GIMA

PROFESSIONAL MEDICAL PRODUCTS

ANALIZZATORE URINE
URINE ANALYZER
ANALYSEUR D'URINES
ANALIZADOR DE ORINA
URINANALYSATOR

Manuale d'uso - User manual Notice d'utilisation
Manual del usuario - Användarmanual

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*

ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto*

OBSERVERA: *Operatörer måste läs och förstå detta till fullo bruksanvisning innan du använder produkten*

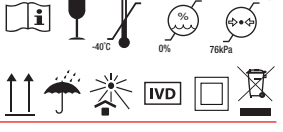
REF BC401 (GIMA 24046)

Contec Medical Systems Co., Ltd.
No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Made in China

CE

EC REP Prolinx GmbH, Brehmstr. 56,40239, Duesseldorf, Germany

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



M-24046-M-Rev.1.03.23

URINE ANALYZER

Contec Medical Systems Co., Ltd.

User Notice

1. Thanks for purchasing Urine Analyzer! Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly.
2. This manual detailed introduce the steps must be noted when using the product, operation which may result in abnormal. Any anomalies or personal injury and device damage arising from use, maintain, store do not follow requirements of the User Manual, Our company is not responsible for the safety, reliability and performance guarantees! The manufacturer's warranty service does not cover such faults!
3. The device with data storage function, for user losses which caused by data loss due to device damage or user's operation, our company does not assume any responsibility.
4. Test strip can only choose regular products, it's recommended to use the test strip which supplied with the device, so better ensure the accuracy of the test.
5. Our Company reserves the right to change the content of the manual, the contents of this manual are subject to change without notice.

Statement

Our company assumes no responsibility for incidental or consequential damage in use caused by any error appear in this document. In case of product

upgrades, the information contained in this manual is subject to change without notice.
Our company reserves the final elucidative right.
Meaning of symbol

⚠ **Note ⚠: Tips, advice and suggestions.**

⚠ **Warning ⚠: Warnings must be complied strictly to ensure that the Urine Analyzer can operation normally and the test result are correct and true.**

IVD	In vitro diagnostic medical device		Direct current
	Class II applied		Temperature limit
	Consult instructions for use		Atmospheric pressure limit
SN	Serial number		Humidity limit
REF	Product code		Keep away from sunlight
LOT	Lot number		This side up
	Date of manufacture		Keep in a cool, dry place
	Manufacturer		Fragile, handle with care
	ISO7000-0659, Biohazard		Imported by
EC REP	Authorized representative in the European community		
	WEEE disposal		
CE	In vitro diagnostic medical device compliant with Regulation (EU) 2017/746		

Summary

CHAPTER 1 OVERVIEW

1.1 Summarization

Urine test is the most common method for checking disease in clinical test, and checking with urine test strip is the most effective method. urine test strip and urine sample produce a chemical reaction, the color of each test color-area will change after reaction, the corresponding test results can be obtained according to the color change. The analyzer is researched and developed basing on modern photoelectric and microprocessor technology for clinical inspection of urine, and it integrates the advantages of easy and quick operation, exact result.

Features:

High-luminance and white LED, improves Signal Noise Ratio;
High-performance photoelectric receiving components, RGB tricolor test theory, which makes the analyzer possess the function of good anti-interference and adaptability;
User-friendly interface, features in vivid arrangement and convenient use;
With flash memory technology, automatic synchronization storage during testing process, and the data doesn't lose when the device power off or unexpected shut down;
Store up to 500 test results, manage according to date and sample NO, which is convenient for consulting;
Compatible with 8 items, 10 items ,11 items ,12 items and 14 items of test paper(Optional based on the type of test strip);
With a rechargeable battery that can be tested anytime, anywhere.

Purpose:

The device is a semi-automatic instrument for clinical tests of human urine with high-precision and intelligence, its research and development are based on advanced technologies such as modern optics, electronics and computer science. The device is used together with special test strips to test the urine parameters in a semi-quantitative method, the parameters include PH, nitrite, glucose, protein, occult blood, ketone body, bilirubin, urobilinogen, specific gravity, leukocytes, VC, microalbumin, creatinine and urinary calcium. It is suitable for use in hospitals, communities, clinics, epidemic and prevention stations. The operators of this device should be professionals with clinical experience.

Life:

Under the conditions of daily maintenance, normal use time is not less than five years.

1.2 Precautions for Use

⚠ Note ⚠

Before using, please read the Manual carefully and strictly operate according to it.

Please don't use the accessories not provided by manufacture.
Please don't use the analyzer in condition that the test strip is expired or the device is damaged.
Please transport, install and operate the analyzer following the User Manual.
To ensure the accuracy, the operation temperature should be in range of 10°C~30°C, if exceeds this range, place the analyzer in required environment for 20~30 minutes before using.
Away from the strong electric field (magnetic field) when using, avoid direct sunlight.
Use the supporting test strip which specified by the manufacturer.
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.3 Technical Specification

Test item	Glucose(GLU),Bilirubin(BIL),Specific gravity (SG),PH,Ketone body(KET),Occult blood(BLD),Protein(PRO),Urobilinogen(URO),Nitrite(NIT),Leukocytes(-LEU),Ascorbic acid (VC),Microalbumin(MAL),Creatinine(CR),Calcium ion(UCA).(Optional based on the type of test strip)
Test mode	Single-step test
Language	Italian and English
Display	LCD, resolution:320*240
Communication interface	Micro USB interface, Bluetooth wireless communication(optional Bluetooth)
Repeatability	CV≤1%
Stability	CV≤1%
Record mode	LCD display, FlashROM data storage
Relative humidity	≤80%

Power supply	Built-in rechargeable lithium battery 3.7V Host computer: DC 5V, 1A Adapter: AC 100V~240V, 50/60Hz
Test range	Refer to Grads Table in appendix
Operating environment	Temperature: 10°C~30°C Relative humidity: ≤80% Atmospheric pressure: 76kPa~106kPa Away from the strong electric field (magnetic field), avoid direct sunlight
Bluetooth specifications	Operating frequency: 2.4 GHz ISM band Operating Range: 2402 MHz - 2480 MHz Transmitting power: -30dB~+4dBm Default: 0dBm Receiving Sensitivity: -93 dBm Air baud rate: 1Mbps Frequency error: ±30kHz
Dimension	126mm(L)*73.5mm(W)*30mm(H)

1.4 Principle

Urine analyzer is a special dry chemical analyzer. Through the interpretation of the test strip, the content of various related components in urine was calculated. Generally includes mechanical systems, optical systems, data processing systems, etc.

The test strip contains blank color block and measurement item color block. Each color block of the measurement item corresponds to one of the measured indicators. Different samples contain different components to be measured, so that the test strip block generates different shades of color, and the intensity of the reflected light is also different. Photocells are used to measure the intensity of the reflected light, the electrical signal is converted and sent to the data processing system. The data processing system calculates the reflectance of each reagent block and the reflectance of the blank block, and compares with previously stored reflectance and a curve representing the concentration of the analyzed component, then a semi-quantitative rank symbol and concentration value is displayed.

This device uses dual wavelength to determine the color change of the module. The main wavelength is the sensitive characteristic wavelength of the module to

be measured, secondary wavelength is used to eliminate the influence of background light or other stray light. The reflectance R test strip of test strip block:
R test strip = Tm (the reflection intensity of the test strip to the measured wavelength)/Ts (the reflection intensity of the test strip to the reference wavelength)
The reflectance R blank of blank block:
R blank = Cm (reflection intensity of blank to measured wavelength)/Ts (reflection intensity of blank to reference wavelength)
The total reflectance R is the ratio of the reflectance of the test strip to the reflectance of the blank block.
R = R test strip / R blank = Tm Cs / Ts Cm

CHAPTER 2 INSTALLATION

2.1 Operation Environment

As with all precise electronic instruments, the urine analyzer should avoid placing in high temperature and humidity environment for a long time. To get optimal result, please keep relative stable temperature(10°C~30°C) and humidity(≤80%), and the tabletop to be placed the analyzer should be level.
Operating environment:
Temperature: 10°C~30°C
Relative humidity: ≤80%
Atmospheric pressure: 76kPa~106kPa
Transportation and storage environment:
Temperature: -40°C~55°C
Relative humidity: ≤95%
Atmospheric pressure: 76kPa~106kPa

⚠ Warning ⚠

Please don't use the analyzer in the following places:
Direct sunlight areas or the front of open window;
There is flammable and explosive gases;
Near the heating or cooling equipment;
Near strong light-source.

2.2 Dismantlement and Installation

Open the package and remove the material used for transportation. Keep the package for possible future transportation or storage.

1. Take out the urine analyzer from the package.
2. Remove the wrapper, take out the analyzer from the plastic packaging.
3. Check the components according to the packing list.
   If there is any problem, contact our company or agent immediately.

2.3 Appearance and Structure

2.3.1 Front View

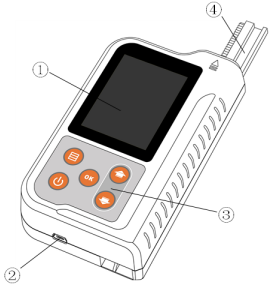


Figure 2-1 Front view

1. LCD display: man-machine conversation window.
2. Micro USB socket: AC adapter power supply socket, interface of data transmission.
3. Keyboard: 5-key touch control keyboard, operate the analyzer with the buttons.
4. Test paper tray: place the strip to be tested on it.

2.3.2 Back View

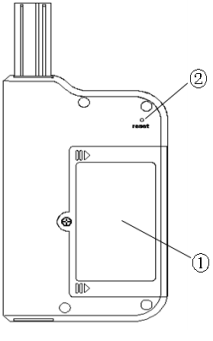


Figure 2-2 Back view

1. Battery cover: it's need to open the battery cover when install and remove the lithium battery;
2. Reset key: if necessary, press this button to reset the urine analyzer.

2.4 Power Supply

The device can use the built-in rechargeable battery as power supply. Connect the urine analyzer to the AC adapter when the built-in battery power is low or it needs to use the external power.

Steps for connecting AC adapter:

Make sure that the AC power complies with the technical specification.

Apply the Micro USB data cable accompanying with the analyzer. Plug data cable to power interface of adapter, plug AC adapter to AC power socket.

⚠ Warning ⚠

AC power outlet must be well connected to ground (zero grounding voltage<5V).

The AC power must be stable, avoid using the same power together with hi-gh-power appliance, and a manostat is recommended to configure.

Please turn off the power supply immediately and contact with the maintenance center, when fog, peculiar smell or strange sound was found in device.

Hold the adapter itself when you unplug it, rather than the data cable.

CHAPTER 3 OPERATION

3.1 Buttons

Figure 3-1 Buttons

	ON/OFF button	Long press this button to turn on/off the device.
	Menu button	In the main interface, short press this button to switch current test user;in the main interface, long press this button for 2 seconds to enter the setup interface;in other interface, execute the return operation.

OK	OK button	Confirm the current operation; In the main interface, press this button to start test.
	Up direction button	In the main interface, long press this button to move the tray up; in the menu interface, press this button to move the cursor up; in history interface, long press this button to quickly move the cursor.
	Down direction button	In the main interface, long press this button to move the tray down; in the menu interface, press this button to move the cursor down; in history interface, long press this button to quickly move the cursor.

3.2 Power On

Under normal power supply situation, long press ON/OFF button for 1 seconds, the urine analyzer will power on and test various parts of the system, enter the main interface after self-test, as shown in Figure 3-2:

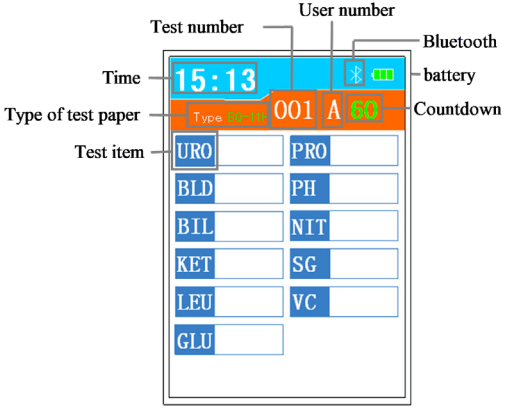


Figure 3-2 Main interface

Note

When self-test information prompt abnormities, first according to the user ma-

nual to resolve abnormities. If abnormalities are still not resolved, please contact the dealer or manufacturer.
When the device prompts to calibrate the clock after the self-test is completed, users need to set time themselves.

3.3 Start Test

Preparation before test:

- **Urine test strips that matched the device;**
- **Urine sample that stored no more than 4 hours;**
- **Absorbent paper for sucking residual urine;**
- **Protective gloves for preventing contamination.**

After the test strip is immersed in the sample, absorb the excess sample liquid in both sides of test paper with absorbent paper, then put the test strip flat on the device test paper tray. Keep the top of test strip is aligned with the top of test paper tray. The main interface displays test countdown, test sample number, user name and the name of the test item.
According to the need, operate as follows:

	Short press this button once, the sample number add 1; long press this button for 2 seconds, the paper tray out of the storehouse.
	Short press this button once, the sample number reduce 1; long press this button for 2 seconds, the paper tray back to the storehouse.
	Short press this button once to switch testing user; long press this button for 2 seconds to enter the device setup interface; during the test, short press it to exit.
	Short press this button once to begin 60-seconds countdown, enter the test after the countdown return to zero; short press it once again before zeroing, the countdown will directly return to zero and immediately enter the rapid test status.
	Long press this button for 1 seconds, the device will power off.

Test steps:

1. Place the test strip;
2. Under the main interface, press OK button  to begin testing the current sample;
3. Begin 60-seconds countdown. After finishing the countdown or press OK button  once again, the device begin to test data. If there are error messages during the test, follow the prompt, then press OK button to continue the measurement;

4. Measurement is completed, display and store the test result. As Figure 3-3.

⚠ Note ⚠

- **The sample number starting from 1 after the first power-on every day, after testing 1 sample, the sample number automatically add 1. After power on again the same day, the sample number starting from the latest sample number.**
- **Select the history sample number, you can re-test the sample and save the latest test result.**
- **If an error message appears after pressing the OK button, please follow the prompt.**
- **Do not place objects on the front removable part of test paper tray, in order to avoid a collision when the tray is removed, cause the bias of test results.**

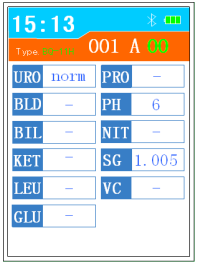


Figure 3-3 Test is completed

3.4 Power Off

Recommended to power off as follows:

1. Under the main interface, long press the direction button for 2 seconds to make the paper tray back to the device storehouse, then long press the direction button for 2 seconds again to make the paper tray out of the device.
2. Remove the tray and rinse the bracket with clear water, then blot up the liquid above and below the tray with absorbent paper.
3. Install the tray into the location where it out of the storehouse, long press the direction button for 2 seconds to make the tray automatically back to the storehouse.
4. Long press ON/OFF button for 1 seconds, the device will automatically power off.

⚠ Note ⚠

Don't directly unplug/ plug the paper tray with hand to avoid damages of mechanical structure.

3.5 Setup Menu

Figure 3-4 Menu

Figure 3-4 shows the device menu interface, it includes historical records, unit, clock, language, factory settings. Select menu option through direction button , press OK button to enter next submenu, press the menu button in any interface to return to the previous interface.

3.5.1 Records

Historical records menu interface, as shown in Figure 3-5.

Figure 3-5 Historical records

All records

Enter the all records query interface, each page shows 10 historical data at most, user can page to see more historical records through direction button , after selecting a record, press OK button to see the corresponding record. As shown in Figure 3-6.

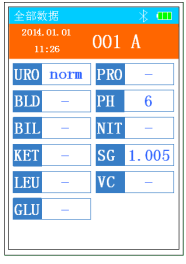


Figure 3-6 Historical records

User list

Query the historical test data of the selected user.

Date list

Query the historical test data of the selected date.

Send

The urine analyzer upload all test results to PC through Micro USB interface or bluetooth equipment.

⚠ **Note** ⚠

Data upload function is customized according to customers' demands, Standard models do not open this function for terminal customers.

Delete

Delete all historical data.

⚠ **Note** ⚠

Data can not be recovered after deletion, please operate carefully.

3.5.2 Unit

The default unit when the urine analyzer leave factory is set to plus system, if you need change the unit, please change it through the unit menu.

3.5.3 Clock

Clock setup menu is used to modify the date and time. User can press the direction button to modify the value in this interface, press OK button

to save the modification of the current item and enter the next modification, after completing modifications in turn, press OK button to complete all modifications, the system automatically saves the new date and time, and exit to the device setup interface. In clock setup interface, users can press menu button at any time to cancel modification and directly return to device setup interface.

⚠ Note ⚠

The system clock always has some cumulative error, the user should calibrate once every two months.

Urine analyzer manages test reports according to the sample number, date and time of test report, please input the date and time according to the facts, otherwise it will lead to disorder of test report management.

3.5.4 Language

Set the language of device interface, the device supports both Italian and English.

3.5.5 Factory Settings

Figure 3-7 The interface of inputing password

User password: 0000.

Modify the value of current item with the direction button , press the OK button to save the modification of current item and enter next item, after inputing the password, press the OK button to enter the factory settings interface, as shown as Figure 3-8.

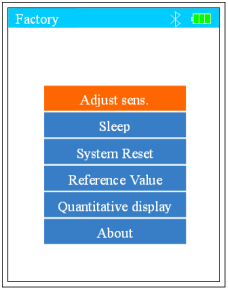


Figure 3-8 Factory settings

Adjust sensitivity

Adjust the sensitivity for the currently selected test strip. During using, the sensitivity can be adjusted when the user wants to increase or decrease the sensitivity of the analyzer.

When you set the sensitivity, must be careful, a valid setting is recommended, you can use urine quality control materials or homemade known content quality control substitutes. For example: gradually dilute known content glucose, home-made PRO standard, use standard of BLD, LEU with microscope, etc.

There are several problems should be pay attention to when use other types of analyzers for comparison:

1. The test paper used by the analyzer made by which standard.
2. The mutual comparability of test strips which made by different standards is very poor, the same control material test different test papers get different results.
3. How is the repeatability of the analyzer, whether has evaluation or self-evaluation.
4. How is the quality of the test paper which used by the analyzer, in the case of the repeatability of the analyzer is excellent, whether the repeatability of test paper is excellent.

After understanding the above, you can securely adjust the sensitivity.

The setup interface of adjusting sensitivity is shown in Figure 3-9.

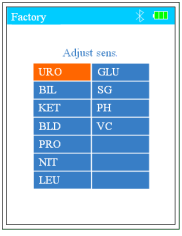


Figure 3-9 Adjust sensitivity

Select the item which need modified, enter the sensitivity adjusting menu of each grads in this item, as shown in Figure 3-10.

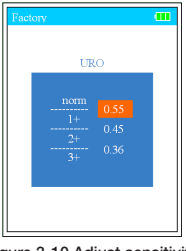


Figure 3-10 Adjust sensitivity

Press direction button to select grads value which need modified, press OK button to enter the modification of current grads value, then modify the corresponding value through direction button, press OK button to confirm the modification, press menu button to cancel the modification.
After finishing modification, press menu button to exit the modification of current item.
After modifing all item, press menu button to return to the factory settings menu.

⚠ **Note** ⚠

- **When you set the sensitivity, must be careful, adjust the sensitivity may**

cause detection errors.
- **After adjusting, the sensitivity value of the test item remains the same size and sequence as before.**

Sleep time
The device is set to enter the sleep state when there is no operation. Under sleep state, the display is turned off, press any button can restore to the working state at this time.

⚠ Note ⚠
Under sleep state, the device will automatically power off without operation for 30 minutes.
System reset
Restore the system to factory settings.

⚠ Note ⚠
After restoring to factory settings, all user settings(including sensitivity adjustment) will be restored to the factory state.

Reference value
Reference range of normal values for each item.
Quantitative display
Switch function of quantitative display. If it is on, it can be selected in Unit.
About
Display the relevant information of the device.

CHAPTER 4 MAINTENANCE

4.1 Maintenance

After daily use, the test tray should be took out for cleaning, and the remained urine should be cleaned with absorbent paper or cotton swab in time, to avoid inaccurate result for cross-pollution.
Often clean the analyzer with soft cloth to keep it clean. If the surface of the analyzer is very dirty, then wipe it with clean water or neutral cleaning fluid. Do not clean with gasoline, paint dilutions, benzene compounds, alcohol and other organic solvents. As these reagents will make the urine analyzer transmogrify, drop lacquer, finally affect performance or appearance.
Do not clean the LCD with water, it is recommended to gently clean it with soft and dry cloth or soft paper.
Do not repair or dismantle the device without authorization, if there are quality problems, it can only be repaired by a factory authorized agency or factory engineers.

⚠ Note ⚠
When cleaning paper tray, do not pollute, scratch, or use chemical solvents to clean the white part on the top of the tray.

4.2 Dismantle and Install the Paper Tray

Dismantle and install the paper tray according to the following steps:

Under the main interface, long press the direction button for 2 seconds to make the paper tray back to the device storehouse, then long press the direction button for 2 seconds again to make the paper tray out of the device.

When installing, insert the clean tray into the device from underside, hold the paper tray gently with hand, at this time, press the direction button for 2 seconds, then the paper tray will move back to the device storehouse.

4.3 Clean the Paper Tray

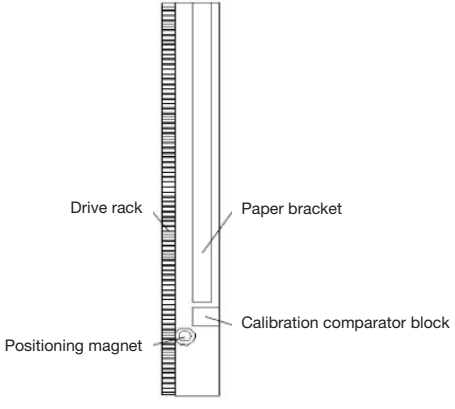


Figure 4-1 Test paper tray

For daily cleaning, use the soft cloth dipped with distilled water or absorbent paper to wipe the paper bracket and the calibration comparator block, and make sure there is no dust, substance, nick, if any found, please replace it with dealer. If there is urine alkali in the paper bracket, use cotton swab dipping with NaOH (concentration: 0.1mol/L) to wipe the paper bracket, and use absorbent paper to wipe.

⚠ **Note** ⚠

Please do not clean with any substance that may scrape the paper bracket and the calibration comparator block.

Please do not clean the calibration comparator block with any solvent.

Please do not contact the calibration comparator block with NaOH.

4.4 Disinfection

1. According to one of the following three methods to configure disinfectant:
- 2% glutaraldehyde solution;
- 0.05% sodium hypochlorite solution -----1:100 dilution: add 1mL sodium hypochlorite solution(concentration:5%) to 99ml water;
- Isopropanol (70% -80%), without dilution.

2. Inject the disinfectant into a tall and narrow container for about 10 cm high.
3. Immerse the paper tray to the disinfectant, and keep the calibration comparator block on the surface.
4. Soak for 10 minutes, then take it out and wipe it with absorbent paper.

4.5 Waste Disposal

According to local regulations about biohazard waste disposal to discard the waste generated during use.

4.6 Troubleshooting

When there is a fault with the urine analyzer or some functions can not be achieved caused by users' improper operation, the urine analyzer will displays error message, all error messages are as follows:

Error message	Solution
Abnormal system information	The memory has problems, the analyzer can not properly read the system parameters, if it still displays abnormal message after restarting please contact the dealer.
Abnormal Motor	Motor rotation is abnormal, check whether there is debris on the paper tray, causing the motor stuck. Low battery, restart after connecting the AC adapter.
Abnormal light source	The light source is strong, weak or damaged. The calibration comparator block is contaminated, please clean it.
Test paper is placed wrong	Please check whether the head of the test strip has been placed to the inner end of the tray flute, even the strip has not been placed, if it is, please correct it within 10 seconds and press OK button OK.
Can't power on	Low battery, restart after connecting the AC adapter, if still can't power on, please contact the dealer.

Appendix

Grads Table

Item	code	Grads code	Special unit	International unit	Conventional unit
URO	1	0 1 2 3	Norm 1+ 2+ 3+	3.3umol/l 33umol/l 66umol/l 131umol/l	0.2mg/dl 2mg/dl 4mg/dl 8mg/dl
BLD	2	0 1 2 3 4	- +- 1+ 2+ 3+	- 10/ul 25/ul 50/ul 250/ul	- 0.03mg/dl 0.08mg/dl 0.15mg/dl 0.75mg/dl
BIL	3	0 1 2 3	- 1+ 2+ 3+	0umol/l 17umol/l 50umol/l 100umol/l	0mg/dl 1mg/dl 3mg/dl 6mg/dl
KET	4	0 1 2 3	- 1+ 2+ 3+	0mmol/l 1.5mmol/l 4.0mmol/l 8.0mmol/l	0mg/dl 15mg/dl 40mg/dl 80mg/dl
LEU	5	0 1 2 3 4	- +- 1+ 2+ 3+	- 15cells/ul 70cells/ul 125cells/ul 500cells/ul	- 15cells/ul 70cells/ul 125cells/ul 500cells/ul
GLU	6	0 1 2 3 4 5	- +- 1+ 2+ 3+ 4+	0mmol/l 2.8mmol/l 5.5mmol/l 14mmol/l 28mmol/l 55mmol/l	0mg/dl 50mg/dl 100mg/dl 250mg/dl 500mg/dl 1000mg/dl
PRO	7	0 1 2 3 4	- +- 1+ 2+ 3+	0g/l 0.15g/l 0.3g/l 1g/l 3g/l	0mg/dl 15mg/dl 30mg/dl 100mg/dl 300mg/dl

PH	8	0 1 2 3 4	5 6 7 8 9	5 6 7 8 9	5 6 7 8 9
NIT	9	0 1	- +	- 18umol/l	- 0.12mg/dl
SG	10	0 1 2 3 4 5	1.005 1.010 1.015 1.020 1.025 1.030	1.005 1.010 1.015 1.020 1.025 1.030	1.005 1.010 1.015 1.020 1.025 1.030
VC	11	0 1 2 3 4	- +- 1+ 2+ 3+	0mmol/l 0.6mmol/l 1.4mmol/l 2.8mmol/l 5.6mmol/l	0mg/dl 10mg/dl 25mg/dl 50mg/dl 100mg/dl
MAL	12	0 1	- +	0.01g/l 0.15g/l	1mg/dl 15mg/dl
CR	13	0 1 2 3 4	- +- 1+ 2+ 3+	0.9mmol/L 4.4mmol/L 8.8mmol/L 17.7mmol/L 26.5mmol/L	10mg/dl 50mg/dl 100mg/dl 200mg/dl 300mg/dl
UCA	14	0 1 2 3 4	- +- 1+ 2+ 3+	1.0mmol/L 2.5mmol/L 5mmol/L 7.5mmol/L 10mmol/L	40mg/dl 100mg/dl 200mg/dl 300mg/dl 400mg/dl

Note:
1. The parameter between in the table and the test strip may be different, please refer to Strip Instruction for details.
2. The data in BLD item represent the number of each microlitre erythrocyte, the data in LEU item represent the number of each microlitre leucocyte.

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies

EU DECLARATION OF CONFORMITY

MANUFACTURER: **CONTEC MEDICAL SYSTEMS CO., LTD**

ADDRESS: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

EC REP Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

PRODUCT : Urine Analyzer, BC401

CONFORMITY ASSESSMENT ROUTE: Annex II

We,（CONTEC MEDICAL SYSTEMS CO., LTD）herewith declare that the stated medical device meets the essential requirements of the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment . All supporting documentation is retained at the premises of the manufacture.
This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

STANDARD(S) APPLIED :
ETSI EN 300 328 V2.2.2 (2019-07) Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band ;Harmonised Standard for access to radio spectrum (article 3.2-Radio);
EN 62479-2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) (article 3.1 (a)-Health);
ETSI EN 301 489-1 V2.2.3 (2019-11) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;Part 1:Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility (article 3.1 (b)-EMC);
ETSI EN 301 489-17 V3.2.4 (2020-09) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;Part 17:Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility (article 3.1 (b)-EMC).

CE MARK: CE

SIGNED FOR AND ON BEHALF OF: **CONTEC MEDICAL SYSTEMS CO., LTD.**

PLACE AND DATE OF ISSUE: Qinhuangdao, CHINA Date: 2023/02/02

SIGNATURE: HUKUN,Chairman/ manufacturer