

Introduction to NycoCard[®] READER II

The NycoCard[®] READER II is a small battery powered instrument, designed to measure all NycoCard[®] products. The coloured responses of the NycoCard[®] products are measured by spectral reflectance in three parts of the visible spectrum.

Description of NycoCard[®] READER II

The NycoCard[®] READER II kit consists of:

NycoCard [®] READER II	1 unit
Battery charger	1 unit
Batteries (rechargeable)	3 units
A1 Calibration devices	10 units
A2 Pen tips	10 units
A3 Pen rings	10 units
A4 Battery clips	3 units
Pad	1 unit
Instruction manual	1 unit
Warranty card	1 unit

The NycoCard[®] READER II consists of two units: the instrument box (1), which is the operational and calculating unit, and the Reader pen (5), which is the measurement unit. The main components of the instrument box are the microprocessor, the LCD display (3) and the push buttons (2) for operation. The key elements of the Reader pen are the Light Emitting Diodes (LED's) (11), a photodiode (12), a light/dark detector (10) and the functional design. A pen cable (4) connects these two units together. The penholder (8) is located to the right of the display on the instrument box. The pen is placed in the holder to protect it when not in use. In front of this holder, there is a lid (6), and on the rear side of the lid a white calibration device (9) is placed.

Basic theory

The Reader pen contains three pairs of LED's: red, green and blue. Reflected light from the test sample is measured, relative to a white sample, by a light-sensitive photodiode circuit. When a specific test from the NycoCard[®] READER II test menu is chosen, the required LED's illuminate the sample to be measured. The sample will reflect some of the light and give rise to a constant current in the photodiode, which will discharge a capacitor linearly from the voltage V_1 to a lower voltage V_2 . When V_2 is reached, a signal is given to the microprocessor. The microprocessor measures the time (T) it takes to change the voltage from V_1 to V_2 . The intensity of reflected light (I) is then inversely proportional to T, and the microprocessor converts the time to a concentration value, which will then be displayed.

When the pen is placed over the sample and the pen sleeve is pushed down, the light/dark detector registers that the environment has changed from light to dark and the measurement is automatically started. The sleeve will ensure that the pen is held stable in a vertical position, and that external light is excluded from the sample.

Adjusting

This procedure compensates for the contribution of reflected light from the inside of the pen tip (14) and slight electrical current leakage in the electronic circuit. Adjusting is performed when the pen is placed in the penholder, i.e. in a dark chamber without any sample present. It is important to adjust the instrument each time the instrument is turned on and when the pen tip is replaced.

White calibration

White calibration adjusts for any differences in measuring conditions and variation of pen tips. The white calibration is performed on a special calibration device, which is stored under the lid, protected from light and dust. The NycoCard[®] READER II should be calibrated prior to each series of measurements (max 20 measurements per series) and prior to each single, sporadic measurement.

Installation and environment

Check that all components listed in the section Description of NycoCard[®] READER II are included in the package and that no components are damaged. Fill in the Instrument Warranty Card and send it back to your local distributor. Make sure that the instrument is acclimatised to room temperature before use. Recommended ambient temperature is 18 – 25°C and humidity must not be condensing. Ensure that the instrument is protected from dirt and direct sunlight.

Your NycoCard[®] READER II is supplied with 3 rechargeable NiMH batteries (1.2 V) (16). Before using the new instrument the batteries should be charged for 18 hours. The connection plug of the battery charger (18) is inserted into the outlet (19) located at the rear side of the instrument box. The Reader pen has a modular plug (20). The NycoCard[®] READER II is equipped with RS 232 port for PC-connection (21).

Using the instrument

Functions

The instrument is operated by three push buttons:



To switch on the instrument and to screen the main menus and the sub menus.



To enter and activate the menu selected by the Select button.



To exit the current menu or function.

The menu

Four main menus are available for selection:

Main menu/Calibrate instructs the instrument to measure the White Calibration Device.

Main menu/Enter test contains sub menus corresponding to each of the NycoCard[®] tests that are available.

Main menu/Options contains two sub menus:

- *Enter language*: To change the language on the display.
- *New white*: To measure a new value of white when a message "Error Recalibrate" appears on the display. The white value will change with ageing, even if pen tips and calibration devices are replaced.

Main menu/Off followed by "ENTER" will turn off the instrument. Pressing QUIT and ENTER simultaneously will also turn off the instrument, regardless of the position in the menu.

Operating procedure

The following three steps must be performed before the result of a NycoCard[®] test is obtained:



1. Adjusting

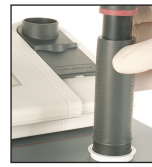
Make sure that the pen is placed in the penholder and turn the Reader on. The instrument automatically performs "Adjusting". Allow the Adjusting procedure to complete without touching the pen. A single beep will indicate that the Adjusting is completed correctly. A double beep will indicate errors in the Adjusting followed by the message "Adjust error". (See troubleshooting).



2. White calibration

Press ENTER to activate the menu and follow the instructions in the display. When the message "Place pen..." is displayed, lift the pen out of the holder

and place it on the White Calibration Device. Hold the pen steady until a single beep indicates that the calibration is finished.



3. Measuring a NycoCard[®] test

The Reader pad (7) should always be used during measurements. The requested NycoCard[®] test is chosen from Main menu / Enter test and the instrument is ready for the measurement. When the pen tip is placed into the test hole and the pen sleeve pushed down, the measurement will start. After a few seconds the test result will be displayed as a concentration value.

If the instrument is placed on stand-by for about 10 minutes, it will automatically switch-off. When the instrument is turned on again, the last measured value will automatically be displayed.

Maintenance

The Reader pen has two replaceable accessories, the pen tip (14) and the pen ring (13). These two parts will be in contact with the assay devices that are exposed to diluted blood/urine. The pen tip must be replaced if it is dirty, to reduce interference during measurements. Be careful not to touch the optics of the Reader pen. It is recommended that the pen tip and white calibration device are inspected regularly. If the calibration device is damaged or dirty, it should be changed.

- Replacing the pen tip: to remove the pen tip, carefully snap the tip off with your fingers. Replace the new pen tip.
 - Replacing the pen ring: to remove the pen ring, hold the case shield with one hand and carefully wriggle the ring off with the other hand. Replace the new pen ring. Make sure it fits correctly.
 - Replacing the calibration device: remove the device by simultaneously pressing the small handle down and the opposite side upwards. Place the new calibration device.
 - Replacing the batteries:
 - Step 1. Use a screwdriver to open the battery lid (15).
 - Step 2. Remove the old batteries. It is recommended to use a small screwdriver when removing the battery clips (17).
 - Step 3. Replace the batteries with three new batteries.
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- Be sure that the batteries are inserted in the right direction.
- Step 4. Replace the battery lid. New batteries need to be charged before using the instrument.

Warnings and precautions

IVD For *in vitro* diagnostic use only.

- Do not interchange Reader pens between different instruments.
- Be aware that the pen tip and pen ring will be in contact with diluted blood/urine.
- Follow general laboratory precautions when handling blood samples.
- Be certain that the outlet voltage has the same rating as the charger.
- Water or any other liquid should not be in contact with the instrument.
- Dispose the batteries according to manufacturer's recommendations.
- Leaving batteries in the instrument for long intervals without charging can lead to spilling of electrolyte and damage the instrument.
- Measuring NycoCard[®] products without using the pad may lead to wrong results.

Troubleshooting

The following conditions or problems may occur when using the NycoCard[®] READER II.

If your problem still exists after corrective action is taken, please contact your local distributor.

Problem	Possible cause	Corrective action
"Battery low" appears on the display.	<ol style="list-style-type: none"> 1. Batteries discharged. 2. Batteries improperly inserted into the battery holders. 3. One of the batteries has short-circuited and is not recharging. 	<ol style="list-style-type: none"> 1. Recharge the batteries. 2. Reinsert batteries. 3. Replace all batteries.
Display screen is blank or unreadable.	<ol style="list-style-type: none"> 1. Batteries discharged. (see other causes under "Battery low".) 2. Sub-optimal viewing conditions. Light too dim. 	<ol style="list-style-type: none"> 1. Recharge the batteries. Check polarity and that the batteries are of the correct type. 2. Increase light level or change light position.
Display fades out during "Adjusting"	<ol style="list-style-type: none"> 1. Batteries discharged. 	<ol style="list-style-type: none"> 1. Recharge batteries.
"Calibrate white/ ERROR! Recalibr." appears on the display.	<ol style="list-style-type: none"> 1. Calibration device used is dirty, scratched or not totally white 2. Ageing of the instrument has changed the internal white value. 3. Pen tip is dirty or damaged. 	<ol style="list-style-type: none"> 1. Replace calibration device and recalibrate. 2. Measurement of new white value. 3. Replace the pen tip. Recalibrate.
"Calibrate white Active. Wait..." persists on the display screen.	<ol style="list-style-type: none"> 1. Pen cable not properly inserted. 	<ol style="list-style-type: none"> 1. Check that the pen cable connector plug is properly inserted into the receptacle of the instrument. Recalibrate.
Program will not proceed from "Place pen" to "Active. Wait..."	<ol style="list-style-type: none"> 1. Room light too strong or unit in direct sunlight. 	<ol style="list-style-type: none"> 1. Reduce light/avoid sunlight on device.
"Adjust ERROR"	<ol style="list-style-type: none"> 1. Pen tip is dirty or damaged. 2. Humidity or temperature is too high. 	<ol style="list-style-type: none"> 1. Replace Pen tip. Perform adjusting and white calibration.
"RAM ERROR" / "Test data error"		<ol style="list-style-type: none"> 1. Contact your local distributor.

Technical specifications

Instrument

Size, instrument box:	200x170x70 mm
Size, Reader pen:	L: 144 mm, D: 29.5 mm
Weight:	540 g (incl. Reader pen and batteries)
Display type:	LCD, 2x16 characters
Computer:	Intel 80 C32
Memory capacity:	Programme memory capacity: 64 Kbytes
Test storage capacity:	2 Kbytes
Power supply:	Batteries, battery charger

Measuring conditions

Temperature range:	15-35°C ¹⁾ (The recommended range is 18-25°C)
Relative humidity:	0-90%
Avoid direct sunlight or too dim light	

¹⁾ See special instructions for each NycoCard® test

Batteries

Rechargeable NiMH batteries only, size AA,
1.2 V, Recharge 8-18 hours

Battery charger

Mascot type 8311/0901 or equivalent
Output: 9VDC/2.5 W
Plug 3630+ (coaxial type):
Polarity; pos. (+) in centre
Length: 12.0 mm
Inner diameter: 2.1 mm
Outer diameter: 5.5 mm

Ordering information

Product	Product no.	Quantity
NycoCard® READER II	1113117	1 unit
A1 Calibration devices	1047782	1x10 units
A2 Pen tips	1047780	1x10 units
A3 Pen rings	1047781	1x10 units