packs to the system:

Hemolyzer 5 NG offers entering reagent pack data using the onboard camera. Analyticon provides reagent packs with QR codes.

To activate QR code reading sequence:

- tap the local menu icon
- tap the small camera icon.

The screen will change, and you will see a live image of what the camera “sees”. The camera is located in the center of the letter “o” in the Hemolyzer 5 NG text at the top right corner of the front cover.



Hold the QR code in front of the analyzer, making sure that the code is not curved or bent. The QR code should be located in the center of the live image.

Use the ON/OFF button with low ambient light and the screen will provide sufficient backlight for scanning a QR code.

Hemolyzer 5 NG will acknowledge the QR code with an audible tone. The data will be entered as a new reagent pack. If you scanned a code that already exists, Hemolyzer 5 NG will show a message.

To load codes from a USB flash drive, use the “Load” icon.



Individual Reagents

Tap on the Reagent icon in the main menu and then select “Individual”.

A list of individual reagents will be displayed.

You can see the details of actual reagents by tapping the row of a specific reagent. The active (currently used) reagent will have a green background. Inactive reagents have no coloring, expired or empty entries will have a dark red background.

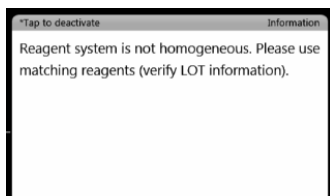
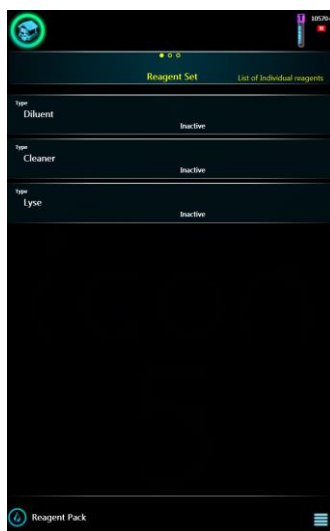
Swiping left on a row will bring up detailed information about the reagent: LOT number, expiration, part (ordering) number, and level of the container with consumption data.

Important note: individual reagents can only be used if the 2nd and 3rd LOT number for all three bulk reagents (Diluent, Lyse, iClean) are identical:

- 17 – reagents manufactured before September 2021.
- 14 – reagents manufactured from September 2021.

Mixing individual reagents is not possible and the analyzer may show an error message.

Tap the local menu button (lower right corner) to display the local menu when reagent data are displayed. Tap the Deactivate icon to stop using a reagent container. Tap the Activate icon to (re-) start using a reagent container.



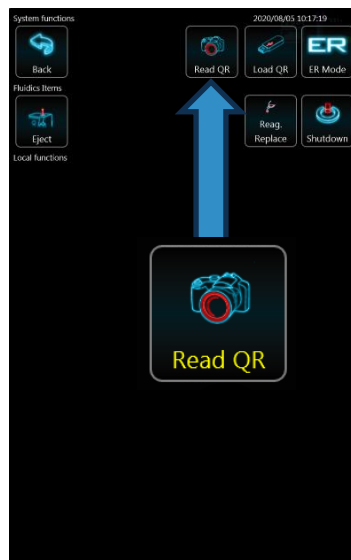
To add reagents to the system:

Hemolyzer 5 NG offers entering reagent data using the onboard camera. Analyticon provides reagents with QR codes.

To activate QR code reading sequence:

- tap the local menu button (lower right corner)
- tap the small camera icon.

The screen will change, and you will see a live image of what the camera “sees”. The camera is located in the center of the letter “o” in the Hemolyzer 5 NG text at the top right corner of the front cover.



Hold the QR code in front of the analyzer, making sure that the code is not curved or bent. The QR code should be visible in the center of the live image.

Hemolyzer 5 NG will acknowledge the QR code with an audible tone. The data will be entered as a new reagent pack. If you scanned a code that already exists, Hemolyzer 5 NG will show a message. All type of reagents should be scanned.

To load codes from a USB flash drive, use the “Load” icon.



Manual QR code entry

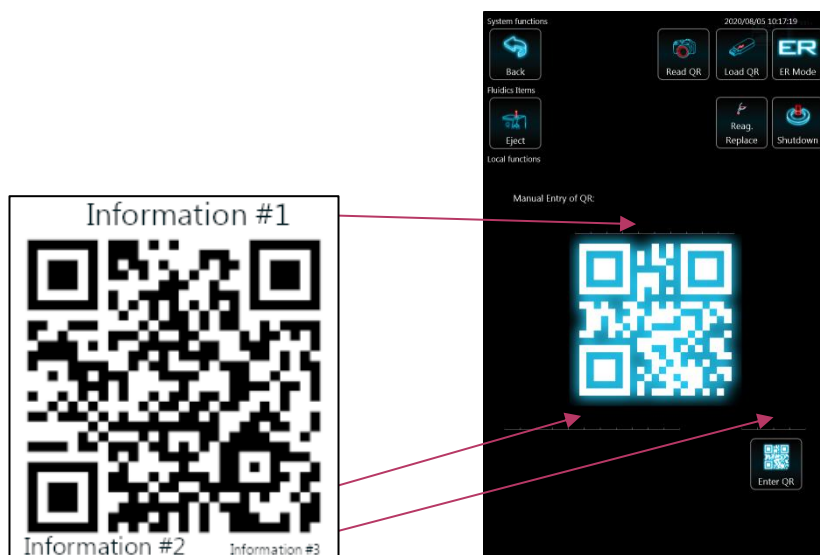
In some cases, the QR code could be damaged. In this situation the user can enter the QR code data manually.

Activate local menu in reagent pack list menu or in diluent, lyse or cleaner list menu.

Enter all data located around QR code into the corresponding data field.

After that tap the button below the data to confirm data.

The analyzer will not allow more than three false data entries. The analyzer must be restarted to try again.



New QR codes are available for reagents that are purchased after May, 2020. In case the older QR code version is damaged, please contact service.

Network Settings

You can make the most of Hemolyzer 5 NG's services if you let it connect to a network with access to the Internet so that it can create and send reports in e-mails, transmit data to your laboratory information system (LIS) and update software when necessary.

Network availability is displayed in the top row of the screen.

When a wired network is available, a network plug icon is displayed.

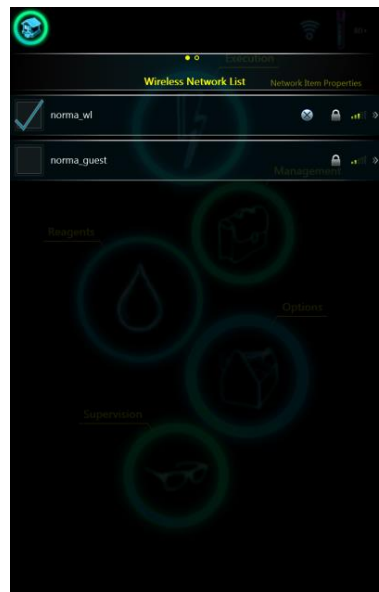
When Wi-Fi is available (a USB Wi-Fi adapter is connected) then a little signal strength icon appears in the top row.



Tapping on this icon brings up the list of available wireless networks.

Tap on a network to access its details.

Tapping on the X in the row of a network will remove it from the list of networks.



Wi-Fi settings

Wireless network connectivity supports the following encryption protocols:

- open
- shared
- WPA2 Personal
- WPA Personal

DHCP is always assumed for Wi-Fi.

If required, you can enter the password for the network, and then tap “Join” to start connecting.

For details on the network, please contact the local network administrator.



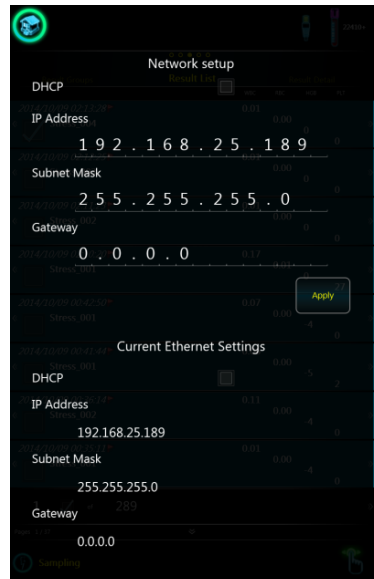
Wired network Settings

Access settings by tapping the network plug icon in the top of the screen.

Actual settings are displayed in the lower half of the screen. Enter your settings in the upper half of the screen.

If DHCP is enabled, you do not need to specify network related data.

If DHCP is not supported, please contact your network administrator for settings.



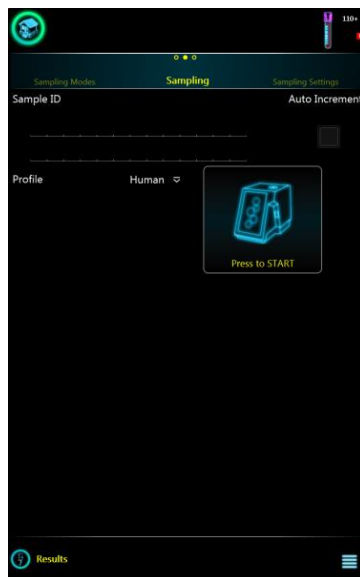
Daily operation

Your daily routine will mostly consist of powering on the analyzer, running samples with unique sample ID's and creating reports.

It is good laboratory practice to run QC material daily to ensure and allow controlling the performance of the analyzer on a day-to-day basis.

You will most probably create reports of the samples run and occasionally you will need to find earlier results of individual patients.

All these tasks are outlined below to give you an easy to follow guide and make laboratory work routine and fun to do.



Power on

Hemolyzer 5 NG will mostly be waiting in stand-by mode.

Push the START button to wake up the analyzer, the status ring on the top will change color.

The user interface will be displayed shortly, and the analyzer is ready for work.

The fluidic system will always require initialization, a programmed startup. This is indicated by a yellow analyzer in measurement mode.

Tap the yellow icon to start the initialization and will display FastBlank (system check) results. For best results, FastBlank values must be under the limits specified below:

- **WBC < 0.2** $10^9/L$
- **RBC < 0.05** $10^{12}/L$
- **PLT < 10** $10^9/L$

The system will repeat the FastBlank process once again if any measurement flags were detected or values were higher than the limits above.



Analyzer status

The backlit frame around the closed vial opening reflects the operation status of the analyzer.

	Color	Status
Device OFF	dark	off
Device OFF	solid red	high voltage from power supply
Device OFF	solid blue	low voltage from power supply
Device ON	pulsating green	ready to measure
Device ON	pulsating orange/amber	instrument is busy
Device ON	solid red	internal power failure
Device ON	flashing red	remove sample

Running samples

To start measurements, tap **Daily routine** and then tap „*Sampling*“.



It is recommended to verify the accuracy of measured parameters. The practical method is running a QC measurement using control material.

Enter data using the on-screen keyboard or the external keyboard.

Select a profile by tapping the Profile list.

You can enter additional patient data by swiping left. You can access LIS order list by swiping to the far right.

Sampling

Enter Sample ID

Select Profile

Start

Sampling Settings

Enter Patient data

LIS order list

Access Worklist and choose sample data

LIS order list data are sent by the LIS server. Tap a record to use the data for sample data fields. Upon completion of a sample, the corresponding record will be removed from the LIS order list.

To delete LIS order list elements without using its patient data, select the actual record, and “Drop” the record. LIS server can also delete entries remotely.

Mix the sample as described on **page 34**, and put the closed sample vial into the sample opening on the top of the analyzer.

Tap START to start sample processing.

Introducing a Sample

	The opening on top of Hemolyzer 5 NG for Closed vials is designed to receive blood collection vials of defined dimensions with caps on.
	To avoid personal injury, do not put your finger into the opening. Avoid placing objects other than blood collection vials to avoid damage to the analyzer.
	Avoid putting vials without caps into the sampling mechanics.
	Avoid putting more than one barcode label onto the blood collection vial to avoid the vial getting stuck in the sampling mechanics.
	Hemolyzer 5 NG's sampling mechanics is equipped with a cap detector. Cap detector operation may be impaired by additional labels put on the sample vial and Hemolyzer 5 NG may refuse to run such vials.

Tapping the analyzer symbol in the center will start the measurement.

Hemolyzer 5 NG will lower the sample vial into the sampling mechanics and will take a sample with its built-in cap piercing needle.

When the sample has been taken, the vial will be returned to the operator.

Results will be available in a minute.

A new available result will be indicated by a small icon in the lower right corner of the screen. Tapping this icon will take you to the Results screen and the latest data will be displayed on the screen. If more than one result is available, then this icon navigates to the list of results, with the latest result highlighted.



Results

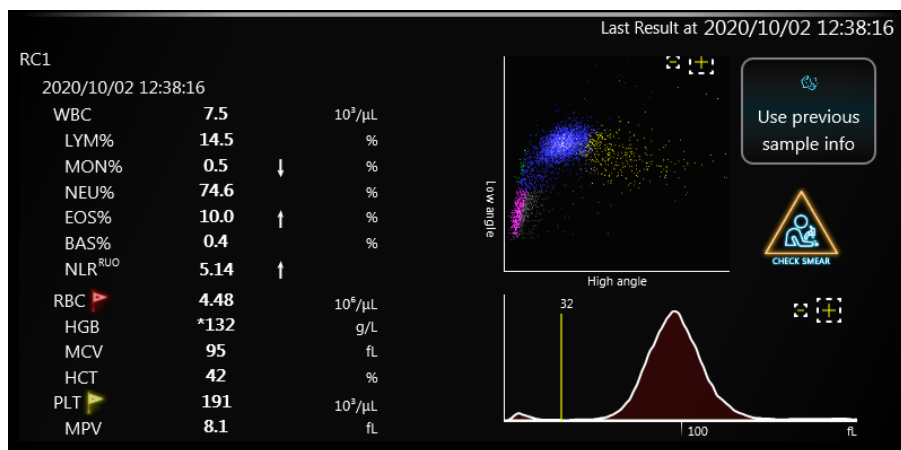
Hemolyzer 5 NG can display results in two ways:

- a short version of results during measurement in the lower half of the screen;
- a full (detailed) view accessible in “Results” (database)

Short (Quick) result

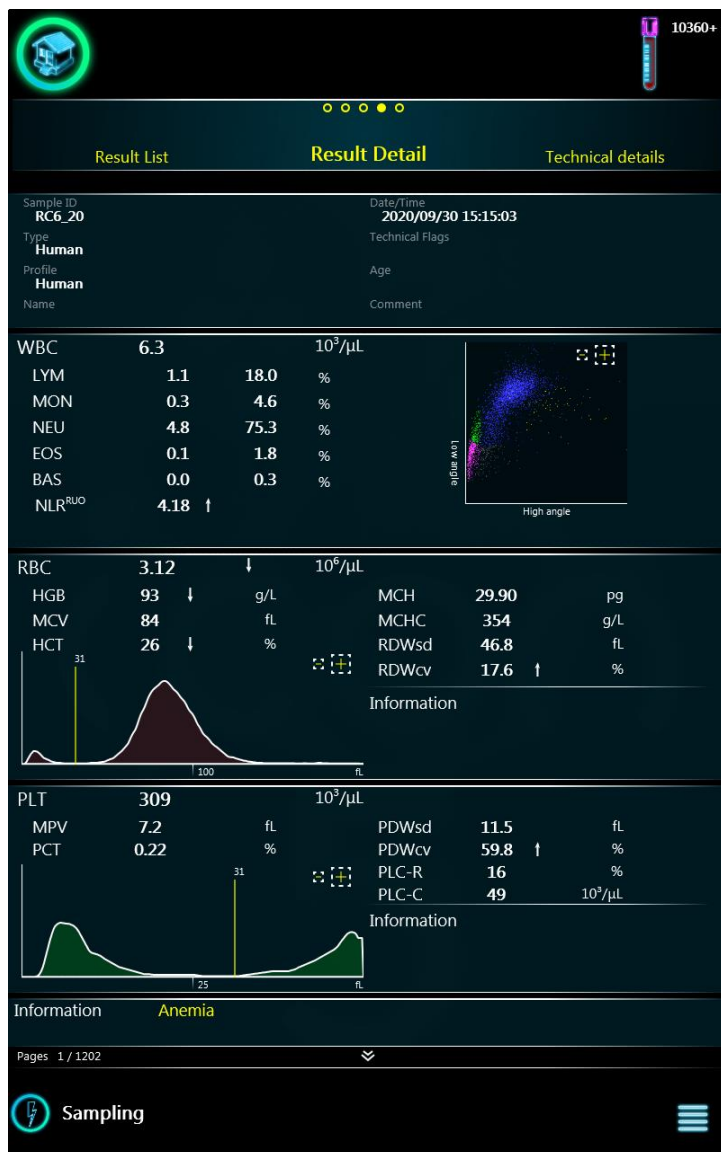
The result appears in the lower half of the screen. Only 13 parameters are displayed. You can tap the values for details, and you can tap the scattergram or histogram for a zoomed view.

If flags are displayed, tap on values to see flag messages.



Full result (Full screen)

Full, detailed results are available from the Main menu under Execution / Results.
Flags are displayed in yellow color.



Flags

The screen below intentionally contains flags.



A small red flag indicates that the system detected a condition that requires attention. Yellow flags mark interpretation data. Flags with yellow text indicate technical and interpretative flags, messages related to the evaluation process of the sample. Most of these flags require the sample to be rerun. Arrow symbols next to values indicate that the numerical result is beyond actual minimum or maximum values of normal or healthy range.

Technical flags

Hemolyzer 5 NG can display technical warning flags. Flags can appear in various locations, depending on significance and relevance. Flags by the Sample ID refer to sampling mistakes. Flags displayed in WBC, RBC and PLT groups refer to parameter related irregularities. Technical flags give guidance for the user, an indication of not operating the analyzer as recommended.

Flags have different levels of significance. Each flag has two confidence levels. As long as results are not negatively influenced by the detected conditions, results will be displayed along with the flags. As soon as severity of the problem goes beyond safe result interpretation, and would impact readings, values will be dashed out.

List of Technical Flags

Abnormal Diff	
Meaning	The scattergram was found abnormal. This may be the result of an over-mixed sample, an old sample (please, see “Sample handling” section – page 35), presence of unlysed RBCs, or bubbles in the optical channel.
Type	WBC
Effect on result	If the significance of the problem is LOW: Diff# and Diff% results are marked with * If the significance of the problem is MEDIUM: Diff# and Diff% results are NOT displayed. If the significance of the problem is HIGH: WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	Let the sample rest for 20 minutes, then rerun the sample. If WBC populations on the scattergram cannot be clearly seen, please, do a microscopic check on the sample. 

Analysis Error	
Meaning	Measurement data processing error in the optical (WBC) or the impedance (RBC) module.
Type	Technical
Effect on result	Results are NOT displayed.
Resolution	Rerun sample. If the problem persists, contact Service.

Contamination	
Meaning	The system detected incorrect cell data over the RBC aperture.
Type	RBC
Effect on result	RBC and PLT parameters are marked with *.
Resolution	Run the “RBC Hard Cleaning” procedure available in the Management / Cleaning menu.

Data Loss	
Meaning	Data acquisition error in the optical (WBC) or the impedance (RBC) module.
Type	WBC, RBC
Effect on result	Results are NOT displayed.
Resolution	Rerun the sample. If the problem persists, contact Service.

Deflected WBC Flow	
Meaning	The flag is displayed when the analyzer detects in a sample almost zero WBC count, while there is also normal HGB values present.
Type	WBC
Effect on result	WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	Rerun the sample.

Diff Fallback	
Meaning	WBC differential algorithm detected overlap of WBC populations, and to avoid misinterpretation, a default algorithm is used for generating DIFF results.
Type	WBC
Effect on result	Diff# and Diff% results are marked with *
Resolution	Rerun sample. If the flag appears, it is recommended to examine blood smear to determine differential results.
	

EOS Fallback	
Meaning	The differentiation algorithm found a NEU-EOS excessive overlap, NEU and EOS values may be inaccurate.
Type	WBC
Effect on result	Diff# and Diff% results are marked with *
Resolution	Consider inspection of blood smear. 

Flow error	
Meaning	RBC/PLT analysis reported unacceptable data.
Type	RBC
Effect on result	RBC and PLT results are NOT displayed.
Resolution	Run RBC cleaning and rerun the sample.

HGB missing	
Meaning	No data (or insufficient amount of data) could be registered during the HGB measurement.
Type	RBC
Effect on result	NO HGB results are displayed.
Resolution	Rerun the sample.

Improper Pressure	
Meaning	During WBC/HGB measurement continuously running injectors build sample flow in the HGB and WBC measuring heads, while a pressure sensor is monitoring the process. If the pressure increases beyond a certain limit, the analyzer stops the measurement to avoid damages caused by overpressure. According to statistical data, such clogging may happen spontaneously in 0.5% of the sample runs, but most likely will disappear by itself.
Type	Technical
Effect on result	WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	Please make sure that the sample has no clot in it. Rerun the sample. If problem persists, run WBC debubbling.

Improper Voltage	
Meaning	During RBC measurement the electrode voltage is monitored. If there is a clogging in the aperture, or the temperature of the diluent/analyzer is too low, then electrode voltage may get too high. If the aperture gets physically broken, then electrode voltage may be too low. This problem can be caused if the reagents are misconnected (e.g. diluent vs lyse).
Type	RBC
Effect on result	RBC and PLT parameters are marked with *. RBC and PLT results are NOT displayed.
Resolution	Check reagent connections. Prime Lyse and Diluent reagents, run RBC cleaning. If problem persists, contact service.

Improper Voltage	
Meaning	Internal liquid flow was disturbed by bubbles or contamination.
Type	WBC
Effect on result	WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	The system runs Debubbling automatically. If the problem persists, run WBC Hard Clean with H5-Opticlean.

Linearity Range Exceeded	
Meaning	The results are beyond the linearity range of the analyzer.
Type	RBC, WBC
Effect on result	WBC results are displayed if >250. RBC results are displayed if >18.
Resolution	Run the sample after 1:1 predilution.

Low Pressure	
Meaning	During WBC/HGB measurement continuously running injectors build sample flow in the HGB and WBC measuring heads, while a pressure sensor is monitoring this process. This flag is triggered if the pressure is not reaching the desired level.
Type	Technical
Effect on result	WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	This can be caused by bubbles, run WBC debubbling. If the problem persists, contact service, there may be a leakage inside the analyzer.

Low Sample Volume		
Meaning	There was an inadequate quantity of sample in the sampling vial. Other causes can be: - Running CSF or PRP sample, or if the sample is prediluted - There may be clogging in the sampling system.	
Type	Technical	
Effect on result	Results are marked with *.	
Resolution	Cause	Solution
	Inadequate quantity of sample	Please observe minimum sample volume guidelines (page 20).
	Running CSF or PRP sample, or if the sample is prediluted	It is normal in such cases.
	There may be clogging in the sampling system	Run H3/H3-Hypoclean as sample to remove clog, then rerun the sample. If the problem persists, contact Service.

Noise		
Meaning	Disturbing signals were detected during RBC/PLT measurement.	
Type	RBC	
Effect on result	RBC and PLT results are NOT displayed.	
Resolution	Cause	Solution
	Internal tubing or aperture is contaminated due to protein or lipid build-up from samples	Run RBC cleaning to clean internal tubing and aperture. Run H3/H3-Hypoclean as sample several times.
	Contaminated diluent	Replace diluent, prime and run several FastBlank cycles to see if the problem is solved.
	Electrical noise generates fake pulses due to improper grounding/electrical interference	Check protective earth and grounding system. In most cases this is caused by incorrect grounding, or a damaged/missing protective earth wire in the power outlet. If the problem persists, contact Service.

Noise	
Meaning	Some bubbles may have formed inside the optical head during WBC analysis.
Type	WBC
Effect on result	If the significance of the problem is LOW : The system will automatically start a WBC debubbling process. If the significance of the problem is HIGH : WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	Rerun sample. If problem persists, run WBC hard cleaning using H5-Opticlean reagent.

Overload	
Meaning	Too many particles (electronic noise) detected during measurement.
Type	RBC
Effect on result	RBC and PLT results are NOT displayed.
Resolution	Rerun the sample. Check reagent connections. Run RBC/WBC Hard cleaning. If problem persists, contact Service.

RBC Slice	
Meaning	RBC/PLT measurement detected an internal homogeneity error, RBC and PLT counts will not be displayed.
Type	RBC
Effect on result	RBC and PLT results are NOT displayed.
Resolution	Rerun the sample. If the problem persists, contact Service.

Sampling Error	
Meaning	MCHC is over 500 g/L. The analyzer calculates MCHC using results of RBC and HGB measurements. Since WBC/HGB and RBC/PLT are measured from two separate sample portions, if the RBC/PLT sample portion contains bubbles or aspiration was improper, then RBC may be lower which leads to high MCHC results.
Type	Technical
Effect on result	Results are NOT displayed.
Resolution	Please observe minimum sample volume guidelines (page 20). If the sample volume is sufficient, rerun the sample. The flag can also indicate an internal obstruction in the sampling system. If flag persists, contact Service.

Unintelligible Histogram	
Meaning	Internal sample flow in the optical head was not homogenous.
Type	WBC
Effect on result	WBC, Diff# and Diff% results are marked with *
Resolution	Rerun the sample. If problem persists, run WBC debubbling and WBC hard cleaning with H5-Opticlean. If problem still persists, contact service.

Unstable HGB	
Meaning	Unstable HGB flag is displayed if the HGB absorbance curve falls outside the boundaries – represented by the yellow lines on the HGB absorbance diagram below. The absorbance curve may move back and forth if bubbles are present in the lyse tubing.  The yellow boundaries are “programmed” into the analyzer by selecting a reference measurement and setting it as “HGB reference”.
Type	RBC
Effect on result	HGB result are marked with *
Resolution	Rerun the sample. If the problem persists, run WBC debubbling. <u>Set another measurement as HGB reference as follows:</u> select a measurement in database, then go to technical view (swipe left) tap on Local menu and then tap on Set as HGB reference. 

Unstable HGB baseline	
Meaning	Unstable HGB baseline is displayed if the beginning of the HGB absorbance curve is not stable. This part of the absorbance curve is HGB blank, there must be at least 3 stable points detected to have a good baseline for HGB calculation.  HGB Max place 10 HGB Arrival 4.79
Type	RBC
Effect on result	HGB results are NOT displayed.
Resolution	Rerun the sample. Run WBC debubbling to remove bubbles. If problem persists, contact Service.

Unstable Voltage	
Meaning	The electrode potential of the RBC/PLT measurement was not stable during counting. This can be caused by bubbles or temporary clogging of the aperture.
Type	RBC
Effect on result	RBC and PLT results are NOT displayed.
Resolution	Rerun the sample. Run RBC clean or run H3/H3-Hypoclean as sample to clean sample path.

Unstable Voltage	
Meaning	Internal liquid flow was disturbed by bubbles, or temporary block of the liquid flow was detected.
Type	WBC
Effect on result	WBC, Diff#, Diff% and HGB results are NOT displayed.
Resolution	Rerun the sample or run WBC debubbling or WBC hard clean using H5-Opticlean.

Interpretative Flags

This flagging function will display text if a given parameter is outside the normal range. These flags will appear in the information box below the results.

Parameter	Low flag	High flag
WBC	Leukopenia	Leukocytosis
LYM	Lymphopenia	Lymphocytosis
MON		Monocytosis
NEU	Neutropenia	Neutrophilia
EOS		Eosinophilia
BAS		Basophilia
RBC	Anemia	Polycythemia
MCV	Microcytosis	Macrocytosis
MCHC	Hypochromia	Hyperchromia
RDW sd		Anisocytosis
PLT	Thrombocytopenia	Thrombocytosis
MPV	Microcytic PLT	Macrocytic PLT

Diagnostic flags

The analytical algorithm can hint presence of populations which may require blood smear analysis of the sample. The flags listed below are triggered by the presence of cells in specific regions of the WBC scattergram.

Text displayed	Meaning
VarLym	Lymphocytes in different sizes and morphology
IG	Immature Granulocytes
Lyse-resistive RBC	Lyse-resistant RBCs (nRBCs or RBCs containing foetal HGB)
PLT Clumps	Aggregated PLTs

It is recommended to inspect samples marked by any of the diagnostic flags under microscope.

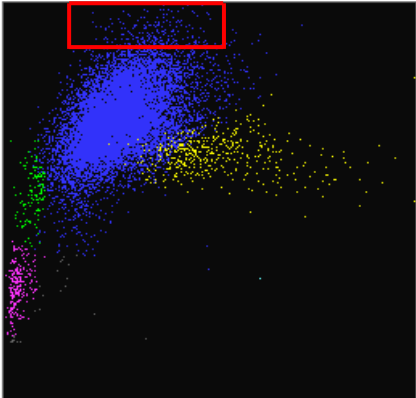
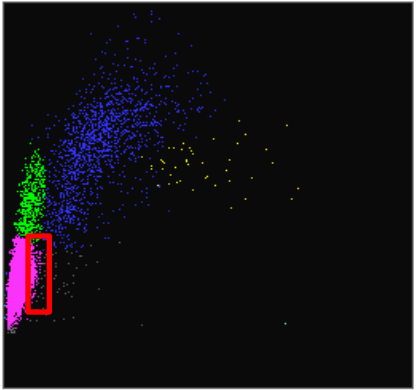
Based on a clinical evaluation by comparing 274 samples on Hemolyzer 5 NG and an Abbott CELL-DYN Sapphire the following specificity and sensitivity performance values were achieved.

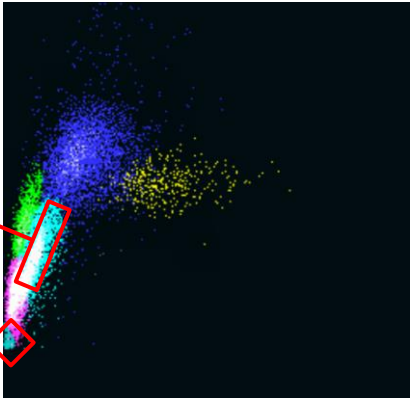
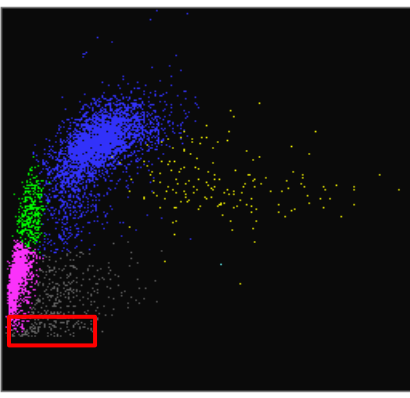
A CELL-DYN Sapphire was chosen for the evaluation as it showed outstanding sensitivity and specificity results in various studies.

Diagnostic accuracy of diagnostic flags	Immature granulocytes	Variant lymphocytes	PLT clumps
<i>Sensitivity</i>	<i>81%</i>	<i>69 %</i>	<i>92 %</i>
<i>Specificity</i>	<i>97%</i>	<i>97 %</i>	<i>93 %</i>

There is no clinical data on sensitivity and specificity of Lyse-resistive RBC flag.

The diagnostic flags will be triggered if high number of cells detected in the following areas of the WBC scattergram indicated by red rectangles.

Flag	Area of relevance on the WBC scattergram
Immature granulocytes (IG)	
Variant Lymphocytes (VarLym)	

Flag	Area of relevance on the WBC scattergram
Lyse-resistant RBC Lyse Resistive RBC #2 Lyse Resistive RBC #1	 A WBC scattergram plot with a black background. It shows several clusters of colored dots: a large blue cluster in the upper center, a green cluster on the left, a yellow cluster on the right, and a magenta cluster at the bottom left. Two red rectangular boxes are drawn on the magenta cluster. Two red lines originate from the text 'Lyse Resistive RBC #2' and point to the upper red box. Another two red lines originate from the text 'Lyse Resistive RBC #1' and point to the lower red box.
PLT clumps	 A WBC scattergram plot with a black background, showing the same distribution of colored dots as the first scattergram. A red rectangular box is drawn on the magenta cluster at the bottom left, which is identified as PLT clumps.

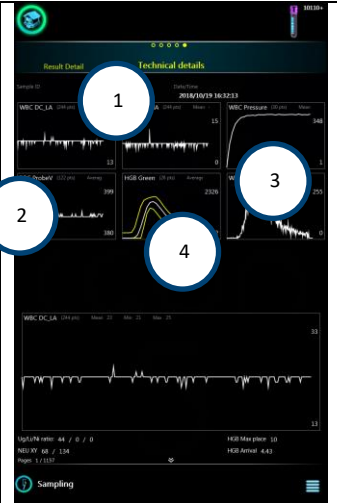
Technical data of a measurement

The measurement process is complicated and requires analyzing lots of data. The system stores and allows revision of some details of the measurement. These data become available upon swiping to the right of the full result screen.

Technical view screen shows:

- 1) optical channel data (laser scatter analysis);
- 2) the condition of the aperture used for particle counting;
- 3) the stability of the sample flow (pressure) over the optical unit;
- 4) the absorbance curve measured by the photometer during HGB measurement process.

The image in the bottom is a zoomed version of the curve you tap on.



These data become important if the analyzer encounters and internal problem that triggered a technical flag.

Most internal problems can be and are resolved either by automated processes or by asking for intervention or help from the operator.

Cleaning actions will be recommended based on the nature of the problem: an optical module based problem (1) will trigger an optical head cleaning process; a problem related to the aperture (orifice) of the particle counting module (2) will trigger the cleaning of the RBC aperture.

Clots, sampling errors can be tracked on the pressure diagram (3) or on the aperture condition curves (2).

Sample concentration over the optical head is also registered by the photometer during HGB content measurement. The sample flow and concentration change are good indicators of the fluidic system. The sample flow speed and the rate of the absorbance change are characteristic to the analyzer. If the system detects

significant change in these parameters, then an “Unstable HGB” or “Unstable HGB baseline” flag will be triggered.

This screen allows adjusting “HGB Reference” that allows fine tuning sample flow characteristic. To access this function, tap on the “local menu” button in the lower right corner of the screen. For details, please check Hemoglobin measurement method (**page 15**) and Technical flags (**page 69**).

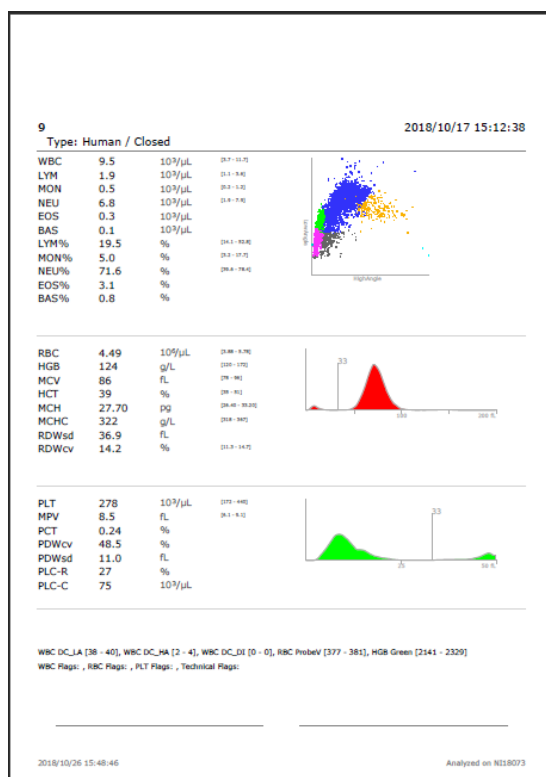
Reports

PDF

Hemolyzer 5 NG is able to send reports ready to be printed via e-mail or is able to save reports to USB mass storage device.

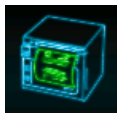
Reports include all entered patient data, along with reported parameters, **scattergram**, histograms and additional notes, comments created using the analyzer during or after analysis.

PDF printout format is selectable in Options menu.



Printer (Thermal)

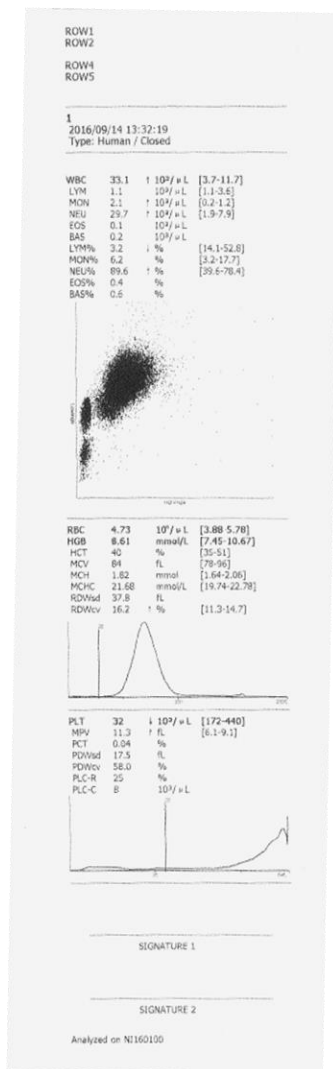
Hemolyzer 5 NG is able to send report to connected thermal printer. When Hemolyzer 5 NG detects Thermal printer is connected proper symbol will be shown on status bar.



A printer report looks as shown on the image to the right.

It is possible to hide histograms from the printout. For details, see Settings / Printout.

Hemolyzer 5 NG will acknowledge a printer as Thermal printer if it supports the ESC/POS language.



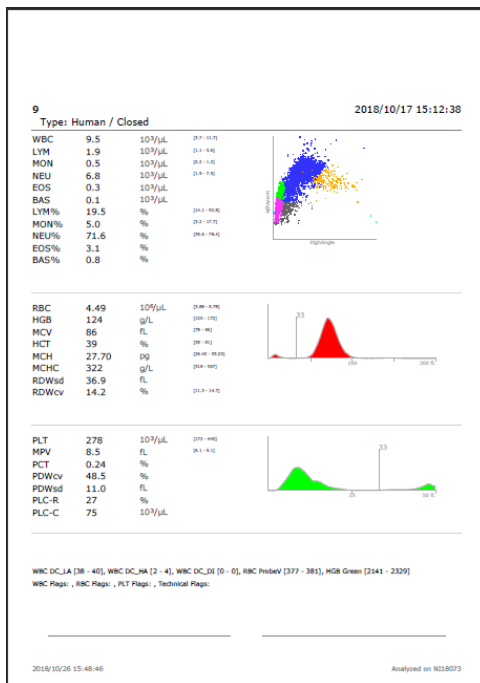
Printer

Hemolyzer 5 NG is able to send report to connected printer. When Hemolyzer 5 NG detects that a compatible printer is connected, then the symbol below will be shown on status bar.



Printout format depends on user setting.

It is possible to hide scattergram/histograms from the printout or change order of parameters. For details, see Settings / Printout.



Hemolyzer 5 NG supports a limited set of printer languages. The printer must support one of the following languages:

- **PLC5/PCL6, Host Based (ZJS)**
- **ESC/POS**

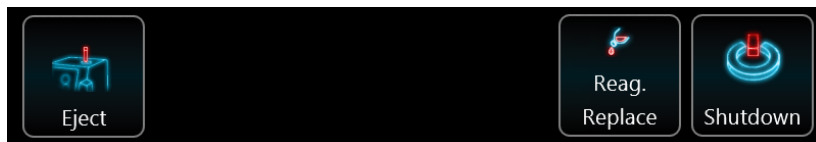
Printers not supporting the above printer languages will trigger a printer symbol with a question mark on the screen, and will print scrambled reports, or a lot of empty pages.

Hemolyzer 5 NG can be forced to use ESC/POS language for unknown printers. Forcing a specific language for a printer may result in empty pages or missing, unrecognized characters.

Power off

A regular power off can be initiated at any time. Processes that actually run the fluidic system cannot be interrupted.

To power off, tap the local menu button. A quick menu will be displayed offering various actions including shutdown (power off).



Shutdown will prepare the system for a longer period of inactivity. The process takes about 3 minutes after which the system will automatically power off, leaving Hemolyzer 5 NG ready to be disconnected from the mains if necessary.

If a control vial with H3/H3-Hypoclean (hypochlorite solution) is inserted into the sample opening of the analyzer, it will automatically perform the Needle Cleaning procedure.

ER mode

Hemolyzer 5 NG is able to run in ER (*"Emergency Room"*) mode. In ER mode user has limited access to user interface functions.

The user can access Sampling, Results and Maintenance functions. This mode allows operating the analyzer in an environment where users do not deal with analyzer setup on a daily basis. Settings are however accessible with a password.

ER Sampling

Some operations are available like in the Execution menu Sampling submenu with restrictions:

- mandatory SampleID function could be activated by service personnel
- Auto-increment option could be disabled by service personnel
- calibration cannot be accessed

Additional feature is automatic QC mode detection. If existing QC LOT identifier is entered into SampleID field Hemolyzer 5 NG will mark the upcoming measurement as QC measurement.

ER mode behavior can be set up in Service Menu. For details, see next pages.

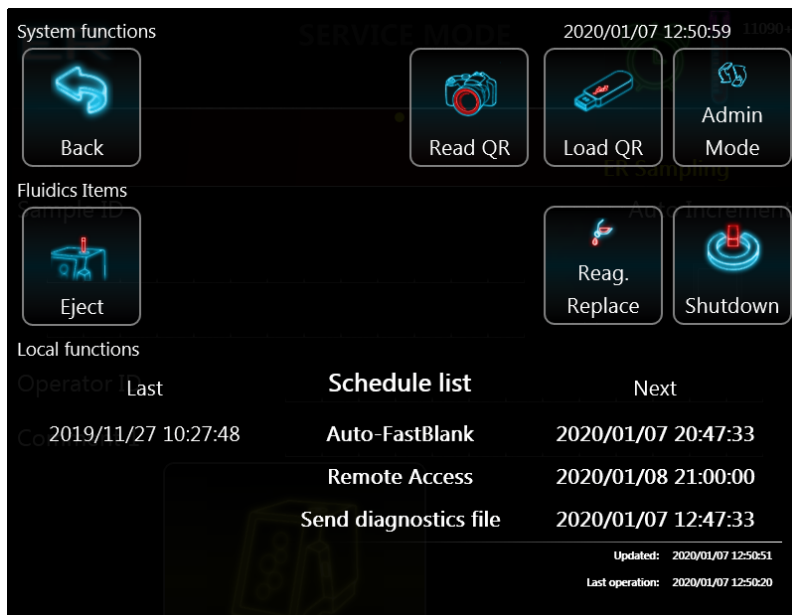


Alarm Clock symbol



When automatic maintenance and management functions are enabled in Service Menu, Hemolyzer 5 NG will display a green alarm clock symbol in the top of the screen.

Tapping on this symbol will display a screen which displays scheduled events.



Note the times and dates when specific functions can be initiated by the analyzer.

ER Results

Same operations are available like in the Execution menu Results submenu with restrictions:

- calibration results are unreachable

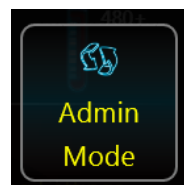
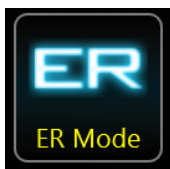
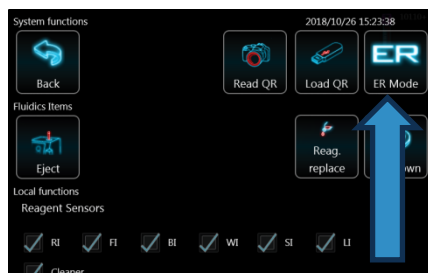


Possible options in ER mode (Service Setting required):

- Forced Sample ID, Operator ID
- Auto increment option can be disabled
- Disable Profile selection (Human limits will be used)
- Use previous SampleID function can be disabled
- WBC differential result can be disabled
- Adjustable FastBlank limits for WBC, RBC and PLT values
- Sampling menu is automatically displayed after 5 minutes of inactivity
- additional vial rotation (5x) via SampleRotor can be enabled

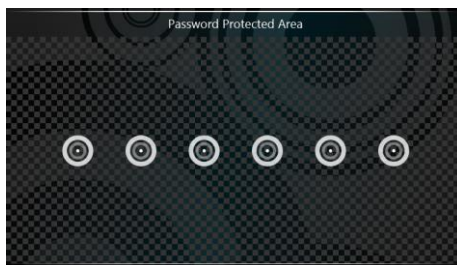
Switching between ER and Admin mode

User can change between ER and Admin mode by accessing local menu.



Switching from ER mode to Admin mode requires a password.

The password is a series of 6 (six) "Tap" gestures



Calibration

Hemolyzer 5 NG just like any laboratory analyzer can be calibrated. For this purpose, Hemolyzer 5 NG offers two ways to perform this task. Hemolyzer 5 NG arrives to your laboratory factory calibrated.

Calibration is necessary if laboratory standards require it, or when maintenance actions require you to do so. You may need to calibrate upon installing new reagents.

Target values

Calibration is performed comparing the reported values of the analyzer to a known specimen, or standard. Hematology analyzers have their own calibrator materials called Hematology Calibrators.

A calibrator material is made by using human samples mixed with specially treated particles to guarantee stable values for parameters over the stability period of the calibrator material. All calibrator products come with a list of the target values of calibrated parameters.

It is recommended to use **Analyticon H3/5-Cal for Hemolyzer 5 NG**.

These target values represent the standard to which your analyzer's reported values are compared.

Automatic calibration

Hemolyzer 5 NG offers an automatic calibration method to keep the process as simple as possible.

The steps of automated calibration are as follows:

- enter target values
- run the calibrator material a specified number of times
- accept the calibration result

Hemolyzer 5 NG can calibrate the below measured parameters:

- WBC, RBC and PLT count
- HGB, MPV, RDWcv and MCV value

Tick the box in front of parameters you want to calibrate.

Enter target values either by defining the expected values of the calibrator found on the accompanying insert or, scan the special barcode containing all these data using Hemolyzer 5 NG's built-in camera.

Sampling type	Auto Calibration		Manual Calibration	
WBC	---	---	-	+
7.50 $10^9/\mu\text{L}$	---	---	-	+
RBC	---	---	-	+
4.50 $10^9/\mu\text{L}$	---	---	-	+
HGB	---	---	-	+
150 g/L	---	---	-	+
MCV	---	---	-	+
89 fL	---	---	-	+
RDWcv	---	---	-	+
%	---	---	-	+
PLT	---	---	-	+
300 $10^9/\mu\text{L}$	---	---	-	+
MPV	---	---	-	+
8.6 fL	---	---	-	+

Press to Init

Results

Insert the vial with the calibrator material into Hemolyzer 5 NG's sample opening, and press START.

Hemolyzer 5 NG will run the sample and will calculate the mean values of the measured parameters. The mean value will be used to calculate the calibration factors using the formula below

$$CAL_{parameter(new)} = \frac{Parameter_{target}}{Parameter_{mean}} * CAL_{parameter(old)}$$

Each sample run will be listed on the screen, with each parameter to be calibrated.

Consequent measurements (samples) will be displayed on small Levey-Jennings charts, each sample represented by a small dot. This screen allows a quick overview of the process, displaying calculated Mean and CV values.

Highlighted samples can be deleted ("Drop") from the list of measurements.

Red highlight indicates that accepting these values would push the calibration factor to its 30% limit. Red highlight is intentional to demonstrate error.

"Reset" will clear values and cancel the calibration process.

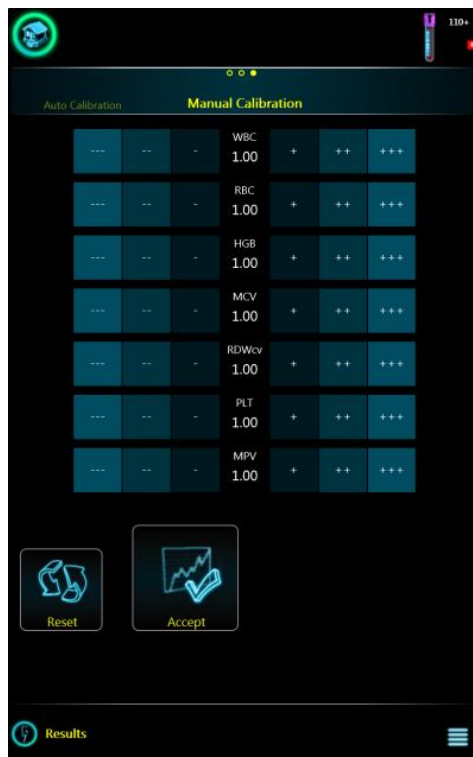


Manual calibration

Hemolyzer 5 NG also offers the option to enter calibration factors manually. Each calibration factor can range from 0.70 to 1.30 allowing a $\pm 30\%$ range for adjustment.

This way the operator can modify calibration factors of parameters individually.

Manual calibration can be a much faster method than the built-in automatic calibration service, but care must be taken when changing parameters manually.



It is recommended to verify the effects of the manual calibration by running specimens (controls) with known values of measured parameters.

QC – Quality Control

Hemolyzer 5 NG, just like any laboratory analyzer needs verification of its performance from time to time. For this purpose, Hemolyzer 5 NG offers the Quality Control service.

Quality Control is a built-in tool offering an easy method to track the performance of Hemolyzer 5 NG. Enabling QC measurement warning allows the system to pop up a message about QC measurement importance after every daily startup.

Expected values

Quality Control is performed measuring the same specimen over a period of time. Hematology analyzers have their own control material called Control Blood.

Control blood is made by using human samples mixed with specially treated particles to guarantee stable values for parameters over the stability period of the control material. All control blood products come with a list of the expected values of parameters.



Please always observe the package insert of the control material; such products require storage in a refrigerator. Prior to using the control material, it must reach optimal (room) temperature. Always follow the instructions accompanying the control product.

These expected values represent the standard to which your analyzer's reported values are compared.

It is recommended to use control material Analyticon H5-Check Complete, developed specifically for Hemolyzer 5 NG.

Recommendation to perform Quality Control measurements after turning on the analyzer – a hint message is displayed on the measurement screen after the first entry each day, to remind users to verify the analyzer's performance by running QC measurement with Analyticon H5-Check Complete control blood.

QC measurement warning



*Tap to deactivate

Information

It is recommended to perform QC measurements at the beginning of each day.

This function can be switched on and off. (Location: Options/Customization)

Assay sheets

Hemolyzer 5 NG offers entering QC Assay values via QR codes using the onboard camera. Analyticon provides Assay Sheet values in QR code form as well. To read the QR code, you will have to print it then present it to the analyzer as described below:

- To activate QR code reading sequence, tap the local menu button.
- Tap the small camera icon.

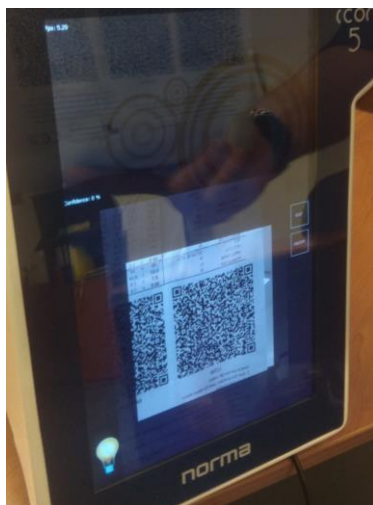
The screen will change, and you will see a live image of what the camera “sees”. The camera is located in the center of the letter “o” in the Hemolyzer 5 NG text at the top right corner of the display.



Hold the printed sheet in front of the analyzer, making sure that the sheet is not curved or bent. The QR code should be located in the center of the live image.

Hemolyzer 5 NG will acknowledge the Assay Sheet with an audible tone. The data will be entered in the QC mode available for measurement.

Make sure to show one QR code at once, so that the SW can read data properly.



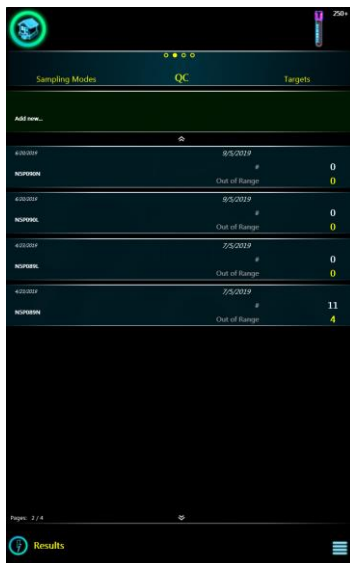
Assay sheet data can also be entered manually.

The list of QC materials can be seen with a manual entry point in the top row.

Banks can be selected as targets for measurement by ticking the box in front of the specific row.

Banks can be deleted by ticking the box in front of the specific row and going to the local menu and selecting "DROP".

Tapping the first (top) row will enter the screen where manual definition of parameters is possible.



With manual entry you can define expected values and tolerances along with LOT ID and expiration date.

Your changes will only be saved if you tap the “ACCEPT” icon. You can cancel data entry by tapping the “RESET” icon and discarding changes by tapping the HOME icon in the top of the screen.

QC materials (banks) once saved, cannot be edited. If you made a mistake and corrections must be made, please delete the actual QC bank and enter a new bank.



QC diagrams

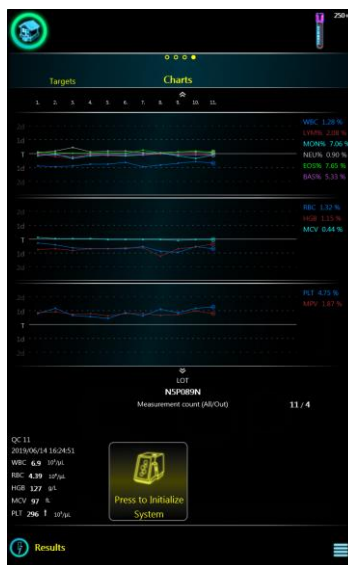
Hemolyzer 5 NG can represent QC data in two views. QC data are only shown if there are actual QC measurements stored in the analyzer's memory.

One view lists data in a graph where values of parameters are displayed against measurements in sequence (time).

You can initiate a measurement by tapping the analyzer icon on the screen.

New QC measurements will be displayed on the chart.

Quick result of the last/selected measurement could be seen in the bottom left corner.



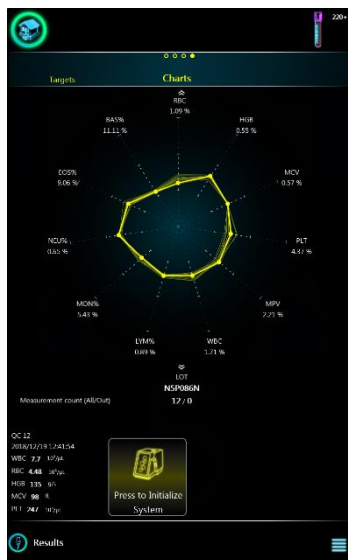
The second view displays records and the respective parameter values on a circular diagram (radar chart).

You can initiate a measurement by tapping the analyzer icon on the screen.

New QC measurements will be displayed on the chart.

Quick result of the last/selected measurement could be seen in the bottom left corner.

Note: The number of displayed parameter depends on QC Parameter setting (Short/All).



Database functions

Browsing records

The database allows browsing records listed in rows. Swiping (scrolling) gestures can be used to access various views of the database.

The database is arranged into five separate sets of data:

- Samples
- QC measurements
- Calibration data
- Fast Blanks
- Recycle Bin

Within each set, you can browse by date. Swiping LEFT will reveal more and more detailed data of the row, record examined.

Results	Human	↑	↑	↑
		Date	Record	Details
		↓	↓	↓
	QC	↑	↑	↑
		Date	Record	Details
		↓	↓	↓
	Calibration	↑	↑	↑
		Date	Record	Details
		↓	↓	↓
	Fast Blank	↑	↑	↑
		Date	Record	Details
		↓	↓	↓
	Recycle Bin	↑	↑	↑
		Date	Record	Details
		↓	↓	↓

Swiping the screen in the left or right direction will switch pages displayed.

Swiping the screen up or down will scroll the view up or down: you can scroll between dates, groups of records and individual records.

All deleted records are moved to the Recycle Bin. Records in the Bin can be restored.

Selection

You can select records manually one-by-one by ticking the checkbox of individual records in database view.

When at least one record is selected, the screen will display the number of selected records.

Select All – the feature is available if at least one record was selected.

You can deselect all records by clearing the checkbox showing the number of selected.



Database local menu

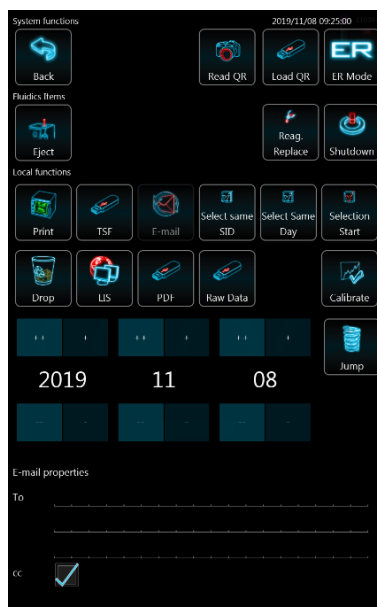
Tap the local menu button in the lower right corner of the screen brings up a so-called local menu screen.

The screen has operation related functions in the top. The central region has icons representing functions related to actions corresponding to database records.

“Select same Day” will select records measured on the day of the actual result.

“Select same SID” will select records matching the same SampleID of the actual result.

“Selection Start” allows multi-selection of results. You will be taken back to the database table view. You can select the END of the selection by ticking the box in front of any sample (you can scroll up and down prior to selecting the last record). All samples between the “first” (where selection started) and the “last” (the one you ticked) will be selected.



Selecting records between two dates

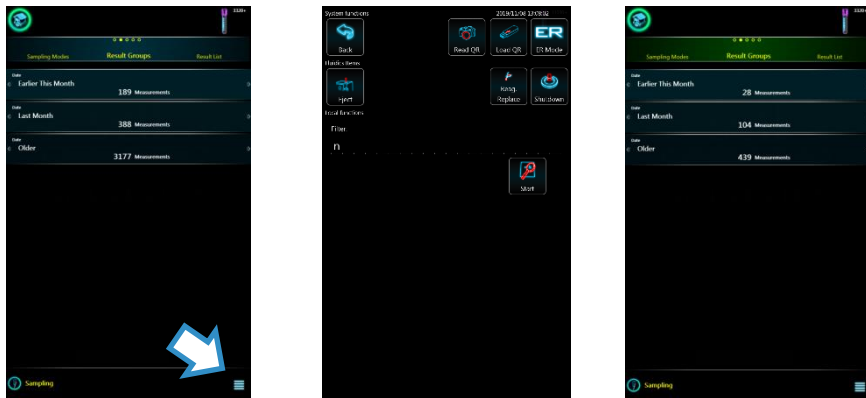
Follow the process below to select all records between two dates:

1. Tap local menu
2. Enter start date
3. Tap “Jump”
4. Select first record
5. Tap local menu
6. Tap “Selection start” – Checkbox of first record turns red
7. Tap local menu
8. Enter end date
9. Tap “Jump”
10. Select last record – All records between start and end dates will be selected

Search (filtered view)

You can search for any text/number contained in Sample ID and in Comment1-3 fields.

You can start the search only from the **database category view**.

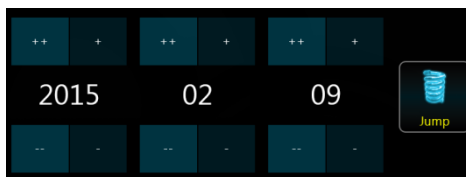


Tap the menu symbol, enter your search criteria. Enter minimum 2 characters. Search function works on both normal and autoloader measurement results, including those in the Recycle Bin.

Matching results will be displayed in a separate database view.

Moving to specific date in database

After selecting date with date picker tap “Jump” button to move the corresponding results in database list. Hemolyzer 5 NG will execute the jump operation if database contains records with the selected date otherwise it jumps to the closest older date.



Managing data

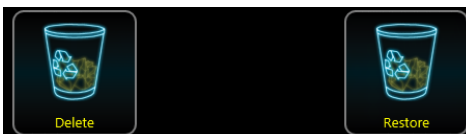
Tap the corresponding icon to activate the function:



- print results via connected or network printer
- export results in TSF format to USB HD (Tab Separated File – ideal for external processing)
- e-mail results in PDF format (network connection required)
- save reports in PDF format to USB HD
- save reports in raw data format to USB HD
- send results to LIS (network connection required)
- drop selected records into Recycle Bin
- CV% calculates CV data of selected results.

Managing data in Recycle Bin

Tap the corresponding icon to activate the function:



- permanent delete selected records
- restore selected records

Sending e-mail

To e-mail enter the address of the recipient. E-mail settings are available under Options menu Functionality submenu.

 A screenshot of a form titled 'E-mail properties'. It has a 'To' field with three horizontal lines for text entry. Below it is a 'cc' field with a checked checkbox and a single horizontal line for text entry.

Keeping “CC” checkbox selected will send a copy to the default e-mail address (as defined under e-mail settings)

Maintenance

Cleaning the analyzer

The outer cover of Hemolyzer 5 NG is made of plastic and Plexi-glass. The back plate is made of stainless steel.

The external plastic parts can be cleaned with lint free cloths soaked in light soapy water, or alcohol-based cleaning materials, typically alcohol-based window or computer display cleaning solutions.

Cleaning the stainless steel back plate should be done using alcohol-based cleaning materials, typically alcohol-based window or computer display cleaning solutions.



WARNING

Never make the system aspirate liquids with alcohol content. Alcohol will damage internal plastic components.

Daily maintenance

- Clean outer surface
- Check reagent connector
- Run needle cleaning process

Needle cleaning process

The analyzer, while running, will eventually collect some spilled blood from sample vials. This blood does not interfere with results, does not cause cross-contamination of results, but it may cause faults in the needle cleaning procedure. Dried blood may obstruct operation of the needle cleaning mechanism. The needle is not accessible to the operator.

To avoid such problems, it is strongly recommended to use a needle cleaning vial at the end of the daily routine.

Fill an empty black cap cleaning vial or empty and cleaned control blood vial with 2-3ml of H3/H3-Hypoclean and close the vial. Standard vials may not reach the areas of the needle that need cleaning.

When you are ready to shut down the analyzer at the end of the day, insert the vial to the sample opening and start the regular shutdown process. (Local menu, Shut Down)

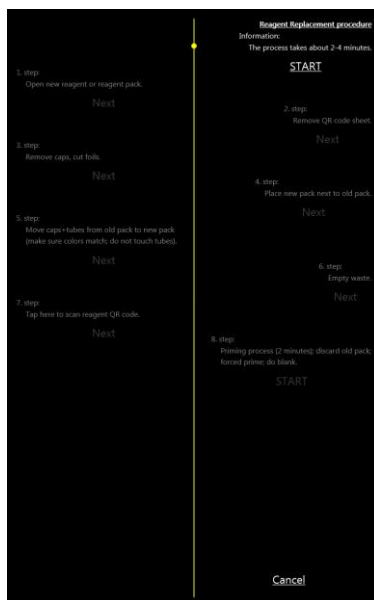
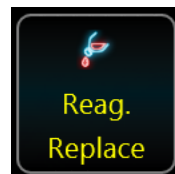
The analyzer will use the vial to clean and rub the needle. The vial is left over the needle for 20 seconds so that the cleaning liquid inside will dissolve eventually dried blood. At the end of the process the cleaning vial will be returned to its top position and will be ready to be removed.

Emergency procedures

- Cleaning
- Power off

Reagent pack replacement

- When a pack is empty (because reagent credit ran out) then a new pack must be installed.
- The process is supported by a wizard guiding you through the process.
- To access the wizard, tap the local menu button or the sample vial symbol on the screen and tap on the reagent replacement icon.
- Follow the instructions on the screen:
 - o Open new pack, locate IFU with QR code
 - o Remove caps, open vial seals
 - o Move reagent tubes from old pack to new pack
 - o Empty waste
 - o Scan QR code
 - o Initiate auto-prime



Replacing reagent bottles

- In case of using bulk reagents, and one of the reagent containers becomes empty, scan the QR code of a new bottle and connect the bottle to the analyzer.

Regular cleaning procedures

- Whenever instructed by the system, perform WBC and RBC hard clean procedures
- WBC hard cleaning is recommended to be performed when the system repeatedly reports 3 consecutive samples with WBC Improper Voltage and WBC Noise flags (optical sensitivity and optical noise)
- RBC hard cleaning is recommended to be performed if the device reports 5 consecutive samples with Contamination flag (RBC sample path flow obstruction)

Software updates

You can initiate this process by tapping the proper button in Supervision menu / About submenu. Contact your Service team for details.

Management menu

Maintenance

Maintenance menu allows running processes related to maintaining reliable operation:

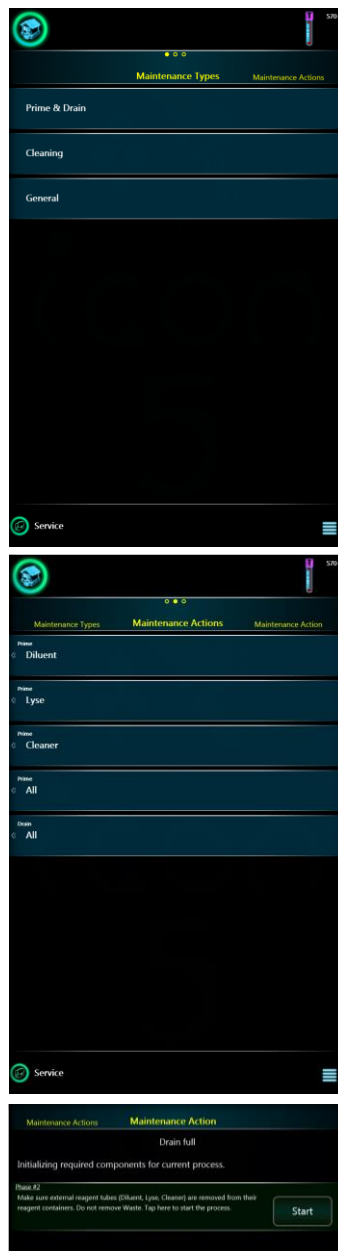
- Priming, draining reagents
- Cleaning procedures
- Other functions

Prime & Drain

Swiping left on the Prime & Drain line of Maintenance opens the Prime menu, where the user can instruct the analyzer to aspirate, prime reagents individually if necessary.

Prime All will prime all three reagents.

Drain all will drain the system; reagents must be disconnected as instructed by the analyzer.



Cleaning

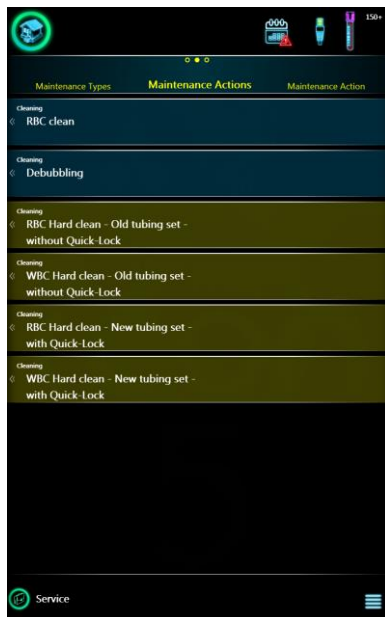
Various cleaning actions can be started that help keeping the system in good working conditions. Cleaning action is highlighted with yellow color if the cleaning action is recommended.

RBC cleaning

The process uses the system cleaner to prime, rinse and clean the RBC aperture. This may be necessary if you experience RBC noise or unstable voltage flags. The cleaning liquid will remove buildups from the aperture and the electrode.

Debubbling

This procedure will drain and prime the optical head to remove bubbles that may have gotten caught in small tube connections. The process has multiple stages, and the system will continuously check if the bubble could be removed. If the cleaning does not seem to have an effect, then run “WBC Hard Cleaning”.



RBC Hard Cleaning – Old tubing set or new tubing set (Quick Lock)

Samples will leave some tube sections contaminated with various substances over time. These may have an effect over how evenly liquids are flowing through critical tube sections. An obstructed flow may influence cell detection and as such must be corrected.

The next steps need to be followed in order to perform the cleaning procedure:

New Tubing Set – With Quick-Lock

Preparation

- Go to Management/Cleaning/RBC Hard Clean menu
- Wear protective rubber gloves.
- Prepare a bottle of Analyticon H3/5-Hypoclean with minimum 40mL liquid inside (about half full)
- Install the small, white bottle cap with tubes and Quick-Lock to the H3/5-Hypoclean bottle
- Keep the Quick-Lock connector and the tube upright to avoid liquid flowing out!

Instruction for Use

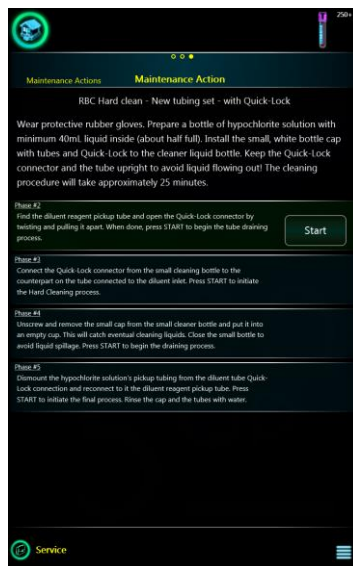
The cleaning process takes approximately 25 minutes. Please do not interrupt the procedure. The software guides you through the process by the following steps:

Phase #1

Find the diluent reagent pickup tube and open the Quick-Lock connector by twisting and pulling it apart. When done, press START to begin the tube draining process.

Phase #2

Connect the Quick-Lock connector from the H3/H3-Hypoclean bottle to the counterpart on the tube connected to the diluent inlet. Press START to initiate the Hard Cleaning process.



Phase #3

Unscrew and remove the small cap from the H3/H3-Hypoclean bottle and put it into an empty cup. This will catch eventual cleaning liquids. Close the H3/H3-Hypoclean bottle to avoid liquid spillage. Press START to begin the draining process.

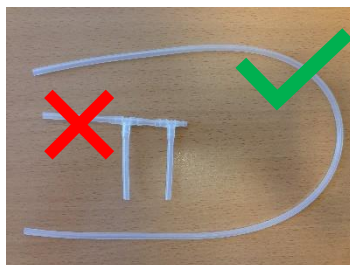
Phase #4

Dismount the H3/H3-Hypoclean's pickup tubing from the diluent tube Quick-Lock connection and reconnect to it the diluent reagent pickup tube. Press START to initiate the final process. Rinse the cap and the tubes with water.

Old Tubing Set – Without Quick-Lock

Preparation

- Go to Management/Clean/RBC Hard Clean menu
- Wear protective rubber gloves.
- Prepare a bottle of Analyticon H3/5-Hypoclean with minimum 40mL liquid inside (about half full)
- Use the draining tube kit to connect the H3/5-Hypoclean solution to the analyzer. The draining tube kit consists of two parts: 3-way branching tube and one long straight tube. Separate them and use only the long tube for connection.



Instruction for Use

The cleaning process takes approximately 25 minutes. Please do not interrupt the procedure. The software guides you through the process by the following steps:

Phase #1

Close tubing clamp, then remove diluent reagent pickup tube from the metal connector. When done, press START to begin the tube draining process.

Phase #2

Connect the long draining tube's one end to the analyzer's diluent metal reagent connector and put the other end into the H3/H3-Hypoclean solution. Please make sure the inside and outside surface of the tube is clean to avoid contamination in the solution! Press START to initiate the Hard Cleaning process. It takes approximately 5 minutes.

Phase #3

Remove the long draining tube from the analyzer's metal connector. Press START to begin the tube draining process.

Phase #4

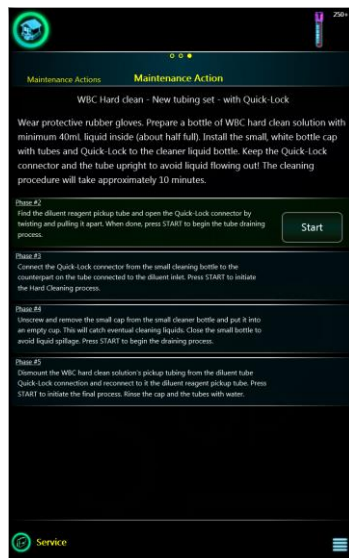
Connect back the diluent reagent pickup tube to the analyzer's metal connector and open the tubing clamp. Rinse the cap and the tubes with water.

WBC Hard Cleaning – Old tubing set or new tubing set (Quick Lock)

The optical head can lose its sensitivity over time, since samples going through are getting in contact with the transparent surfaces. Sensitivity is reduced when buildups are created over these surfaces. The buildups will make the transparent surfaces somewhat opaque and laser light will become less concentrated, as if you are looking through a foggy window.

This “fog” can be removed effectively by the WBC Hard Cleaning process.

The next steps need to be followed in order to perform the cleaning procedure:



New Tubing Set – With Quick-Lock

Preparation

- Go to Management/Clean/WBC Hard Clean menu
- Wear protective rubber gloves.
- Prepare a bottle of Analyticon H5-Opticlean with minimum of 40mL liquid inside (about half full)
- Install the small, white bottle cap with tubes and Quick-Lock to the H5-Opticlean bottle
- Keep the Quick-Lock connector and the tube upright to avoid liquid flowing out!

Instruction for Use

The cleaning process takes approximately 10 minutes. Please do not interrupt the procedure. The software guides you through the process by the following steps:

Phase #1

Find the diluent reagent pickup tube and open the Quick-Lock connector by twisting and pulling it apart. When done, press START to begin the tube draining process.

Phase #2

Connect the Quick-Lock connector from the H5-Opticlean bottle to the counterpart on the tube connected to the diluent inlet. Press START to initiate the Hard Cleaning process.

Phase #3

Unscrew and remove the small cap from the H5-Opticlean bottle and put it into an empty cup. This will catch eventual cleaning liquids. Close the H5-Opticlean bottle to avoid liquid spillage. Press START to begin the draining process.

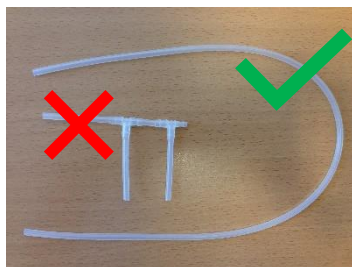
Phase #4

Dismount the H5-Opticlean's pickup tubing from the diluent tube Quick-Lock connection and reconnect to it the diluent reagent pickup tube. Press START to initiate the final process. Rinse the cap and the tubes with water.

Old Tubing Set – Without Quick-Lock

Preparation

- Go to Management/Clean/WBC Hard Clean menu
- Wear protective rubber gloves.
- Prepare a bottle of Analyticon H5-Opticlean with minimum of 40mL liquid inside (about half full)
- Use the draining tube kit to connect the H5-Opticlean solution to the analyzer. The draining tube kit consists of two parts: 3-way branching tube and one long straight tube. Separate them and use only the long tube for connection.



Instruction for Use

The cleaning process takes approximately 10 minutes. Please do not interrupt the procedure. The software guides you through the process by the following steps:

Phase #1

Close tubing clamp, then remove diluent reagent pickup tube from the metal connector. When done, press START to begin the tube draining process.

Phase #2

Connect the long draining tube's one end to the analyser's diluent metal reagent connector and put the other end into the H5-Opticlean solution. Please make sure the inside and outside surface of the tube is clean to avoid contamination in the solution! Press "Start" to initiate the Hard Cleaning process. It takes approximately 5 minutes.

Phase #3

Remove the long draining tube from the analyser's metal connector. Press START to begin the tube draining process.

Phase #4

Connect back the diluent reagent pickup tube to the analyser's metal connector and open the tubing clamp. Rinse the cap and the tubes with water.

Other

These functions are used when the analyzer is to be out of operation for a longer period of time.

Preparing for shipment supports draining and cleaning all tubing paths inside so that the analyzer can be transported or stored for a longer time.

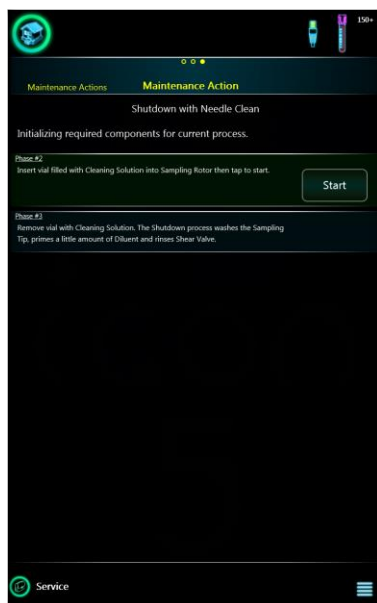
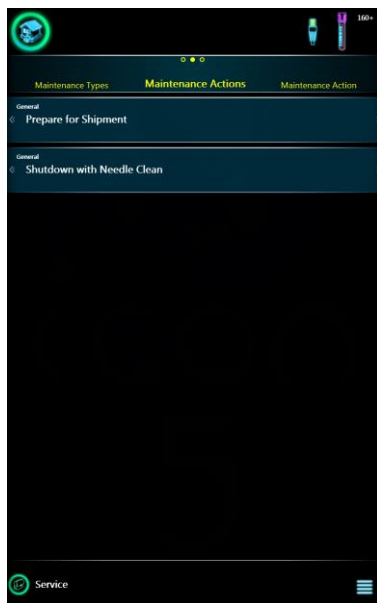
Shutdown with Needle Clean: the analyzer, while running, will eventually collect some spilled blood from sample vials. This blood does not interfere with results, does not cause cross-contamination of results, but it may cause faults in the needle cleaning procedure. Dried blood may obstruct operation of the needle cleaning mechanism. The needle is not accessible to the operator.

To avoid such problems, it is strongly recommended to use a needle cleaning vial at the end of the daily routine.

Fill an empty control blood vial with 2-3ml of H3/H3-Hypoclean and close the vial. Standard sample vials may not reach the areas of the needle that need cleaning.

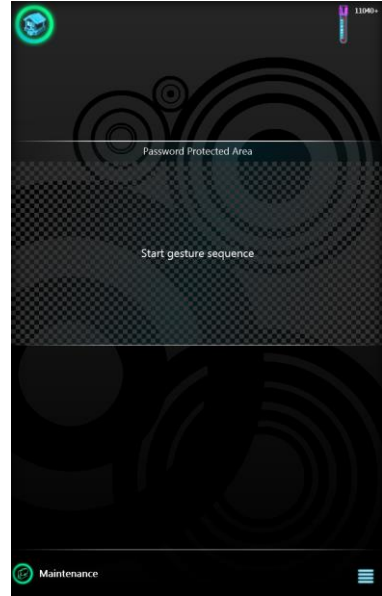
When you are ready to shut down the analyzer at the end of the day, insert the vial to the sample opening and start the Shutdown with Needle Clean process.

The analyzer will use the vial to clean and rub the needle. The vial is left over the needle for 20 seconds so that the cleaning liquid inside will dissolve eventually dried blood. At the end of the process the cleaning vial will be returned to its top position and will be ready to be removed.



Service

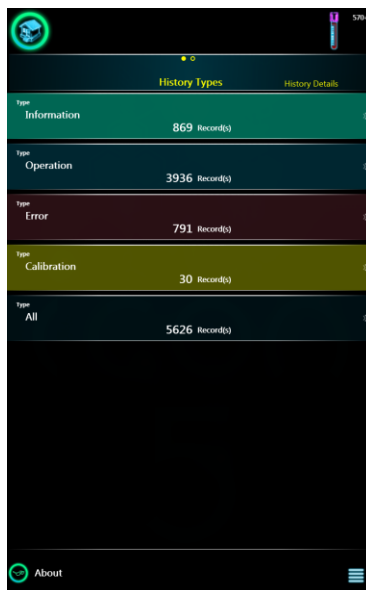
This menu is password protected and it is only available for and should be used by authorized service personnel.



Supervision

History

History will list all user activity in a log, grouped into activity types. You can review Information, User action, Errors.



History details

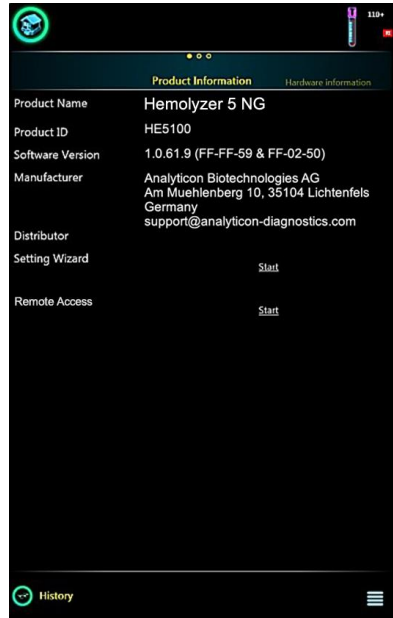
Swiping left on a specific line of History will show the details of a specific message. You can swipe up and down to access further pages, lines.



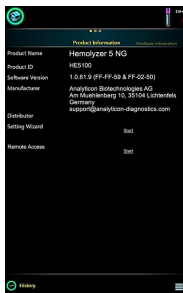
About

The About screen will display instrument specific information

- SW version,
- Language Pack version,
- Product ID,
- Manufacturer data,
- Service contact to your local service personnel,
- You can restart the setting wizard,
- You can initiate Remote Management (refer to your service personnel).

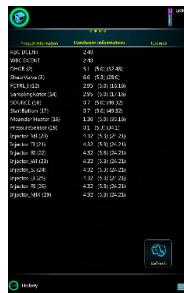


About



Basic device information

Hardware
information



Internal
component data

SW upgrade



Software update,
Language update,
Migration

Database



Database
capacity
management

SW upgrade

Software and language upgrade are available from the manufacturer on a regular basis. Consult your distributor for availability.

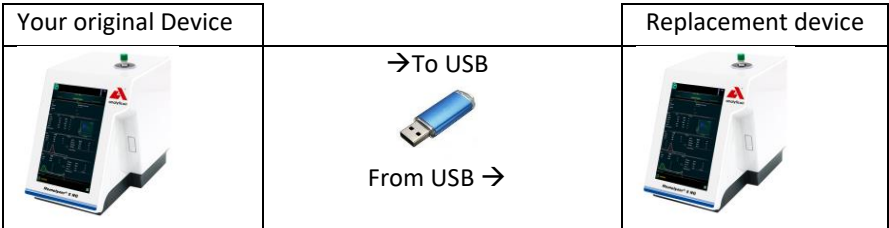
It is possible to save a so-called diagnostic file for troubleshooting purposes. Saving the file requires a USB storage device.

When necessary, your distributor will guide you over the process to extract diagnostic data from the analyzer.



Migration

This is a process designed to move all settings and data from one device to another. This may be necessary if your analyzer needs a major upgrade or service, and you want to access your database and settings on a loaner device.



Migration allows moving specific data from one Hemolyzer 5 NG to another

- all HUMAN and AL measurement results (including results in Recycle Bin),
 - o No FastBlank, calibration results or QC results are exported.
- all user settings, reference ranges for all profiles, available reagent credits.

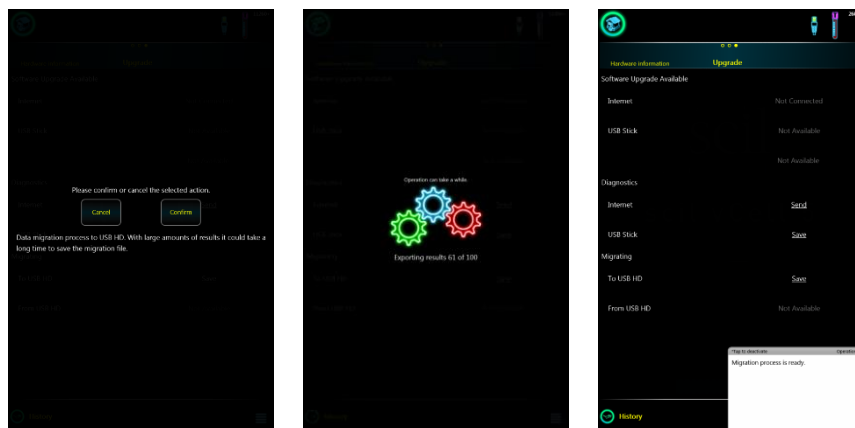
A USB storage device is needed and “Migration” becomes available. This process will collect specific data and saves them to a USB storage device: Migrating folder, **Migration.mgr** file.

	Migration may take long (depends on database size), up to 30 minutes.
---	---

Migration is only possible if:

	To USB HD: only if a USB storage device was connected and there is no Migration.mgr file present in the Migrating folder. The Migrating folder is generated by the software, there is no need to create this folder in advance.
	From USB HD: only if a USB storage device was connected and there is a Migration.mgr file present in its Migrating folder.

Migration to USB

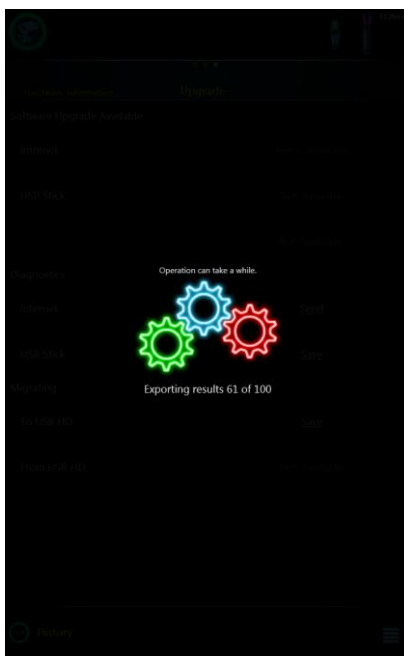
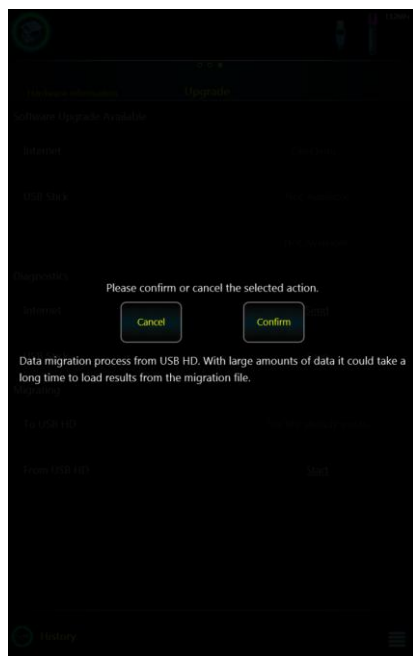


When the user taps on “Save” at To USB HD, then the software will ask for confirmation: the process may take long. (e.g. saving 5000 samples with corresponding data may take up to 15 minutes.) The progress is continuously displayed to the user. The user will be notified when the process is over. No measurements or any other functions can be performed on the device during the data export (save) process.

Data on the device remain intact, the following data will be reset to factory values (will be empty):

- email address, password for the email address
- state of the fluidics (operation status)

Migration from USB



When the user taps on “Start” at “From USB HD”, then the software will ask for confirmation: the process may take long. (e.g. importing 5000 samples with corresponding data may take up to 30 minutes.) The progress is continuously displayed to the user. The analyzer will restart when the process is over. No measurements or any other functions can be performed on the device during the data import process.

After completion of the importing process:

- all HUMAN measurement results will be deleted and overwritten with data from the imported file,
- all profile normal ranges will be overwritten with data from the imported file,
- all reagents will be dropped, and reagent data from the file will be imported,
- all user settings will be overwritten with data from the file
- the *Migration.mgr* file will be deleted from the USB storage device.

Database capacity

The analyzer allows managing database capacity and helps free up space as necessary. Running 50 samples a day will create about $50 \times 250 = 12500$ records over a year. The system can easily store 40.000 records, yet system speed will gradually drop as more and more records are stored.

This page offers deleting records by their age. To avoid final loss of records, you can choose to export the records selected for deleting before they are actually deleted. You can choose PDF or TSF (Text) export.

To allow exporting before deleting, you need to connect a USB storage device.

It is also possible to empty the Recycle Bin.



Upgrade	Database	AutoLoader
Database size	38.3 MB	
Allowable database size	400 MB	
Record all	3685	Drop
Record(s) older than 1 year	597	Drop
Record(s) older than 8 months	2292	Drop
Record(s) older than 4 months	3315	Drop
Record(s) older than 1 month	3655	Drop
Record(s) in Recycle Bin	0	Drop

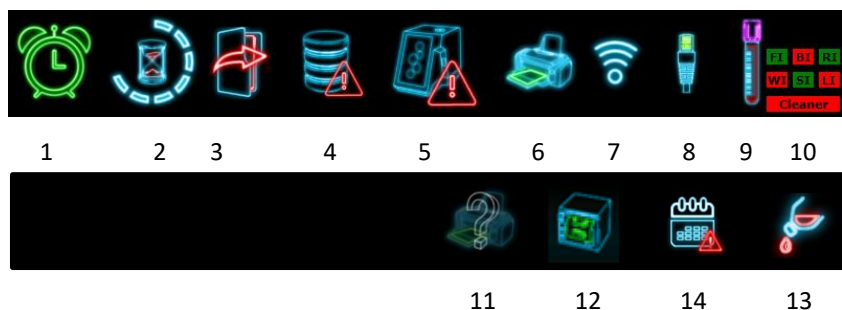
Save TSF before deletion ☒

Save PDF before deletion ☒

History

Status bar

The status bar can display symbols that represent messages or various conditions of the device. Below you can find these symbols and their meanings.



1. Display scheduled events (only in ER mode)
2. progress symbol when fluidics action is in progress (animated)
3. Unsent records in the LIS queue
4. Database error
5. Internal communication error. Restart device or contact service.
6. Printer symbol when a compatible printer is connected (PCL5, PCL6 or Host Based)
7. Wireless network symbol when wireless USB dongle is connected
 - a. the symbol will become green if a network is connected
8. Ethernet connector symbol when wired network cable is connected
9. Available measurement count with messages:
 - a. Sample count based on actual reagent level
 - b. Expired
 - c. Inactive
10. Reagent sensor indicators. When a (reagent) sensor is disabled, then its corresponding letter will receive a **red** background.
 FI – FrontSheath (Diluent), BI – BackSheath (Diluent),
 RI – RBCSheath (Diluent), WI – WASH (Diluent),
 SI – SampleInjector (Diluent), LI – LyselInjector (Lyse),
 Cleaner (Cleaner)
11. An unknown printer was detected. Printing is not recommended.
12. An ESC/POS compatible printer was detected
13. External waste container full
14. Calendar icon. Cleaning is recommended. Tap the icon to obtain information about required cleaning.

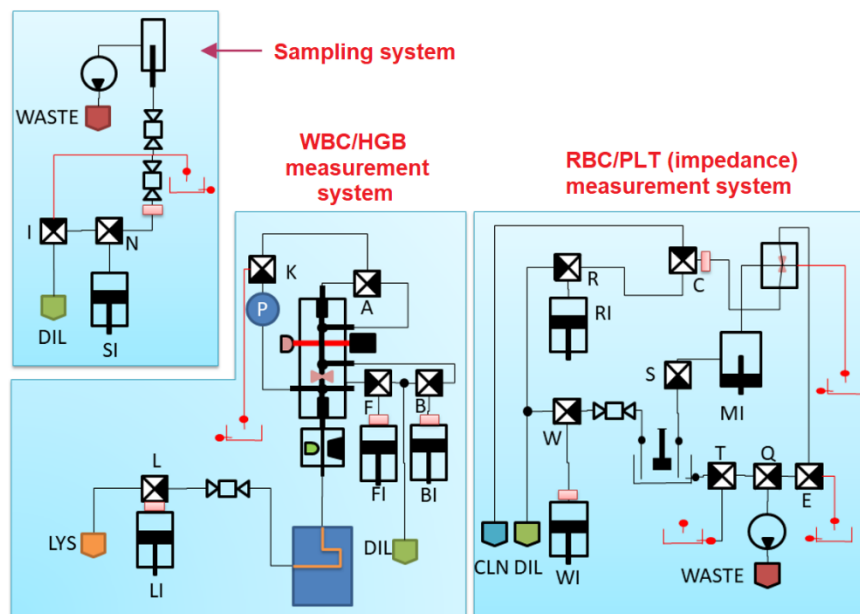
Technical Specifications

Item	Description, details
Measured parameters	WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, NLR RBC, HGB, HCT, MCV, RDWsd/cv, MCH, MCHC, PLT, MPV, PCT, PDWsd/cv, PLC-R%, PLC-C
Measurement technology	Laser based forward-scattered light detection for WBC Volumetric impedance method for RBC Photometric method for HGB
Scattergram	WBC 5-part
Histograms	RBC, PLT
Sampling mode	Closed vial mode
Aspirated sample volume	38 µl whole blood
Processed sample volume	2 x 1.4 µl whole blood
Throughput	60 tests / hour
Precision (CV%)	WBC<3%, RBC<2%, PLT<5% MCV<1%, HGB<2%
Storage capacity	40,000 (max.) test results including scattergram, histograms and patient data
User interface	LCD, 10.1", 1280 × 800 with capacitive touchscreen, portrait
Languages	English, Italian, French, Russian, Hungarian, Spanish, Romanian, Portuguese, Vietnamese, Ukrainian, Bosnian
Connectivity	2 x USB ports, Ethernet connector, LIS (HL7)
Dimensions (HxWxD)	280 x 216 x 336 mm
Weight	9.4 kg
Power	External power supply, 12 VDC, 5A (100-240 VAC 50-60 Hz);
Power consumption	Maximum 60W
Reagents connected	H5-DIL diluent, H5-LYSE lyse, H5-CLEAN cleaner
Optional detergents	H3/H3-Hypoclean – hypochlorite solution H5-Opticlean – WBC hard clean solution

Storage temperature	10-40°C (50-104°F)
Operating temperature	15-32°C (59-90°F)
Humidity	20-80% relative
Altitude	The analyzer is designed to be operated up to 2000 m/6500 ft above sea level.

	WARNING Only qualified service personnel may replace the internal fuse and battery.
	When not in use or relocating, always store the analyzer in its original packaging to avoid physical damage. Storing the analyzer outside the above specified environmental conditions or outside its original packaging may impair operation and may also cause erroneous or faulty operation. Do not place the analyzer near a direct heat source or into direct sunlight. The desk supporting the instrument should be flat, horizontal and stable enough to support the weight of the analyzer and accessories.
	Operating the analyzer outside the above specified environmental conditions may impair operation and may also cause erroneous or faulty operation.

Hydraulic diagram



Hemolyzer 5 NG contains the following key components:

- Electronic boards (main board, signal processing boards, controller boards for moving components, display)
- 14 valves (A,B,C,E,F,I,K,L,N,Q,R,S,T,W)
- A shear valve with two sampling sections: R and W
- Motors (syringe movement, ceramic valve movement, pump),
- Measuring assembly incorporating ruby aperture (70µm)
- Peristaltic pump ("PUMP")
- An optical module for WBC classification (equipped with Laser)
- Sample sensor (BS), and reagent sensors: (FI, BI, LI, WI, RI)

	There are no user serviceable components inside the analyzer.
	Do not attempt to open the external covers to avoid damage to the system and avoid mechanical injury and can invalidate warranty.

Reagent consumption

All values are expressed in mL (milliliter). Values below indicate are worst case aspirated volumes.

Process	Conditions	H5-DIL	H5-LYSE	H5-CLEAN
Start-up	Initial + wake up with empty tubing	57.5	16.5	4.8
Start-up	Daily routine	44	10.5	4.8
Measure sample		10	1.6	0.2
Fast Blank	One attempt/cycle	9	2	0.2
RBC clean		4	0	0.6
WBC De-Bubbling		2	1.5	0
RBC hard clean		13,8	1,7	0,8
WBC hard clean		12,4	2,6	0,3
Prime iDil5	One attempt/cycle	7	0	0
Prime iLyse5	One attempt/cycle	0	1	0
Prime iClean5	One attempt/cycle	0	0	1.4
Shutdown		20	2	3.2

Limitations, interfering substances

Lipemic sample

In case of **measuring lipemic samples**, lipid particles will increase absorbance which **results in increased HGB value**. For determination of real HGB value for a lipemic sample, it is recommended to replace plasma in it.

Icteric sample

Increased bilirubin contents of icteric sample may affect **WBC and HGB results**.

Hemolytic sample

A sample can get **hemolyzed if stored incorrectly** (exposed to excess heat or got frozen) or its **age is more than 24 hours**.

It is not easy to detect such condition, unless the sample is centrifuged, and pink plasma is found.

Hemolysis of a sample – depending on its grade – affects all counted parameters (e.g. elevated PLT count) and WBC differential results as well.

Running non whole-blood samples

Hemolyzer 5 NG utilizes an optical sample sensor, it verifies if sampling from the sample tube was correct.

If the sample is not continuous – there is not enough sample in the vial, or there are bubbles in it, or the analyzer is unable to aspirate the sample – then the SW will trigger a “low sample volume” flag.

If the sample has HGB < 35 g/L, the sample detector will not see it, a “low sample volume” flag will be triggered. This may be also the case if running CSF or PRP samples.

Important notice: Hemolyzer 5 NG is not validated for measuring CSF or PRP samples, for this reason it is not recommended to run such samples.

Immature granulocytes, variant lymphocytes, blasts, atypical cells

Such types of cells are detected and counted by the analyzer as WBC.

However – except immature granulocytes and variant lymphocytes – it is uncertain at which area such cells appear on the WBC scattergram.

If cells appear at specific locations on the scattergram, then the SW indicates it by specific flags – see at Diagnostic flags section (**page 77**).

Microscopic analysis of blood smear is recommended, if presence of immature, blast or atypical cells is suspected or diagnostics flags suggest so.

PLT clumps

Some samples may contain PLTs that tend to form clumps and thus may falsely report low PLT count with elevated MPV values in an otherwise normal sample. If PLT is low, microscopic inspection of blood smear is recommended.

PLT clumps may be induced by the EDTA anticoagulant, can be spontaneous or as an effect of some medication.

Please note that accurate PLT counts cannot be achieved if clumps are present in the sample. See also Diagnostic flags section (**page 77**).

If PLT clumps are detected, it is recommended – for counting PLT only – to take blood from the patient into a sample tube containing citrate.

Nucleated RBC

Nucleated RBC (N-RBC) is rarely present in blood samples taken from healthy patients. These cells are immature RBCs. Having a nucleus, these cells will still be detected after lysis – the nucleus may even remain in the size range of WBC. **They may interfere with LYM counts** by representing an additional population below or around the lymphocytes.

See also Diagnostic flags section (**page 77**).

HGB interference of extremely high WBC count

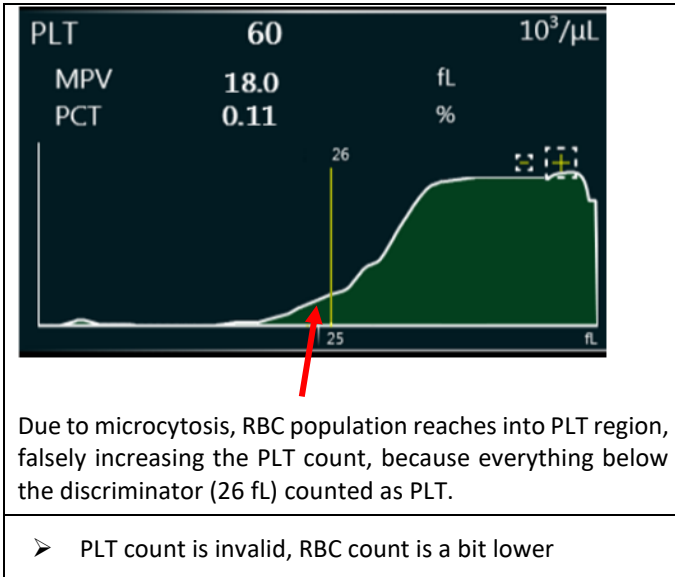
For $WBC > 100 \cdot 10^9/L$, the linear correction formula described at HGB correction section (**page 16**) may not be accurate. In such cases, to measure more precise HGB result, it is recommended to run the same sample prediluted in 1:1 ratio. Do not forget to multiply the results by 2 in case of a 1:1 prediluted sample.

Samples with very low MCV

In case of running samples with very low MCV, some smaller RBCs may fall into the PLT size region, consequently PLT count can be higher. The magnitude of this error can be very high for samples containing extremely low PLT.

In such cases, if the PLT and MCV are very low, and the discriminator placement is questionable, a blood smear examination is highly recommended.

Low PLT count with microcytic RBC interference



Performance Data

Precision

Precision data are listed for primary and derived parameters for $n > 30$ below:

Parameter	CV%	Conditions	Unit
WBC	3.0	$2.0 < \text{WBC} < 20.0$	$10^9/\text{L}$
HGB	2.0	$100 < \text{HGB} < 240$	g/L
RBC	2.0	$3.0 < \text{RBC} < 6.0$	$10^{12}/\text{L}$
MCV	2.0	$70 < \text{MCV} < 100$	fL
PLT	5.0	$100 < \text{PLT} < 800$	$10^9/\text{L}$
MPV	3.0	$5 < \text{MPV} < 15$	fL

Accuracy

Data listed below are from a comparative study with Abbott Cell-Dyn 3700:

Parameter	R ²	Conditions	Unit
WBC	0.96	$1.0 < \text{WBC} < 20.0$	$10^9/\text{L}$
HGB	0.97	$100 < \text{HGB} < 240$	g/L
RBC	0.97	$3.0 < \text{RBC} < 6.0$	$10^{12}/\text{L}$
MCV	0.98	$70 < \text{MCV} < 100$	fL
PLT	0.96	$100 < \text{PLT} < 800$	$10^9/\text{L}$
MPV	0.96	$5 < \text{MPV} < 15$	fL

Linearity

Below linearity claims were measured using hematology linearity kits.

Parameter	Linearity range	Reproducibility (1)	Unit
WBC	0 – 250	3% / 0.3 (absolute)	$10^9/\text{L}$
HGB	0 – 250	2% / 3.0 (absolute)	g/L
RBC	0 – 8.0	2% / 0.2 (absolute)	$10^{12}/\text{L}$
PLT	8 – 1500	5% / 20 (absolute)	$10^9/\text{L}$

(1): in % of expected value or in absolute count (whichever is higher)

Display range of parameters

Parameter	Display Limit	Unit	Notes
WBC	0-250	$10^9/L$	(2)
LYM	0-250	$10^9/L$ (1)	
LYM%	0-100	%	
MON	0-250	$10^9/L$ (1)	
MON%	0-100	%	
NEU	0-250	$10^9/L$ (1)	
NEU%	0-100	%	
EOS	0-250	$10^9/L$ (1)	
EOS%	0-100	%	
BAS	0-250	$10^9/L$ (1)	
BAS%	0-100	%	
HGB	0-350	g/L	
RBC	0-15	$10^{12}/L$	
MCV	30-160	fL	RBC > 0.5
PLT	0-1500	$10^9/L$	
MPV	0-50	fL	PLT > 10
HCT	0-80	%	MCV > 30
RDWsd	1-100	fL	RBC > 0.5
RDWcv	1-50	%	RBC > 0.5
PCT	0-10	%	PLT > 20
PDWsd	1-30	fL	PLT > 10
PDWcv	1-100	%	PLT > 10
PLCC	0-1000	$10^9/L$	
PLCR	0-100%	%	PLT > 20
MCH	0-50	pg	MCV > 30
MCHC	0-500	g/L	MCV > 30
NLR	0<		NEU%>0 and LYM%>0

Values measured below or beyond the limits listed above will be marked with < or > symbols and the actual limit itself. E.g. PLT $1600 \times 10^9/L$ will be displayed as: "PLT >1500 $10^9/L$ " accompanied by a linearity range flag.

Note (1): display precision is 1 decimal digit for diff absolute counts

Note (2): if WBC is below $0.1 \times 10^3/\mu L$, then diff values will NOT be displayed.

If $0.1 < WBC < 1.0 [10^3/\mu L]$ then diff values get an * mark

Carry-over

High-to-low carry-over performance of Hemolyzer 5 NG.

Parameter	Carryover %
WBC	<1%
RBC	<1%
HGB	<1%
PLT	<1%

List of measured parameters

Parameter	Measured	Calculated	Calibrated
WBC	X		X
LYM, MON, NEU, EOS, BAS	X	X	
LYM%, MON%, NEU%, EOS%, BAS%	X	X	
RBC	X		X
HGB	X		X
HCT		X	
MCV	X		X
MCH		X	
MCHC		X	
RDWsd/RDWcv		X	X
PLT	X		X
MPV	X	X	X
PCT		X	
PDWsd/PDWcv		X	
PLC-R%		X	
PLC-C		X	
NLR		X	

Error messages

The analyzer can report various errors. Error messages are displayed in a small pop-up bubble in the lower right corner of the screen. Errors have technical details which are useful when contacting Technical Support.

Technical Support will ask for diagnostic files to facilitate problem resolution.

Either have the analyzer connected to the Internet or have a USB mass storage device ready for saving and emailing data.

Error message	Cause / Meaning	Resolution
An error occurred while attempting to set volume.	Database/System error	Restart the analyzer. If problem persists, contact support.
An error occurred while attempting to use the pump.	Database/System error	Restart the analyzer. If problem persists, contact support.
An error occurred while decoding QR code (invalid QR code).	You tried to scan and use an invalid or damaged QR code. The system could not recognize it.	Ask help from technical support.
An error occurred while sending an e-mail (Check username and password).	Email account or server setup error	Check password, security settings, firewall, network connection.
Back Sheath Injector error. An error occurred while attempting to execute fluidics function.	An injector module detected error.	Restart the procedure. If the problem persists, contact Service.
Camera error. An error occurred while activating camera.	The camera cannot communicate. Power the system off, then on again.	If the problem persists, contact Service.
Check if Cleaner is available, verify tube connections. Make sure there are no visible bubbles in the external reagent tube.	Check external bottle for liquid level. Observe if liquid is moving into analyzer during operation.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.

Error message	Cause / Meaning	Resolution
Check if Diluent is available, verify tube connections. Make sure there are no visible bubbles in the external reagent tube.	Check external bottle for liquid level. Observe if liquid is moving into analyzer during operation.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Check if Lyse is available, verify tube connections. Make sure there are no visible bubbles in the external reagent tube.	Check external bottle for liquid level. Observe if liquid is moving into analyzer during operation.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Closed Washing Head error. An error occurred while closing Washing Head at Shear Valve. Contact Service without executing any process except Eject Vial.	The system detected a mechanical failure inside and disabled operation until the problem has been resolved.	Contact Service with error message.
Closed Washing Head maintenance required.	A leak has been detected inside the analyzer.	Contact Service with error message.
Communication error. An error occurred while attempting to accept IP settings. (Check IP address)	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to communicate with HL7 server. (IP address? Port?)	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to communicate with HL7 server. (ReceiveTimeout)	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to connect of HL7 server (IP address? Port? Is the server running? Firewall?).	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.

Error message	Cause / Meaning	Resolution
Communication error. An error occurred while attempting to download software upgrade file (Network error?).	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to interpret IP address of HL7 server. (Check IP address)	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to interpret port of HL7 server. (Check Port ID)	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to interpret received HL7 answer.	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to print to the printer.	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to read/write Product ID.	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to receive HL7 message.	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to send e-mail (unspecified error).	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Communication error. An error occurred while attempting to send HL7 message.	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.

Error message	Cause / Meaning	Resolution
Communication error. An error occurred while sending an e-mail (No network? Firewall?).	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Component error. The following components are missing:	Some internal modules cannot communicate.	Restart the analyzer. If the problem persists, contact Service.
Control assay sheet already exists.	The assay values of the referred LOT have already been scanned. No data was lost.	Check if you tried to use the correct assay sheet.
Corrupt Database file was successfully fixed.	The database file was found to have errors – the software could fix the problem.	Nothing to do, you can use the analyzer.
Database error. An error occurred while attempting to create a record in database.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Database error. An error occurred while attempting to read/write database.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Date error. An error occurred while attempting to initiate a measurement process. Set correct date. If problem persist replace battery to avoid resetting date and time.	A “suspicious” date (May 1 st , 2009) is used by the system. Most probably the CMOS battery located on the LILIOM board has been depleted.	Replace battery, set time and date.
Exporting error. An error occurred while attempting to export PDF.	USB stick is reported to be full, the system cannot write data.	Check “write-protection”, check available space. Try another USB socket
Exporting error. An error occurred while attempting to export Tab Separated File.	USB stick is reported to be full, the system cannot write data.	Check “write-protection”, check available space. Try another USB socket
Firmware Error	Internal error.	Contact Support (and send a diagnostic file)

Error message	Cause / Meaning	Resolution
Fluidics error. A low-level error occurred while attempting to execute fluidics function.	An internal process error was detected during operation.	A diagnostic file, or all numerical data displayed along with this error are necessary to clarify the source of the problem.
Fluidics error. An error occurred while attempting to access fluidics subsystem data.	An internal process error was detected during operation.	A diagnostic file, or all numerical data displayed along with this error are necessary to clarify the source of the problem.
Fluidics error. An error occurred while attempting to execute fluidics function.	An internal process error was detected during operation.	A diagnostic file, or all numerical data displayed along with this error are necessary to clarify the source of the problem.
Front Sheath Injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.
High Temperature	The system is overheating inside. (Possibly due to heavy workload or increased ambient temperature.)	Turn off the analyzer, let it cool for 10-20 minutes.
Impedance Amplifier error. Unable to communicate with Impedance Amplifier.	Some internal modules cannot communicate.	Restart the analyzer. If the problem persists, contact Service.
Lyse injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.
Meander heater protection error. Please Restart the analyzer.	The system is overheating, or there was an error.	Turn off the analyzer and turn it back on again after waiting 30 seconds.
Meander heater temperature error. Analyzer inside temperature is out of range.	The system is overheating	Turn off the analyzer and turn it back on again in 10 minutes. External room temperature should not be above 32°C (90°F)

Error message	Cause / Meaning	Resolution
Meander heater temperature error. Heat sink temperature is out of range.	The system is overheating, or there was an error.	Turn off the analyzer and turn it back on again in 10 minutes. External room temperature should not be above 32°C (90°F)
Meander heater temperature error. Module temperature is out of range.	The system is overheating, or there was an error.	Turn off the analyzer and turn it back on again after waiting 30 seconds.
Measurement error	General measurement error.	Contact service with error details.
Mechanical error	General mechanical error.	Contact service with error details.
Mix Injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.
Network error. An error occurred while attempting to connect of HL7 server (Network cable is unconnected?).	Problem with settings or network error.	Contact your local system administrator for proper settings, and problem diagnosis.
Obsolete QR code.	The QR code is not supported by the software.	Contact Service with QR code details.
Optical Amplifier error. Unable to communicate with Optical Amplifier.	Some internal modules cannot communicate. Restart the analyzer	If the problem persists, contact Service.
Optical Head error. Cover is missing.	An internal safety switch reported error. It may be the consequence of an incomplete maintenance, or it can be an internal error.	Contact Service with error message
Possible clogging detected in Optical Head. If the error persists, contact Service	Liquid flow was obstructed inside the flow cell, overpressure was detected.	Retry the operation. If the problem persists, contact Service. (If you failed to perform a shutdown, the system may have been clogged. Contact Service)

Error message	Cause / Meaning	Resolution
Processing error. An error occurred while attempting to process raw measurement data.	An internal process error was detected during operation.	A diagnostic file, or all numerical data displayed along with this error are necessary to clarify the source of the problem. Contact Service.
Processing error. An error occurred while attempting to process raw measurement data.	General measurement error.	Contact service with error details.
QC LOT already exists.	The LOT has already been defined.	Verify LOT ID
QC LOT field cannot be empty.	You did not enter a LOT ID.	Enter a LOT ID.
RBC Injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.
Reagent detection error. An error occurred while attempting to auto-calibrate reagent sensor. Calibration value is not within expected range.	The external reagent tubes may be kinked, and the system could not move liquids.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Reagent detection error. An error occurred while attempting to calibrate reagent sensor at Cleaner inlet.	The external reagent tubes may be kinked, and the system could not move liquids.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Reagent detection error. An error occurred while attempting to calibrate reagent sensor at Diluent inlet.	The external reagent tubes may be kinked, and the system could not move liquids.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Reagent detection error. An error occurred while attempting to calibrate reagent sensor at Lyse inlet.	The external reagent tubes may be kinked, and the system could not move liquids.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.

Error message	Cause / Meaning	Resolution
Reagent detection error. An error occurred while attempting to read reagent sensor data.	A temporary internal error prevented internal data communication.	If liquid is moving OK, you may temporarily disable the corresponding liquid detector. Inform Service about the problem.
Reagent system error. An error occurred while attempting to activate reagent (already expired).	Some internal modules cannot communicate. Restart the analyzer	If the problem persists, contact Service.
Reagent system is not homogeneous. Please use matching reagents (verify LOT information).	You are using an incorrect reagent setup.	Contact Service. Have LOT information at hand.
Remote Management error.	Communication link error between analyzer and remote system. Possible setting or network error.	Contact your local system administrator and Service to resolve problems.
Sample Injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.
Saving error. An error occurred while attempting to save Background file.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Saving error. An error occurred while attempting to save Calibration factors.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Shear Valve error. An error occurred while attempting to execute fluidics function.	Mechanical error detected during internal self-test	Restart the analyzer. If the problem persists, contact Service
Shear Valve error. An error occurred while testing Shear Valve backlash.	Mechanical error detected during internal self-test	Restart the analyzer. If the problem persists, contact Service

Error message	Cause / Meaning	Resolution
Shear Valve recovery is successfully finished from Shear Valve error. System requires initialization.	There was a mechanical error, but the system could perform a recovery action.	Restart the process. If the error persists, contact Service.
Software Component Error. An error occurred while attempting to check software integrity.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Software error	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error. An error occurred while attempting to initiate system (unspecified error).	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error. An error occurred while attempting to modify reagent's tracking level.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error. An error occurred while attempting to play sound file.	Database/System error	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error. An error occurred while attempting to query active QC LOT.	Database/System error	Maybe you dropped an active reagent pack? Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
System error. An error occurred while attempting to query active reagents (inactive or expired reagents).	Database/System error	Maybe you dropped an active reagent pack or the reagent really expired. (180 days open stability) Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.

Error message	Cause / Meaning	Resolution
System error. An error occurred while attempting to read optos.	Some internal modules cannot communicate.	Restart the analyzer. If the problem persists, contact Service.
User error	Database/System error related to User activity	Restart the analyzer. If problem persists, contact support. Send a diagnostic file as well.
Valve error. An error occurred while attempting to set valve.	Some internal modules cannot communicate.	Restart the analyzer. If the problem persists, contact Service.
Wash Head error. An error occurred while attempting to execute fluidics function.	Some internal modules cannot communicate.	Restart the analyzer. If the problem persists, contact Service.
Wash Injector error. An error occurred while attempting to execute fluidics function.	A mechanical module (syringe pump) reported an error.	Restart the process. If the problem persists, contact Service.

Troubleshooting

Measurement problems

Symptom	Possible cause	Remedy
High BLANK values PLT/RBC	Physical particles	Repeat the measurement. Run a control (or live) sample, and repeat the BLANK measurement
	Contaminated reagents	Replace reagents
	Cold reagents	Make sure reagents reached room temperature
	Unearthed power outlet	Install grounding for power supply
	Minor internal contamination	Repeat FastBlank 3-4 times

Symptom	Possible cause	Remedy
High BLANK values WBC/HGB	Physical particles or air bubbles detected	Start some FastBlank measurements to flush the optical measurement module. If the problem persists, prime diluent and lyse reagents, then run a couple more FastBlank cycles.
Missing reagents reported, wrong results	One reagent is out Reagents are not connected Reagent connector sealing failure	Replace reagents. Verify reagent connector Replace reagent pack, or replace connector. Prime reagents. Look for bubbles in the tubes outside the analyzer. If the problem persists, contact Service.
Incorrect WBC differentiation	Sample mixing error Lysing reagent errors	Make sure not to overmix the sample: sample should be inverted 5 times prior to measurement. Make sure sample age is within 24hrs from taking the blood sample. Prime Lyse reagent 2-3 times.
Low sample volume reported	Too low blood sample volume	Run vials with correct sample volume Check minimum sample volume guidelines (page 20). If the problem persists, contact Service
Noise flags (RBC, PLT)	Electrical noise Contamination Bubbles are trapped inside critical tube sections.	Use a grounded electrical outlet. Verify grounding. A faulty or missing protective earth is not only hazardous but will make the analyzer sensitive to external electrical noise. Run RBC Hard cleaning. Prime reagents.

Symptom	Possible cause	Remedy
Improper voltage	Reagent insufficiency, or block inside the analyzer	Prime DIL and LYSE Run WBC Hard Clean or WBC Debubbling functions If the problem persists, contact Service.
Unstable voltage	Reagent or sample insufficient. Partial clogging of the system	Run WBC Debubbling / RBC cleaning. Inform Service.

Electrical problems

Symptom	Possible cause	Remedy
Instrument cannot be powered on	Power is not connected Power voltage is too high, or too low Fuse is blown inside analyzer	Connect power source, verify connections Replace / check power supply (is LED on?) Contact Service
Indicator on top/front of the analyzer glows in RED or BLUE color BEFORE power ON	Power voltage is too high/low	Replace power supply
Instrument powers down during operation	Power system fluctuations	Try to start the analyzer again. Use a UPS. Contact Service
Software error message	Corrupted SW system.	Contact Service

Mechanical problems

Symptom	Possible cause	Remedy
Sample vial is stuck in sample rotor	Power outage during operation Oversized vial, vial stuck Mechanical Problem	Start analyzer again, initiate measurement sequence Go to local menu and initiate "Eject" Mechanical error. Contact Service
Sample vial is not lowered, system reports missing vial, yet the vial and cap are present	Cap detector failure.	Contact Service
Sample vial is not returned to operator	Vial is stuck on sampling needle Mechanical error (strong grinding noise)	Start analyzer again, initiate measurement sequence. Go to local menu and initiate "Eject" Contact Service

Symptom	Possible cause	Remedy
Grinding noise from inside of analyzer	Mechanical blocking	Try to rerun the operation. If the problem persists, contact Service
Analyzer reports empty measurements	Too low blood sample volume	Run vials with correct sample volume Rerun sample.
	Clogged sampling paths	Contact Service
Leakage beneath analyzer	Leaking reagent connector	Check reagent connectors
	Blocked sampling valve/needle system	If it still fails, contact Service

Hydraulic problems

Symptom	Possible cause	Remedy
Instrument reports clogging	Bad quality sample used	Run RBC cleaning. Try to rerun sample. Built in functions will attempt to unclog needle and apertures. If the problem persists, contact Service.

Network problems

Symptom	Possible cause	Remedy
Network error message at the end of every sample	HL7 or email communication is enabled (forced) but settings/network does not comply.	Verify HL7 / email settings. Disable email (clear account data) or clear HL7 settings
Remote Management error message	Remote Management data are incorrect	Contact Service for correct settings
WIFI dongle not recognized	Driver error	Check supported list of WIFI chipsets

Printer problems

Symptom	Possible cause	Remedy
Scrambled printout	Incorrect printer model	Use Printers with PLC5 or ESC/POS language support
Empty pages printed	Incorrect printer model	Install compatible printer Contact Service for instructions
Printer connected, but no printer icon in top row of screen	Printer is not supported, USB cable is wrong Printer is OFF	Test the printer and USB cable with a PC. Restart Hemolyzer 5 NG. Make sure to use the same grounded electrical outlet for Hemolyzer 5 NG and peripherals. Test USB sockets with an external Keyboard or with a USB stick (and try to save diagnostic files to the USB)

Default normal ranges

The analyzer SW is preset with the following normal ranges for the profiles listed.

These preset limit values should be modified based on the local patient population.

Parameters	Human	Male	Female
WBC ($10^9/L$)	3.7 – 11.7	3.7 – 9.7	3.9 – 11.7
LYM ($10^9/L$)	1.1 – 3.6	1.1 – 3.3	1.3 – 3.6
LYM%	14.1 – 52.8	14.1 – 45.8	21.1 – 52.8
MON ($10^9/L$)	0.2 – 0.7	0.2 – 0.7	0.2 – 0.5
MON%	2.7 – 9.2	3.3 – 9.2	2.7 – 6.6
NEU ($10^9/L$)	1.9 – 7.9	2.0 – 6.7	1.9 – 7.9
NEU%	39.6 – 78.4	42.9 – 78.4	39.6 – 74.7
EOS ($10^9/L$)	0.0 – 0.4	0.0 – 0.4	0.0 – 0.4
EOS%	0.3 – 7.2	0.3 – 6.2	0.5 – 7.2
BAS ($10^9/L$)	0.0 – 0.1	0.0 – 0.1	0.0 – 0.1
BAS%	0.2 – 1.3	0.3 – 1.3	0.2 – 1.0
NLR	0 – 3.13	0 – 3.13	0 – 3.13
RBC ($10^{12}/L$)	3.85 – 5.78	4.54 – 5.78	3.85 – 5.16
HGB (g/L)	120 – 172	133 – 172	120 – 150
MCV (fL)	78 – 96	81 – 94	78 – 96
HCT	35 – 51	39 – 51	35 – 45
MCH (pg)	26.40 – 33.20	27.10 – 32.50	26.40 – 33.20
MCHC (g/L)	318 – 367	325 – 367	318 – 359
RDWsd (fL)	40.0 – 60.0	40.0 – 60.0	40.0 – 60.0
RDWcv%	11.3 – 14.7	11.5 – 14.1	11.3 – 14.7
PLT ($10^9/L$)	172 – 440	179 – 373	172 – 440
MPV (fL)	6.1 – 9.1	6.1 – 8.9	6.3 – 9.1
PCT%	0.10 – 0.50	0.10 – 0.50	0.10 – 0.50
PDWsd (fL)	9.5 – 15.2	9.5 – 15.2	9.5 – 15.2
PDWcv%	9.1 – 15.4	9.1 – 15.4	9.1 – 15.4
PLC-R%	19 – 44	19 – 44	19 – 44
PLC-C ($10^9/L$)	33 – 192	33 – 192	33 – 192

Appendix 1. Explanation of NLR parameter

Interpretation and application of the NLR parameter

What is the NLR parameter?

The **NLR** or **Neutrophil-to-Lymphocyte Ratio** is calculated by dividing the number of neutrophils by the number of lymphocytes. It is often used as a marker of subclinical inflammation.

$$\text{NLR} = \text{NEU} / \text{LYM}$$

The importance of the NLR parameter is described in a Chinese medical publication: ***Neutrophil-to-Lymphocyte Ratio Predicts Severe Illness Patients with 2019 Novel Coronavirus in the Early Stage***³ (the link and an excerpt of this article can be found below). In this study the data of 61 patients with 2019-nCoV pneumonia were analyzed. The study concludes that the **age of the patient and the NLR value can be an early indication on the severity progress of the disease**. Mindray Co., a Chinese hematology cell counter manufacturer, also issued a press release recommending the use of the NLR parameter to monitor, assess, and verify the severity course of COVID-19.

How to interpret the NLR parameter?

- Unfortunately, the **NLR value alone is not sufficient for coronavirus screening** as it does not indicate the presence or absence of the infection.
- Unfortunately, the NLR parameter alone is not capable of indicating the current status or future course of the disease of healthy or asymptomatic virus infected individuals.
- The NLR parameter alone CANNOT be used to give diagnosis and/or treatment and cannot by itself provide a basis for assessing or deciding on a patient's condition.
- **NLR can provide a foresight and a decision point** for doctors at the front line of the epidemic that if someone is proven to be infected and has symptoms, he or she is under care and the patient's immune system is fighting the virus, then **based on the patient's age and the measured NLR, the severity of the disease course can be estimated and preparations can be made in advance.**
- The NLR value can change drastically from day to day during the course of the disease.

- According to the article¹, the results showed that **NLR was the most significant factor affecting the severe illness incidence, and it had significant predictive value.**

Based on this article's recommendation, how to use the NLR parameter?

Age (year)	NLR	Course/Treatment
≥ 50	NLR ≥ 3.13	50% of patients developed severe course of the disease ↓ intensive care and invasive ventilation are likely
≥ 50	NLR < 3.13	9.1% of patients developed severe course of the disease ↓ hospital isolation with respiratory monitoring should be considered
< 50	NLR ≥ 3.13	the necessity of hospital isolation is likely
< 50	NLR < 3.13	the necessity of hospitalization or home isolation is likely

How does the NLR parameter appear on Hemolyzer 5 NG (closed and open mode) analyzers?

The analyzer displays the NLR parameter among other WBC parameters; high value receives an arrow – based on Chinese experience, the factory default NLR threshold is 3.13, but it is adjustable. Please note that **NLR** is calculated from the **neutrophil percentage (NEU%)** and **lymphocyte percentage (LYM%)** values in our analyzers.

To the left is the full screen result screen, and to the right is the abbreviated quick result screen.



*The NLR parameter is displayed as a **Research Use Only (RUO)** parameter.

References

1st Article:

Neutrophil-to-Lymphocyte Ratio Predicts Severe Illness Patients with 2019 Novel Coronavirus in the Early Stage, DOI:

<https://doi.org/10.1101/2020.02.10.20021584>

A follow-up analysis of 61 COVID-19 patients that were treated in Beijing's Ditan Hospital from January 13 to 31, 2020, found that out of 26 quantitative health risk indicators for patients, NLR, age and the presence of hypertension had most predictive value indicating the severity course of the disease.

Compared to several risk statistical models (MUBSTA, CURB-65), the NLR parameter in terms of its specificity and selectivity (as summed by the so-called Youden index) performed better than the other two in predicting the severity course of the disease.

2nd Article:

Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study, DOI:

[https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(20\)30211-7.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)30211-7.pdf)

By analyzing data from 99 patients who were treated in Wuhan Hospital between January 1 and 20, 2020, the study concludes that the NLR changes over time during the course of COVID-19, due to the fact that the disease reduces the number of T-lymphocytes while increasing the neutrophil granulocyte count. It is important to note that the NLR has increased above 3.13 between the 5th and 9th day after the onset of symptoms. This is important because during this period patients typically only have fever, cough and muscle stiffness externally, and the more severe symptoms can only be observed by chest X-rays (pulmonary lesions, see Mindray summary), however, the NLR parameter can already indicate at this point whether the symptoms will worsen over the next few days or not.

Directives and Standards

Hemolyzer 5 NG complies with the following directives and standards as listed below.

Directives		
1.	98/79/EC	on in vitro diagnostic medical devices (IVD)
2.	2011/65/EU	on restriction of hazardous substances (ROHS)
3.	2014/30/EC	on electromagnetic compatibility (EMC)
4.	2014/35/EC	on low voltage (LVD)
5.	2012/19/EU WEEE	on waste electrical and electronic equipment (WEEE)
Standards		
1.	EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
2.	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
3.	EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
4.	EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
5.	EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
6.	EN ISO 18113-3:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
7.	EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
8.	EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
9.	EN 62304:2006	Medical device software – Software life-cycle processes

Hypochlorite Solution

► Product Information ◀

Product name	Product code
H3/5-Hypoclean	HE3413

► Product Content ◀

	HE3413
H3/5-Hypoclean	5x100 mL
Instructions for Use	1 pc

► Intended Use and Test Principle ◀

H3/5-Hypoclean detergent is a stabilized and micro-filtered hypochlorite solution for intensive oxidative rinsing and cleaning of capillaries, tubing, and chambers of Hemolyzer® semi-automated hematology analyzers.

The detergent is intended for laboratory professional use as an in vitro diagnostic medical device.

► Detergent Preparation ◀

The product is ready to use, please follow the installation procedures of this instructions for use.

► Product Composition ◀

	H3/5-Hypoclean
Detergents	< 0.1 %
Sodium hypochlorite	< 5.0 %
Stabilizers	< 0.1 %
Sodium hydroxide	< 1.0 %
Ion-free water	> 93.8 %



► Warnings and Precautions ◀

- Read instructions for use carefully before use.
- Do not use the product beyond the expiry date.
- Do not use the product if the primary package is damaged or there is visible sign of chemical deterioration of the liquid inside. In both cases the product should be replaced.
- Always keep the detergent in its original container.
- Store at the recommended temperature range.
- Do not use the product if it has been frozen or kept at excessive heat. Use the product at room temperature (18-30°C). If it has been stored below 18°C or above 30°C, leave it at normal room temperature for 3 hours before use.
- Do not mix the remains of a detergent with another container.
- Do NOT place the product above the instrument or on the ground! Place it on the same level as the analyzer.
- Users are advised to wear approved protective clothing when handling chemical products: lab coat, gloves, and eye protection.
- Observe standard laboratory precautions for use and follow national or local health and safety guidelines.
- Avoid contact with eyes, skin, and clothing. In case of contact with eyes or skin, rinse immediately with plenty of water.
- Please refer to the product's Safety Data Sheet.
- Please report any serious incident involving the product to the manufacturer and the competent local authority.

► Storage and Shelf Life ◀

- Storage conditions: **2-35°C.**
- Shelf life: **2 years.**
- Open bottle stability: **6 months.**
- Expiry date: **refer to the product's labeling.**

► Waste Management ◀

Dispose waste product, unused product, and contaminated packaging in compliance with local regulations.



► How to Use: Hemolyzer® 3 NG ◀

Materials required but not provided

- Hemolyzer® 3 NG hematology analyzer.
- Empty cleaning tube.

Cleaning procedure

The detergent is used to perform weekly maintenance procedures on the Hemolyzer® 3 NG hematology analyzer, such as closed sampling cleaning, open sampling cleaning, rinsing and RBC cleaning. When cleaning is required, the calendar icon will appear on the screen.



To perform these regular cleaning procedures, tap on »Management« in the main menu, then go to the »Cleaning« submenu. Please follow the instructions on the analyzer. The software guides you through the cleaning processes.

► How to Use: Hemolyzer® 5 NG ◀

Materials required but not provided

- Hemolyzer® 5 NG hematology analyzer.
- Reagent pickup tubes and caps.

Detergent installation precautions

- Person installing the detergent must be trained laboratory professional.
- Use the reagent pickup tubes and caps supplied with the instrument.
- Clean the pickup tubes by wiping them from top to bottom, using lint-free tissue dampened with distilled water. Avoid any dust or microbial contamination of the tubing and detergent.

Cleaning procedure

The detergent is used to perform RBC Hard Clean cleaning procedure on the Hemolyzer® 5 NG hematology analyzers. Performing the cleaning is recommended if the analyzer reports 5 consecutive samples with Contamination flag.

To perform RBC Hard Clean, tap on »Management« in the main menu, then go to the »Cleaning« submenu. There are two different cleaning options to choose from depending on which reagent pickup tube set is in use:

- Cleaning with old tubing set – without Quick Lock
- Cleaning with new tubing set – with Quick Lock

Please follow the instructions on the analyzer. The software guides you through the cleaning processes.

► Explanation of Symbols ◀

	Catalogue number		Batch number
	Expiry date		In vitro diagnostic medical device
	Permitted storage temperature		CE mark
	See the instructions for use		Manufacturer
	Corrosion – causes severe skin burns and eye damage.		Content
	Date of manufacture		Distributor

H5-Check

Hemolyzer® 5 NG Control Set



Order information:

Catalog-No.	Article name	Content
HE5504	H5-Check Complete	6 x 3.0 mL (L, N, H)
HE5505	H5-Check Normal	6 x 3.0 mL (N)

Intended Use:

H5-Check Control Sets are intended for quality control measurements on Analyticon hematology analyzers Hemolyzer® 5 NG (open and closed mode) (HE5100 and HE5200), and serve to validate the measurement results.

Reagents:

The H5-Check Control Set contains human erythrocytes, mammalian leukocytes, and mammalian platelets suspended in a plasma-like fluid with preservatives. For lot-specific target values, please refer to the table below.

Warning and Precautions:

For in vitro diagnostic use only.

For trained laboratory professional only.



All body fluid samples should be considered potentially infectious materials. The product was tested negative against anti-HIV 1 and 2, anti-HCV and HBsAg, but since no test method can rule out the danger of infection with absolute certainty, treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.

Exercise the normal precautions required for handling all laboratory reagents. Disposal of the product should be in accordance with local regulations. The material safety data sheet contains further safety-related information. It is available for download from our homepage <http://www.analyticon-diagnostics.com>.

Storage and Stability:

Unopened tube	Until the expiration date	2 – 8 °C
Opened tube	8 days	2 – 8 °C

Store the tubes in upright position. Do not freeze!

Indications of Deterioration:

After mixing, product should be similar in appearance to fresh whole blood. In unmixed vials, the supernatant may appear cloudy and reddish, which is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration. Do not use the product if deterioration is suspected.

Procedure:

1. Allow the tubes to warm to room temperature (15 to 30 °C) for at least 15 minutes.
2. Prior to the first use of the control, make sure to open the cap, and gently tighten it back ensuring no leaks. Do not overtighten the cap, otherwise you may experience needle clogs.
3. Invert the tubes for at least 20–30 seconds to mix the control material thoroughly. The red precipitate at the bottom of the tube has to be completely suspended and the red color of the fluid needs to be evenly distributed. Tubes stored for a long time might require longer mixing.
4. Gently invert the tube 8–10 times immediately before sampling and analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
5. If the tube has been open for sampling, clean residual material from the cap and tube rim with a lint-free tissue after the sampling. Close the cap tightly.
6. Return the tubes to refrigerator (2–8 °C) within 30 minutes of use.

Results and Expected Values:

Verify that the lot number on the tube matches the lot number on the table of target values.

Target values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents. The "Expected Range" takes inherent imprecision of the method and expected biological variability of the control material into account.

Minor variations may derive from different reagent batches, maintenance status, operating technique, and calibration and might contribute to inter-laboratory variation.

For greater control sensitivity, it is recommended that each laboratory establishes its own target value and expected range, and periodically re-evaluates the target value. The expected range of the laboratory may include values outside of the expected range given by the manufacturer.

Limitations of the Procedure:

The performance of this product is assured only if it is properly stored and handled as described in this insert. Incomplete mixing of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Control vials can be pierced maximum 40 times. After that the rubber part of the cap has the risk of dropping into the control, causing clogs in the instrument.

Text passages with grey background were changed in the latest revision of this package insert.



H5-Check

Hemolyzer® 5 NG Control Set



Bestellinformation:

Katalog-Nr.	Artikelname	Inhalt
HE5504	H5-Check Complete	6 x 3,0 mL (L, N, H)
HE5505	H5-Check Normal	6 x 3,0 mL (N)

Anwendungszweck:

Die H5-Check Kontrollsets sind für Qualitätskontrollmessungen an den Analyticon Hämatologie Analysegeräten Hemolyzer® 5 NG (open und closed mode) (HE5100 und HE5200) vorgesehen und dienen zur Validierung der Messergebnisse.

Reagenzien:

Das H5-Check Kontrollset enthält humane Erythrozyten, und Leukozyten und Blutplättchen von Säugetieren in einer Plasma-ähnlichen konservierten Flüssigkeit mit Konservierungsmitteln. Für Lot-spezifische Zielwerte, beziehen Sie sich bitte auf die Tabelle am Ende des Textes.

Warn- und Vorsichtshinweise:

Nur zum Gebrauch als in vitro Diagnostikum.

Anwendung nur durch geschultes Laborpersonal.



Alle Körperflüssigkeiten sollten als potentiell infektiöses Material betrachtet werden. Das Produkt wurde negativ auf anti-HIV 1 und 2, anti-HCV und HBsAg getestet, doch da keine Testmethode das Risiko einer Infektion mit absoluter Sicherheit ausschließen kann, behandeln Sie alle Blutproben und andere potentiell infektiöse Materialien mit den entsprechenden Vorsichtsmaßnahmen. Verwenden Sie Handschuhe, Atemschutz und Laborkleidung, falls der Kontakt mit Blut zu erwarten ist.

Die beim Umgang mit Laborreagenzien üblichen Vorsichtsmaßnahmen beachten. Bei der Entsorgung des Produktes müssen die jeweiligen gesetzlichen Vorschriften beachtet werden.

Weitere sicherheitsrelevante Informationen sind im Sicherheitsdatenblatt enthalten. Dieses steht auf unserer Homepage <http://www.analyticon-diagnostics.com> zum Download bereit.

Lagerung und Stabilität:

Ungeöffnetes Röhrchen	Bis zum Ende des Haltbarkeitsdatums	2 – 8 °C
Geöffnetes Röhrchen	8 Tage	2 – 8 °C

Lagern Sie die Röhrchen in aufrechter Position. Nicht einfrieren!

Anzeichen von Verfall des Produktes:

Nach dem Mischen sollte das Produkt ein ähnliches Aussehen wie frisches Vollblut aufweisen. In ungemischten Röhrchen kann der Überstand wolkig rötlich erscheinen, was normal und kein Zeichen von Verfall ist. Andere Verfärbungen, ein sehr dunkelroter Überstand oder unerwartete Ergebnisse können Zeichen von Verfall sein. Verwenden Sie das Produkt nicht, wenn Sie Verfall vermuten.

Vorgehen:

1. Geben Sie den Röhrchen mindestens 15 Minuten Zeit, um Raumtemperatur (15 bis 30 °C) zu erreichen.
2. Achten Sie darauf, dass die Kappe der Kontrolle vor dem ersten Gebrauch geöffnet und vorsichtig wieder angezogen wird, um Undichtigkeiten zu vermeiden. Ziehen Sie die Kappe nicht zu fest an, da es sonst zu Verstopfungen der Nadel kommen kann.
3. Invertieren Sie die Röhrchen für mindestens 20–30 Sekunden, um das Kontrollmaterial gründlich durchzumischen. Der rote Niederschlag auf dem Boden der Röhrchen muss vollständig aufgelöst und die rote Farbe der Flüssigkeit gleichmäßig verteilt sein. Röhrchen, die für längere Zeit gelagert wurden, bedürfen eventuell längerem Mischen.
4. Invertieren Sie die Röhrchen kurz vor der Probenahme noch einmal 8–10 Mal. Messen Sie die Proben wie in dem Kapitel zur Qualitätskontrolle in Ihrem Gerätehandbuch beschrieben.
5. Falls das Röhrchen während der Probenentnahme geöffnet worden ist, reinigen Sie die Kappe und den Rand des Röhrchens mit einem fusselfreien Tuch, bevor Sie es wieder fest verschließen.
6. Stellen Sie die Röhrchen innerhalb von 30 Minuten wieder kühl (2–8 °C).

Ergebnisse und Zielwerte:

Stellen Sie sicher, dass die Lot Nummern auf den Röhrchen und der Tabelle mit Zielwerten übereinstimmen. Die Zielwerte wurden auf gut gewarteten, sorgfältig kalibrierten Analysegeräten mit den vom Hersteller empfohlenen Reagenzien bestimmt. Der akzeptable Bereich bezieht die inhärente Ungenauigkeit der Methode und die erwartete biologische Variabilität des Kontrollmaterials mit ein.

Verschiedene Reagenzchargen, Wartungsstatus, Durchführung und Kalibration können geringe Schwankungen ergeben, die zu Abweichungen zwischen verschiedenen Laboren beitragen.

Um eine erhöhte Kontrollsensitivität zu erreichen, wird empfohlen, eigene Sollwerte und einen akzeptablen Bereich zu bestimmen und diesen regelmäßig zu bestätigen. Der akzeptable Bereich des einzelnen Labors kann Werte außerhalb des akzeptablen Bereiches des Herstellers enthalten.

Einschränkungen der Anwendung:

Die Leistung dieses Produktes ist bei ordnungsgemäßer Lagerung und Handhabung sichergestellt. Ungenügendes Mischen vor der Verwendung macht die eingesetzte Probe und das verbliebene Material im Probenröhrchen unbrauchbar.

Der Gummiteil der Kappe des Kontrollröhrchens kann maximal 40 Mal durchstochen werden. Danach besteht die Gefahr, dass Gummiteile der Kappe in die Kontrolle fallen und im Anschluss das Gerät verstopfen.

Grau hinterlegte Textpassagen wurden in der letzten Überarbeitung dieser Gebrauchsanweisung geändert.



H5-Check

Hemolyzer® 5 NG Control Set



Información del pedido:

No. de Catálogo	Nombre del artículo	Contenido
HE5504	H5-Check Complete	6 x 3,0 mL (L, N, H)
HE5505	H5-Check Normal	6 x 3,0 mL (N)

Uso previsto:

H5-Check Control Sets están diseñados para las mediciones de control de calidad en los analizadores hematológicos Analyticon® Hemolyzer® 5 NG (modo abierto y cerrado) (HE5100 y HE5200) y se utilizan para validar los resultados de la medición.

Reactivos:

El H5-Check Control Set contiene eritrocitos humanos, leucocitos de mamífero y plaquetas de mamífero suspendidas en un líquido similar al plasma con conservantes. Para los valores previstos específicos del lote, consulte la tabla siguiente.

Advertencias y precauciones:

Solamente para uso en diagnóstico in vitro.

Sólo para uso del profesional de laboratorio capacitado



Todas las muestras de fluidos corporales deben considerarse materiales potencialmente infecciosos. El producto dio negativo contra el VIH 1 y 2, el VHC y el HBsAg, pero como ningún método de prueba puede descartar el peligro de infección con absoluta certeza, trate toda la sangre y otros materiales potencialmente infecciosos con las precauciones adecuadas. Use guantes, máscaras y batas si se prevé la exposición a la sangre.

Siga las precauciones habituales requeridas al manipular todos los reactivos de laboratorio. La eliminación del producto debe realizarse de acuerdo con las normativas locales.

La ficha de datos de seguridad de materia contiene mayor información relacionada a la seguridad. Disponible en nuestro sitio <http://www.analyticon-diagnostics.com>.

Almacenamiento y estabilidad:

Envase sin abrir	Hasta la fecha de vencimiento	2 – 8 °C
Envase abierto	8 días	2 – 8 °C

Guarde los tubos en posición vertical. ¡No congelar!

Indicaciones de deterioro:

Después de mezclar, el producto debe tener un aspecto similar al de la sangre entera fresca. En viales no mezclados, el sobrenadante puede aparecer turbio y rojizo; esto es normal y no indica deterioro. Otra decoloración, un sobrenadante de color rojo muy oscuro o resultados inaceptables pueden indicar deterioro. No utilice el producto si sospecha que está deteriorado.

Procedimiento:

1. Dejar que los tubos alcancen la temperatura ambiente (de 15 a 30 ° C) durante al menos 15 minutos.
2. Asegúrese de abrir la tapa del tubo del control antes del primer uso y vuelva a apretarla suavemente para evitar fugas. No apriete demasiado la tapa, ya que esto podría bloquear la aguja.
3. Invierta los tubos durante al menos 20-30 segundos para mezclar bien el material de control. El precipitado rojo en el fondo del tubo tiene que estar completamente suspendido y el color rojo del fluido tiene que ser distribuido uniformemente. Los tubos almacenados durante mucho tiempo pueden requerir una mezcla más larga.
4. Invierta suavemente el tubo de 8 a 10 veces inmediatamente antes del muestreo y analice la muestra como se indica en la sección de Control de Calidad del Manual del Operador de su instrumento.
5. Si el tubo ha sido abierto para el muestreo, limpie el material residual de la tapa y el borde del tubo con un pañuelo sin pelusa después del muestreo. Cierre bien la tapa.
6. Regrese los tubos al refrigerador (2–8 ° C) dentro de los 30 minutos de uso.

Resultados y valores esperados:

Verifique que el número de lote en el tubo coincida con el número de lote en la tabla de valores objetivo.

Los valores objetivo se determinan en instrumentos bien mantenidos y debidamente calibrados utilizando los reactivos recomendados por el fabricante del instrumento. El "Rango esperado" tiene en cuenta la imprecisión inherente del método y la variabilidad biológica esperada del material de control.

Las variaciones menores pueden derivarse de diferentes lotes de reactivos, estado de mantenimiento, técnica operativa y calibración, y pueden contribuir a la variación entre laboratorios.

Para una mayor sensibilidad de control, se recomienda que cada laboratorio establezca su propio valor objetivo y rango esperado, y que reevalúe periódicamente el valor objetivo. El rango esperado del laboratorio puede incluir valores fuera del rango esperado dado por el fabricante.

Limitaciones del procedimiento:

El rendimiento de este producto sólo está garantizado si se almacena y manipula correctamente tal y como se describe en este prospecto. La mezcla incompleta de un tubo antes de su uso invalida tanto la muestra extraída como cualquier material remanente en el tubo.

La parte de goma de la tapa del tubo del control puede perforarse un máximo de 40 veces. Después de esto existe el riesgo de que las partes de goma de la tapa caigan en el control pudiendo obstruir posteriormente el dispositivo.

Los pasajes de texto con fondo gris se cambiaron en la última revisión de este prospecto.



Информация о заказе:

Но. по каталогу	Название изделия	Содержимое
HE5504	H5-Check полный	6 x 3,0 мл (L, N, H)
HE5505	H5-Check нормальный	6 x 3,0 мл (N)

Предназначенное использование:

Контрольные наборы H5-Check предназначены для измерений контроля качества гематологических анализаторов компании «Analyticon» Hemolyzer® 5 NG (закрытый и открытый режим) (HE5100 и HE5200) и служат для подтверждения результатов измерений.

Реагенты:

Контрольный набор H5-Check состоит из эритроцитов человека, лейкоцитов млекопитающих и тромбоцитов млекопитающих, суспендированных в сходной с плазмой жидкости с консервантами. Для заданных значений специфических лотов, пожалуйста, обратитесь к таблице ниже.

Предупреждение и меры предосторожности:

Только для диагностики in vitro.

Только для обученных лабораторных специалистов.



Все образцы жидкостей организма должны рассматриваться как потенциально инфекционные материалы. Были получены отрицательные результаты в испытаниях продукта в отношении анти-HIV 1 и 2, анти-HCV и HBsAg, но, поскольку ни один метод тестирования не может исключить опасность инфекции с абсолютной уверенностью, обрабатывайте всю кровь и другие потенциально инфекционные материалы с соответствующими мерами предосторожности. Используйте перчатки, маски и халаты, если предполагается возможное попадание крови.

Соблюдайте обычные меры предосторожности, необходимые для работы со всеми лабораторными реагентами. Утилизация продукта должна осуществляться в соответствии с местными правилами. Паспорт безопасности материала содержит дополнительную информацию, касающуюся безопасности. Ее можно загрузить с нашей домашней страницы <http://www.analyticon-diagnostics.com>.

Хранение и стабильность:

Неоткрытая пробирка	до истечения срока годности	2 - 8 ° C
Открытая пробирка	8 дней	2 - 8 ° C

Хранить пробирки в вертикальном положении. Не замораживать!

Признаки испорченности продукта:

После размешивания продукт должен быть внешне похож на свежую цельную кровь. В неразмешанных флаконах супернатант может выглядеть мутным и красноватым, что является нормальным и не указывает на испорченность. Другие изменения цвета, очень темный красный супернатант или неприемлемые результаты могут указывать на испорченность продукта. Не используйте продукт, если есть подозрение на его испорченность.

Процедура:

1. Дайте пробиркам согреться до комнатной температуры (от 15 до 30°C) в течение не менее чем 15 минут.
2. Перед первым использованием регулятора убедитесь в том, что крышка открыта и аккуратно затяните ее назад, чтобы не допустить утечек. Не затягивайте крышку слишком сильно, иначе может возникнуть засор иглы.
3. Переверачивайте пробирки в течение не менее 20–30 секунд, чтобы полностью перемешать контрольный материал. Красный осадок на дне пробирки должен быть полностью растворён, а красный цвет жидкости должен быть равномерно распределен. Пробирки, хранящиеся в течение длительного времени, могут потребовать более длительного перемешивания.
4. Осторожно переверните пробирку 8–10 раз непосредственно перед отбором образцов и проанализируйте образец, как указано в разделе «Контроль качества» руководства по эксплуатации вашего прибора.
5. Если пробирка открыта для отбора образцов, то после отбора образцов удалите остатки материала с крышки и края пробирки безворсовой тканью. Закройте плотно крышку.
6. Верните пробирки в холодильник (2–8° C) в течение 30 минут после использования.

Результаты и ожидаемые значения:

Убедитесь, что номер лота на пробирке соответствует номеру лота в таблице заданных значений.

Заданные значения определяются на приборах в хорошем состоянии с правильным техническим обслуживанием и правильно откалиброванных с использованием рекомендованных производителем реагентов. «Ожидаемый диапазон» учитывает внутреннюю неточность метода и ожидаемую биологическую изменчивость контрольного материала.

Незначительные отклонения могут быть вызваны различными партиями реагентов, состоянием технического обслуживания, техникой эксплуатации и калибровкой, и могут вызывать отклонения в межлабораторные вариации.

Для большей чувствительности контроля рекомендуется, чтобы каждая лаборатория устанавливала свое собственное заданное значение и ожидаемый диапазон и периодически проводила повторную оценку заданного значения. Ожидаемый диапазон конкретной лаборатории может включать в себя значения за пределами ожидаемого диапазона, указанного производителем.

Ограничения процедуры:

Результативность этого продукта гарантируется, только если он правильно хранится и обрабатывается, как описано в этом вкладыше. Неполное размешивание пробирки перед использованием делает недействительным как отобранный образец, так и любой остаточный материал в пробирке.

Резиновая часть колпачка контрольного флакона может быть проколота максимум 40 раз. После этого существует риск попадания резиновых частей колпачка в контрольный флакон, что приведет к засорению прибора.

Текстовые фрагменты отмеченные серым фоном были изменены в последней редакции данного руководства.



H5-Compact

Hemolyzer® 5 NG Reagent Pack



Order information:

Catalog-No.	Content	Volume	Total
HE5701	H5-DIL H5-LYSE H5-CLEAN	3400 mL 600 mL 300 mL	100 Tests
HE5704	H5-DIL H5-LYSE H5-CLEAN	5000 mL 1000 mL 300 mL	400 Tests

Intended use:

H5-Compact is a set of reagents intended to be used on the Analyticon hematology analyzer Hemolyzer® 5 NG (closed mode) (HE5100).

The reagents of the H5-Compact should only be replaced with Analyticon reagents. Erroneous results may be obtained if the reagent pack is applied with third party reagents. Please refer to the instrument's User Manual for further information.

Summary and Explanation:

HE5701: This reagent pack is designed to supply suitable amount of reagent to run 100 tests on the Analyticon hematology analyzer Hemolyzer® 5 NG (closed mode) (HE5100) under the condition that the user runs 3 measurements per day. Further conditions that need to be fulfilled are listed under "Reagent Preparation and Replacement".

HE5704: This reagent pack is designed to supply suitable amount of reagent to run 400 tests on the Analyticon hematology analyzer Hemolyzer® 5 NG (closed mode) (HE5100) under the condition that the user runs 25 measurements per day. Further conditions that need to be fulfilled are listed under "Reagent Preparation and Replacement".

Reagent Concentration:	H5-DIL	H5-LYSE	H5-CLEAN
Sodium chloride	< 1.6 %		
Buffers	< 1.1 %	< 1.8 %	< 1.0 %
Stabilizers	< 1.0 %	< 1.1 %	< 0.9 %
Preservatives	< 0.7 %	< 1.0 %	< 0.8 %
Surfactants		< 0.5 %	< 1.1 %
in ion-free water			

Warning and Precautions:

For in vitro diagnostic use only.

For trained laboratory professional only.

The reagents are environmental friendly, azide-free and do not contain harmful ingredients. Exercise the normal precautions required for handling all laboratory reagents. Disposal of the product should be in accordance with local regulations.

The material safety data sheet contains further safety-related information. It is available for download from our homepage <http://www.analyticon-diagnostics.com>.

Reagent Preparation and Replacement:

The reagent is ready for use.

1. Leave the reagent to reach room temperature before using it.
2. Open the caps of the bottles inside the reagent pack. Cut the sealing foil on the new reagents to allow the tubes go through. Immerse the caps with tubes into the reagents and tighten the caps. Make sure that the color on each tube, reagent container label and connector in the back of the instrument match (green=H5-DIL; yellow=H5-LYSE; white=H5-CLEAN).
3. Always keep the reagent in its original container and do not mix the remains of two reagent containers.
4. Do not touch the tubes that go into the reagents. Avoid any dust or microbial contamination of the tubing and reagents. If you find the tubes dirty, you can clean them using a dampened lint-free wiping paper. Clean the tubes by swiping them top-down.
5. Do not close the pack lid to not pinch the tubes!
6. Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
7. When installing a new lot of reagent, verify calibration by running control material. Recalibrate the instrument if necessary as specified in your User Manual.
8. Scan the QR code which can be found on the inside on the package insert of the pack (refer to the User Manual).



The reagent pack can be used for the designated number of tests, as long as the following conditions are fulfilled:

- The user measures more than the minimum number of tests per day (refer to "Summary and Explanation").
- The analyzer performs two Fast Blank measurements each day.
- The analyzer is powered off every day.
- The user performs necessary maintenance actions prompted by the analyzer's operating software.

The analyzer software will stop automatically after the specified number of tests were performed. Depending on usage, the amount of leftover reagent inside the package may vary.

Quality Control samples, Calibration samples, Open mode and Closed mode Samples will equally reduce the number of tests that can be performed with the package.

Running a lower number of tests per day than the conditions listed above will use relatively more reagents, and the pack will run out before the designated number of tests.

Fast Blank measurements consume less reagent than sample measurements, however, running Fast Blank measurements beyond the conditions listed above will also decrease the available number of tests.

In case the conditions described above are not fulfilled, there is no warranty that the designated number of tests that can be performed with the volume of the reagent pack. No liability is accepted for leftover reagent in the pack after all available tests have been performed.

Storage and Stability:

Unopened container	Up to the expiration date	2 – 35°C
Open container	6 months	2 – 35°C

Keep the reagent containers closed when not in use.

Do not freeze!

Specimen Collection and Preparation:

H5-Compact is intended for use with blood specimens collected by venipuncture in EDTA anticoagulant.

Specimens for hematological analysis may be stored for up to 6 hours at 15–30°C or up to 10 hours after collection when refrigerated at 2–8°C.

If the specimen is refrigerated at 2–8°C, please wait 30 minutes for the specimens to warm up before proceeding to the measurement.

All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.

Place QR code



H5-Compact

Hemolyzer® 5 NG Reagent Pack



Bestellinformation:

Katalog-Nr.	Inhalt	Volumen	Gesamt
HE5701	H5-DIL	3400 mL	100 Tests
	H5-LYSE	600 mL	
	H5-CLEAN	300 mL	
HE5704	H5-DIL	5000 mL	400 Tests
	H5-LYSE	1000 mL	
	H5-CLEAN	300 mL	

Anwendungszweck:

H5-Compact ist ein Set von Reagenzien für die Anwendung auf dem Analyticon Hämatologie-Analysegerät Hemolyzer® 5 NG (closed mode) (HE5100).

Die Reagenzien des H5-Compact sollten nur mit Analyticon Reagenzien erneuert werden. Falsche Resultate können erzielt werden, wenn das Reagenzpack mit Drittparteireagenzien genutzt wird. Weitere Informationen finden Sie im Benutzerhandbuch des Geräts.

Zusammenfassung und Erläuterung:

HE5701: Diese Reagenzpackung enthält genügend Volumen, um 100 Messungen auf dem Analyticon Hämatologie-Analysegerät Hemolyzer® 5 NG (closed mode) (HE5100) durchführen zu können, unter der Voraussetzung von 3 Tests pro Tag. Außerdem müssen die Bedingungen im Absatz „Vorbereitung und Platzierung der Lösung“ erfüllt sein.

HE5704: Diese Reagenzpackung enthält genügend Volumen, um 400 Messungen auf dem Analyticon Hämatologie-Analysegerät Hemolyzer® 5 NG (closed mode) (HE5100) durchführen zu können, unter der Voraussetzung von 25 Tests pro Tag. Außerdem müssen die Bedingungen im Absatz „Vorbereitung und Platzierung der Lösung“ erfüllt sein.

Reagenzkonzentration:	H5-DIL	H5-LYSE	H5-CLEAN
Natriumchlorid	< 1,6 %		
Puffer	< 1,1 %	< 1,8 %	< 1,0 %
Stabilisatoren	< 1,0 %	< 1,1 %	< 0,9 %
Konservierungsmittel	< 0,7 %	< 1,0 %	< 0,8 %
Tenside		< 0,5 %	< 1,1 %

in deionisiertem Wasser

Warn- und Vorsichtshinweise:

Nur zum Gebrauch als in vitro Diagnostikum.
Anwendung nur durch geschultes Labormaterial.
Die Reagenzien sind umweltfreundlich, frei von Aziden und schädlichen Inhaltsstoffen. Die beim Umgang mit Laborreagenzien üblichen Vorsichtsmaßnahmen beachten. Bei der Entsorgung des Produktes müssen die jeweiligen gesetzlichen Vorschriften beachtet werden.
Weitere sicherheitsrelevante Informationen sind im Sicherheitsdatenblatt enthalten. Dieses steht auf unserer Homepage <http://www.analyticon-diagnostics.com> zum Download bereit.

Vorbereitung und Platzierung der Lösung:

Die Lösungen sind gebrauchsfertig.

- Lassen Sie das Reagenz Raumtemperatur erreichen.
- Entfernen Sie die Einlassverschraubung vom zu ersetzenden Container. Öffnen Sie die Versiegelungsfolie des neuen Reagenzbehälters, um die Schläuche hindurchstecken zu können. Schließen Sie den Reagenzeingang an den neuen Reagenzbehälter an. Versichern Sie sich, dass die Farbe auf dem Schlauch, dem Reagenzcontainer und dem Verbindungsstück auf der Rückseite des Instruments zusammenpassen (grün=H5-DIL; gelb=H5-LYSE; weiß=H5-CLEAN).
- Bewahren Sie das Reagenz stets in seinem Originalbehälter auf und vermischen Sie nicht verbliebenes Reagenz von zwei verschiedenen Behältern.
- Vermeiden Sie Kontakt mit den Schläuchen, die mit Reagenz in Berührung kommen. Vermeiden Sie jeglichen Staub oder bakterielle Kontamination der Schläuche und der Reagenzien. Bei Verunreinigungen können Sie die Schläuche mit einem feuchten faserfreien Tuch von oben nach unten abwischen.
- Schließen Sie den Deckel des Kartons nicht, um die Schläuche nicht abzuklemmen.
- Spülen Sie gründlich mit dem neuen Reagenz und messen Sie den Hintergrund entsprechend den Angaben des Benutzerhandbuchs.
- Bei Installation von neuen Reagenz-Lots, verifizieren Sie die Kalibration mittels Qualitätskontrollproben. Rekalibrieren Sie das Instrument wie in Ihrem Benutzerhandbuch spezifiziert.
- Scannen Sie den QR Code auf der Gebrauchsanweisung der Reagenzpackung (siehe Benutzerhandbuch).



Die Reagenzpackung kann für die angegebene Anzahl an Tests verwendet werden, solange die folgenden Bedingungen erfüllt sind:

- Der Benutzer misst die minimal angegebene Anzahl an Tests pro Tag (siehe „Zusammenfassung und Erläuterung“).
- Das Gerät führt zwei Fast Blank Messungen pro Tag durch.
- Das Gerät wird am Ende jedes Tages heruntergefahren.
- Der Benutzer führt die notwendigen Wartungsprozeduren durch, zu denen die Software des Gerätes auffordert.

Die Gerätesoftware stoppt automatisch, nachdem die angegebene Anzahl an Messungen durchgeführt wurde. Die verbliebene Menge an Reagenz in den Behältern kann abhängig von der Benutzung variieren.

Messung von Qualitätskontrollproben, Kalibrationsproben, Open Mode und Closed Mode Proben verringert gleichermaßen die angegebene Anzahl an verbliebenen Messungen, die mit der Reagenzpackung durchgeführt werden können.

Eine geringere Anzahl an Tests pro Tag verbraucht relativ mehr Reagenz, sodass die Reagenzpackung vor Erreichen der angegebenen Anzahl an Messungen verbraucht sein wird.

Fast Blank Messungen verbrauchen weniger Reagenz als Probenmessungen, doch verringern eine höhere Anzahl an Fast Blank Messungen als oben angegeben ebenfalls die Anzahl der zur Verfügung stehenden Tests.

Falls die oben genannten Bedingungen nicht erfüllt wurden, ist die angegebene Anzahl an durchführbaren Tests mit dem Volumen der Reagenzpackung nicht gewährleistet. Für Restvolumina in der Reagenzpackung nach Durchführung aller verfügbaren Tests wird keine Haftung übernommen.

Lagerung und Stabilität:

Ungeöffneter Behälter	Bis zum Ablauf des Haltbarkeitsdatums	2 – 35°C
Geöffneter Behälter	6 Monate	2 – 35°C

Verschließen Sie die Behälter, wenn sie nicht in Benutzung sind.

Nicht einfrieren!

Probennahme und -vorbereitung:

H5-Compact ist für die Verwendung mit Blutproben bestimmt, die durch Venenpunktion in EDTA-Antikoagulans gesammelt wurden.

Proben für die hämatologische Untersuchung können nach Probenentnahme bis zu 6 Stunden bei 15–30 °C oder bis zu 10 Stunden bei 2–8°C gelagert werden.

Wenn die Proben bei 2–8°C gelagert wurden, inkubieren Sie sie 30 Minuten bei Raumtemperatur, bevor Sie mit der Messung beginnen.

Alle Körperflüssigkeiten sollten als potentiell infektiöses Material betrachtet werden. Behandeln Sie alle Blutproben und andere potentiell infektiöse Materialien mit den entsprechenden Vorsichtsmaßnahmen. Verwenden Sie Handschuhe, Atemschutz und Laborkleidung, falls der Kontakt mit Blut zu erwarten ist.

Place QR code



H5-Compact

Hemolyzer® 5 NG Reagent Pack



Información del pedido:

No. de Catálogo	Contenido	Volumen	Total
HE5701	H5-DIL	3400 mL	100 pruebas
	H5-LYSE	600 mL	
	H5-CLEAN	300 mL	
HE5704	H5-DIL	5000 mL	400 pruebas
	H5-LYSE	1000 mL	
	H5-CLEAN	300 mL	

Uso previsto:

H5-Compact es un conjunto de reactivos destinados a ser utilizados en el analizador hematológico Analyticon Hemolyzer® 5 NG (modo cerrado) (HE5100).

Los reactivos del H5-Compact sólo deben sustituirse por reactivos de Analyticon. Pueden obtenerse resultados erróneos si el paquete de reactivos se aplica con reactivos de terceros. Para mayor información, sírvase consultar el Manual del Usuario del equipo.

Resumen y explicación:

HE5701: Este paquete de reactivos está diseñado para suministrar la cantidad adecuada de reactivo para realizar 100 pruebas en el analizador hematológico Hemolyzer® 5 NG (modo cerrado) (HE5100) bajo la condición de que el usuario realice 3 mediciones al día. En "Preparación y reemplazo de reactivos" se enumeran otras condiciones que deben cumplirse.

HE5704: Este paquete de reactivos está diseñado para suministrar la cantidad adecuada de reactivo para realizar 400 pruebas en el analizador hematológico Hemolyzer® 5 NG (modo cerrado) (HE5100) bajo la condición de que el usuario realice 25 mediciones al día. En "Preparación y reemplazo de reactivos" se enumeran otras condiciones que deben cumplirse.

Concentración del Reactivo:	H5-DIL	H5-LYSE	H5-CLEAN
Cloruro de sodio	< 1,6 %		
Solución amortiguadora	< 1,1 %	< 1,8 %	< 1,0 %
Estabilizadores	< 1,0 %	< 1,1 %	< 0,9 %
Conservante	< 0,7 %	< 1,0 %	< 0,8 %
Surfactantes		< 0,5 %	< 1,1 %
en agua libre de iones			

Advertencias y precauciones:

Solamente para uso en diagnóstico in vitro.

Sólo para uso del profesional de laboratorio capacitado

Los reactivos son respetuosos con el medio ambiente, libres de azidas y no contienen ingredientes nocivos. Siga las precauciones habituales requeridas al manipular todos los reactivos de laboratorio. La eliminación del producto debe realizarse de acuerdo con las normativas locales.

La ficha de datos de seguridad de materia contiene mayor información relacionada a la seguridad. Disponible en nuestro sitio <http://www.analyticon-diagnostics.com>.

Preparación y reemplazo de reactivos:

El reactivo está listo para ser utilizado.

- Deje que el reactivo alcance la temperatura ambiente antes de usarlo.
- Retire la tapa de entrada del envase del reactivo que será reemplazado. Corte la lámina de sellado del reactivo nuevo para permitir el paso de los tubos. Conecte la entrada del reactivo al envase del nuevo reactivo. Asegúrese de que el color de cada tubo, la etiqueta del envase del reactivo y el conector en la parte posterior del equipo coincidan (verde=H5-DIL; amarillo=H5-LYSE; blanco=H5-CLEAN).
- Mantenga siempre el reactivo en su envase original y no mezcle los restos de dos envases de reactivos.
- No toque los tubos que entran en los reactivos. Evite cualquier contaminación, microbiana o debido al polvo, de los tubos y reactivos. Si encuentra los tubos sucios, puede limpiarlos con un paño de limpieza humedecido y sin pelusas. Limpie los tubos deslizándolos de arriba hacia abajo.
- No** cierre la tapa del envase para no pellizcar los tubos!
- Cebe cuidadosamente el nuevo reactivo y mida los parámetros según las especificaciones del Manual del Usuario.
- Al instalar un nuevo lote de reactivos, verifique la calibración ejecutando el material de control. Recalibre el equipo si es necesario tal como se especifica en su Manual del Usuario.
- Escanee el código QR que se encuentra en el interior del prospecto del paquete (consulte el Manual de Usuario).



El paquete de reactivos se puede utilizar para el número designado de pruebas, siempre que se cumplan las siguientes condiciones:

- El usuario mide más que el número mínimo de pruebas por día (consulte "Resumen y Explicación").
- El analizador realiza dos mediciones de Fast Blank cada día.
- El analizador se apaga todos los días.
- El usuario realiza las acciones de mantenimiento necesarias solicitadas por el software operativo del analizador.

El software del analizador se detendrá automáticamente después de que se haya realizado el número especificado de pruebas. Dependiendo del uso, la cantidad de reactivo sobrante dentro del paquete puede variar.

Muestras de Control de Calidad, Muestras de Calibración, Muestras en Modo Abierto y en Modo Cerrado reducirán igualmente el número de pruebas que se pueden realizar con el paquete.

Si se realiza un número menor de pruebas por día que las condiciones mencionadas anteriormente, se utilizarán relativamente más reactivos, y el paquete se agotará antes de que se realice el número designado de pruebas.

Las mediciones de Fast Blank consumen menos reactivos que las mediciones de muestras, sin embargo, si se realizan mediciones de Fast Blank más allá de las condiciones mencionadas anteriormente, también se reducirá el número de pruebas disponibles.

En caso de que no se cumplan las condiciones descritas anteriormente, no hay garantía de que se pueda realizar el número designado de pruebas con el volumen del paquete de reactivos. No se acepta ninguna responsabilidad por los restos de reactivos en el paquete después de que se hayan realizado todas las pruebas disponibles.

Almacenamiento y estabilidad:

Envase sin abrir	Hasta la fecha de vencimiento	2 – 35°C
Envase abierto	6 meses	2 – 35°C

Mantenga el envase del reactivo cerrado cuando no esté en uso.

¡No congelar!

Recolección y preparación de muestras:

El H5-Compact está ideado para utilizarse con muestras de sangre recogidas por venopunción en anticoagulante EDTA.

Las muestras para análisis hematológico pueden almacenarse hasta por 6 horas a 15–30°C, o hasta por 10 horas después de la recolección cuando se refrigeran (2–8 °C).

Si la muestra está refrigerada a 2–8°C, por favor espere 30 minutos para que se caliente antes de proceder a la medición.

Todas las muestras de fluidos corporales deben considerarse materiales potencialmente infecciosos. Trate toda la sangre y otros materiales potencialmente infecciosos con las precauciones apropiadas. Use guantes, máscaras y batas si se prevé la exposición a la sangre.

Place QR code



Analyticon® Biotechnologies AG
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(PH5-Compact_GB-D-ES_21_001_02.01_2018-11-26)



Authorization Certificate



Vitalie Goreacii

SANMEDICO SRL

This is to certify that the above named general manager has successfully completed the full application and technical training which was specifically prepared and carried out on the Analyticon Biotechnologies GmbH equipment mentioned below on May 24th to 25th, 2023

Hemolyzer[®] 3 NG
Hemolyzer[®] 5 NG

We hereby state that the general manager is authorized and qualified by Analyticon to do installation, operation, user and technical training, service and maintenance of the equipment listed above.

Analyticon
Biotechnologies GmbH
Customer Support & Trainings



Nathalie Mütze
Manager Customer Support

Leon Preljvukaj
Customer Support

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