HumaCombilyzer

| User Manual

CE

REF 17630/1

Human

Diagnostics Worldwide

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System version

Software V3.3.04

Copyright

Service and support

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS" describing the appropriate operating procedures. Please contact the technical Service in the event of instrument failure or other difficulties with the instrument.

1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, diskettes, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer‘s instructions, altered in any way not

specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.
HUMAN shall be relieved of any obligation under this warranty, unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.
This warranty does not apply to damages incurred in shipment of goods. Any damage so incurred shall be reported to the freight carrier for settlement or claim.

1.3 Use of the Instrument

The instrument must be used for its intended purpose (chapter 2.1) . It must be operated in perfect technical conditions by qualified personnel in such working conditions and maintained as described in this manual in the GENERAL SAFETY WARNINGS. This manual contains instructions for qualified professional operators.

1.4 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual.
Place the product so that it has proper ventilation.
The instrument should be installed on a flat, stationary working surface that is free of vibrations.
Do not operate in area with excessive dust.
Operate at room temperature and at a humidity level in accordance with the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.
Use only the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.
Use only the fuse type and rating specified by the manufacturer for this instrument. The use of fuses with improper ratings may pose electrical and fire hazards.
To avoid fire or shock hazard, observe all ratings and markings on the instrument.
Do not power the instrument in environments that are potentially explosive or at risk of fire.
Prior to cleaning and/or performing maintenance on the instrument, switch off the instrument and remove the power cord.
Only cleaning materials described in this manual may be used, as other materials may damage parts.
It is recommended to always wear protective apparel and eye protection while using this instrument.
All warning symbols that appear in this manual must be carefully observed.
For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

1.5 Disposal Management Concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for the proper disposal of the individual components.

All parts which may contain potentially infectious materials must be disinfected by suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal must be carefully observed.

The instruments and electronic accessories (without batteries, power packs etc.) must be disposed of according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power sources must be removed from electric/electronic parts and disposed of in accordance with applicable local regulations.

1.6 Biohazard Warning

Analytical instruments for use in the clinical laboratory environment may come into contact with human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious. For safety reasons, we recommend to label such instruments with the "BIOHAZARD" warning label below.

FIGURE 1
Biological Hazard Symbol

1.7 Instrument Disinfection

Instruments or parts which may come in contact with biological samples (patient specimens, controls etc.) should be considered at least potentially infectious.

Before performing any service work on the instrument, it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated/disinfected. Decontamination/disinfection must be performed by authorised, well trained personnel and in observance of all necessary safety precautions. Instruments to be returned must be accompanied by a disinfection certificate completed by the responsible laboratory manager. If a disinfection certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre or from intervention by governmental authorities.

1.8 Notice

Every effort has been made to avoid errors in text and diagrams. HUMAN, however, assumes no responsibility for any errors which may appear in this publication. It is the policy of HUMAN to improve products as new techniques and components become available. HUMAN therefore reserves the right to change specifications if necessary in the course of such improvements.

2 SYSTEM DESCRIPTION

2.1 Intended purpose

HumaCombilyzer is a semi-automated urine test-strip reader for qualitative or semi-quantitative detection of urobilinogen, bilirubin, ketones, creatinine, blood, protein, microalbumin, nitrite, leukocytes, glucose, specific gravity, pH and ascorbic acid (vitamin C), calcium in human urine. In combination with HumaCombina urine test strips it may be used to screen for a range of medical conditions. For laboratory professional use only.

2.2 General description

The HumaCombilyzer urine strip reader consists of a movement transmission system, optical measurement components (source and receiver), a control unit (computer system), a touchscreen, output options (LED screen and printer), ports, casing, and a power supply.

Urine Analyzer is a kind of analytical instrument for semi-quantitative assessment of urine by using dry chemical methods. According to the principle of photoelectric colorimetry, urine analyzer is used to evaluate the content of biochemical components in the urine through the change of color caused by the reaction of the reagent and urine biochemical components.

After putting the test strip impregnated with urine sample on the strip tray, the transmission device of the instrument transfers the test strip directly below the detector. After each reagent section that has triggered a chemical reaction on

the test strip is illuminated by the light source, the reflected light is received by the detector. Then, each reagent section reacts independently with the corresponding components in the urine, different color can be found. The depth of color is a monotonic relation to some component in the urine. The darker the color, the greater the amount of absorbed light, then the smaller the amount of reflected light, so the smaller the reflectivity. On the contrary, the lighter the color, the smaller the amount of absorbed light, then the greater the amount of reflected light, thereby the greater the reflectivity. In other words, there is a monotonic relationship between the depth of color and concentration of various components in the urine sample.

2.3 Technical specifications

TABLE 1

Specifications	Parameters
Test philosophy	By using reflection photometer to evaluate the color change of urine test strip, then calculate the concentration of related items and output semi-quantitative results
Test item	Glucose (GLU), Bilirubin (BIL), Specific Gravity (SG), PH, Ketone (KET), Blood (BLD), Protein (PRO), Urobilinogen (URO), Nitrite (NIT), Leucocyte (LEU), ascorbic acid (VC), Creatinine (CRE), Calcium (CA), Microalbumin (ALB)
Test wavelength	470 nm, 525 nm, 625 nm

Reading time	60 seconds per strip
Report method	LED, Serial output Internal 57mm Micro Heat-sensitive printer Chinese and English
Display	320 x 240 LED
Input method	Touch Screen
Report storage	10000 Reports
External Interface	Standard RS-232, can be connected with PC
Working Voltage	AC 100-240V 50/60Hz DC 5.0V - 3.0A (AA×4 Battery)
Power consumption of input	35 VA
Dimensions	200 × 137 × 52 mm
Weight	600 g
Repeatability	CV (%) ≤ 5.0
Accuracy	Variable coefficient (%) ≤ 5.0
Carry over	The negative sample remains unchanged just after positive sample tested with highest concentration result

Normal working conditions:

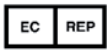
1. Ambient temperature: 10 °C ~ 30 °C
2. Relative humidity: No more than 80 %
3. Atmospheric pressure: 50 kPa ~ 106 kPa
4. Power supply: 100-240 V, 50/60 Hz
5. Light: Avoid direct sunlight.

Storage conditions:

1. Ambient temperature: 10 °C ~ 50 °C
2. Relative humidity: No more than 93 %
3. Atmospheric pressure: 50 kPa ~ 106 kPa

4. Light: strong light source and strong electromagnetic interference source

2.4 Symbols

	Indicates that caution is necessary when operating the instrument or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. Touching this object may cause personal injury and/or damage to the analyzer. Located next to the power connector and on some of the external interfaces.
	Indicates the manufacturer's catalogue number so that the medical instrument can be identified.
	Indicates the instrument serial number.
	Identifies the instrument as an in-vitro diagnostic medical instrument.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the authorized representative in the European Community.
	Indicates the entry importing the medical instrumento in the locale.

CE	Indicates manufacturer declaration that the product complies with the essential/ general safety & performance requirements of the relevant European medical instrument, health, safety and environmental protection legislations.
	Indicates the name of the manufacturer followed by the address.
	Indicates the date of manufacture.
	Indicates a biological hazard - located where contact with biological materials is possible. The symbol is black against a yellow background.
	Indicates the allowable temperature range of the instrument during storage and transportation.
	Indicates the range of humidity to which the instrument can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical instrument can be safely exposed.
	Important note in the user manual.

	Indicates the need for the user to consult the user manual.
	The WEEE symbol on the product and on the packaging indicates that the product may not be disposed of with your normal household waste. All discarded electrical and electronic equipment must be taken to appropriate collection points.
	Warning Electrical Risk: This label warns the operator of the presence of high electrical voltage.
	Laser radiation risk (BCR)
	Alternating current: Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	Protective ground: Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	Use by: Indicates that the instrument should not be used after the date accompanying the symbol, for example on a medical instrument or its packaging.

3 INSTALLATION

3.1 Environment requirements

1. The HumaCombilyzer should be located on a stable, flat and vibration-free surface which can bear at least 2 kg.
2. Keep away from chemicals and avoid the effect from corrosive gas and strong electromagnetic waves.
3. Keep out of direct sunshine, dampness, and high temperature.
4. Ambient temperature range for operating is 15 °C~35 °C (20 °C~25 °C is ideal); relative humidity ≤75 %.
5. Keep a good ventilation status. If needed, a ventilation instrument can be used; if so, make sure it does not blow towards the HumaCombilyzer directly. Otherwise, the test accuracy can be affected.

3.2 Unpacking, packing content and accessories

The HumaCombilyzer is shipped in a cardboard box. Prior to unpacking, clear the space where the instrument will be installed. Note the shipping marks on the box while handling. Open the box. Cut the tape only, leave the carton material intact (it is recommended to retain the packaging materials). Take out the HumaCombilyzer urine strip reader and its accessories and compare them with the packing content list below. If there is damage to any of these parts or a missing part, contact the supplier immediately.

REF	Content	Quantity
17630	HumaCombilyzer	1
17630/1	User manual	1
17630/5	Quick Guide	1
17630/15	Calibration strip (in a protecting plastic tube)	1
17630/18	Power supply	1
15024/100	Printing paper (supported dimension max D30mm L57mm)	1
Accessory not supplied with HumaCombilyzer. Item to be ordered separately		
17630/50	Hand-held barcode reader (with adapter cable for USB micro to USB-A)	1
17630/51	Serial adapter cable (for COM USB Mini to RS232) for LIS and software update	1

FIGURE 2

Top view of the instrument

1 **Main screen**
2 **Strip tray**
3 **Power Button**
4 **Menu Button**
5 **Status LED 2x**
6 **Printer**

FIGURE 3

Side view of the instrument

1 DC Port

2 COM Port

3 Micro USB Ports 2x

3.3 Power supply

Power Supply: AC 100-240V 50/60Hz or DC 5.0V=3.0A (AA×4)

1. DC Port
2. COM Port
3. Micro USB Ports 2x

The HumaCombilyzer and its external package should not be opened without authorization.

All parts should only be inspected and supplied by the manufacturer or authorized dealers.

The HumaCombilyzer should be kept in a convenient place for cutting off the power supply in case of emergency as well as disconnection of the power cord.

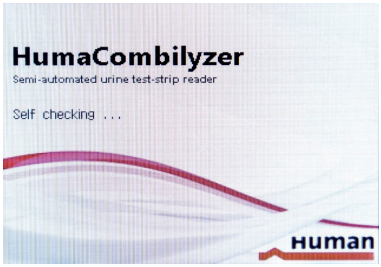
Any performance against the direction in this user manual may cause damage and risk to the protections provided by the instrument.

In the use of dry batteries as power supply, please remove batteries if the instrument remains unused for a few days or even longer to avoid damaging the instrument caused by leakage of batteries.

3.4 Switching on the HumaCombilyzer

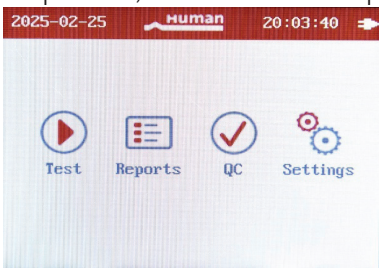
Plug on the power cord or insert 4x AA batteries on the back of the instrument, press the power button, the software starts by showing the HumaCombilyzer loading screen, and the self-check is performed by moving the strip tray out and in.

FIGURE 4



When the startup is done, the main menu is displayed.

FIGURE 5



3.5 Insert printing paper roll

Open the printer cover.

FIGURE 6

Remove the printer roll.

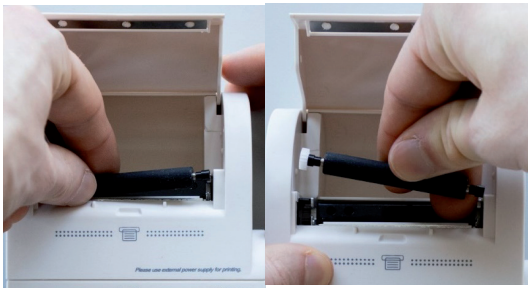


FIGURE 7

FIGURE 8

Insert the printer paper like shown below and re-mount the printer roll.

Heat sensitive paper must be placed flat in middle, to avoid the paper goes slant or blocked.

FIGURE 9

FIGURE 10

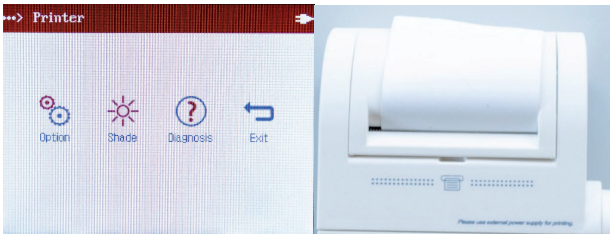
Lay the beginning of paper into the printer gap.

FIGURE 11
FIGURE 12
FIGURE 13

Print a test paper by navigating to **Settings > Printer** and click on **Diagnosis**.

Then, if the test print and the movement of the paper roll were successful without an error, close the printer cover completely.

FIGURE 14
FIGURE 15



Note: Printing is only supported with external power supply connected, not with batterie.

3.6 Switching off the HumaCombilyzer

Before shutdown, make sure that there are no test strips or other items on the strip tray. The instrument will automatically move in the strip tray and shut down afterwards. Press the power button for 3 seconds, then the instrument will turn off.

4 OPERATION

4.1 Select strip type

From main menu click on **Settings** and then on **Strip**.

FIGURE 16

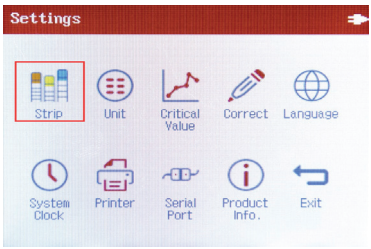
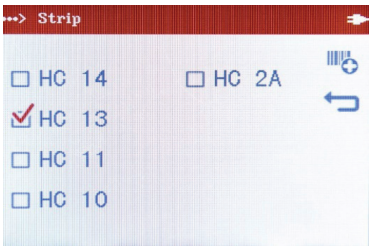


FIGURE 17



This interface displays the test strip models compatible with the HumaCombilyzer. Select the strip type which you want to use. Please note that the instrument only supports the HumaCombina 13 (HC 13) and HumaCombina 10 (HC 10) at the moment.

The HumaCombilyzer can support multiple types of strips. Make sure the HumaCombina strip type which is used for measurements is the same strip type which was selected in the menu Settings>Strip, otherwise incorrect results will be obtained.

4.2 Load test credits

Each box of HumaCombina urine strips has a barcode, which contains 100 test credits.

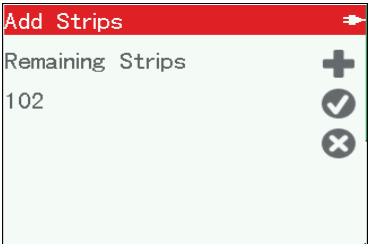
If there are no loaded test credits in the instrument, the HumaCombilyzer will not read any further test strips until a new barcode has been entered.

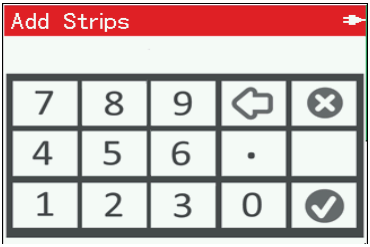
After entering a valid barcode, the instrument displays the number of remaining strips (credits). Each measurement will reduce the number of remaining strips by one.

To load new test credits, click on the strip menu and click the Barcode button and then click on the ✚ button. Enter credit code of HumaCombina strip label either manually or by using a barcode reader and confirm with ✔.

FIGURE 18

FIGURE 19



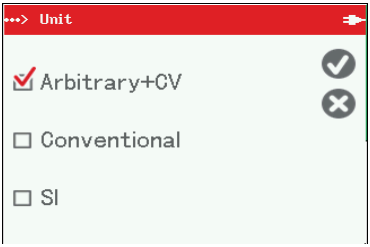


Each barcode can be entered only once. When the screen displays “invalid barcode”, check that you have entered the correct barcode number.

4.3 Gradient unit

Select “Unit” in the setting menu:

FIGURE 20



Click on the gradient unit that you want to use. After that the instrument will show the new selected gradient unit system on screen or in printed reports. Click ✔ button in the top right corner to save your choice and return “setting” menu. Otherwise, if you want to give up your choice, just click ✖. The factory default for this item is English.

! Note: CV = Critical Values = Ref Value

See example printout with the different units below.

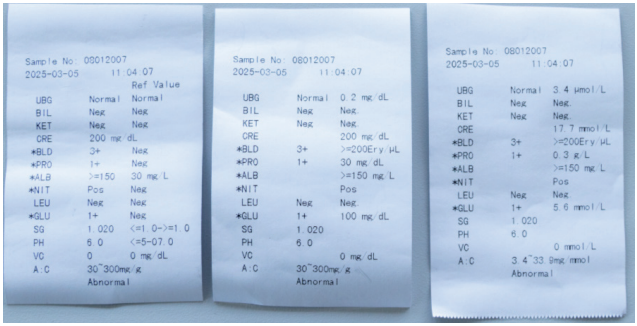


FIGURE 21

4.4 Critical value (Reference Range)

Select “Critical Value” in the setting menu:

In Critical Values the user can define lab specific reference range for patient samples.

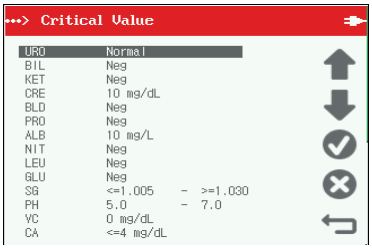


FIGURE 22

The interface lists all items and reference values of the current urine test strip. Click ⬆ or ⬇ to navigate through all parameters and press ✔ to select one parameter after this you can adjust the parameter with ✚ and ➖ in the pop-up dialog box.
Press ✚ to increase one level gradient or press ➖ to decrease the gradient value. Then press ✔ to validate your selection and return to the interface or press ✖ to discard changes and return.

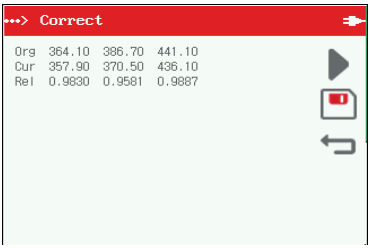
Press ⮌ to save changes and return to “setting “menu or press ✖ to abandon your choice and return.

When the instrument displays or prints out report, a sign of “*” will be marked in front of any item in case the result exceeds the reference value to remind users to notice.

4.5 Calibration

Before calibration, please wash the strip tray according to the cleaning instructions, dismantle, wash and sterilize the strip tray” to avoid accuracy caused by contamination of the calibration strip.
Click “Correct” to enter “setting > calibration” menu.

FIGURE 23



There are three lines of data showed in the table. The first line is the reading of calibration strip before the instrument leaves the factory which belongs to the original value. The second line shows the last calibrated reading, and the third line shows the relative value of these two readings. Figure 24 shows the situation that the instrument is calibrated for the first time after leaving the factory.

Click ▶ to start calibration test. The instrument shows:

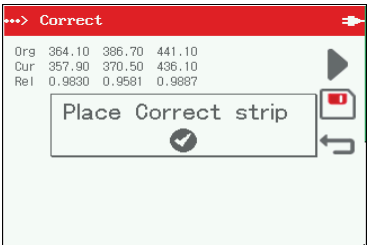


FIGURE 24

Place the white side of the random calibration strip upward on the strip tray then click ✔. The instrument shows “Testing.” and begins to test. After completing the test, the results are shown:

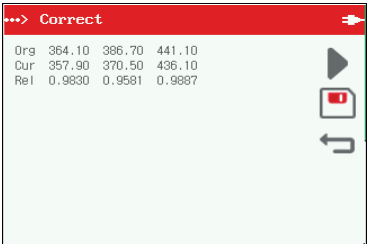


FIGURE 25

Click the save symbol and affect the calibration data and click ↩ to return to the main menu.

4.6 Date & time settings

To change the time, go to the settings and then press the clock symbol .

FIGURE 26

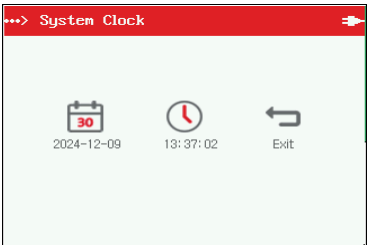
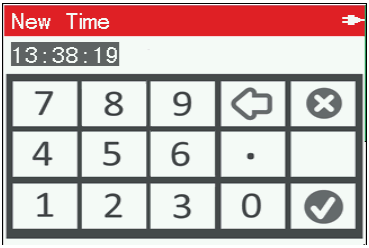


FIGURE 27



The screen then appears where the user can enter a new time. The format is HH-mm-ss, the dot on the keyboard is used to differentiate between hours, minutes, and seconds. To save the new time use the symbol to delete the time and go back use symbol.

To change the date, go to the settings and then press the calendar symbol .

FIGURE 28

The screen then appears where the user can enter a new date. The format is MM-DD-YY, the dot on the keyboard is used to differentiate between month, day, and year. To save the new date use the symbol to delete the date and go back use symbol.

4.7 Printer settings

To get to the printer settings first click in the main menu the settings button and then select the printer button .

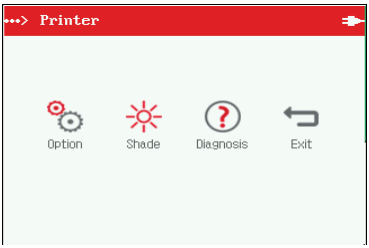
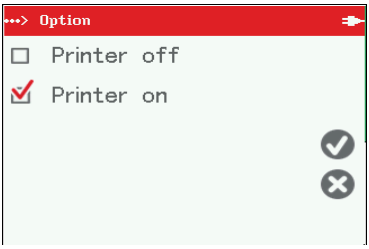


FIGURE 29

Under Option user can turn on or off the printer function:

FIGURE 30



Click on shade to and use ✚ or ▬ to make the screen brighter or darker and safe it with ✔ symbol or go back with ✖ symbol.

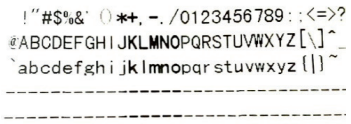
Concentration is divided into 16 degrees and a black-white bar is used to indicate it. The longer the white bar is, the darker the printed letters are.

If letters are clear enough to discern, for quicker print speed and prolonging printer's lifespan, we suggest you choose as lighter concentration as possible. The season is another fact for concentration selection. In warmer seasons, you can select 1-2 degree lower than normal, while in cooler seasons choose 1-2 degree higher than normal.

Click the diagnosis button ? for printing a test page to make sure that the print is in a good condition.

The full test page is shown in Figure 31. If it is incomplete, please contact the customer service or dealers in time so as not to affect the normal use of the instrument.

FIGURE 31



Remark: Only when the external power is supplied, the built-in printer can work properly.

4.8 Serial port

Go to settings and then select serial port to change the baud rates.

This menu is used to set the communication baud rate, five options are designed for you to choose: “9600”, “19200”, “38400”, “57600” and “115200”. Click the option that you want to choose and press to go back to the menu the information will be saved automatically.

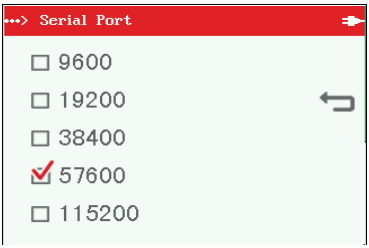


FIGURE 32

5 TESTING

Make sure that the type of the urine test strip used is exactly the same as the module not, inaccurate result may incur.

During operation, you will likely be exposed to a urine sample. It is recommended to wear protective gloves to avoid direct contact with urine samples especially in contact with infectious urine samples.

When you touch components and parts labeled with biological symbols, please pay attention to protection, wearing protective gloves to avoid direct contact with the skin.

Place the test strip at the designed position of the strip tray immediately after immersion then start testing to avoid affecting the accuracy of results due to exceeding the reaction time.

The excess urine taken from the urine test strip should be removed as much as possible to avoid excessive accumulation of residual urine on the strip tray, resulting in cross contamination.

Urine test strip is a disposable product which cannot be reused.

The used urine sample should be treated in accordance with the relevant medical waste disposal regulations, and should not be discarded at will.

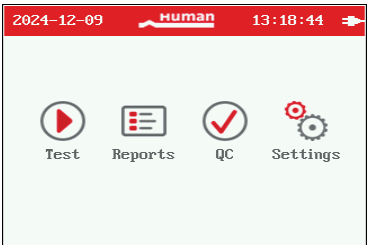
During operation, the moving parts of the instrument should not be touched in order to avoid damage. For emergency shutdown, press the power button or disconnect the adapter.

	The disassembly of the strip tray should be carried out in accordance with the instructions in chapter 8.2 “Cleaning”. Brute force operation will lead to irreversible damage
	Clean the strip tray regularly. Operating the instrument should be according to specifications of Lab Waste Disposal and instrument maintenance.
	When there is no sample to be processed temporarily, you do not have to quit the test menu or shut down the instrument.
	Take a HumaCombina strip and dip it into the Control sample. Read the IFU of HumaCombina strip regarding the correct sample handling. Remove excess urine from the strip by wiping the edge of the strip on absorbent paper.
	When there is no sample to be processed temporarily, you do not have to quit the test menu or shut down the instrument.

5.1 Run a test

Press ▶ in the main menu to start testing.

FIGURE 33



At the beginning the user gets an information about left test credits.
If it is the first time to use the test strip, input strip barcode information which can be found at the bottle of the purchased test strip. Please input correctly.
The strip barcode information includes the test number of times. When the actual test times exceed the number specified by the strip barcode, the message dialog of “input test strip barcode’ will be shown again to request re-entering the strip barcode information. At this moment, you need to input the new barcode information displayed at the bottom of newly purchased strip box. The test strip barcode is just for one-time use. Re-use the same bar code information, the instrument will report errors.
Only after being inputted the correct and effective strip barcode information, the instrument can be operated normally.

FIGURE 34

In the next screen user can enter the sample it and confirm it with ✓ button or go back with the ✗ button.

The instrument first retrieves the report of the day. Then it prompts the operator for a report number which is just after the latest report of that day. If you want to modify it, press the

number key to enter and click to confirm your choice. If not necessary, click directly. Click to delete the last number and click to abandon testing and go back to the main menu.

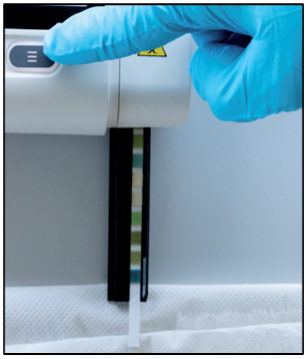
Take a urine strip and immerse in the urine sample tube to be tested and remove quickly after fully wetting. Also, scrape on the edge of the test tube to avoid taking too much urine and then absorb excess urine on the absorbent paper.

Put the urine strip that has been dipped in urine and has already been sucked excess urine on the strip tray according to the picture below.

Urine test strip should be placed upward of the reaction block.

Testing process: Take sample 000001 for testing as an example.

FIGURE 35



Press Menu Button on the instrument to start testing. The strip tray moves automatically back to the instrument and the software displays the incubation screen by showing the timer of 60 seconds and the information “Strips reacting...”.

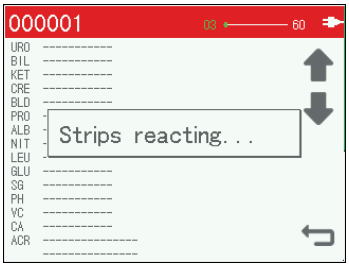


FIGURE 36

After the incubation time has elapsed, the strip is read by the instrument.
Upon completion of the test, the screen displays the test results of the current sample which can be printed out and serial port output through the built-in printer.

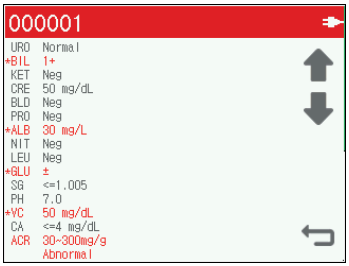
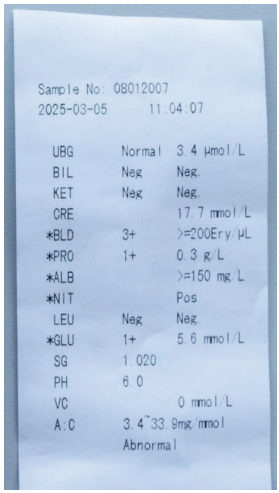


FIGURE 37

At any time during the wait or test, press ⮌ to cease testing and return to the system main menu.

Values showed in red and marked with * are out of range acc the set values in Chapter 4.4 Critical value (reference range for patient samples).

FIGURE 38


Sample No: 08012007
2025-03-05 11:04:07
UBG Normal 3.4 μmol/L
BIL Neg. Neg.
KET Neg. Neg.
CRE 17.7 mmol/L
*BLD 3+ >=200Ery/μL
*PRO 1+ 0.3 g/L
*ALB >=150 mg/L
*NIT Pos
LEU Neg. Neg.
*GLU 1+ 5.6 mmol/L
SG 1.020
PH 6.0
VC 0 mmol/L
A:C 3.4~33.9mg/mmol
Abnormal

6 REPORT RETRIEVAL

Press the menu button to return to the main menu under any interface mentioned in the following chapter.

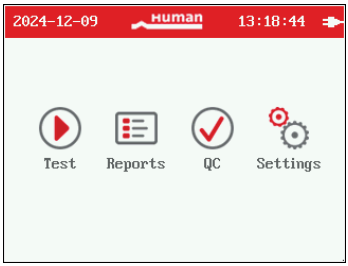


FIGURE 39

Press reports in the system main menu to view the list of reports. The screen will list the report dates in descending order. Flip to next page for more than 7 reports.

The highlighted date on the screen is the currently selected date. Click on the date to edit the selected date.

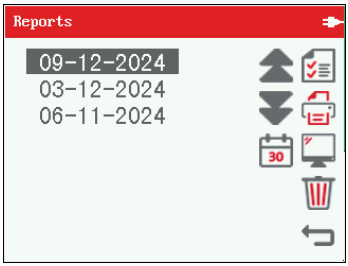


FIGURE 40

6.1 Button description

Button	Operation
	View the list of dates on the previous page
	View the list of dates on the next page
	Search for a report of a certain date
	Browse the reports under the selected date
	Bulk print
	Bulk transfer
	Delete the selected date and the report
	Back to the main menu

6.2 Bulk print

Select a date and print all or part of the reports generated under the date.

Select a date under the menu displayed in and press  . The instrument will ask for the starting report number. The default value is the first report under the selected date. Input the starting report number and press  to confirm.

FIGURE 41

The instrument will then ask for the ending report number. The default value is the last report under the selected date. Input the ending report number and press to confirm.

FIGURE 42

The instrument starts to print the reports of the specified range via the built-in printer. Press to stop printing.

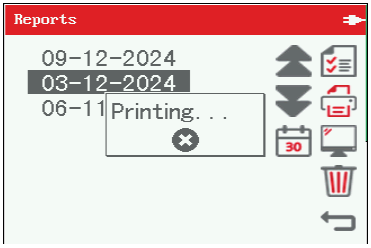


FIGURE 43

6.3 Bulk transfer

Select a date, transfer all or part of the reports under the selected date to the computer via the serial port at the back of the instrument.

Select a date under the menu and press . The instrument will ask for the starting report number. The default value is the first report under the selected date. Input the starting report number and press to confirm.

FIGURE 44

The instrument will then ask for the ending report number. The default value is the last report under the selected date. Input the ending report number and press to confirm.

FIGURE 45

The instrument starts to transfer the reports of the specified range. Press to stop transmitting.

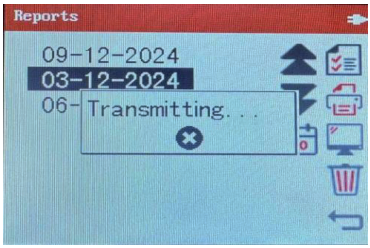


FIGURE 46

Select a date under the menu displayed in the below picture and press to delete a report. The instrument will then ask the user to confirm:

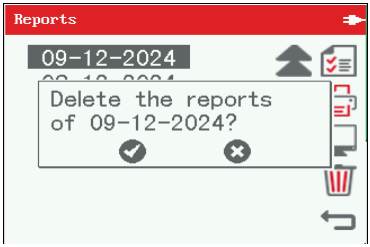


FIGURE 47

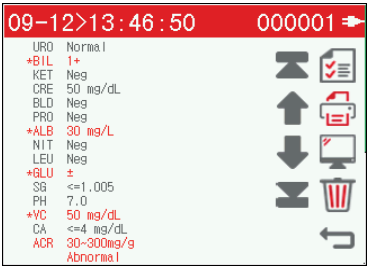
Press to confirm and to cancel.

The data cannot be recovered after deleting. Please use this function with caution.

6.4 Browse reports

Select a date under the menu displayed in Figure 48 and press to browse the report. The screen will display the first report under the selected date:

FIGURE 48



Definition of each button:

Button	Operation
	Browse the last report of the selected date
	Browse the previous report
	Browse the next report
	Browse the first report of the selected date
	Input the report number or date to look for the report
	Print the current report
	Transfer the current report
	Delete the current report
	Back to the report browsing menu (Figure 48)

7 QC MODULE

Initially no reports will be displayed.

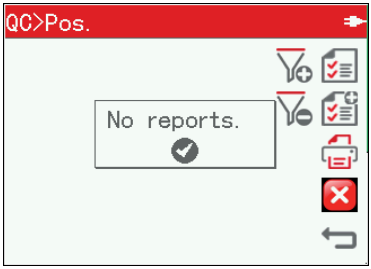


FIGURE 49

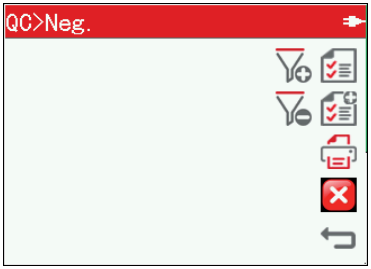


FIGURE 50

To switch between negative and positive QC use these two buttons plus for positive or minus for negative.

In order to read HumaCombina urine strip with QC material, press  , then insert the HumaCombina urine strip and press  to run a positive control or negative control, like shown in the pictures below. The pictures show the expected target values for the negative or positive controls.

To set new target values use these two buttons, plus for positive or minus for negative.

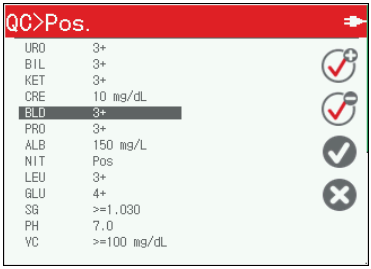


FIGURE 51

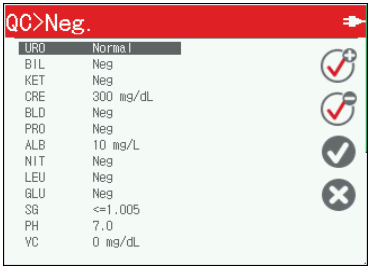
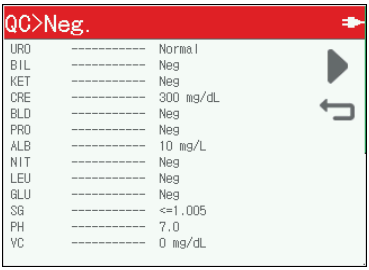


FIGURE 52

While the HumaCombina strip is being processed the following screen is being displayed.

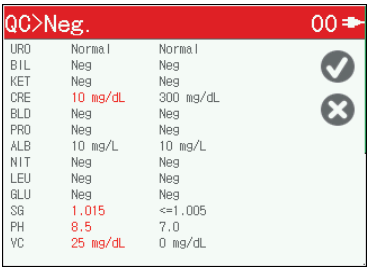
FIGURE 53



After placing the HumaCombina strip, press ▶ to run the test.

After 60 seconds of incubation, the strip is read and the results (middle column) will be shown compared to the target values (right column), see picture below.

FIGURE 54



The evaluation of the results is being shown in % of correspondence to the target values in 100% or 0%.

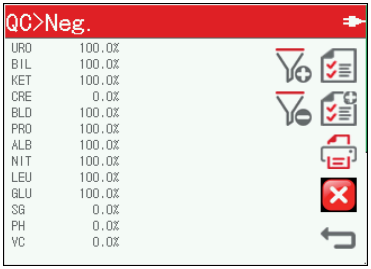


FIGURE 55

To browse through all QC reports, start with figure 1 and press . The reports can be scrolled up and down.

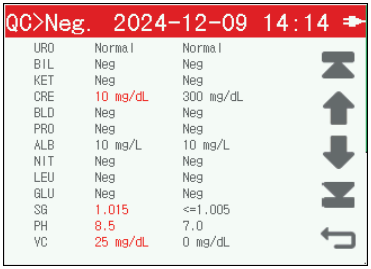


FIGURE 56

Red marked values are out of range of the target value set for the Pos / Neg QC.

8 MAINTENANCE

8.1 Maintenance procedure

A good operation specification needs to be established at the very beginning. A regular maintenance is necessary to extend the service lifetime and keep the output of the service correct, because the instrument has motion part, running automatically and has a direct contact with urine.

Biological danger: Notice, protection and processing protocol should allow the processing specification carried out by medical institutions.

This instrument is a professional precision medical instrument. All consumables and accessories should be purchased from the manufacturer or manufacturer's authorized dealer. Need a designated worker to replace and maintain the instrument.

8.2 Cleaning

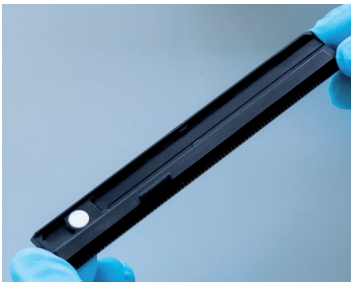
Perform the Cleaning of the strip tray with distilled water at least once per day (end of day). The strip tray should be also cleaned with distilled water after a measurement, when there is remaining urine on the strip tray. Any remaining urine on the strip tray can lead to cross contamination and to wrong strip results. In case of heavy contamination clean with 75% ethanol instead.

STEPS: Turn the power on, long press the menu button main menu page. The strip tray moves out and the instrument switches off automatically. Clean the strip tray, both, the strip area and the toothed rack, with distilled water. In case of heavy contamination clean with 75% ethanol instead.

After washed the strip tray, dry it with absorbent paper. Make sure there are no paper rests (no scraps, no lint) remaining on the tray, neither on the strip area nor on the toothed rack. Insert the strip tray into the HumaCombilyzer. Move the tray as far as you hear a “CLICK” sound, do not push it further to the end. Press the power button, then the instrument automatically moves in the strip tray and performs the self-test. If there is no error message, inserting the tray was correctly. If an error is shown, switch off the instrument and repeat inserting the tray.

The following picture is the strip tray.

FIGURE 57



Biological danger: Notice the protection and processing.The strip tray is an important part of the test system, which must be maintained properly. Do not use detergent or hot water for cleaning. Do not autoclave. Test results will be affected if the shape is changed. Operation will be exposed to human urine, pay attention to wearing protective gloves, to avoid direct contact with urine samples, especially for infectious urine samples.

8.3 Dry battery installation and attention to use

Battery choices and how to use it.

- Please only use a branded battery or a quality guaranteed battery.
- Please check the battery type carefully. Otherwise, it will cause the battery not being installed correctly or the instrument not being used normally.
- Pay attention to the battery polarity while installing, instrument identification and battery installation should be consistent, otherwise it may cause instrument error or cause the battery short circuit, more even will cause fire or battery explosion.
- Poor quality battery may shorten the lifetime of the instrument and may cause error of the instrument, which more even will cause fire or battery explosion.
- Carefully handle and dispose of the battery.
- Don't put battery to fire.
- Do not store batteries in the vicinity of water heaters, microwave ovens, hot cookers, high pressure vessels or

internal storage, as this may cause battery leakage or explosion.

- The battery can't be frozen in the freezer compartment. The process of freezing after the battery shell may be deformed, due to temperature difference, but also the formation of dew, may cause short circuit.
- To prevent the battery from touching metal objects, otherwise it may cause the battery to connect the positive and negative terminals, resulting in temporary or permanent damage.
- Don't store the instrument near magnetic fields. When exposed to a magnetic field, the battery may discharge.
- When dealing used batteries or equipment, please comply with local regulations.
- Don't bite or suck the instrument or batteries.
- Bite or suck may cause battery damage, more even will cause fire or battery explosion.
- Children or animals will suffocate by swallowing small parts.
- Do not apply pressure to the battery.
- Pay attention to the battery situation when using the instrument.
- Don't use the instrument with the battery cover removed. Battery may fall from the instrument, May cause battery damage or instrument error.
- Do not apply pressure to the external of the battery.
- Turn off the instrument before removing the battery. If removing the battery while the instrument is still on, it may cause the instrument error.

- Long-term placement of the instrument may cause it discharging. Need check the battery before use.
- When the instrument is not in use, disconnect the power and remove the battery.
- After a long time not in use, battery may shorten its life and reduce performance.

It is recommended that store the battery in a hard box that can protect the battery when the battery is not in use.
Do not use any equipment to charge non-rechargeable batteries, which may cause fire or battery explosion and other security incidents.

9 TROUBLESHOOTING

9.1 Errors and solutions

The HumaCombilyzer will work normally if all operations and maintenances are performed according to the instructions. When the instrument detects some abnormal situation, it will display an error message to let the operator figure out the problem or ask either the distributor or manufacturer for help. The following is a list of error messages. It lists error mode, error contents and solutions.

Error code	Error message	Solution
E01	system storage error	System storage is broke down, the instrument cannot work normally, please contact with the distributor for the maintenance.
E02	system data error	The factory data of system testing has lost, the instrument cannot work normally, please contact with the distributor for the maintenance.
E03	Workbench error	Workbench cannot find the origin, whether the workbench is installed, please retry it after turning off the instrument, after several failures, please contact with the distributor for the maintenance.

Error code	Error message	Solution
E04	calibration data error	Please turn off the instrument, clean the white plastic board according to the instructions of dismounting, clean and disinfect the objective table in 8.2. Then retry it after turning on the instrument, if the error still exists, please contact with the distributor for the maintenance.
E05	Objective table pollution	Please make sure that there is no urine test paper or other foreign bodies on the objective tale when turn on the instrument. If so, please retry it after removing them; if not, please retry it according to the instructions of dismounting, clean and disinfect the objective table in 8.2
E10	Background light abnormal	Please check whether the instrument is working in the place with direct sunlight, whether there has a strong light source, please refer to the work desktop requirements in 3.1 to rearrange the working environment of the instrument.

Error code	Error message	Solution
E11	alignment error	The sample report for the current test is invalid, please re-test. If this situation happens frequently, you need to clean the guide rail of the objective table, if the problem still exists, please contact with the distributor for the maintenance.
E21	printer out of paper	Please refer to the printer paper instructions in 3.8 to put new paper.
-	Date at year 2000	Internal CR2032 for system clock is empty and need to be replaced by a service technician

If the instrument breaks down, follow the above prompt message, or follow the bellowing information to solve the problem.

AC 220V±22V 50Hz±1Hz DC 5.85V±0.45V (AA×4). If the voltage is over limit too high, the instrument may produce an abnormal sound, or emit a burnt smell, or smoke, operator should turn off the power immediately, pull out the power cord, and inform the manufacturer, you can only use the instrument again after the maintenance.

The instrument must not be disassembled without permission. If so, cut off the power, pull out the power supply cable. After opening the front cover, special attention should be paid to internal warning signs. If electrical testing is required, precautions should be taken to prevent electric shock hazard.

If accidental splashing liquid into the instrument, the power supply shall be immediately cut off, check the situation of splashing liquid, open the cover and watch it when necessary, especially to check the situation of power supply and circuit board, clear liquid immediately, dry or dry naturally, after drying try to energize again, shut off the power supply immediately once shows abnormal.

Random serial cable should be properly kept for connecting to the computer. If any loss or damage happens, you should purchase them from the original factory or in accordance with the original specification.

Confirm that the use of the urine test paper is exactly the same as the model set in the instrument, and within the effective period, or it will lead to the wrong result.

The instrument should be handled with care. If you want to move it, it is better to use the original package to prevent damage which caused by severe shaking.

If the used instrument is to be shipped, it should be sterilized according to the internal standard of the medical institution before shipping, labeled „disinfected", otherwise "non-disinfected" should be labeled, remind those staff who receive the instrument to take precautions.

10 SERIAL COMMUNICATION

The serial cable in the instrument accessory can normally realize the connection of the PC and RS-232, the round head of the cable is connected to the instrument, the other side is USB-Mini plug, and it can connect with the USB Mini male plug.

Parameters	Specification
Communication mode:	asynchronous serial communication
Signals use:	TXD, RXD, GND
Baud rate:	9600, 19200, 38400, 57600, 115200 bps
Verification mode:	Odd
Data length:	8 Bits
Stop bit:	1 Bit

When the instrument transfers data to the PC, the instrument as the sending end, it just sends, not accept; PC as the receiving end, it just receives, no response.

Take “frame” as the unit of the data content, a single frame of data is a complete report; Frames consist of several “lines”, it ends with 0DH, 0AH; Lines are made up of several fields, the fields are separated by 09H.

Line	1 Field 1	2 Field 2	Instruction
1	Date, 20XX-XX-XX		Only got one field
2	Time, XX:XX:XX		Only got one field
3	Catalogue number, XXXXXX		Only got one field
4			Null string

Line	1 Field 1	2 Field 2	Instruction
5	name of project 1	project 1 test results	
6	name of project 2	project 2 test results	
7	name of project 3	project 3 test results	
8	name of project 4	project 4 test results	
9	name of project 5	project 5 test results	
10	name of project 6	project 6 test results	
11	name of project 7	project 7 test results	
12	name of project 8	project 8 test results	
13	name of project 9	project 9 test results	
14	name of project 10	project 10 test results	
15	name of project 11	project 11 test results	
16	name of project 12	project 12 test results	
17	name of project 13	project 13 test results	
18	name of project 14	project 14 test results	

If the character string in the project test result contains characters “±” and “µ”, it will be replaced by “+-” “u”. PC no need to response any characters after received a frame.

11 GRADIENT TABLE

TABLE 2

	Arbitrary	International (SI)	Conventional
UBG	Normal	3.4 µmol/L	0.2 mg/dL
	Normal	17 µmol/L	1 mg/dL
	1+	34 µmol/L	2 mg/dL
	2+	68 µmol/L	4 mg/dL
	3+	≥135 µmol/L	≥8 mg/dL
BIL	Neg.	Neg.	Neg.
	1+	17 µmol/L	1 mg/dL
	2+	51 µmol/L	3 mg/dL
	3+	≥103 µmol/L	≥6 mg/dL
KET	Neg.	Neg.	Neg.
	±	0.5 mmol/L	5 mg/dL
	1+	1.5 mmol/L	15 mg/dL
	2+	3.9 mmol/L	39 mg/dL
	3+	7.8 mmol/L	78 mg/dL
	4+	≥16 mmol/L	≥160 mg/dL
CRE	0.9	0.9 mmol/L	10 mg/dL
	4.4	4.4 mmol/L	50 mg/dL
	8.8	8.8 mmol/L	100 mg/dL
	17.7	17.7 mmol/L	200 mg/dL
	26.5	26.5 mmol/L	300 mg/dL
BLD	Neg.	Neg.	Neg.
	±	ca.10 Ery/uL	ca.10 Ery/uL
	1+	ca.25 Ery/uL	ca.25 Ery/uL
	2+	ca.80 Ery/uL	ca.80 Ery/uL
	3+	≥ca.200 Ery/uL	≥ca.200 Ery/uL
PRO	Neg.	Neg.	Neg.
	±	Trace	Trace
	1+	0.3 g/L	30 mg/dL
	2+	1.0 g/L	100 mg/dL
	3+	3.0 g/L	300 mg/dL
	4+	≥20.0 g/L	≥2000 mg/dL

	Arbitrary	International (SI)	Conventional
MALB	10	10 mg/L	10 mg/L
	30	30 mg/L	30 mg/L
	80	80 mg/L	80 mg/L
	150	≥150 mg/L	≥150 mg/L
NIT	Neg.	Neg.	Neg.
	Pos.	Pos.	Pos.
LEU	Neg.	Neg.	Neg.
	±	ca.15 Leu/µL	ca.15 Leu/µL
	1+	ca.70 Leu/µL	ca.70 Leu/µL
	2+	ca.125 Leu/µL	ca.125 Leu/µL
	3+	≥ca.500 Leu/µL	≥ca.500 Leu/µL
GLU	Neg.	Neg.	Neg.
	±	2.8 mmol/L	50 mg/dL
	1+	5.6 mmol/L	100 mg/dL
	2+	14 mmol/L	250 mg/dL
	3+	28 mmol/L	500 mg/dL
	4+	≥56 mmol/L	≥1000 mg/dL
SG	≤1.000	≤1.000	≤1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	≥1.030	≥1.030	≥1.030
PH	≤5.0	≤5.0	≤5.0
	5.5	5.5	5.5
	6.0	6.0	6.0
	6.5	6.5	6.5
	7.0	7.0	7.0
	7.5	7.5	7.5
	8.0	8.0	8.0
	8.5	8.5	8.5
	≥9.0	≥9.0	≥9.0

	Arbitrary	International (SI)	Conventional
VC	0 0.6 1.4 2.8 ≥5.7	0 mmol/L 0.6 mmol/L 1.4 mmol/L 2.8 mmol/L ≥5.7 mmol/L	0 mg/dL 10 mg/dL 25 mg/dL 50 mg/dL ≥100 mg/dL
CA	≤1.0 2.5 5.0 7.5 ≥10	≤1.0 mmol/L 2.5 mmol/L 5.0 mmol/L 7.5 mmol/L ≥10 mmol/L	≤4 mg/dL 10 mg/dL 20 mg/dL 30 mg/dL ≥40 mg/dL
A:C	Normal Abnormal High abnormal	<3.4 mg/mmoL (N) 3.4-33.9 mg/mmoL (Ab) >33.9 mg/mmoL (High Ab)	<30 mg/g (N) 30-300 mg/g (Ab) >300 mg/g (High Ab)

12 LATEST INFORMATION/UPDATES

Information about the latest software and manual version is accessible via:

https://www.human.de/sw-hcl

or by scanning the following QR Code with a mobile device supporting QR Codes. This QR code can also be found as a label on the instrument.

FIGURE 58

If the information about the latest versions is not accessible via internet, it can be obtained free of charge from your local distributor.
If the installed software is not the latest one, please contact your local distributor.
If you can't download the latest manual, please contact your local distributor.

This information including software and suppliers information could also be found in the product info ⓘ in the settings menu.

FIGURE 59

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