

combi® scan 100



User's Manual



**Analyzer for
CombiScreen® 11SYS
urine test strips**

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1. Introduction

1.1. Methodology of urine test

The urinalysis is part of the medical diagnosis methods frequently used by medical doctors in laboratories in order to reveal diseases.

The most cost-effective device used to screen urine is a reagent test strip.

This microchemistry system has been available for many years and allows qualitative or semi-quantitative analysis within one minute by simple but careful observation. The colour change occurring on each test pad of the strip is compared to a colour chart to obtain the result. However, misreading or misinterpreting of results, caused by individual handling habits of the user or different light conditions, may happen.

Urine analyzer (urine strip reader) equipment is designed specifically to improve the accuracy and security of urine strip evaluation by using light and photometric reader in order to detect colour changes on the test strips. The **CombiScan® 100** supports test data management and report generation by offering data storage and computerized data processing features.

The **CombiScan® 100** is using modern CCD-technology to analyse the colour and intensity of the light reflected from the test pad surface, and it reports the results in clinically meaningful units. No further calculation is needed by the user. When a strip is moved into the measuring position under the optical unit, the reflectance of each test pad is measured. The light reflected at specific wavelengths from the test pad depends upon the degree of colour change of the pad, which is related to the concentration of the particular parameter in urine. The intelligent image analyzer software reads the reagent areas and the values are calculated automatically. Results are stored, then printed out by the built-in printer and can optionally be sent to host computer via serial connection.

1.2. Test strip

The base of the urine analysis is the good quality dry reagent urine test strip. These strips have separated test pads for each analyte. The test pads contain reagents, which cause colour changes according to the analyte concentration in the urine.

The **CombiScan® 100** is calibrated to **CombiScreen® 11SYS** urine test strips and guarantees accurate results all time. The **CombiScreen® 11SYS** urine test strip contains reagents for testing:

- Bilirubin
- Urobilinogen
- Ketones
- Ascorbic Acid
- Glucose
- Protein
- Blood
- pH
- Nitrite
- Leukocytes
- Specific Gravity

Besides the **Combi Screen® 11SYS**, the **Combi Screen® 11SYS PLUS** can also be used with this instrument. To facilitate reading of the manual, the test strip is always named **Combi Screen® 11SYS** in this manual.

Before using the test strip read carefully the CombiScreen® 11 SYS packing insert!
The meter can only be used with the CombiScreen® 11 SYS urine test strip!



1.3. Intended use

CombiScan® 100 is an instrument for measurement of urine test strips **CombiScreen® 11SYS** for in-vitro determination of Ascorbic acid, Bilirubin, Blood, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Specific Gravity and Urobilinogen from urine. These measurements are used in the evaluation of diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders or metabolic abnormalities. For professional use, not for self testing.

2. Description of the equipment

The **CombiScan® 100** is a small, compact, easy-to-use urine strip analyzer. It is ideal for small-scale laboratories and physicians' offices.

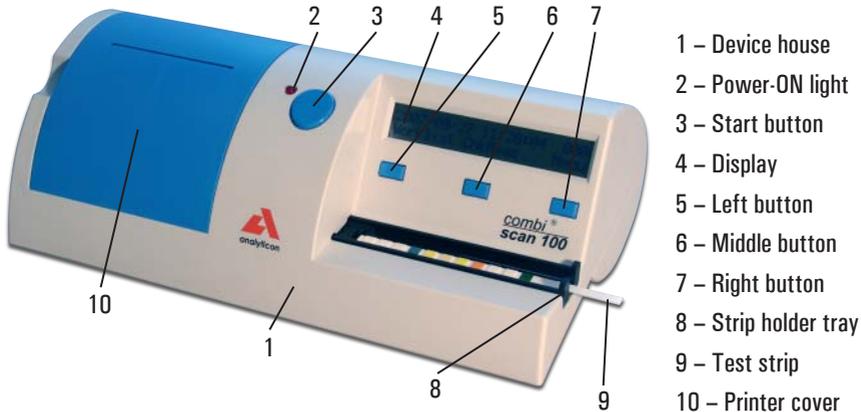


Fig.1 Front view of the **CombiScan® 100** urine analyzer

The optical system is designed especially for the evaluation of the **CombiScreen® 11SYS**. The test strip is illuminated by white light and the reflected light from the reagent strip is detected by a colour CCD sensor. The signals are digitalized and this digitalized image is evaluated by the built-in program. Due to the CCD-technology, the instrument is able to distinct between colour changes caused by reaction of the test pad chemistry and non-specific colour development, caused by the sample. Operation is very simple, and doesn't require any special knowledge or difficult practice.

Each time a strip is read, the grey reference pad in the tray is evaluated to check the optical system. If the reference pad is badly soiled or a LED is defective and cannot emit the required amount of light, an error message is displayed (see section 6.).

 **Warning! Be careful not to harm or scrape calibration pad surface.**

All the program information that is necessary to measure and evaluate a test strip are stored in the code key plug (can be found under printer cover). Generally user do not need to do anything more with this plug, than to control, whether it is plugged in properly. It can be changed if analyticon® Biotechnologies AG offers an updated program version. In this case analyticon® Biotechnologies AG delivers detailed information on how to use the new code key.

 **Warning! Do not remove the code key plug from its place! Without the code key plug the equipment is unable to operate.**

The interface connectors are located on the back panel. The external barcode reader or keyboard can be connected to the “keyboard” (PS2) connector. The host computer can be connected to the USB or to the serial interface connector. To use the serial interface a special RS232 cable with the appropriate connector is needed. Please contact your distributor to order this accessory. You may damage the instrument when using the wrong cable for serial port connection.

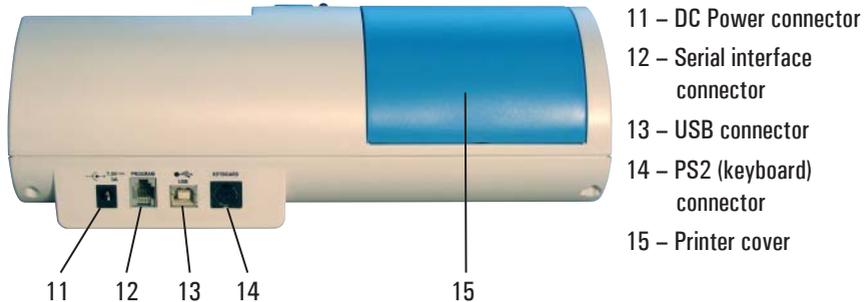


Fig. 2 Rear view of the **CombiScan® 100** urine analyzer

2.1. Packing list

- 1 Instrument
- 3 Strip holder
- 1 Adapter
- 1 Strip holder with grey strip
- 1 Manual
- 1 CD
- 1 Cable USB
- 1 Paper roll

3. Installation

Important!



Please check first whether the shipment is complete (see Packing list 2.1.). If it is complete follow the instructions below, otherwise please contact your distributor immediately.

The **CombiScan® 100** is shipped in a carton box. Prior to unpacking, clear the area where the instrument is to be operated. Please take care of shipping marks on the box while handling. It is recommended to keep the packaging materials, in case the instrument needs to be moved to another location or must be shipped for repair.

Prepare the accessories: power adapter and printer paper, and if required, USB cable, keyboard and/or barcode reader.

- Place the **CombiScan® 100** to its working position.
- Connect power adapter first to DC socket at the back of the equipment, then to the mains. The **CombiScan® 100** will automatically switch on. (Disconnect the instrument from the mains to switch off.)
- Open the printer cover.
- Take a roll of printer paper. If the edge of the paper is not straight, cut it. Insert the roll into its cave and load the free end of paper into the printer by inserting paper into the feeding slot. The paper will be loaded automatically. Feed the end of the paper through the slot of the cover and close it.



Fig. 3 View into the paper roll cave

- If you want to use the worklist, connect your external keyboard and/or barcode reader to the interface connector.
- If you want to transfer data to a host, use the included USB cable, connect the **CombiScan® 100** to your computer's USB port (see section 4.7.)

Now, the **CombiScan® 100** is ready to work.

4. Operation

4.1. Overview of the Menu system

The software of the **CombiScan® 100** provides a user interface that enables all laboratory-specific settings and recurrent functions to be selected via the buttons.

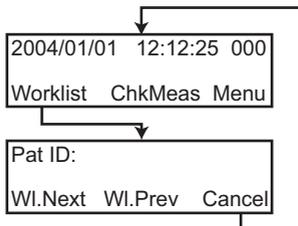
When the **CombiScan® 100** is connected to a power supply the screen of the Main Menu is displayed, showing date, time and number of measurements since the instrument has been started (upper line). The three buttons refers to a particular function displayed in the second line of the LCD. Select the desired function by pressing the buttons below the displayed menu items. The first line of the display is used to show your actual position in the menu system. Also the first line is used to screen the selection that you have made in a sub-menu.

Pressing the Start button within any submenu returns the system to Main Menu (excepting the worklist menu). 

Operation and functions of the **CombiScan® 100** can be studied by its menu system's chart (see Appendix). Each selected menu allows the user to control one of the operational or setup functions. By pressing the Start button you can always return to Main-menu. From Main Menu you can enter either to **Worklist** menu, to **Check Measurement** menu or to **Menu**

4.2. Worklist

The worklist is a predefined sequence of samples. The worklist contains maximum 20 patients ID's in the sequence of planned evaluation. A worklist can be generated through a connected external keyboard or barcode reader. The patient ID is a maximum 13 character long string containing either numeric or alphabetic characters. If you wish to delete an ID from worklist select the ID first and press the delete key on the keyboard. To set this modification press enter.



4.2.1. Worklist with keyboard

The worklist can be typed in by a keyboard. Connect the keyboard to the **CombiScan® 100** and press the left button of the **CombiScan® 100** to reach the worklist menu. In the worklist menu, a name or a patient ID of up to 13 characters can be typed in. If you have finalized one name or patient ID, press enter to go to the next ID. Please use the up and down cursor keys to move to different patient IDs in the worklist. To go back to the main menu without printing the worklist, please press the escape key. The worklist can be printed out by pressing the print button on the **CombiScan® 100**, in that case the **CombiScan® 100** will reach the main menu automatically. You can also start the measurement of the first ID of the worklist by pressing the Start button.

4.2.2. Worklist with barcode reader:

The worklist can be read in by a barcode reader. Connect the barcode reader to the **CombiScan® 100** via the PS2 connector and press the left button of the **CombiScan® 100** to reach the worklist menu. Now the instrument is ready to read barcodes. When a code is added the list automatically jump to the next ID position. If you have finalized the list you either print out the list or you immediately start measuring the first sample by pressing the Start button. To go back to the Main menu without printing the worklist please press the escape key on the keyboard.

4.3. Self check

Users should always follow the appropriate federal, state and local guidelines concerning the use of external quality control materials.

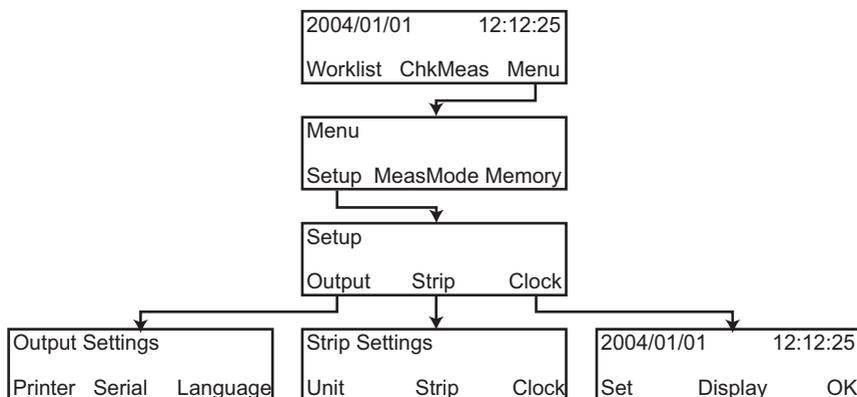
It is necessary to periodically ensure that your device is working properly. Every day before doing the first measurement you should perform a self check. To test your instrument please follow the instructions below:

- Place the strip holder with attached grey strip onto the strip holder tray.
- Press the ChkMeas button in Main Menu.
- The **CombiScan® 100** will automatically do a self-check and print out the results after finishing the measurement.

If the check is repeatedly invalid, please contact your distributor.

4.4. Setup menu

The Setup menu is adapted to customize the **CombiScan® 100** according to your individual requirements or working methods. By selecting this menu, you can configure the communication with your host computer, the built-in printer and the printout format including the result units, the sensitivity of different pads, etc. To get familiar with these features please follow the flowchart below.



4.4.1. Output settings

4.4.1.1. Printer setting

The **CombiScan® 100** automatically prints out the results if the printer is switched on. You can switch on and off the printer in the **Menu/Setup/Output/Printer** sub-menu by pressing the “On” or “Off” buttons. The actual status of the printer is displayed in the first line of the LCD. You can accept the desired state of the printer by pressing “OK”.

4.4.1.2. Serial port settings

You can connect the **CombiScan® 100** via the included USB cable to your computer’s USB port, if you want to upload and collect data in a database on your PC. For serial communication the **CombiScan® 100** offers two protocols: PC unidirectional protocol when upon a Start signal the selected records are sent to the receiving computer in a data flow, or Network bidirectional protocol when data is sent in blocks. In Network protocol the blocks also include an indicator being able to sign if the sequence number (Seq) or patient ID (ID) identifies the result reports.

Enter the **Menu/Setup/Output/Serial/Protocol** sub-menu to set the desired serial communication protocol. Pressing the “Netw/PC” button you can choose between Network and PC proto-

col. The actually selected protocol is displayed in the first line of the LCD. If you select Network protocol by pressing the “Seq/ID” button you can decide the way records should be identified: according their sequence ID or by the patients name. In case you choose PC Unidirectional protocol the “Seq/ID” button is inactive.

You can also change the speed of serial communication. After entering the **Menu/Setup/Output/Serial/Speed** sub-menu you can choose with the Up and Down buttons one of the following baud rates: 2400, 4800, 9600, 19200, 38400, 57600, 115200.

 **Note:** PC unidirectional protocol does not apply control sum checking.

For successful data transfer between the **CombiScan® 100** and the computer, the **CombiScan® 100** needs to be connected to host computer (PC) via USB interface cable (included).

4.4.1.3. Language setting

You can select the language in the **Menu/Setup/Output/Language** sub-menu with the help of the “Previous” and “Next” buttons. There are six languages that you can choose from: English, German, French, Spanish, Italian and Chinese. You can set the selected language by pressing the “OK” button. If you choose Chinese, the printout will show Chinese characters, the menu on the display will be in English.

4.4.2. Strip settings

4.4.2.1. Selecting the measuring Unit

The **Menu/Setup/Strip/Unit** sub-menu allows to select measurement Units of test results on printed reports. After entering this sub-menu with the use of “Previous” and “Next” buttons you can choose a Unit from the following list:

- Conventional (Conv)
- SI
- Arbitrary (Arb)
- Conventional+ Arbitrary (Conv + Arb)
- SI + Arbitrary (SI + Arb)

You can save your choice by pressing “OK”.

4.4.2.2. Sensitivity adjustment

The **CombiScan® 100** provides semi-quantitative results. In special cases, it may be useful to adjust the sensitivity of single analytes by the user, although it is not recommended. To adjust

the sensitivity enter the **Menu/Setup/Strip/Strip/Sens** sub-menu. Selecting the Set option the first pad name and the actual setting are displayed. Pad measurement sensitivity can be set in two levels in both directions by the Up and Down buttons. After setting the proper sensitivity of the actual pad you can proceed with the next pad by pressing the NextPar button. After having finished the final test-pad sensitivity setting the program will automatically return to Main Menu. It is not possible to escape until all pad sensitivities are set. To skip a pad without any modification just select NextPar.

To reset the settings adjusted by the manufacturer for all pads, select the Default option in the **Menu/Setup/Strip/Strip/Sens** sub-menu.

Note: When the reader is adjusted different from manufacturer setting it will be indicated by asterisks in the footer of the printout! 

4.4.2.3. Changing the pad sequence in printout

By default the **CombiScan® 100** prints out the result in the sequence of the pads physical position but it is possible to customize the layout.

Important!

This setup option effects only the printout and data transfer. The CombiScan® 100 can be used with CombiScreen® 11SYS urine test strip only. 

In the **Menu/Setup/Strip/Strip/Sequence** sub-menu you can restore either the default sequence or set up your own sequence by selecting the Set option. Selecting Set you can arrange the pads to appear in the desired sequence of printout lines. On the left side of the first line of the LCD the line number is displayed and next to it on the right side the actual analytes name can be seen. Using the Up and Down buttons you can perform changes and by selecting the NextPar function next printout line will be displayed. When the last line is reached, the program returns to Main Menu. It is possible to create a printout which is not showing all analytes, if the END function is selected before all analytes had been selected.

To reset the default sequence of the pads in printout select the Default option in the **Menu/Setup/Strip/Strip/Sequence** sub-menu.

Note: You can not define empty printout lines or the same analyte twice or more times. 

4.4.3 Settings of date and time

4.4.3.1. Adjust date and time

The built-in digital clock enables to store the date and time of the measurement. To get correct information it is necessary to set the clock exactly. The clock is working even when power supply is not connected to the equipment.

You can adjust the time in the *Menu/Setup/Clock/Set* sub-menu. The time or date unit highlighted by the cursor can be increased or decreased by pressing the Up or Down buttons. Pressing the Right button (> > >) moves the blinking cursor to the right. When the blinking cursor reached the right corner of the display by pressing the Right button (> > >) again the new time will be set and Main Menu appears on the display.

4.4.3.2. Changing the display format of date and time

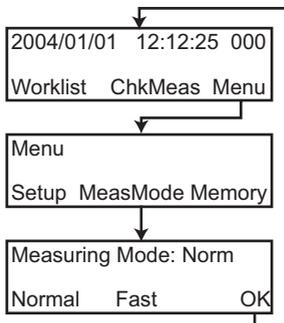
To adjust the display format according to your individual requirements the **CombiScan® 100** supports different date and time formats. You can change the display mode of date and time after entering the *Menu/Setup/Clock/Display* sub-menu. Pressing the Left button (Sequence) allows the date format to be changed to Year/Month/Day or Day/Month/Year or Month/Day/Year. You can choose between the 24-hour or the 12-hour plus a.m/p.m system by pressing the "12/24" button.

4.5. Measuring mode

The **CombiScan® 100** can be operated in two different modes:

In Normal mode, the equipment waits for the strip to incubate before it reads the first pad. Throughput in this mode is 40 tests per hour and in this case incubation is controlled by the instrument.

In Fast mode, the test strip is measured directly after Start is pressed. In this case it is up to the user to time the incubation period outside the analyzer. Using Fast mode enables a throughput of 120 strips per hour.



You can switch between Fast and Normal mode in the **Menu/MeasMode** sub-menu. The actually selected measuring mode is displayed in the first line of the LCD. You can change the mode by pressing either the Normal or the Fast button. Pressing OK will store your change and return to Main Menu. Choose the mode you would like to use and follow the instructions in the referring section (4.5.1. and 4.5.2.). In the upper line in the main menu on the right hand side the number of measurements is displayed, that had been done since the meter has been switched on.

There is no further special operation needed to calibrate the instrument before starting the daily routine urinalysis. It is recommended to use urine controls at least daily to check the system.

4.5.1. Measuring in Normal mode (single readings)

Day-to-day operation of the **CombiScan® 100** is easy and will be explained below. For this type of reading, "Normal Mode" should be selected from the **Menu/MeasMod** sub-menu by pressing the Left button (Normal).

- Have the urine test sample tube(s) prepared.
- Optional: You can enter a single patient ID's with the help of a connected external keyboard or barcode reader. (see section 4.2. for details)
- Dip an unused test strip in the urine sample and carefully wipe off any excess urine. Briefly dab the side edge of the strip on a clean, absorbent surface (for example kitchen roll).
- Place the test strip, with the test pads facing upward, on the tray.
- Make sure that the top end of the strip is touching the edge of the area for the test strip on the tray (see picture). Wrong positioning may cause wrong results.

right



Fig. 4a

wrong



Fig. 4b

Fig. 4 Correct positioning of the urine strip: The top end of the strip has to touch the top edge of the area for the test strip on the strip holder tray, as shown in Fig. 4a. Wrong positioning is shown in Fig. 4b.

Warning!

 It is important that the strip is correctly positioned on the tray, and the Start button pressed within 5 – 10 seconds of dipping the strip.

- To start the measurements without patient ID for identification press the Start button. (If you have entered patient ID's in a worklist the instrument measures samples according to the sequence of ID's of the worklist. You can start measuring ID's from worklist direct from worklist sub-menu or from Main Menu. To enter a worklist please see section 4.2.)
- 60 seconds after the Start button is pressed the first test pad is measured followed by the others. After evaluation of the last pad the tray returns to start position and the equipment will display Main Menu options.
- Remove and dispose the used test strip. Wipe any urine residues from the tray with a lint-free cloth.
- The result will be printed out automatically after evaluation, if the printer is enabled (see section 4.4.1.1.)
- The next test strip can be dipped, wiped off, placed in the tray and read by pressing the Start button or you can finish evaluating.

 **Note: All instructions must be followed thoroughly to get accurate results!**

4.5.2. Measuring in Fast mode (serial readings)

You can also perform serial readings suggesting that the strips are dipped and incubated for about 55 seconds outside the **CombiScan® 100**. For this type of reading, "Fast Mode" should be selected from the **Menu/MeasMod** sub-menu by pressing the Middle button (Fast). To complete measurements in Fast mode follow the instructions below:

- Place dipped test strips with the test pads facing upward on the tray after allowing them to incubate for approximately 55 seconds.
- Optional: You can enter single patient ID's. with the help of a connected external keyboard or barcode reader. (see section 4.2. for details)
- Make sure that the top end of the strip is touching the edge of the area for the test strip on the tray (see picture). Wrong positioning may cause wrong results.

Warning!

 It is important that the strip is correctly positioned on the tray, and the Start button pressed within 5 – 10 seconds after positioning.

right



Fig. 5a

wrong



Fig. 5b

Fig. 5 Correct positioning of the urine strip: The top end of the strip has to touch the top edge of the area for the test strip on the strip holder tray, as shown in Fig. 5a. Wrong positioning is shown in Fig. 5b.

- To start the measurements without patient ID for identification press the Start button. (If you have entered patient ID's in a worklist the instrument measures samples according to the sequence of ID's of the worklist. You can start measuring ID's from worklist direct from worklist sub-menu or from Main Menu. To enter a worklist please see chapter 4.2.)
- After reading is finished the result will be printed out automatically if the printer is enabled (see section 4.4.1.1 on how to enable/disable the printer). The evaluation of a test strip and the printing of the result will be complete in less than 20 seconds. This guarantees a throughput of at least 120 strips per hour.
- After the printing is ready you can proceed with the next measurement.

WARNING!

When performing serial measurements in Fast mode, allow the strips to react for approximately 55 seconds before inserting them in the CombiScan® 100 and pressing Start. False-low or false-negative results may be obtained for some analytes if the reaction time is too short. Likewise, false-high results may be obtained for some analytes if the incubation time outside the CombiScan® 100 is too long.



Note: All instructions must be followed thoroughly to get accurate results!



4.5.3. Results printout

Printed/sent result contains a lot of data: type of measurement, device type, date and time, serial number of test, patient identifier, result with analyte names, values, units, markings of pathological values and an end line. Before each analyte name the pathological value is marked with an asterisk (*). If one or more result classification limits (see section 4.4.2.2 for changing

sensitivity) have been changed, end line of result starts and ends with an asterisk (*....*). Each classification range has a name and a unit, corresponding to the analyte. Result printout can be in Chinese, too, if it is selected as language.

Typical result printout

■ Values are displayed in conventional units

■ Pathological values are marked with an asterisk (*).

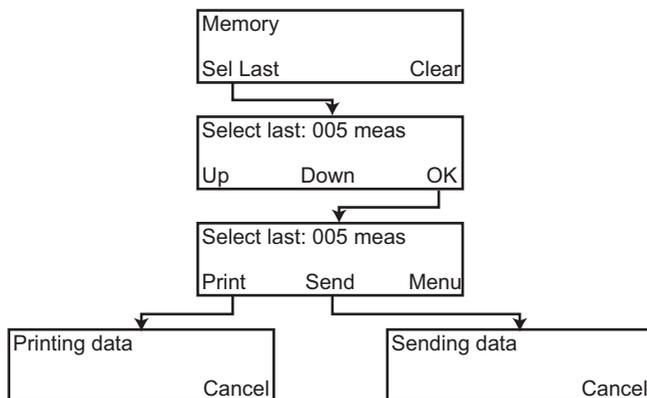
■ If one or more result classification limits have been changed, end line of result starts and ends with an asterisk (*....*).

Date	2004/03/22	CombiScan100	11:33
Sequence Nr. given by the reader	No: 125.		
Patient ID	Pat. ID: @ABCDEFGHI		
	BIL	neg	
	*UBG	12	mg/dl
	*KET	150	mg/dl
	ASC	40	mg/dl
	GLU	norm	
	*PRO	500	mg/dl
	*ERY	50	Ery/ul
	pH	6	
	*NIT	pos	
	*LEU	75	Leu/ul
	SG	1.020	

 **Note:** The printing on thermal paper may fade during storage, or if it is covered with transparent tape.

4.6. Memory management

The **CombiScan® 100** stores the last 500 results in memory. With the results entered patient ID, time and date of measurement are stored as well. In this *Menu/Memory* sub-menu you can clear results from memory or transfer stored data to the built in printer or to a device connected to the serial port (i.e. host computer). To achieve the functions mentioned above follow the flowchart below.



4.6.1. Memory data transfer

The **CombiScan® 100** is able to print out or send to a host (see section 4.7. data download) the stored data. In both cases you can select a memory range to be transferred. To do so enter the **Menu/Memory** sub-menu where after pressing the “Sel Last” key you can determine by using the Up and Down buttons how many of the last measurements should be transferred. If you successfully set the memory range you would like to transfer, press OK. This will lead you to the next menu option, where you can select the device to which you would like to transfer the selected range of data. By pressing the Print button the selected memory range will be printed out. It will be sent to a host if you press the Send button. By pressing the Start button the selection will be cancelled and the Main Menu appears. After transmission has done the display returns to Menu. You can cancel the transmission by pressing Cancel any time during transfer.

4.6.2. Clearing data from memory

By this option you can delete all stored data. All you have to do is to press the Clear button in the **Menu/Memory** sub-menu and all previously stored data will be removed. After clearing the memory the equipment automatically returns to Main Menu.

4.7. Data download

The results of measurements can be downloaded to a host computer using the **CombiScanner** data management software. You can find the software on the CD which is delivered together with the instrument. The data will be stored only if the measurement refers to a patient ID which has been added to the worklist (see section 4.2.). To use the CombiScanner data management software please follow the instructions below:

System requirements:	Hardware: Pentium III. 300Mhz Memory: 256 MB RAM Hard disk: 300 MB HDD Monitor: 1024*768 color
Software Requirements:	Operating Systems: Windows XP, Windows 2000 or Windows 98 Microsoft Internet Explorer 5.01 or higher

Installation:

1. Install the **CombiScanner** data management software on your computer. Please carefully read the *readme.txt* first
2. Switch on the **CombiScan[®] 100** without connecting it to the host computer
3. Connect the USB cable to the computer and follow the installer to install the USB driver (you will find the USB driver on CD)
4. Adjust the **CombiScan[®] 100** as follows:
 - **Menu/Setup/Output/Serial/Protocol** to PC
 - **Menu/Setup/Output/Serial/Speed** to 9600
 - **Menu/Setup/Clock/Display** date format to YYYY/MM/DD
 - **Menu/Setup/Clock/Display** clock format to 24h mode
 - **Menu/Setup/Strip/Unit** to Conv or SI
5. Open the CombiScanner data management program and follow the instructions in Help menu (user's guide). See also chapter Memory data transfer (see section 4.6.1). Make sure that the baud rate of selected port of the computer is adjusted to 9600.

5. Care of the instrument

Operation of the instrument doesn't require any special maintenance, besides cleaning and disinfection there is no need for further care.

 **Protect the instrument from extremes of temperature and high atmospheric humidity and keep it out of bright light (direct sunlight, spot lamps, etc.).**

Maintain hygiene by keeping the exterior parts and surfaces of the instrument clean. For daily cleaning we recommend applying a commercial cleaning agent or disinfectant (preferably 70% alcohol) with a moist cloth.

 **Take care that no liquids enter the instrument.**

We recommend to clean the strip holder tray each day finishing the use of device. Tray can be pulled out of device and cleaned and disinfected separately. Be sure, tray is clean and dry and calibration pad is in place, when you push tray back into device.



Fig. 6 Correct handling of the strip holder for positioning it into the device after cleaning.

 **Be careful not to harm or scrape calibration pad surface.**

6. Warnings / Precautions

The **CombiScan® 100** must be used in the manner described and specified in this manual in order to provide the safety and performance standards specified.

The instrument is calibrated for **CombiScreen® 11SYS** test strips. With other **CombiScreen** test strips or with test strips of other manufacturers, wrong results will be obtained.

In order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with **CombiScan® 100** should be verified with other medical and diagnostic results.

To check the performance of the system (instrument + test strips) and to ensure reliable results, it is recommended to use control solutions regularly and to record the results. Especially in the following situations, the use of urine controls is highly recommended:

- a) at the beginning of the daily routine measurements
- b) if a new bottle of test strips is opened
- c) if test results are in doubt
- d) if operators are trained on the system

Urine samples should be handled as a potentially infectious liquid. The equipment which comes into contact with urine, should be disinfected thoroughly after having finished working.

Always apply safe laboratory practices when operating the **CombiScan® 100**

The **CombiScan® 100** is an electrical device. Take care that no liquids like water, urine or disinfectants enter the instrument, because this may damage the device or may lead to a dangerous situation for the user.

Do not open the housing of the **CombiScan® 100** when connected to power supply. In case of problems, call your distributor.

Protect the instrument from extreme temperatures or high atmospheric humidity, and keep it out of bright light! For measuring, keep the specifications concerning temperature (15 - 30°C) and relative atmospheric humidity (< 85%).

7. Troubleshooting

During operation different errors and error messages may appear. Below you will find the list of error messages and some suggestions what to do. If the problem persists, please contact your distributor.

E1	Tray error	May be the tray is missing or it's moving is blocked. Check the tray and restart the reader.
E2	Calibration error	Some problem with calibration pad on strip holder tray. Clean the pad or use a new strip holder tray and restart the reader.
E3	Codekey error	Codekey plug is missing or wrong. Check if the plug is connected properly, then restart the reader.
E4	Netware error	Some problem in bidirectional serial port communication. Check communication cable or the communication settings.
E5	Worklist frame error	Some problem with received worklist from PC. Check communication cable or the communication settings.
E6	Worklist full	More than 20 data in received worklist. Remove the records above 20 from the transfer list and try downloading again.
E7	Printer out of paper	Refill the printer and try printing again.
E11	No strip	Place a strip on the stripholder before pressing the start button!
W1	Memory empty	You can't print out entries from the memory if it's empty.

8. Technical data

Methodology	Reflectance photometer
Detection	CCD image processing
Throughput	At least 40 tests/hour in Normal mode (Incubation time ~60sec) At least 120 tests/hour in Fast mode (No built-in incubation time)
Memory	last 500 results
Display	2x 24 character LCD
Printer	57 mm thermal printer (2 lines/sec)
Size	W265 x D135 x H90 mm
Weight	ca. 0.8kg
External power-adapter	7,5 V DC / 3A
Operating temperature	+ 15 to + 30°C (room temperature)
Relative humidity	< 85 % RH

Interfaces:

USB port	host communication
RS232 serial port (RJ11 6/6 socket)	host communication
AT/PC keyboard input (PS2)	keyboard, barcode reader (PS2)

Factory settings:

Date	YYYY / MM / DD
Time	HH / MM / SS (24-hour mode)
Printer	ON
Meas. Mode	Normal
Sensitivity	Default
Pad Sequence	Default
Unit	Conv
Protocol	PC
Speed	9600
Language	English
Memory	Cleared

9. Spareparts / consumables

A93150	CombiScreen 11SYS (pack size 150 pcs.)
A93100	CombiScreen 11SYS (pack size 100 pcs.)
A94150	CombiScreen 11SYS PLUS (pack size 150 pcs.)
A94100	CombiScreen 11SYS PLUS (pack size 100 pcs.)
A93010	Paper for thermal printer (57 mm x 25 m)
UCP-4404-1	Stripholder
UCP-4414-1	Stripholder with greystrip
UCP-4604-1	Serial-cable
358USBAB	USB-cable
1ASA7V1A	Power adapter

11. Symbols



In vitro diagnosticum



Warning



Read package insert



Serial number



Manufacturer



This product is conform to the directive 98/79EG dated 27.10.1998



For members of the European Union only:
According to Guideline 2002/96/EC (WEEE),
this instrument must be recycled profes-
sionally. Please return it to your distributor
at the end of the economic lifetime.



Tested to comply with FCC standards
For home or office use

ANALYTICON BIOTECHNOLOGIES AG

35104 Lichtenfels

Germany

Phone: (+49) 64 54 79 91-0

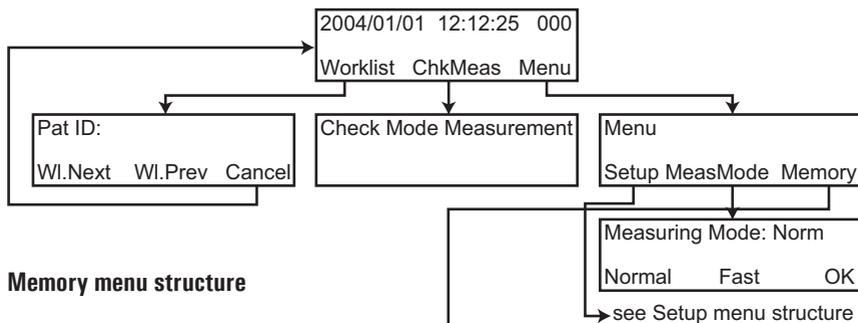
Fax: (+49) 64 54 79 91-30

info@analyticon.de

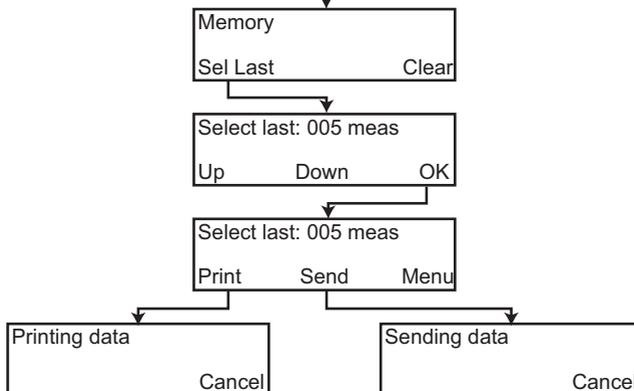
www.analyticon.de

Appendix

Main menu structure



Memory menu structure



Setup menu structure

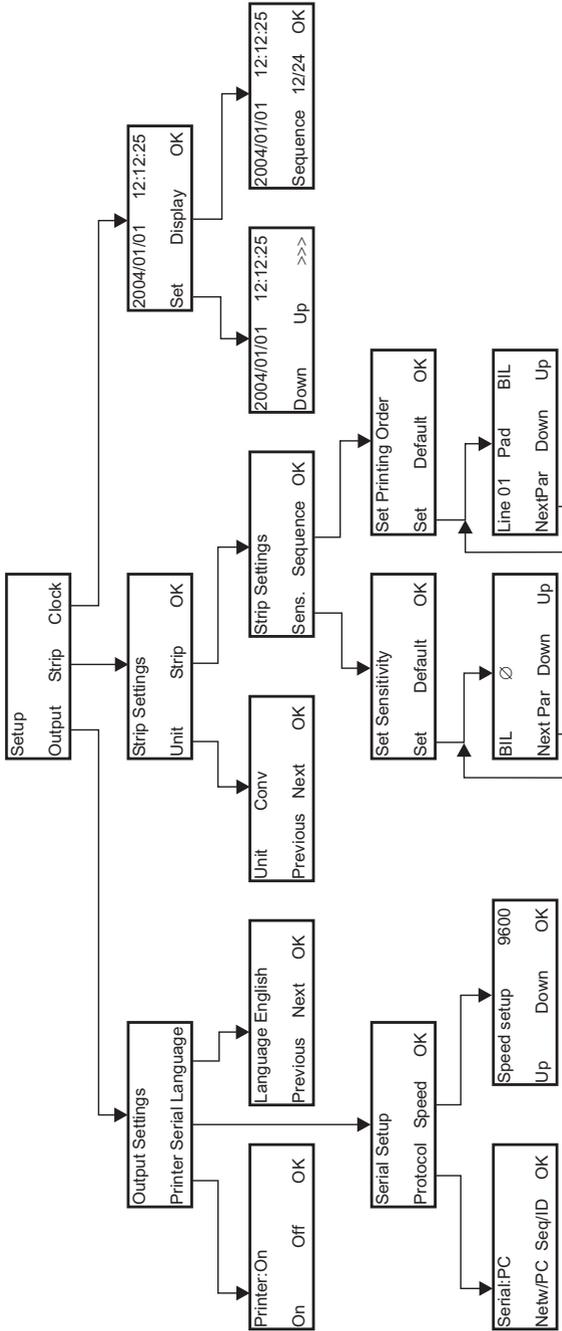


Table of results

english

Bilirubin BIL	Conv.	neg	1	2	4				mg/dl
	SI	neg	15	35	70				µmol/l
	Arbitrary	neg	+	++	+++				
Urobilinogen UBG	Conv.	norm	2	4	8	12			mg/dl
	SI	norm	35	70	140	200			µmol/l
	Arbitrary	norm	+	++	+++	++++			
Ketones KET	Conv.	neg	10	25	100	300			mg/dl
	SI	neg	1	2,5	10	30			mmol/l
	Arbitrary	neg	(+)	+	++	+++			
Glucose GLU	Conv.	norm	50	100	250	500	1000		mg/dl
	SI	norm	2,8	5,6	14	28	56		mmol/l
	Arbitrary	norm	+	++	+++	++++	+++++		
Protein PRO	Conv.	neg	30	100	500				mg/dl
	SI	neg	0,3	1,0	5,0				g/l
	Arbitrary	neg	+	++	+++				
Blood BLD	Conv.	neg	10	50	300				Ery/µl
	SI	neg	10	50	300				Ery/µl
	Arbitrary	neg	+	++	+++				
Nitrite NIT	Conv.	neg	pos						
	SI	neg	pos						
	Arbitrary	neg	pos						
pH pH pH	Conv.	5	6	7	8	9			
	SI	5	6	7	8	9			
	Arbitrary	5	6	7	8	9			
Specific gravity SG	Conv.	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
	SI	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
	Arbitrary	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
Leucocytes LEU	Conv.	neg	25	75	500				Leu/µl
	SI	neg	25	75	500				Leu/µl
	Arbitrary	neg	+	++	+++				

chinese

胆红素	Conv.	-	1	2	4				mg/dl
	SI	-	15	35	70				$\mu\text{mol/l}$
	Arbitrary	-	+	++	+++				
尿胆原	Conv.	norm	2	4	8	12			mg/dl
	SI	norm	35	70	140	200			$\mu\text{mol/l}$
	Arbitrary	norm	+	++	+++	++++			
酮体	Conv.	-	10	25	100	300			mg/dl
	SI	-	1	2,5	10	30			mmol/l
	Arbitrary	-	(+)	+	++	+++			
尿糖	Conv.	norm	50	100	250	500	1000		mg/dl
	SI	norm	2,8	5,6	14	28	56		mmol/l
	Arbitrary	norm	+	++	+++	++++	+++++		
尿蛋白	Conv.	-	30	100	500				mg/dl
	SI	-	0,3	1,0	5,0				g/l
	Arbitrary	-	+	++	+++				
潜血	Conv.	-	10	50	300				Ery/ μl
	SI	-	10	50	300				Ery/ μl
	Arbitrary	-	+	++	+++				
亚硝酸盐	Conv.	-	+						
	SI	-	+						
	Arbitrary	-	+						
pH	Conv.	5	6	7	8	9			
	SI	5	6	7	8	9			
	Arbitrary	5	6	7	8	9			
比重	Conv.	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
	SI	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
	Arbitrary	1.000	1.005	1.010	1.015	1.020	1.025	1.030	
白细胞	Conv.	-	25	75	500				Leu/ μl
	SI	-	25	75	500				Leu/ μl
	Arbitrary	-	+	++	+++				