

Magnetic Immunoassay Reader – Operator Manual

E-25-0025-01




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1 Introduction

The purpose of this manual is to provide instructions on how to safely and correctly use and service Magnia Reader (also “Reader” in this document).


Here are the symbols that are used throughout this documentation:

- 
WARNING | Information presented in this box warns about serious danger or damage to people and/or to equipment that may also lead to unreliable results. The instructions offer a safe way of proceeding
- 
CAUTION | Information presented in this box warns about possible damage to equipment and may also lead to unreliable results. The instructions offer a safe way of proceeding.
- 
NOTE | Information presented in this box needs to be especially carefully considered.

2 Magnetic Immunoassay Reader

The Reader is used for analyzing the magnetic particle content in various types of immunodiagnostic lateral flow tests. It offers superior detection limit for particles and a wide dynamic range and sensitiveness for measuring analytes under investigation.

The Reader supports analyzing several different types of test cartridges. New types of tests can be introduced without the need for alterations in the Reader.

 **NOTE** | The Reader may only be used for the purpose defined in this chapter, following the user and safety instructions specified in this manual. Lifeassays AB does not accept liability for any damage to people or equipment due to the misuse of the Reader.

2.1 Contact information and spare parts


LifeAssays AB
 Sölvegatan 43A
 22370 Lund
 SWEDEN
 Phone: +46 46 286 54 00
 Email: info@lifeassays.com
 Web: www.lifeassays.com

3 Contents of delivery

The following items are included in the delivery:

- 1 User Manual E-25-0025
- 1 Magnia Reader art no. 50101-10
- 1 USB cable art no. 50201-13
- 1 carrier art no. 50201-14
- 1 battery recharger art no. 50201-16
- 1 “Check calibration” card for manual calibration check art no. 50201-16
- 2 calibration cartridges for manual calibration check









In case some of these listed items are missing or damaged during transportation, please contact Lifeassays AB.

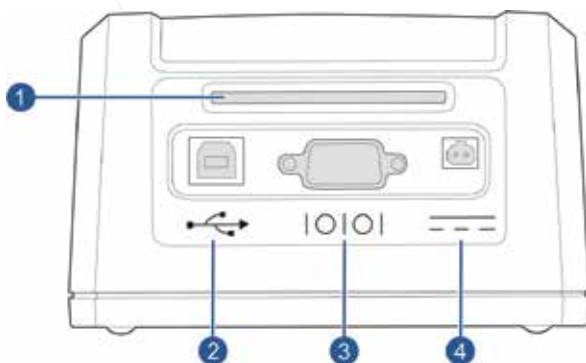
 **WARNING** | Do not use damaged equipment. It may cause serious damage or danger to people and/or equipment.

4 Technical information

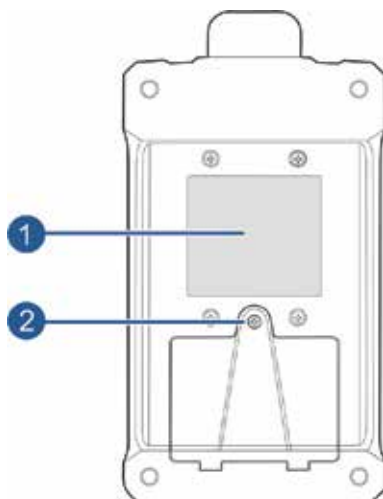
Technical data	
Battery recharger supply voltage	100 ... 240 V 50 ... 60 Hz
Battery	6 V 1650 mAh NiMH Product code 2350018
Weight of the Reader	910 g
Dimensions (width x length x height)	119 x 205 x 74 mm (without carrier)



No.	Part	Function
1.		Power button is used for switching the Reader power on and off. This button is also used for exiting error message states.
		Measure button is used for initiating the measurement sequence after the test cartridge has been inserted on the carrier.
		Transfer button is used for transferring the result from the Reader to a computer or a printer.
2	Recharging indication light	This light indicates the status of the battery recharging. When the battery is being recharged, the light blinks. When the light stays on, the battery is fully recharged.
		No function. Reserved for future updates.
		No function. Reserved for future updates.
		No function. Reserved for future updates.
		No function. Reserved for future updates.
		No function. Reserved for future updates.
3	Test cartridge	A test cartridge contains the test that is being measured.
4	Carrier	The carrier positions the test cartridge correctly for measurement. Inside the Reader there is a swing bed, which must be released so that it is down before the carrier is pushed in.
5.	Kensington lock location	A standard Kensington lock can be applied to lock the Reader in place.

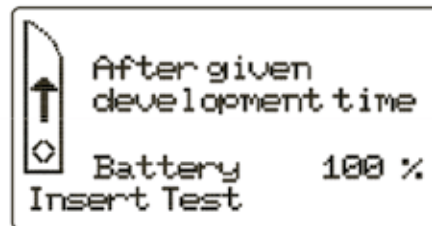


No.	Part	Function
1.	Memory card slot	Different kinds of data cards for different purposes – for example a calibration key or a software update memory card – are inserted here.
2.	USB port	The port where the USB cable is attached for connection with a computer.
3.	RS port	The port for connecting external peripherals, for example a printer.
4.	Recharger connection	The socket where the recharger is connected.



No.	Part	Function
1.	Type plate	Information about the Reader.
2.	Battery hatch screw	The screw that needs to be removed when replacing the battery.

4.1 The display

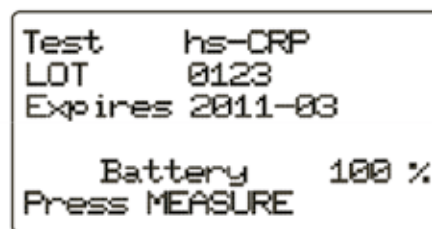


This is the main view of the display.

The last row gives instructions on what to do to proceed with the selected task, for example "Insert Test".

Warning messages are shown on the second last row, if there are any and the row is not otherwise used. Normally, the second last row indicates the battery status.

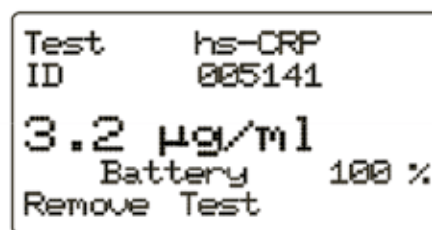
The warning messages are prioritized and the most critical is always shown.



During the testing sequence, the display shows the

- name of the test
- lot of the test
- expiration date of the test

And gives instructions on how to proceed.

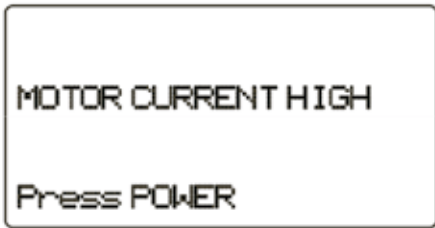


After the measurement is carried out, the display shows the

- name of the test
- identification number of the measurement
- result of the measurement

And gives instructions on how to proceed.

(4.1 The display. Cont.)



Error messages are shown on the display when such a failure occurs that requires actions to solve the situation. You can return to the display main view by pressing POWER button.

For more information, see chapter Warning and error messages.

4.2 Carrier

The Reader has a replaceable carrier. Test cartridges of various shapes and sizes can be read with the same Reader by using a carrier that is suitable for that particular test cartridge.

New replaceable carriers can be ordered from Lifeassays AB.

5. Setting up Reader

Lifeassays AB follows the quality system according to ISO 13485. The Reader is designed according to Directive 98/79/EC on in vitro diagnostic medical devices.

To make sure the Reader operates correctly, the following conditions for the operational environment must be met.

Operating conditions

Positioning	<ul style="list-style-type: none"> • Do not use or store the Reader in direct sunlight. • Do not use the Reader any closer than one (1) meter from computers, mobile phones or other electronic appliances. • Do not use the Reader in strong air current or draft. • Place the Reader on stable, horizontal setting (such as table)
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Operating temperature	<p>+15°C – +35 °C</p> <p>This temperature must be reached before the Reader can be reliably used</p>
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Relative humidity	30 – 90 % (non-condensing)
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Ambient air pressure	60 – 120 kPa
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CAUTION Quick temperature variations and other external factors may affect the measurement results.

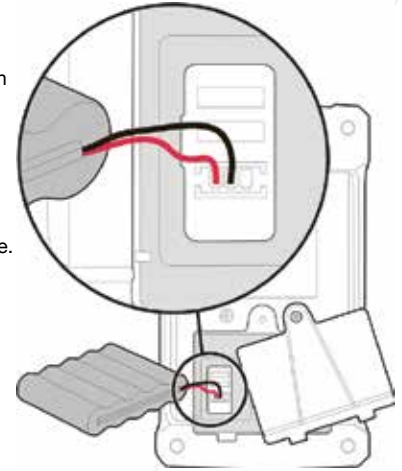
NOTE Depending on the temperature difference it may take hours for the equipment's temperature to stabilize to the allowed operating temperature.

5.1 Connecting battery

Before the Reader can be taken into use after storage or transportation, its battery must be connected and recharged (for recharging see chapter 5.3). When taking first time the reader into use, the battery is already located inside the Reader but the battery connection plug is detached for shipping.

To connect the battery,

1. Turn the Reader upside down. The battery hatch is in the bottom of the Reader.
2. Remove the screw of the battery hatch.
3. Turn the Reader over to make the battery come loose.
4. Connect the battery connector.
5. Lower the battery in its place.
6. Close the battery hatch with the screw.



5.2 Recharging battery

Before the Reader can be taken into use, its battery must be recharged. The battery is already installed in the Reader.

It takes approximately 14 hours to recharge an empty battery to full capacity.

CAUTION Do not use any other type of recharger than the one especially intended for the Reader.

CAUTION Make sure that battery is connected as instructed in chapter 5.2..

To recharge the battery,

1. Attach the battery recharger to the Reader.
2. Connect the battery recharger in a wall outlet. The white light on the Reader's panel begins to blink, indicating that the battery is being recharged.

NOTE You may operate the Reader during recharging, provided that the voltage level is sufficient. If the battery was completely empty, please allow the battery to be recharged at least for 10 minutes before using the Reader.

3. Disconnect the recharger when the light stops blinking and stays on. The battery is now fully recharged. You may leave the Reader connected to the recharger even when the battery is already full.

NOTE To save battery life time keep the recharger connected all times expect storage and transportation, see chapter 7.5.

5.3 Activating Reader

To start up the Reader,

1. Push the Power button on the Reader panel.
The Reader starts up.
2. Check the display for warning of low battery.
If the battery is low, recharge the battery as instructed in chapter Recharging battery.
3. Make sure the swing bed is released to downward position so that the carrier will not damage the sensor head.
4. Make sure you are holding the carrier the right way.
The thicker head of the carrier goes in the Reader first.
5. Push the carrier gently into the Reader until it locks in place.
Push the carrier in a slanted position so that the head that goes in first is slightly higher than the other end of the carrier.

CAUTION

Do not lift the carrier up when pushing it into the Reader. That might damage the sensor head inside the Reader.



5.4 Replacing carrier

If some other types of test cartridges are taken into use, the carrier may have to be replaced by a carrier that matches the used test cartridge type.

To replace the carrier,

1. Start the Reader.
If the Reader is turned on but the carrier remains in upward position inside the Reader, restart the Reader to release the swing bed to downward position.
2. Pull the carrier levelly out from the Reader.
3. Insert the new carrier as instructed in chapter Installing carrier.

6 Operating Reader

6.1 Measuring



NOTE

If you want to record the measurement results, make sure to connect the Reader to a computer or a printer before you start the measurement sequence.

To carry out a measurement, follow the instructions 1-14. As an example of the measuring procedure, the eSAA test is described below.

1. Start the Reader by pressing the Power button. "Follow testkit instructions" and then "insert test" are displayed.



2. If you want to record the results to a computer, place the computer cursor in the desired test result input field of the software that is used for recording information.

3. Open the aluminum test pouch having one LifeAssays[®] test device and one disposable pipette inside. Insert the LifeAssays[®] test device into the Reader so that the small arrow on the end of the test device is visible and pointing towards you. The sample well marked with "S" will remain outside the Reader. The Reader prompts: "Use Calibration Key" and then "Insert Card".

4. Insert the Calibration key card into the reader.



CAUTION

Make sure the Calibration key and the test cartridge (lot) match. Otherwise, the measurement result is not correct.

5. Collect the drop of serum or plasma into the provided glass capillary. Hold the capillary horizontally and fill completely.
Note: Use the capillary holder (sold as an accessory) for capillary handling. Avoid the introduction of air bubbles into the glass capillary. Be sure to fill the entire length of the capillary with serum or plasma. Avoid excess sample on the outside of the capillary by "wiping off" excess with a clean tissue.
6. Place the capillary into a sample dilution buffer vial and mix by inverting the tube until the serum or plasma has been completely eluted from the capillary and mixed with the buffer. Note that complete mixing requires inverting the tube at least 30 times. **Tip:** For easier and quicker mixing use the LifeAssays Vortex.
- 6a. **Optionally, instead of using the capillary, add 3 µL of serum or plasma into the buffer vial with a micropipette.** Please ensure that no additional serum or plasma is transferred into the buffer vial e.g. via the pipette tip.
7. **Before opening the buffer vial, allow the liquid to settle to the bottom of the tube.** If necessary, shake / tap to remove the liquid from the cap.
8. **Aspirate the diluted sample with the pipette provided and add 3 drops to the sample well (round opening in the Cartridge) marked with "S" and immediately press "MEASURE".**

9. Press the Measure button.



! CAUTION

After you have pressed the Measure button, do not touch the carrier or the test until the measurement result is displayed. Prohibiting the movement of the carrier results to an error message and / or to a faulty measurement result.

Keep your hands away from the Reader while the measurement sequence is running.

10. Wait 5 mins for the results of the measurement.

11. Read the test result from the display.

! CAUTION

Turning off the Reader power or carrying out another measurement deletes the result from the Reader permanently. Do not do either of these actions until you have recorded the measurement results.

Depending on the instructions given for the particular test, it may be possible to carry out the measurement sequence again, in case the results are lost. Check the development time from the test specific User Manual.

12. In case the the Reader is connected to computer, you can transfer the results to the computer

by pressing the Transfer button.



13. Remove the test cartridge from the carrier.

i NOTE

If you are using the same Calibration key for more testing, you can continue testing without removing and re-inserting the card.

14. Turn off the Reader.

i NOTE

If you do not turn the Reader off, it will turn itself off automatically if it has not been used for 20 minutes.

7 Maintenance

7.1 Checking calibration

The factory calibration of the Reader can be checked. Calibration check is recommended to be done as per Quality System of the user. Lifeassays AB recommends monthly calibration check. Calibration check is recommended to be conducted always when contamination of the device is suspected or Reader does not meet user defined system suitability test.

7.1.1 Manual calibration check

To check calibration manually,

1. Turn on the Reader.
2. Insert the "Check Calibration" card in the Reader.
3. Insert the calibration cartridge.
4. Press the Measure button.
5. After the results are ready, record them.
6. Compare the results with the allowed values printed on the Calibration cartridge.
7. Repeat the steps from 3-6 using second Calibration sample.

If the results do not match with the allowed values, clean the sensor head as instructed in chapter *Cleaning sensor head* and carry out the calibration check again from the beginning.

! CAUTION

Do not inject any liquids into the standard sample.

If the sensor heads is dirty, it may have contaminated the standard samples for calibration as well. Do not try to clean the samples in any way.

i NOTE

Store the standard samples in dry place in the original package.

If there is any doubt of the functionality of the standard samples, contact Lifeassays AB to order more samples.

7.1.2 Cleaning sensor head

If the calibration check is unsuccessful, the Reader sensor head must be cleaned. To clean the sensor head,

1. Turn off the Reader.
2. Remove the carrier as instructed in chapter Replacing carrier.
3. Turn the Reader upside down for the swing bed to open and look inside. The sensor head is located on the top of the triangular shape inside the Reader.
4. Clean the sensor head carefully using a cotton tip stick dipped lightly in a mixture of 70% ethanol and 30% distilled water. Cleaning mixture **can** be ordered from Lifeassays AB.
5. Repeat the Calibration check. In case Calibration check does not meet requirements after repeated cleaning, contact Lifeassays AB.

! **CAUTION** Make sure the cotton tip is only lightly saturated and does not drip mixture inside the Reader.

Do not touch anywhere else than sensor head with the cotton stick to avoid damaging the Reader

7.2 Cleaning Reader

Clean the Reader from the outside using a soft cloth moistened with water or alcohol.

! **CAUTION** Make sure no excess liquid can enter the openings of the Reader.

7.3 Updating software

If necessary, the software can be easily updated with a dedicated memory card. Updates may take place for example when new features to the Reader are introduced.

Lifeassays AB informs you whenever updates for the Reader are necessary.

i **NOTE** Before updating software, remove the test cartridge and memory card from the Reader, if there are any.

To update the Reader software,

1. Start the Reader.
2. Insert the Software update memory card into the Reader.

The Reader loads the update from the memory card automatically. This process lasts approximately 20 seconds and is indicated by a beeping signal. When the update is finished, the Reader displays the serial number and new software version on the display for a few seconds and then returns to the main display.

3. Remove the Software update memory card from the Reader.

The Reader is now ready to use.

i **NOTE** Software version of the Reader is shown on the display always when the Reader is turned on.

7.4 Replacing battery

If the Reader gives a warning "Replace battery", it means the battery is closing the end of its lifespan and needs to be replaced with a new one.

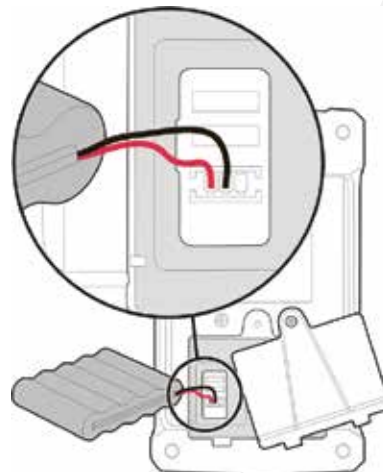
! **CAUTION** Do not use any other type of batteries than the ones especially intended for the Reader.

New batteries can be ordered from Lifeassays AB.

To replace the battery,

1. Turn off the Reader.
 2. Turn the Reader upside down.
- The battery hatch is in the bottom of the Reader.
3. Remove the screw of the battery hatch.
 4. Turn the Reader over to make the battery come loose.
 5. Disconnect the battery connector.

! **CAUTION** Be very careful when disconnecting the battery. Do not pull hard on the wires! The use of tweezers or other such instrument is recommended.



i **NOTE** For information on how to discard the used battery, see chapter Disposing of Reader.

6. Connect the new battery.
7. Lower the battery in its place.
8. Close the battery hatch.

7.5 Storing or transporting Reader

To make sure the Reader operates correctly, the following conditions for the storing and transportation must be met:

- Store the Reader and the batteries in dry conditions in the temperature between -20°C – +50 °C.
- Store the batteries fully recharged, detached from the Reader.
- Remove the carrier when transporting and / or storing the Reader to avoid damage to the Reader.
- Reattach the piece of cardboard back into the swing bed to protect it during transportation and / storing.

8 Troubleshooting

8.1 Warning and error messages

The Reader display shows warning and error messages.

Warning messages inform about a problem or a failure, but it is possible to continue working with the Reader after receiving one.

Warning messages	Explanation
USE RECHARGER	The Reader battery is running out of power. You should recharge the battery as soon as possible. You can continue working while the battery is recharging.
NOT CALIBRATED	Please contact Lifeassays AB.
TEMPERATURE HIGH	High temperature of the Reader may affect the measurement results. This warning will disappear when suitable operating temperature has been reached.
TEMPERATURE LOW	Low temperature of the Reader may affect the measurement results. This warning will disappear when suitable operating temperature has been reached.
NOISE LEVEL HIGH	Please contact Lifeassays AB.
REPLACE BATTERY	The Reader battery is reaching the end of its lifespan. The battery needs to be replaced. New batteries can be ordered from Lifeassays AB.

Error messages inform about a problem or failure and require actions before you can continue working with the Reader, for example pressing the POWER button.



NOTE

if pressing POWER button does not solve the situation, contact Lifeassays AB.

Warning messages	Explanation
BATTERY VOLTAGE LOW	The Reader battery is running out of power. Connect the Reader to the recharger to be able to carry out the measurement sequence. You can continue working while the battery is recharging.
RECEIVER FAILURE	Electronics failure in the receiver. Press POWER button to return to the main display view.
TRANSMITTER FAILURE	Electronics failure in the transmitter. Press POWER button to return to the main display view.
POSITIONING FAILED	The position of the carrier is incorrect. Press POWER button to return to the main display view.
MOTOR CURRENT HIGH	The carrier could not be lifted. Press POWER button to return to the main display view.

9 Disposing of Reader

When the Reader has reached the end of its lifespan, it must be disposed of with other electronic waste. The battery must be removed and disposed of according to the national and / or regional legislations.

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