

Skannexi

Lateral Flow Multi-Reader Manual

Model X500



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1 General description

SkannFlexi is a reader for analyzing colorimetric assays by capturing a scanned image. One or multiple tests can be analyzed in one run. The scanning allows the detection of qualitative and/or quantitative result depending on the test run and/or software information. The data are automatically stored and can be printed and/or exported to external system.

The IVD equipment complies with the emission and immunity requirements described in the part of the IEC 61326 series, and the electrical and electronically safety requirements described in IEC 61010.

SkannFlexi has the following advantages:

- Reliable and Compact Hardware Design
- Adopts RGB images from Plustek OS550 plus scanner for high quality results.
- Adopts power adaptor of professional manufacturer for safety and adaptability.
- Possibility to read many different cassettes/strips in one scan.
- Possibility to read many different cassettes/strips in one scan.
- Extract batch specific information from barcode on each cassette/strip.
- Compute qualitative and/or quantitative results.
- Friendly user interface. Easy to learn, easy to use.
- Stores more than 75000 results.
- Software upgrade can be done by connecting the analyzer to Internet or upgrade from an USB memory stick.

The following signs are used in this document.



Risk of electric shock



Dangerous! Be careful. Reference the requirements of this manual



In vitro diagnostic devices

2 Reader technical parameters

This analyzer can be used in medical institution of any type and any level.



The reader is a dedicated instrument, all operations must be according to the manual. If not, the reader may be damaged or test performance cannot be guaranteed.



Risk of electric shock.

2.1 Main Technical Parameters

Specification	Technical Parameter
Testing Principles	Colorimetric measurements of lateral flow test and control lines
Operating system	Windows 10
External Ports	Three USB ports, for connection to printer, external barcode reader or USB memory stick One Ethernet port, for connection to network (Lan or Wan). One RS232 port, for connection to hospital platform
WiFi	Wireless connection
Power Supply	100-250 V (AC)
Frequency range	50 -60 Hz
Current rating	5 Amp
Operating conditions	For indoor use only. To be placed on a suitable bench.
Temperature range	15- 30°C
Relative Humidity	20-80% RH
Storage capacity	Stores more than 75000 sets of results (15 GB)
Dimension	37.8x35.2x22.2 cm (LxWxH)
Weight	4,5 kg

2.2 Calibration and performance characteristics

The SkanFlexi reader's touch display and the scanner part are calibrated and the optical performance quality checked as part of the QC in the manufacturing process. The scanner part is further recalibrated by the SW every 2nd week.

The performance characteristics of the reader have been evaluated. In a study the intra variation and inter variation between 4 SkanFlexi readers showed CVs below 5%. The computed results were calculated as property values; $(\text{test} - \text{background}) / (\text{control} - \text{background})$.

Standard curves or thresholds for the different tests are established by the test manufacturer. It is included as part of the barcode following each cassette or template and read by the reader's SW.

3 Intended use

“The intended use of the SkanFlexi reader is to scan, read and calculate results from lateral flow tests within the market areas *in vitro* diagnostics (IVD), e.g. lateral flow cassettes in Myocardial markers, CtnI, Myoglobin, CK-MB, H-FABP, etc., or infectious disease, HbsAg, HbsAb, HCV, HP, etc., or venereal disease, TP, Chlamydia, NGH, PSA, CEA, etc., drugs of abuse, veterinary diagnostics, food and feed and environmental in body fluids and other extracted biological liquids.”

Indications for use:

It is indicated for both quantitative and qualitative tests. To detect variable biomolecules within human body fluids, and liquid extracts from agricultural, animal and environmental samples.

The SkanFlexi product is enabled by a program key allowing customers to upgrade the proprietary software directly from Web or a USB memory stick.

It is indicated for rapid analysis on site. The user interface shall be designed such that a lay user shall be able to operate the system in such a way that errors of operation and result interpretation are minimized to an acceptable level.

4 Unpack and Installation

4.1 Unpack

Carefully remove the SkanFlexi reader from the shipping box. Inspect the reader for visible signs of damage. If damage to the reader exists, please file a complaint to the logistic company or retailers as soon as possible.

List of content:

Item	Quantity
SkanFlexi reader	1
Certificate of Quality	1
Warranty Card	1
SkanFlexi manual	1
Power supply	1
Reset pin	1
Package list	1

4.2 Working Environment

For operator's safety and the proper operation of the reader, the power cord must be plugged into an appropriately grounded AC electrical outlet. Connecting any dual cord power surge protector is strictly prohibited.

SkanFlexi is a professional instrument. Opening the cover without authorization is prohibited. The instrument and instrument parts are only to be inspected and provided by the manufacturer.

Operation violating the manual's descriptions will cause the analyzer damaged.

Place the reader on a firm, level designed work area.

Please avoid operating in the following environment:

- In direct sunlight
- Near flammable and explosive gas
- Next to an opening window
- Next to heating or refrigeration equipment

- Near strong light source

4.3 Installation of SkanFlexi

At the back of the reader there are three USB ports, one Ethernet port, one RS232 port, one on/off button and power supply connection.



- Connect power supply to SkanFlexi
- Connect power supply to electrical socket

5 Operating SkanFlexi reader

5.1 Switching reader on and off

- Switch on reader by setting on/off button (at the rear of the reader) to position “On”
- Computer will be switched on and power indicated led (at front left corner of the reader) becomes green and is flashing until reader program starts.



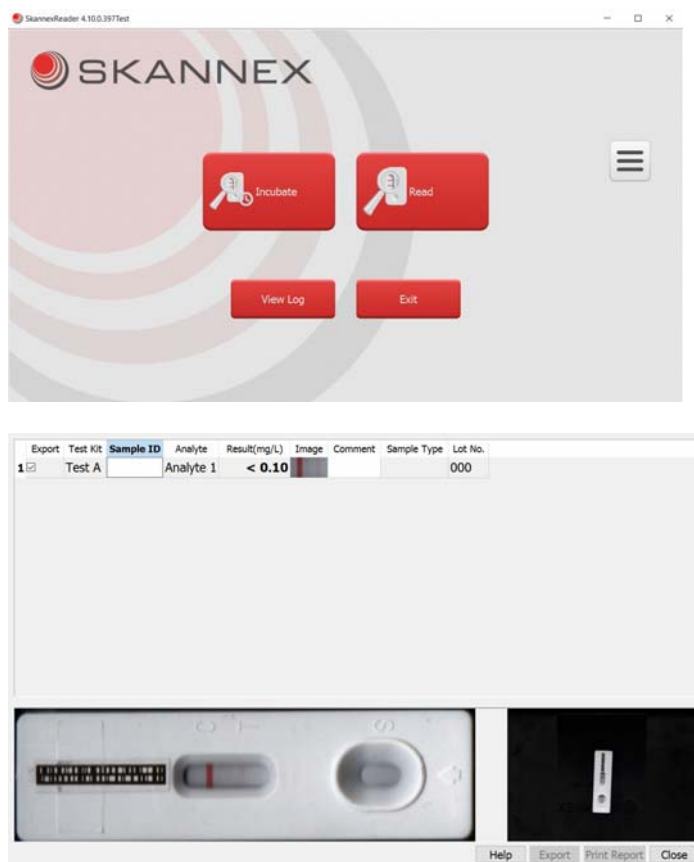
- SkanFlexi is ready for use
- When switching off the reader press “Exit” button in the reader program
- Power off reader by setting the on/off button to position “Off”. The power indication led will switch off.

Warning: After SkanFlexi is switched off by either pressing exit button in SkanFlexi software or switching the on/off button to off, then wait at least 10 seconds before switching the on/off button on.

If the SkanFlexi is not starting please follow procedure in Ch. 5.4

5.2 Reading test devices

1. Push and open the drawer
2. Place the test device right side up on the scanner surface
3. Ensure that test and control lines are placed in the scanner's movement direction.
4. Incubation can be performed before or after placing the test device into the drawer.
5. Multiple test devices can be placed in the drawer and be read at the same time.
6. Close drawer before scanning to avoid interference from surrounding lights.
7. Press "Read Test" button in program. Scanning of the cassette will start and result will appear after a few seconds.



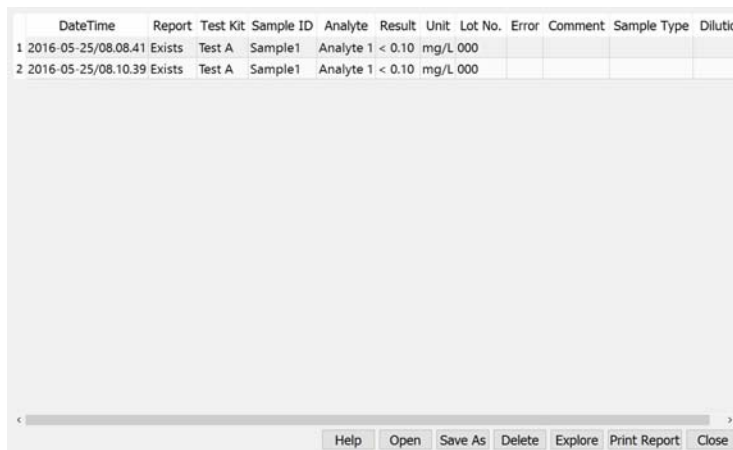
8. Enter required information in result screen.



9. Results are automatically stored in historic log.

10. A pdf report may be printed from this screen if “Print Report” button is selected and printer is installed and connected.

11. Pdf report can also anytime be printed from the historic log screen. The log is opened when “View Log” button in main screen is selected.



DateTime	Report	Test Kit	Sample ID	Analyte	Result	Unit	Lot No.	Error	Comment	Sample Type	Dilutio
1 2016-05-25/08.08.41	Exists	Test A	Sample1	Analyte 1	< 0.10	mg/L	000				
2 2016-05-25/08.10.39	Exists	Test A	Sample1	Analyte 1	< 0.10	mg/L	000				

12. When result screen is filled in with required data, close this screen by selecting “Close” button. You will return to main screen and program is ready for reading new test devices.

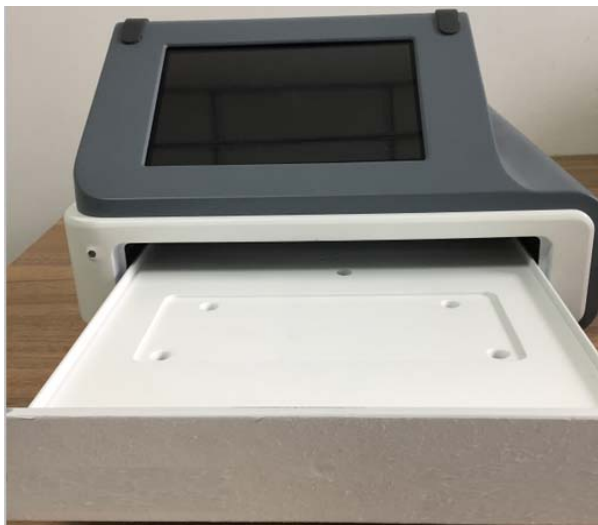
5.2.1 Printing from SkanFlexi X500

SkanFlexi X500 is using a Windows tablet. Any Windows operating printer can be used.

5.3 Cleaning the reader scanner

The scanner can be cleaned by following the steps below.

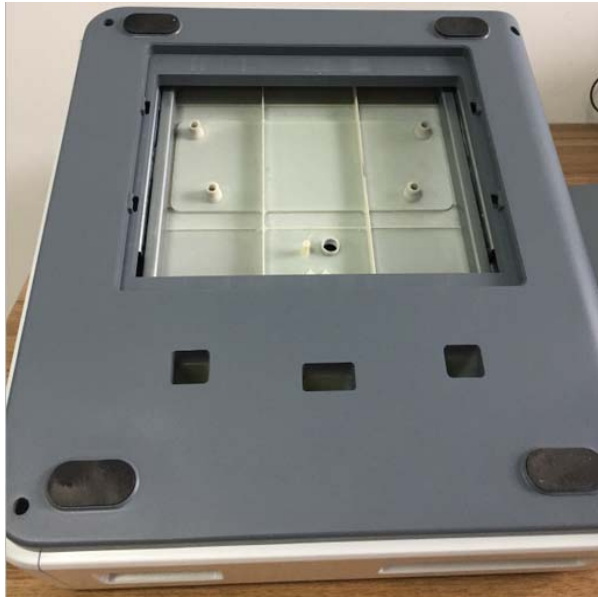
- Close the instrument and disconnect the power supply cord. Open the drawer and take out the template.



- Close the drawer and turn over the instrument.



- Push the “Open” side and remove the bottom plate.



- Open the drawer and rotate the black holder to lock it .



- Clean the scanner with humid cloth or with alcohol.



- Rotate the black holder ,close the drawer and put back the bottom plate.



- Push the “Close” side and fix the bottom plate. Turn over the instrument and put back the template into the drawer.

5.4 SkanFlexi is not working

SkanFlexi’s touch panel has a battery inside. In the case SkanFlexi has not been used for days, the touch panel will have no power. Therefore, please charge the SkanFlexi for at least 10 minutes if SkanFlexi has not been working for days.

- 1) Connect power supply to SkanFlexi
- 2) Switch on reader by setting on/off button (at the rear of the reader) to position “On”
- 3) After charging the SkanFlexi for at least 10 minutes, switch off the reader by setting on/off button (at rear of the reader) to position “Off”
- 4) Switch on reader again, and SkanFlexi will start

5.4.1 Use of reset pin

If SkanFlexi is still not working after performing the above steps in 5.4, please follow below reset procedure:

- 1) Switch on reader by setting on/off button (at the rear of the reader) to position “On”
- 2) Use the provided Reset pin to push the reset button for 15-20 seconds
- 3) Switch off the reader by setting on/off button (at the rear of the reader) to position “Off”
- 4) Switch on the reader again by setting on/off button (at the rear of the reader) to position “On”
- 5) SkanFlexi will start



If the SkanFlexi is still not working, please contact Skannex AS at:

support@skannex.com

As with any other instruments the tablet in SkanFlexi might appear with the following:

1. System crash/tablet seem to be “frozen”
2. Blurred screen when you start up SkanFlexi or when SkanFlexi is running
3. Recovery notification when you start up SkanFlexi

In all these cases the “Reset pin” should be used. Please follow description above.

6 Maintenance

6.1 Daily cleaning

- Keep reader clean by using a damp cloth
- Scanner surface may be cleaned/decontaminated with alcohol if necessary
- Touch screen shall be cleaned with special tissues intended for resistive screen
- Do not use aggressive solvents such as acetone.

7 Precautions

7.1 Environment light

Keep SkanFlexi out of direct sun light or other strong light sources as this can cause interference when scanning, which again can result in wrong or no results.

7.2 Environment in general

Protect the reader from high humidity and extensive contact to liquids.
Do not expose the reader to extensive heat.

In some cases a poor ground connection in socket and interference of some large medical equipment (X-ray machine, CT machine), can cause that the SkanFlexi get Electro Magnetic Interference (EMI) problem. This can be seen as a series of small circles/rectangles appearing when touching the panel. This can make it difficult to touch the correct position. Changing to socket with better grounding or moving SkanFlexi away from interference environment will resolve this kind of problem.

8 Transportation and storage

8.1 Transportation

SkanFlexi must be transported in the same packing material as it was received in. Transportation should be done using a common shipping company under normal conditions.

8.2. Storage

SkanFlexi should be stored in an up-right position in the original packing material, indoor and under normal room temperature and environment conditions. Avoid direct sunlight. For more details see table 2.1.

FCC STATEMENT

1. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

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

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

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

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure requirement.

The device can be used in portable exposure condition without RF restriction