CE

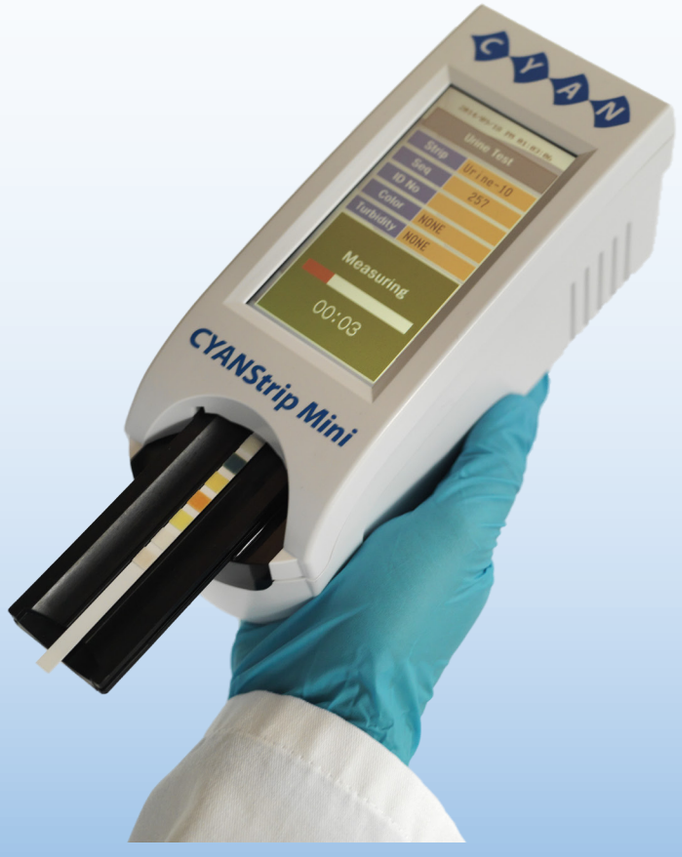
CYPRESS DIAGNOSTICS

CY011

English

CYANStrip Mini

User Manual



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! WARNING !

Please read the user manual before operating the CYANStrip Mini.

1. Once the carrier has taken possession of the system for transportation from the factory, the carrier takes total responsibility until delivery. All claims for damage due to transportation must be filed against the carrier as soon as this damage is noticed.

2. Upon receiving the package, check the content (Refer to **2.1 Unpacking**). If any items should be missing, immediately contact your distributor.

3. The CYANStrip Mini will be in good working order on the day it is installed, and it will be conform to CYANStrip specifications. If the installation, usage, and maintenance directions given in this manual are not strictly followed and/or the safety instructions were not respected, Cypress Diagnostics cannot guarantee correct functioning of the instrument. Misuse will void the warranty.
   Consumables are not included in the warranty.

4. Clean the instrument daily to prevent malfunctioning. Refer to **6 Maintenance** for instructions.

BIOHAZARD: Wear personal protective equipment. Use universal precautions. Refer to **12 Safety information** for recommended precautions when working with biohazard materials.

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1 INTRODUCTION

Urine test strips simplify diagnosis of a wide range of diseases through **ease of use**, **high sensitivity** and **high specificity**. These benefits allow the user to quickly and reliably identify pathological changes in urine in order to determine a patient's health. This analysis is extremely useful in providing an **early diagnosis** of various diseases even if there are no visible symptoms yet. Unlike many other clinical tests, urine analysis is easy and painless; it is one of the basic and fundamental physical tests.

CYPRESS Urine Strips are dip-and-read test strips for *In Vitro* Diagnostic use only. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. Also, **treatment monitoring** with the aid of urine test strips allows a health professional to check on the results of the prescribed therapy, and if necessary to introduce any changes into the course of therapy.

The test strips consist of pads impregnated with chemicals that react with the compounds present in urine producing a characteristic color. Urine samples are screened by dipping a specified test strip into the sample and comparing the coloration of the strip against a pre-defined color chart blocks.

CYPRESS Urine Strips are **semi-quantitative** test strips. In addition to providing a positive or negative reaction, they also provide an estimation of concentration range. The color reactions are approximately proportional to the concentration of the substance being tested for in the sample. Semi-quantitative values will be reported in arbitrary, conventional or SI units.

The strips may be read visually or instrumentally, using CYANStrip Mini. The use of the CYANStrip Mini instrument to the urinalysis process allows for **standardization** and **efficiency** of urine testing by **eliminating potential sources of error** associated with the visual reading of test strips such as improper lightning at the workplace, objective discrimination of color by the user or different timing of reading. Besides that, leukocyte results can be read at 60 seconds, together with other results. While for manual reading, the leukocyte pad needs 90 seconds of incubation before the correct result can be read.

The test strips that are to be used with the instrument are (multi) parameter strips for the determination in urine of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood, micro albumin and creatinine.

CYANStrip Mini has been optimized for and can only be used with CYPRESS Urine strips. The system is closed. Only tests for CYPRESS Urine strips have been preprogrammed on the instrument.

1.1 INTENDED USE

The CYANStrip Mini is an easy to use *in vitro*-diagnostic device for professional use. Depending on the product being used, CYPRESS Urine strips contains reagent areas for testing 10 physical test items. Once the dipped strip is positioned on the instrument, press the start button. This automatically activates the strip movement and reading cycle. The analytical test results are displayed on the LCD screen and can be printed on the (optional) thermal printer. Furthermore, the optional PC user's program offers easy data storage of a patients' health via a personal computer.

The CYANStrip mini can analyse **40-50 samples per hour** and stores the operating parameters and records of up to **2000 samples** in a built-in EEPROM. The instrument is a reflectance spectrophotometer that analyses the colour and intensity of the light reflected from the reagent area and reports in clinically meaningful units (Refer to **10 Results table**).

One of the key features of CYANStrip Mini is that it can run on batteries as well. The instrument can easily be taken to other places outside the lab or to places with unreliable electric current. The results can still be uploaded to the PC software afterwards.

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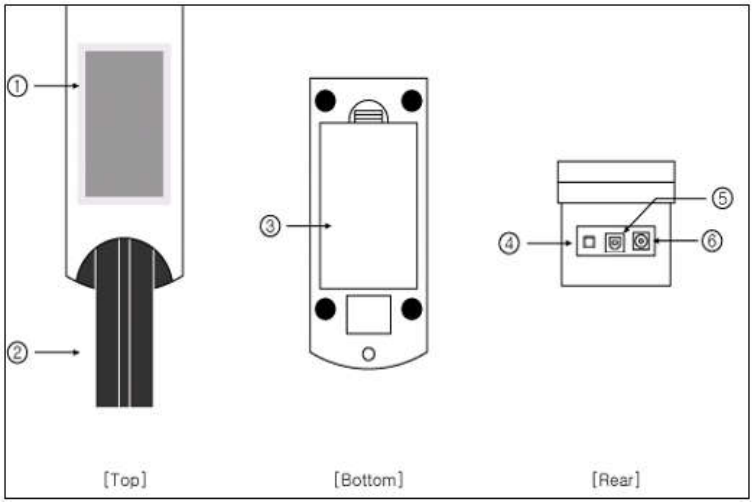
1.2 PRINCIPLE OF MEASUREMENT

The CYANStrip Mini is a urine strip analyzing device. The reader is semiautomatic, but the forwarding, read-out and evaluation of results are automated. The only operation to be performed by the user is to dip the strip into the urine sample and place it on the strip loading plate.

The CYANStrip Mini is a reflectance photometer. The strip is illuminated by white light and the light reflected by the strip is detected by a sensor. The RGB signals are digitized and this digitized image is interpreted by the processor. The intelligent image analyzer software locates the strip and the pads, and determines the parameter values based on these color data. No calculations are required by the user. The result reports include date and time of measurement, strip type, sequence number and ID (if entered by the user).

1.3 SYSTEM DESCRIPTION



	COMPONENT	FUNCTION
1	Full-color touch screen TFT–LCD	Displays the process and result of the test
2	Strip loading plate	Moves the test strip to the measuring position
3	Battery cover	Protection
4	Power button	Turns the system on/off
5	USB port	Serial interface port for connection to a PC or central laboratory (host) computer or to the optional thermal printer (CY011-S02)
6	Power connector	Socket used to connect the analyzer to the external power supply

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1.4 TECHNICAL INFORMATION

Measuring method	Reflectance photometer
Wave length	470, 530, 626 nm
Dimensions	Width 188 mm Depth 74 mm Height 77 mm
Weight	460g
Power supply	Input 100 - 240V, 50/60Hz Output DC 12V, 3.33A
Battery	8 batteries, type AAA 1.5V
Throughput	40-50 tests/hour (120 tests per hour in « Quick mode », refer to **5.2.4.2 System settings**)
Memory	Up to 2000 samples
Operating conditions	Temperature 2 - 30°C Humidity 10 - 70%
Serial communication	USB Port
Options	External thermal printer (CY011-S02)

1.5 INTERFACE SYSTEM

Users can connect the CYANStrip Mini to a host computer through the USB port.

- Baud rate: 38400
- Data bit: 8
- Parity: none

2 INSTALLATION

2.1 UNPACKING

Upon receiving the CYANStrip Mini urine analyzer, open the shipping box and check the contents against the following packing list:

- CYANStrip Mini
- Strip Loading Plate
- AC adapter 100-240V / 12V DC 3.33A
- Power cable
- User manual
- USB A to B cable
- Software CD, including a digital version of the user manual

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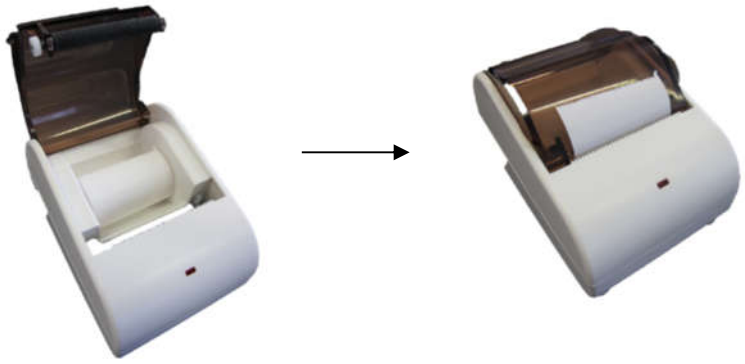
2.2 OPTIONAL ACCESSORIES

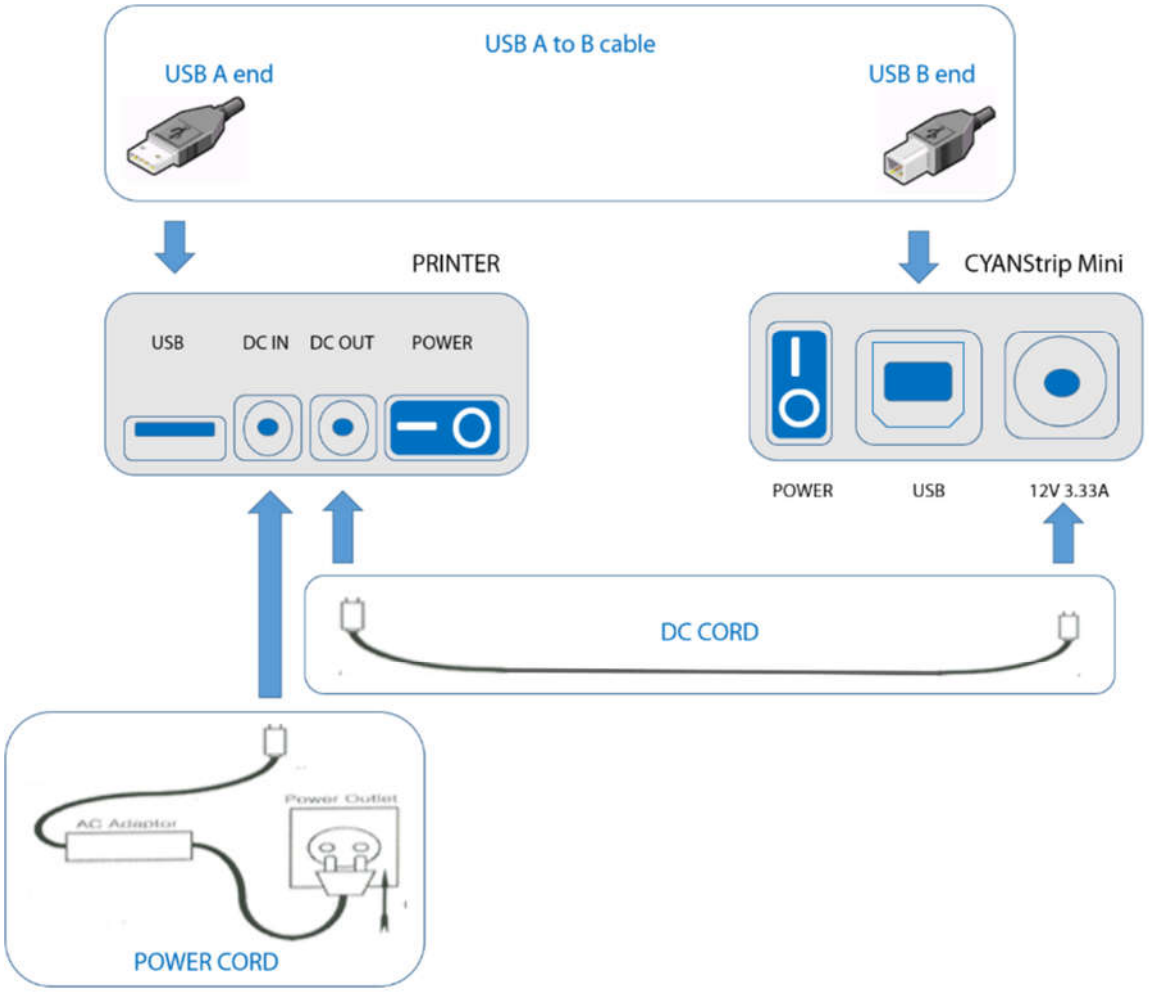
External printer for exclusive use with CYANStrip Mini (Cod. CY011-S02). Supplied with printer are:

- 2 paper print rolls. For ordering extra, please use product Cod. CY011-S01.
- DC cord for power supply between printer and CYANStrip Mini.

To install the paper roll, open the cover of the printer and insert the roll so that 1 cm comes over the edge of the cutting teeth. Make sure to insert the paper in the right direction. The printer can only print on one side of the paper (Refer to **11 Troubleshooting**).



The correct driver software for operation with CYANStrip Mini has already been installed on the printer. To start operation with the instrument, connect USB cable and power cords as follows:



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2.3 LOCATION SPECIFICATIONS

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and high temperature should be avoided. Place the instrument where it will not be subjected to extreme temperature variations.

Avoid the following locations to prevent malfunctioning of the analyzer:

- High humidity, high-temperature, and low-temperature storage places
- Dusty places
- Very hot places near heating appliances, such as ovens, hot plates, open burners, radiators, etc.
- Do not leave the instrument exposed to direct sunlight for long periods of time. This may deform or discolor the instrument and cause malfunctioning.

Do not use benzene, thinner, gasoline, etc. to clean the instrument body. This may discolor the body of instrument. Dry with a towel after cleaning with a cloth dampened with a neutral detergent or water.
Do not touch the power-plug with wet hands, this may cause an electric shock.

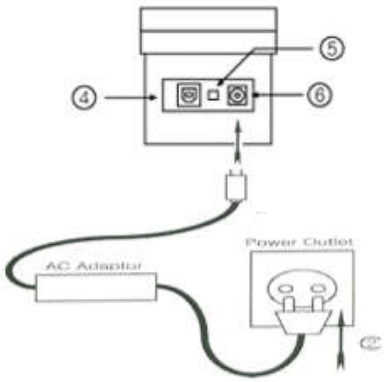
2.4 ELECTRICITY REQUIREMENTS

2.4.1 AC adapter

(AC CORD Type, Input Voltage: AC 100~240V, 50/60Hz, 1.2A; Output Voltage: DC 12V/3.33A)

Carefully handle the AC adapter. Improper handling is dangerous.

- Do not touch the adapter with wet hands.
- Do not place heavy objects on top of the adapter.
  - Only connect the AC adapter that is provided with the instrument (product Cod. CY011-S09).
  - Disconnect the AC adapter from the power outlet if the instrument is not going to be used for a long time.



In order to ensure proper instrument functioning, the manufacturer strongly advises to use a stable tension supply outlet (±10 %). If this cannot be guaranteed, use of the following supplementary devices is recommended:

1. **Electronic Stabilizer**

   This is used to stabilize the electric voltage in the laboratory. Any stabilizer, currently available on the market, with a power potential of at least 0.5 KW can be used.

2. **No Break module UPS - (Uninterrupted Power Supply)**

   This module provides two important functions:

   - Stabilizes the main-line power

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- Supplies current to the instrument in case of a main-line power failure

2.4.2 Batteries

The instrument also runs on batteries: 8 pieces, type AAA 1.5V. Insert them in the correct way in the empty space below the bottom panel of the instrument.
It is still possible to make connection with PC software, or results can be uploaded to the software later by using the supplied USB cable.
In order to print results through the external printer, the instrument and the printer should be connected through the power cord. Printing on the external printer is not possible when using batteries.

2.5 AUTOTUNING

Performing an autotuning is not applicable on this instrument.

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3 INSTRUCTIONS FOR USE

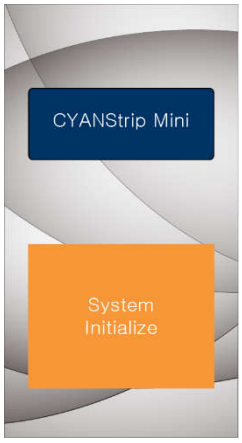
3.1 INITIALIZATION & CALIBRATION

The instrument is calibrated as it leaves the company. However, calibration may be affected during transport. **Always perform a system check and calibration prior to first use** (for instructions refer to **5.2.2 System check**).

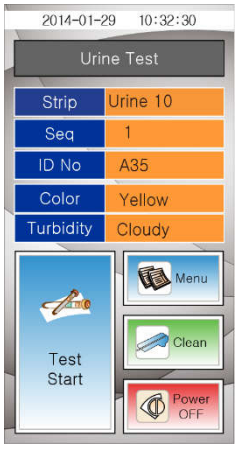
After moving the instrument to a different place, perform a system check and calibration before restarting measurements.

3.2 START UP

Switch on the power (back switch) and wait for the instrument to finish the initialization before continuing. This will happen automatically every time the instrument is started. After initialization, the « Test menu » is shown.



System initialization



Test menu

3.3 START TEST

1. Touch the « Strip » field. The menu for strip selection will automatically open. Select the correct strip type. Click on « Test » to return to the Test menu.
2. The instrument will automatically increment the sequence number when you enter a new sample.
3. Enter the ID number (up to 16 digits).
4. If necessary, define color and turbidity of the sample.
5. Take a strip out the strip container (**! close the container lid right after taking out the strip, exposure to air can affect the test results ! Refer to 4 Tips and tricks for using CYPRESS Urine strips and CYANStrip Mini).**
6. Dip the strip into a fresh and homogenous urine sample. Make sure all pads are fully submerged for no longer than 3 seconds. Otherwise the chemical materials of the strip can be dissolved in the urine sample.
7. Remove the excess urine by slightly pressing both side edges of the strip on a soft absorbent tissue.
8. Correctly place the strip on the strip loader.
9. Start the test by touching « Test Start ».

Complete steps 5 – 9 within 15 seconds.

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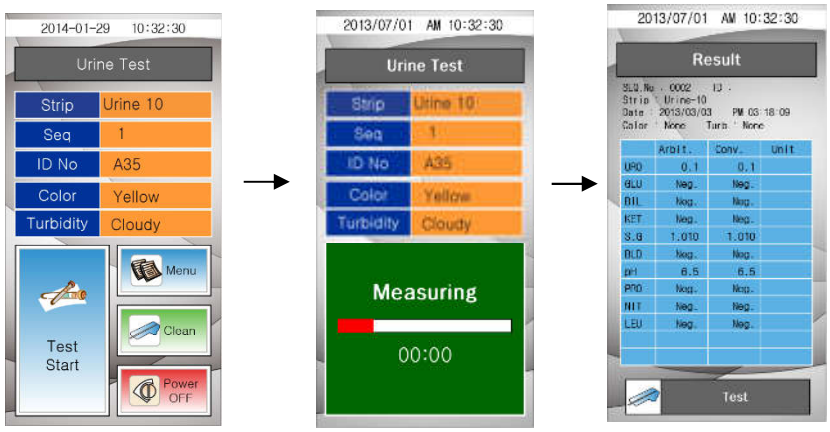
3.4 RESULT

After completion of the test and analysis, the result is displayed. In case the external printer is connected through the USB cable, the result will automatically be printed.

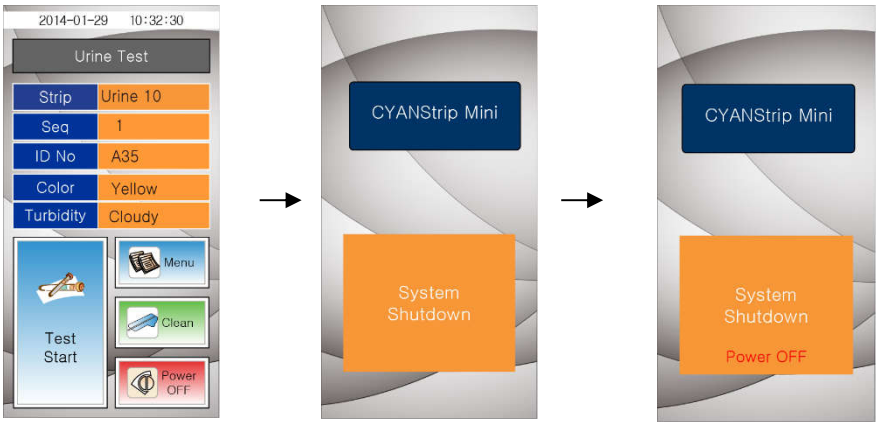


Analysis and display of result

To return to the test menu, press « Test » in the bottom of the screen. You can now start measurement of the next sample.
These results are automatically stored and can be looked up and viewed afterwards. Additionally, the data can also be transmitted to a computer (**9.6 Transfer of results from instrument to PC software**).

3.5 SHUT DOWN

Press « Power OFF ». When the system shutdown is completed, it's safe to switch off the instrument (back switch).



Shut down

3.6 IMPORTANT NOTES

- Do not alter or remodel the instrument.
- Do not drop or put strong impacts on the instrument.
- Do not forcibly pull or push the strip loading plate.
- Do not open the instrument. Opening of the instrument by the user will void the warranty.

This may all cause malfunctioning or damaging of the instrument. Carefully read the user manual before operating the instrument.

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4 TIPS AND TRICKS FOR USING CYPRESS URINE STRIPS AND CYANSTRIP MINI

A. Only use CYPRESS Urine strips with CYANStrip Mini analyzer

CYANStrip Mini has been developed for exclusive use with CYPRESS Urine strips. Using strips from other suppliers may lead to improper result interpretation.

B. Immediately close the bottle after taking out a new strip

It is crucial that the strips stay dry. Therefore, a desiccant bag is added to the bottle for the absorption of water. If the bottle is not properly closed, the desiccant bag gets saturated which renders wet urine strips. Do NOT remove the desiccant bag from the bottle.

C. Dipping technique

An improper technique can produce false results, for example, leukocytes and erythrocytes precipitate at the bottom of the container and may not be detected if the sample is not properly mixed. The procedure must be followed exactly to achieve reliable results.

1. Dip the strip into the urine up to the test area for no more than two seconds.
2. Draw the edge of the strip along the brim of the vessel to remove excess urine. At this time, don't make the test areas touch the brim of the vessel. If an excess of urine remains on the strip after it has been removed from the test sample, it may cause the reagents to leak from the pads onto adjacent pads resulting in mixing and distortion of the colors. To ensure that this does not occur it is recommended the edges of the strip are dried on absorbent paper.

D. Always respect the correct incubation time

The soaked urine strips should be read ± 60 seconds after urine immersion. Handling of the urine strip (dipping and removing redundant urine) takes ± 15 seconds.

- General mode: place the strip on the strip loader within 15 seconds. This mode includes an incubation time of 30 seconds inside the instrument.
- Quick mode: place the strip on the strip loader within 45 seconds. The analyzer immediately reads the strip without the incubation time. This implies that the soaked strip should be incubated at room temperature for 30 seconds prior to launching analyses (= outside of the reader).

E. Preparation and handling of samples

Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen as soon as possible, with the sample well mixed but not centrifuged. The use of fresh morning urine is recommended for optimal nitrite tests, as well as for the valid determination of bilirubin and urobilinogen, since these compounds are unstable when exposed to light. If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination. If cleanly voided specimens are not collected from females, positive results for leukocytes may be found due to contamination from outside the urinary tract. Skin cleansers containing chlorhexidine may affect protein test results if specimen contamination occurs. Note: collect mid-stream urine for sample analysis (first/mid-stream/end).

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F. **Never use a strip that was bent**

G. **Store the urine strips at ambient temperature: 2 – 30°C (as indicated on the bottle)**
If storage temperature is too high, results might be faulty. Creatinine and pH results are known to be influenced by too high storage temperatures.

H. **Store the strips at correct humidity: max. 50%**
Do not store the strips at a moist location.

I. **Once the bottle has been opened, the strips remain stable for up to 6 months**

J. **The color indicated on the bottle corresponds to wet strips**
Never use a dry strip to compare color as indicated on the bottle.

K. **For best results, performance of reagent strips should be confirmed by testing known negative and positive specimen or controls**
Quality control should be performed every time a new bottle is opened. By using for example MAS UA Control, BIO-RAD Liquichek Urinalysis Control, and Quantimetrix Dipper Urine Dipstick Control. Do NOT use water as a negative control.
Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that it complies with government and local requirements.

L. **High ascorbic acid and ketone levels may cause false negative results for low-glucose samples**
- Ascorbic Acid (more than 40mg/dl) may cause a false negative for a specimen containing a small amount of glucose.
- High Ketone level (> 40mg/dl) may cause a false negative for a specimen containing a small amount of glucose.

M. **Creatinine results might be influenced by following sample interferences:**
- The urine sample is very fatty
- The urine sample obtained from a jaundiced person

N. **Pad color of specific gravity (S.G.) might become yellow if:**
- The value for specific gravity is higher than 1.030
- The strip has been incubating for more than 10 minutes

O. **LEU concentration may vary between negative and 25 WBC/µl (+ 1) if:**
- The urine sample has a concentration of 18 – 19 WBC/µl

This issue seems to occur more frequently in samples from women.

P. **Analysis by quantitative biochemistry analyzers provides exact concentration**
CYPRESS Urine strips are semi-quantitative. The goal is to determine whether a sample is positive or negative for a specific parameter and give an indication about concentration range. For confirmation and determination of the exact concentration, retesting of the sample by other technologies – like biochemistry analysis – are recommended.

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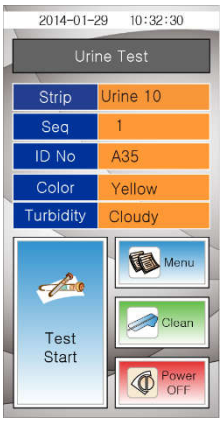
5 INSTRUMENT MENUS

5.1 TEST MENU

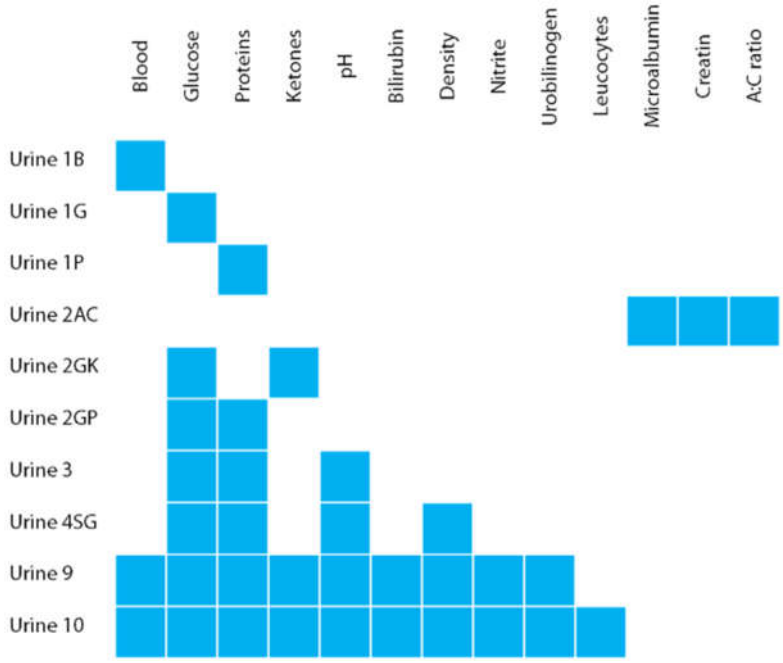


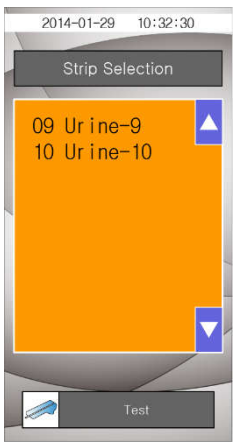
Test menu

After initialization, the test menu is shown. In here, patient data can be entered like strip type, ID number, color and turbidity.

5.1.1 Strip types

Following strip types can be used for analysis by CYANStrip Mini.





Test selection

Touch the « Strip » button in order to change the type of test to be executed. Use the arrows up (▲) and down (▼) to scroll through the list until the test you want to use is reached.
Touch the test type to confirm and the selected test will change color from black to blue. Touch « Test » and return to the « Test menu » screen.

Do not use any strip product other than what is shown on the display. Using the wrong strip will give incorrect results.

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5.1.2 SEQ (sequence)

Memory full

The test sequence numbers go from 1 to 2000 and can be reset when deleting all data. In case of full memory, before starting the next test you will get a warning « Memory full!! Sure to delete data? ».
To avoid loss of data, make sure to first transfer all results before continuing measurements (Refer to **9.6 Transfer of results from instrument to PC software**). To start again at SEQ 1 for the next test, all memory data must first be deleted (Refer to **5.2.3.3 Delete data**).

5.1.3 ID No

ID No.

- Enter the patient's ID number (max. 16 digits) by touching the « ID No » keypad of the display.
- Use the left key (◄) or C (clr) to erase the existing ID number.
- Touch « Test » to return to the « Test menu » screen after entering the ID number.

5.1.4 Color

Color selection

The urine sample must be observed visually to select the appropriate color.

- Touch the color name to confirm. The area of the selected color will change from black to blue.
- Touch « Test » to return to the « Test menu » screen.

This field is for information purposes only and will not influence diagnosis of the patient sample. It will only contribute to a more complete patient test report.

5.1.5 Turbidity

Selection of turbidity

The urine sample must be visually observed to select the appropriate turbidity.

- Touch the turbidity name to confirm. The area of the selected color will change from black to blue.
- Touch « Test » to return to the « Test menu » screen.

This field is for information purposes only and will not influence diagnosis of the patient sample. It will only contribute to a more complete patient test report.

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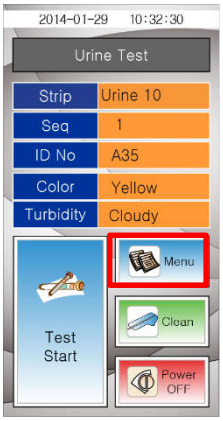
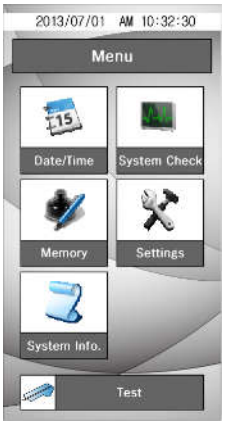
5.2 MENU



From the main screen, the menu can be entered. In here different options like date/time, system check, settings and system info are available.



Menu

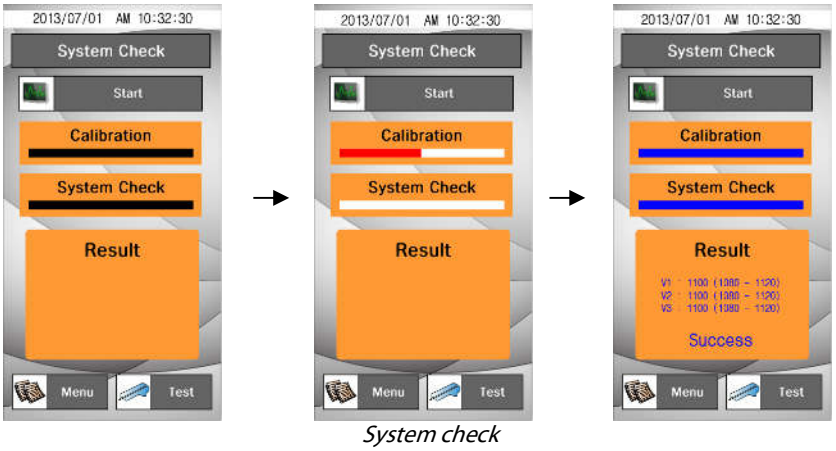
5.2.1 Date/Time

The date and time are displayed on the screen and are recorded with test results. If the date and time values are incorrect, change it by touching the number keys on the display.

- Touch « Test » to return to the « Test menu » screen.
- Touch « Menu » to return to the « Menu » screen.

Date/Time

5.2.2 System check



System check

« System check » is used for verifying and adjusting for the aging processes of the optical system and the variation of other internal conditions of the instrument.

At installation, after moving the instrument or in case of error, the system check and calibration have to be performed before starting measurements.

If the values are within the normal range, the message « Success » will be displayed.

- Touch « Test » to return to the « Test menu » screen
- Touch « Menu » to return to the « Menu » screen

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If the values are not within the normal range, the message « Fail » will be displayed.
In case of failure, repeat the « System check ». If the system check still gives a failure message after the second time, please follow instructions for cleaning the strip loader (**6.2 Cleaning of strip loading plate after use**). If this does not solve the problem, please replace the strip loader, Cod. CY011-S05.

5.2.3 Memory

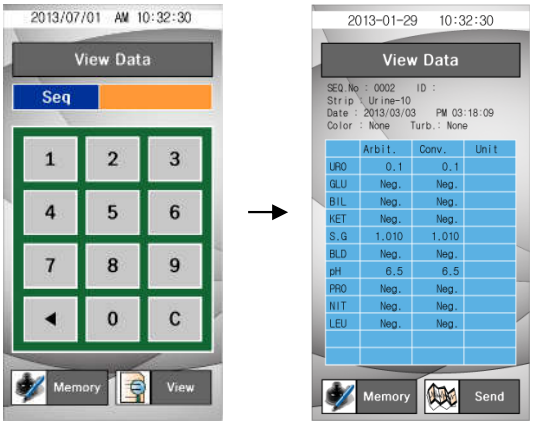
Memory

This menu allows managing of the result data saved in the memory. To enter, touch « Memory » on the « Menu » screen.

- Touch « Test » to return to the « Test menu » screen.
- Touch « Menu » to return to the « Menu » screen.

5.2.3.1 VIEW DATA

In this menu, selected result data can be viewed.



View data

After selecting the SEQ number, touch « View » to see the saved result. The data of the selected SEQ number will be shown on the screen. If you press « Send », the result will either be transferred to:

- The external printer and will be printed
- The PC software, but only if the specified « Transfer » menu is activated at the same time (**see 9.6 Transfer of results from instrument to PC software**)

Depending on the instrument that is connected at the time of sending the result.

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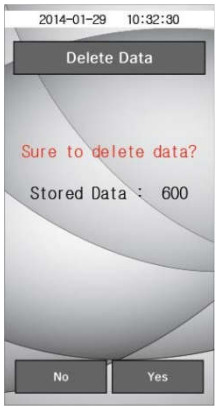
5.2.3.2 SEND DATA

Send data

This menu allows sending saved data to a connected PC. After selecting the Start- and End-number or results to be sent, touch the « Send » icon. The selected data will be sent to the PC **(see 9.6 Transfer of results from instrument to PC software)**. Confirm the condition of connecting communication with the PC before performing the command.

5.2.3.3 DELETE DATA



Delete data

This menu allows deleting the saved data. Touch the « Delete » icon, to delete all stored data. You will now receive a message « Sure to delete data? » and the number of stored results. To delete all saved data, press « Yes » to return to the memory menu, press « No ».
Partial data deletion is not possible. In case of full memory (2000 stored results), please make a backup of all results by transfer to the PC software before deleting all results.
Please confirm full memory deletion after the warning « Sure to delete data? ».

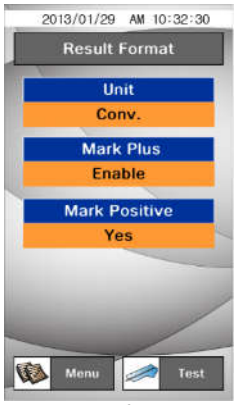
5.2.4 Instrument settings

Instrument settings

The instrument has a series of screens to control and change the result format, system settings and %R value.

- Touch « Test » to return to the « Test menu » screen.
- Touch « Menu » to return to the « Menu » screen.

5.2.4.1 RESULT FORMAT



Result format

This menu allows selection and change of the result display format.

- Unit: selection of result units (Conventional / SI)
- Mark Plus: inclusion of arbitrary results.
  - Select « Enable » if you wish to include arbitrary units in the displayed result.
  - Select « Disable » if you wish to express the result only in conventional or SI units, as selected in the « Unit » area (see above).
- Mark Positive: allows you to choose whether the positive results are highlighted in red.
  - Select « Yes » to make a distinction between positive (red) and normal (blue) results.
  - Select « No » if you wish to express all results in the same color.

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