User's Manual for

Glycohemoglobin Analyzer

(Boronate Affinity Chromatography)

Guidelines:

To ensure accurate HbA1c results from your A1C EZ 2.0 Glycohemoglobin Analysis System, please follow these guidelines:

- The screen blinking part while using is marked in red in this user manual for a better understanding.
- The Power button can be used as the Confirm (Ok) button.
    - Press the button to confirm.
    - Press and hold the button for 2 seconds to turn the analyzer off in the setup mode and test mode.
    - Press the button to turn the analyzer off in all other modes.
- System factory default time is 12:00:00 Jan. 1, 2015.
- System final setting time is 23:59:59 Dec. 31, 2030.
- In the date and time setting, press and hold the Up or Down button can change the displayed date or time in a rapid way.
- The analyzer will be turned off automatically if not use for more than 5 minutes.
- Keep out of reach of children.

Glycohemoglobin Analysis System

Thanks for choosing BioHermes A1C EZ 2.0 Glycohemoglobin Analysis System. This product is intended for testing glycohemoglobin concentration as an aid to monitor the risk of developing diabetes and to control the status of diabetes. The HbA1c analyzer is specifically designed to be used with the corresponding test strip.

IMPORTANT

For proper use of the A1C EZ 2.0 Glycohemoglobin Analysis System, please note the following points:

1. Please read the user's manual carefully before using.
2. Make sure the code number of the HbA1c test strip matches with that on the code chip inserted in the analyzer.
3. The analyzer should be only used with the corresponding test strip.
4. Test only with capillary finger blood and venous blood sample.
5. Before adjusting your medication, diet or daily activities, please consult your doctor or healthcare provider.
6. Keep out of reach of children.
7. Do not use the analysis system over high temperature changes. If moving to an environment where there is a significant difference in temperature, the analyzer and test strips must be kept in the new environment for at least 30 mins for temperature balance before testing.
8. The analyzer is a low voltage handheld device and thus will not expose the user to any electrical hazards. The product does not contain any chemical or other ingredients that may cause adverse side effects.

IMPORTANT SAFETY INSTRUCTIONS

1. **The user should comply with the appropriate safety standards when using this system.**
2. **All parts of the system should be seen as potential infectant, and may have the possibility to spread pathogens.**
3. **The system is used for testing glycohemoglobin only. Please use it according to the purpose described in the manual.**
4. **Please do not use accessories, which are not supplied or recommended by the manufacturer.**
5. **Please do not use the system if it has been damaged or appears abnormal.**
6. **Please do not use the system under direct sunlight.**
7. **Self-protective features of the system are likely to fail if the system is not used in the proper manner required by manufacturer.**
8. **Please do not connect the system to the power of electricity grid.**
9. **Please do not put the system into the liquid.**
10. **The operating voltage of the system is 6.0 V at a current rating of 200 mA. The suggested operation environment condition is: temperature is 10~40℃, humidity: 30%~75%. For storage temperature: temperature is -20 ~ 55℃, humidity is < 80%.**
11. **Please handle with care during transportation. Avoid transporting in high temperatures, and high humidity. Avoid dropping or violent vibrations. It is strictly prohibited to roll or place heavy articles on it. Related notes please refer to index of symbols in section Ⅷ of this manual.**
12. **Before transporting, the system should be cleaned free of biological hazards by disinfecting the surface of the analyzer with a 75% alcohol solution.**
13. **The used batteries, test strips, blood samples and all the related waste produced in the process of using the system should be properly disposed of according to the local disposal rules.**
14. **Please do not contact the analyzer with a hot surface.**
15. **Please do not place any item on the top of the analyzer.**
16. **Please do not allow any contaminants or other objects to fall into or be inserted into the openings of the analyzer, piping or joint.**
17. **The system is designed and produced by BioHermes. After-sales service will be provided by BioHermes or by ~~a~~ the local company authorized by BioHermes.**

Contents

Ⅰ、Introduction and installation

Please read the user's manual carefully before use, understand the Glycohemoglobin Analysis System composition and usage. Check if the system is complete according to the components indicated on the package. If any part is missing or any obvious damage is existed, please contact your local dealer.

System composition

Glycohemoglobin analyzer

AAA batteries

Note:
System using DC power supply (⎓).
The system rated supply voltage is 6.0 V.
Be sure to use 4 pieces of AAA batteries. For proper battery installation, please refer to the indicator in battery slot.

Battery installation

1. Please install the batteries into the analyzer before testing.
2. Place the analyzer with its back in the upside direction, push the battery cover following the direction of the arrow to open the battery cover.
3. Place 4 pieces of AAA alkaline batteries into the battery slot, pay attention to the direction of the batteries.
4. Install the battery cover back to the analyzer.

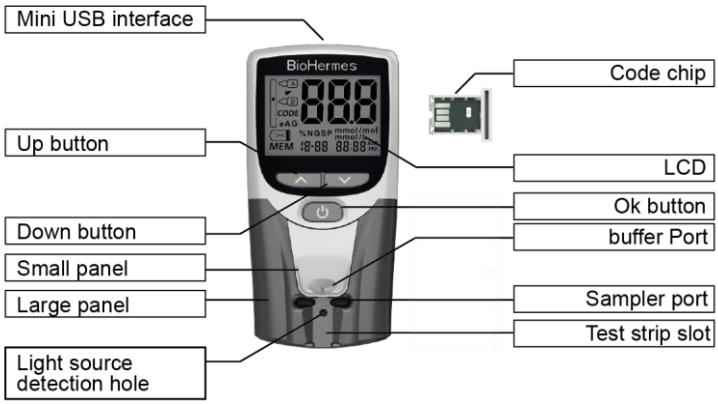
The analyzer will automatically switch on after installing battery, and enter into the setup mode. Please refer to instruction of setting before use.

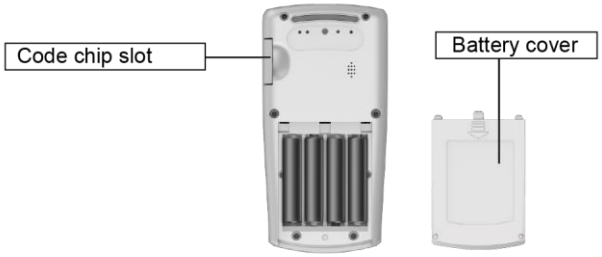
Note:
1. Please remove the batteries if you do not use the analyzer in a long time.
2. Please dispose of the used batteries according to local regulations.

Glycohemoglobin Analyzer

The Glycohemoglobin Analyzer reads the corresponding test strips and displays the glycohemoglobin concentration.

Please refer to the analyzer parts listed below.

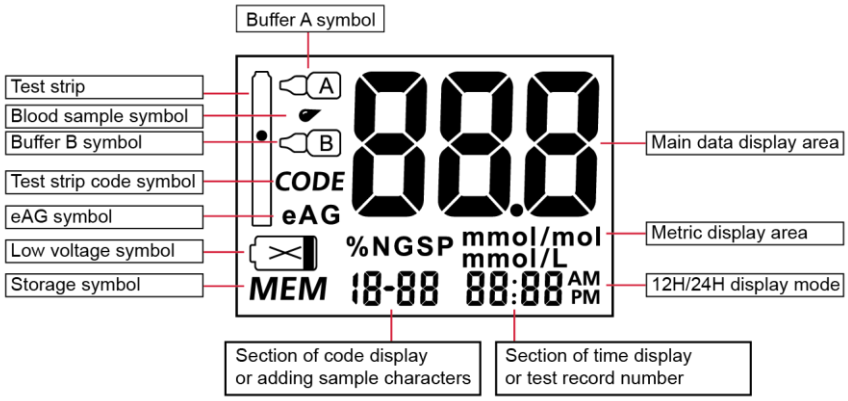




Analyzer indication

.

When the analyzer is switched on, the following display appears on the screen:



IMPORTANT!

1. Please avoid dropping or wetting the analyzer. If you accidentally drop or wet the analyzer, please clean and dry it immediately, and do not use until it dries thoroughly.
2. Please do not disassemble the analyzer by yourself. Any unauthorized disassembling will void the warranty service.
3. Please keep the test strip slot clean.
4. Please keep the buffer port clean.
5. Please keep the light source area clean.
6. Please keep the analyzer dry, do not expose the device in extreme temperature and humidity environment.
7. Please refer to ‘Maintenance and Cleaning’ instructions to clean the analyzer.
8. Keep out of reach of children.
9. The analyzer uses % HbA1c (DCCT) or mmo/mol (IFCC) metrics to display the glycohemoglobin concentration. The mmol/l and mg/dl metrics are used to display the average blood glucose value (eAG).

EMC precautionary warning

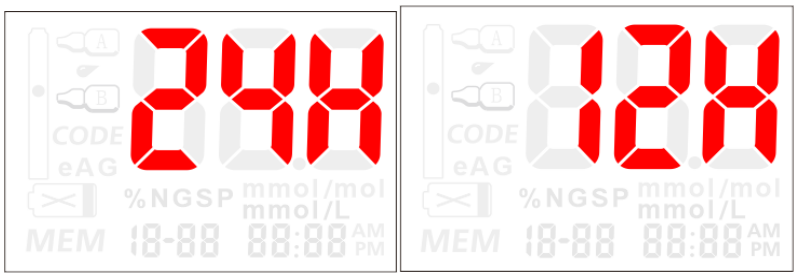
1. The manufacturer has the responsibility to provide the EMC information of the device to customers or users.
2. The user has the responsibility to ensure the EMC environment for the analyzer, make sure it works normally.
3. The analyzer passed the EMC test according to ICE 61326-2-6:2005 standard, but use of the analyzer in a dry environment, where artificial materials (synthetic fabrics, carpet, etc.) exists, may cause damage of electrostatic discharge, and thus leads to wrong conclusions.
4. The analyzer passed electromagnetic radiation and anti-interference test according to ICE 61326-2-6:2005 standard by. Do not use the analyzer near a strong radiation source (for example, non shielded RF source), otherwise it may be interfered with its normal work.
5. It is recommended to assess the current electromagnetic environment before using the analyzer.
6. The analyzer is designed and tested according to the class A equipment of IEC/CISPR 11:2010. In a residential environment, the analyzer may cause radio interference and may need to take protective measures.

Ⅱ、Setting before use

Parameter-settings

After the installation of the battery (include replacing the battery), the system enters the stage of parameter settings. The sequence of parameter settings is time display setting, year setting, month setting, date setting, hour setting, and minute setting.

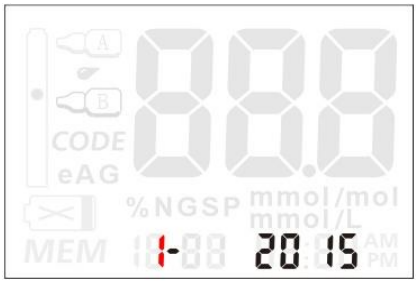
1. Time display setting: After the installation of the battery, the analyzer automatically enters the time mode setting. Press the Up button or Down button to select time display mode 24H/12H. Press the Ok button to confirm. As shown below:



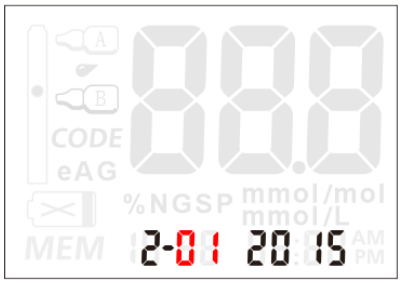
If 12H mode is selected, it will display AM or PM according to the time setting. If 24H mode is selected, it will not display AM and PM at the lower right corner of the screen.

2. Year setting: After the time setting, it automatically enters the year setting. Press the Up button or Down button to select the year between 2015~2030, then press the Ok button to confirm, as shown below:

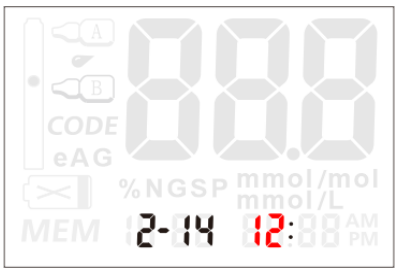
3. Month setting: After the year setting, it automatically enters the month setting. Press the Up button or Down button to select the month between 1~12 or long press to change it rapidly, then press the Ok button to confirm, as shown below:



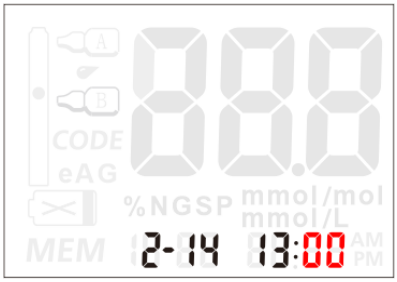
4. Date setting: After the year setting, it automatically enters the date setting. Press the Up button or Down button to select the date or long press to change it rapidly, then press the Ok button to confirm, as shown below:



5. Hour setting: After the date setting, it automatically enters the hour setting, press the Up button or Down button to select the hour or long press to change it rapidly, then press the Ok button to confirm, as shown below:



6. Minute setting: After the hour setting, it automatically enters the minute setting. Press the Up button or Down button to select the minute or long press to change it rapidly, then press the Ok button to confirm, as shown below:

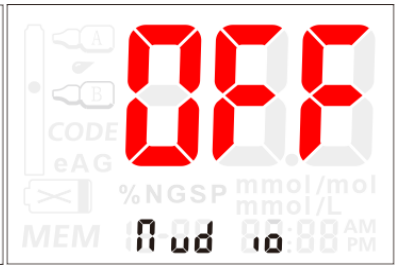


Detailed parameter settings

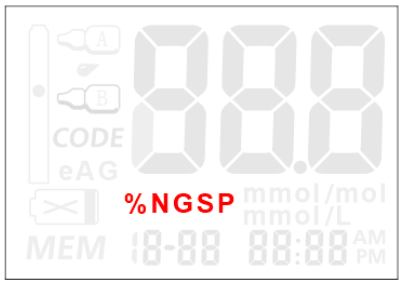
During power-on, press and hold both the Up and Down button, the analyzer will enter into the detailed parameter settings mode. The sequence of parameter settings starts with the 12H/24H display mode first, then the year setting, month setting, date setting, hour setting, minute setting, audio switch setting, metric setting, temperature display, version display.

For time display mode, date, hour and minute settings, please refer to Parameters Settings after the installation of the battery.

52. Audio switch setting: After the minute setting, the analyzer automatically enters the audio switch setting. This setting is used to control the voice prompts on and off. Press the Up button or Down button to choose ON or OFF, then press the Ok button to confirm, as shown below:



2. Metric setting: The system has two kinds of default metrics, % NGSP and mmol/mol. Press the Up button or Down button to choose between the two metrics. Press the Ok button after selecting to confirm, as shown below:



3. Temperature display: After the metric setting, press the Ok button to confirm, the analyzer will then display the current environment temperature (℃), as shown below:

4. Version display: After the environment temperature display, press the Ok button to confirm. The analyzer will then display the current firmware version for 0.5 second, then will automatically turn off, as shown below:

The parameters that were programmed after completion of the above setting operation will be used in the tests.

Please Note:
1. The analyzer will automatically turn off if not use within 5 minutes during the process of parameter settings or the Ok button is pressed for 2 seconds.
2. The parameter settings mode is entered by press and hold the Up button or Down button for 2 seconds after the analyzer is turned on by pressing the Ok button.

Note: if batteries need to be replaced, time and date will also need to be reset.

Ⅲ、HbA1c test

The following contents will introduce how to use the analyzer, test strip, lancet and sampler to test glycohemoglobin.

Preparation before use

1. Item preparations
   Make sure the analyzer, test strip, alcohol swab, dry cotton swab, lancet, buffer A, buffer B and sampler are ready before testing.

2. Code chip insertion
When changing a new package of test strips, make sure to replace the code chip with new one that accompanies each box of test strips. Complete the following steps for inserting a new code chip:

1. Take out the code chip from the test strip package. Compare the code number on the chip with the code number on the vial or pouch of test strip. If the two code

numbers are inconsistent, please contact your local dealer.

2. Before testing, insert the new code chip into the slot located in the analyzer.

3. After the code chip being inserted, the screen will display the ‘CODE’ number. If the ‘CODE’ number on the screen does not match with the code number on the code chip, please contact your local dealer.

Note: under the test status, if no code chip is inserted, the display screen will blink as below (with voice prompt).

3. Blood sampling preparations

1. Disinfect the blood sampling site with alcohol swab. Use warm water to wash the hand to increase the circulation of the blood speed if necessary. Dry your hands and blood sampling site thoroughly. Ensure that no alcohol remains on the blood sampling site. Do not use iodine as disinfectant.

2. Use a disposable lancet to prick the finger. Unplug the safety cap from the disposable lancet, prick finger, and rub from the finger root to the prick site to get enough blood sample for testing.

3. Collect blood samples. Tear off sampler package, take out the sampler, use it to absorb the blood from the finger by touching the sampler cotton thread to the blood drop, wait until the cotton thread is absorbed completely, the sampler is now ready for applying blood sample.

4. Important tips for a successful blood sample collection:

1) Do not use the lancet if the safety cap is lost or detached.
2) Complete the HbA1c test as soon as possible after the blood sample is collected.
3) While testing venous blood which is stored in an anticoagulant tube, gently shake the anticoagulant tube upside down 5~6 times to mix the blood.

1. Inserting the strip

Turn on the analyzer by pressing the Ok button. Insert the test strip as the arrow indicated. If the test strip is not inserted, or not inserted correctly, or a wrong test strip is inserted (used test strip), the test strip symbol on the screen will begin blinking as shown below:

If the voice prompt is set to 'ON' status, it will voice a reminder, 'please insert test strip' or 'please insert the correct test strip' correspondingly. If there is still no correct test strip inserted, the voice prompt will repeat the reminder after 20 seconds.

Note: if you are mistakenly using a used test strip or contaminated strip, the analyzer will make corresponding voice prompt.

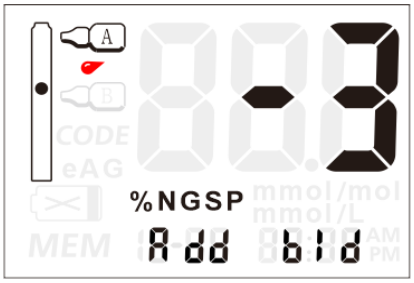
2. Applying buffer A

When the test strip is inserted correctly, the system will prompt to add 3 drops of buffer A. The corresponding buffer A symbol will begin blinking, '-2' and 'Add A', will be displayed, indicating the testing process has entered into the second step. Add 3 continuous drops of buffer A to the buffer port (with voice prompt) as shown below:

After adding buffer A, the system will automatically detect buffer A within 10 seconds. After buffer A has been detected, the system will enter into the 10 seconds countdown. If buffer A is not added, a voice prompt will remind every 15 seconds.

3. Applying the blood sample

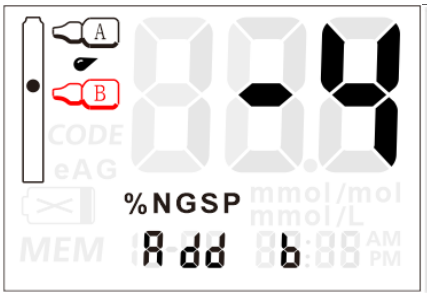
After 10 seconds countdown, the system will voice prompt to add blood sample and the corresponding blood sample symbol will start blinking. '-3' and 'Add bld' will be displayed, indicating the testing process has entered into the third step. Add the blood sample to the sampler port. Remember to keep the sampler in contact with test strip for 3 seconds, then remove the sampler, as shown below:



After adding blood sample, the system will automatically detect blood sample within 15 seconds. After blood sample being detected, the system enters into the 130 seconds countdown.

4. Applying buffer B

After the 130 seconds countdown ends, the system will prompt to add 2 drops of buffer B and corresponding buffer B symbol will blink, '-4' and 'Add B' will be displayed, indicating the testing process has entered into the fourth step. Add 2 continuous drops of buffer B to the buffer port as shown below:

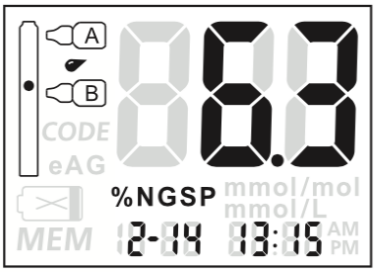


After adding buffer B, the system will automatically detect buffer B within 20-30 seconds. After buffer B is detected, the system enters into the 130 seconds countdown.

Note: In order to get an accurate result, do not move the analyzer or test strip during testing. If any wrongly operation is made, the analyzer will give a corresponding remind.

Reading the result

The analyzer makes the 'beep' sound at the end of the countdown, and displays the test result. The test result can be shown in either %NGSP or mmol/mol units respectively. The type of units displayed is customer selectable. The following result was shown as % NGSP:



Note: if you want to view the average blood glucose (eAG) mmol/l or mg/dl, long press Up button to view.

After showing the result, pull the test strip out, the result will showing on the screen for 10 seconds, then the analyzer will be ready for the next round of testing, or to press Ok button to directly enter into the next round of testing. If you do not pull the test strip out, the screen will show the result for five minutes. Then turned off automatically.

Considerations and limitations

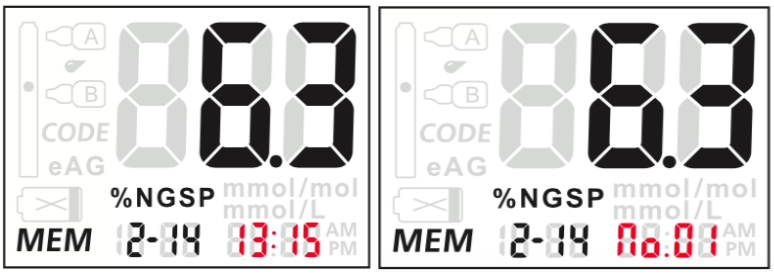
Protections and risks during use of analyzer
1. Please use protective gloves when collecting blood.
2. Please use disposable lancet for puncturing fingertip or disposable venous blood sampling needle and anticoagulant tube.
3. Please use 75% medical alcohol cotton swab to disinfect the blood sampling site and use dry cotton swab to stop the bleeding.
4. The patients may not use this analyzer if hematocrit (HCT) are out of 30~55% due to dehydration, edema, anemia or hemodialysis. Too high (>55%) or too low (< 30%) level of hematocrit may lead to incorrect results.
5. Patients with undefined drugs may not use this analyzer.
6. The analyzer is used for *in vitro* diagnostic testing. Do not use the result to diagnose diabetes or to change therapy without guidance from professionals.
7. The measurement range for the system is 4.0 ~14.0%.
8. All the components of this system, including the analyzer, test strip, buffers, etc. are strictly inspected by BioHermes. Do not mix the BioHermes HbA1c analysis system components with any other brands.

Ⅳ、 Memory function

Displaying the stored data

The analyzer can automatically store 1000 test results with the corresponding testing time and date. After all the 1000 test results have been stored, the earliest result will be eliminated for the new record stored.

To display the test results, start with the analyzer powered off. Press Ok button to switch the analyzer on and enter into the testing mode. Momentarily press the Up button to enter into the memory review mode. In this mode, the result will be displayed with the corresponding storage record number and test time alternately displayed at 0.5 second intervals as shown below:



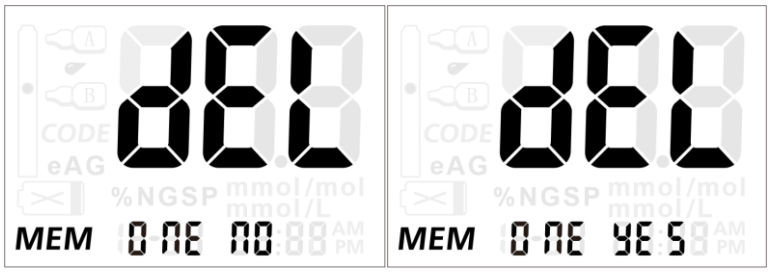
In this mode, you can review historical test results by pressing Up or Down button.
Note: the historical test results will be shown according to the current setting metric model.

Deleting the record

The deleting function can allow you to delete a single record or delete all records. This function should be used cautiously since the testing data is unrecoverable after deleting.

1. Deleting a single record

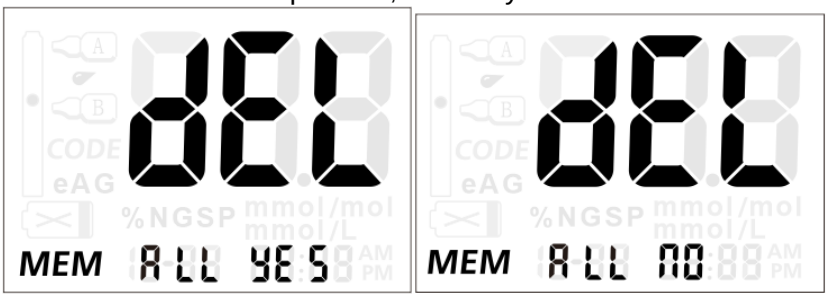
In the memory review mode, press and hold the Down button until hearing the ‘beep’. The analyzer will display the next record to be deleted. Use the Up or Down button to switch between YES and NO to delete this record or continue to save this record. The time displayed on the screen is the time of the record to be deleted.？？？



When determine to choose YES or NO, press Ok button to delete the current record.

2. Deleting all records

To delete all records, power off the analyzer. Press and hold the Down button, until hearing the ‘beep’, and the analyzer enters into the deleting all records mode. Use the UP or Down button to choose YES or NO as shown below to save or delete all records. When YES is chosen and the Ok button is pressed, all the records in the system will be deleted. If NO is chosen and the Ok button is pressed, the analyzer will turn off.

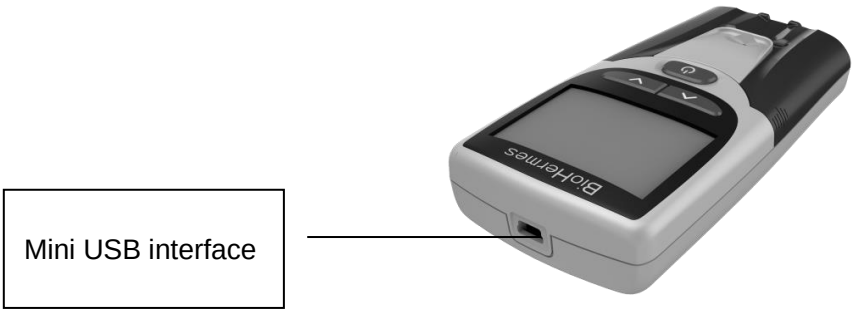


Note: The deleted data is unrecoverable for users. Please operate carefully.

Data transfer

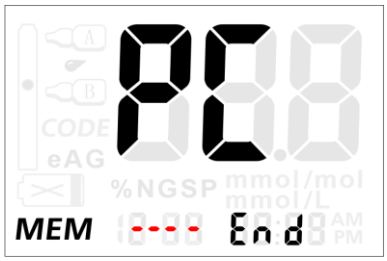
1. Connecting

Plug the USB data transmission cable into the USB interface at the top of the analyzer, and connect the other end to a personal computer (PC) USB port.
Note: the personal computer (PC) must be equipped with the appropriate data acquisition software for receiving and transmitting data from the analyzer.



2. Uploading a single test result record
This mode is used to upload a single test result data record to a personal computer (PC). In the memory review mode, press the Up button until hearing the ‘beep’ and the analyzer enters into the single record transfer mode. At the same time, the screen displays the interface as shown below:

Note:
Open the matched software in the PC before transferring. When the connection is normal, the data will be uploaded to the PC after ‘beep’ sound.
At the end of the data transferring, the screen displays as shown below:



2. Uploading all records
This mode is used to upload all of the test data to a personal computer (PC). In the memory review mode, simultaneously press and hold the Up button and Down button until hearing ‘beep’ and the analyzer enters into upload all test result records mode. In this mode the display is same as the display of the single record transfer mode. A ‘beep’ will be heard after all test result records have been transferred, the analyzer will then enter into the memory review mode and the current record is displayed. The screen display is the same as that in the uploading a single record mode screen display.

Note: the USB data interface is for data transmission purpose only. There is no battery charging or power function

Ⅴ、Maintenance

In order to get the accurate results, the analyzer should be regularly maintained. Common maintenance programs are as follows:

Battery replacement

When the low battery symbol is displayed '', and is flashing, replace with new batteries as soon as possible.

Expected battery life
In the course of normal use, the batteries will last for 1000 test results. Different storage conditions, storage time and usage frequency will affect the battery life. The analyzer's built-in low battery alarm can remind users when to replace the batteries.

Note:

1. Please make sure the analyzer was turned off before replacing the batteries.
2. Remove the old batteries, replace with 4 of new alkaline AAA batteries. Pay attention to the correct polarity direction when replacing the batteries.
3. After the new batteries are replaced, please check and set the parameters. Refer to the settings section before use.

Cleaning

In order to get accurate test results, the analyzer should be cleaned daily after testing. Use a cotton swab to wipe the surface of the analyzer. If necessary, medical alcohol swab can be used. We suggest to keep it in portable bag after use. It is important to avoid any liquids, dust or other particulates from contaminating the test strip port, the code chip port or the USB interface connector port.

To clean the analyzer, first remove the large and small panels according to the direction of the arrows as shown below. Use medical alcohol swab. Carefully wipe the small and large panels and the LED light detection area. After cleaning, securely reinstall the small and large panels.
.

Clean the small and large panels

Note:

52. Do not use organic solvent such as gasoline or paint thinner, this will damage the analyzer.
2. Do not pour liquid into the test strip slot or on the button.
3. Do not soak the analyzer in water or any other liquid.

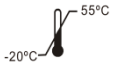
Ⅵ、Trouble shooting

Prompt	Possible cause	Solution
Can not Turn on	Battery was damaged or battery power is too low	Replace the batteries with new ones
E-0	Software problem	Contact local distributor
E-1	Hardware problem	Contact local distributor
E-2	High temperature	Change testing environment
E-3	Inserted the used strip	Change a new strip
E-4	Testing overtime	Read user instruction, follow operating steps
E-5	Strip Removed in the process of testing	Retest
E-6	Operational error	Read user's manual, follow operating steps
E-7	Delay in adding the blood sample	Retest, add blood sample timely after reminding of applying blood sample
E-8	Delay in adding the buffer B	Retest, add buffer B timely after reminding of applying buffer B
	Low battery power	Replace the batteries with new ones
CODE ---	No code chip inserted	Insert the code chip which matches the code of test strip
HI	Test result is higher than the high limit	Please replace with a new strip to test again, if the result still shows 'HI', please contact your doctor for detail suggestions.
LO	Test result is lower than the low limit	Please replace with a new strip to test again, if the result still shows 'LO', after an interval, test again, if the result is still 'LO', contact your doctor

Ⅶ、Specifications and technical parameters

Performance	Technical index
Principle	Boronate affinity chromatography
Test item	Glycohemoglobin (HbA1c)
Test range	4.0%～14.0%
Sample requirement	Finger blood sample or venous blood (EDTA anticoagulated)
Sample volume	About 3μL
Test time	6 ±1 minutes
Result metric	Preset display metric: NGSP metric %; IFCC metric mmol/mol, shift the display of average blood glucose（eAG）metric mmol/L (mg/dL) under test mode
Voice prompt	Voice prompt in the whole process of operation (when the voice is set to 'ON' mode)
Data storage	1000 set of data
Data port	Mini USB interface (can be connected with HIS/LIS system, thermal printer)
Power supply	6.0V(⎓), 4 pieces of AAA battery
Battery life	At least 1000 tests
Factory-calibrated	No calibration required in the process of use
Temperature correction	Using the temperature sensor to correct automatically
Dimension (mm)	122.6mm x 61.0mm x 24.5mm
Screen size	52.0mm x 39.4mm
Weight	112g (without battery)
Working condition	Temperature：10～40℃, humidity 30%～75%
Storage condition	Temperature：-20～55℃, humidity ＜80%

Ⅷ、Index of Symbols

	Refer to user's manual		Validity
	Manufacturer	CODE	Code number
IVD	In vitro diagnostic device	**REF**	Identification of product
LOT	Lot No.		Storage temperature -20～55°C
	Contain strip tested < n > times	SN	Serial No.
	Do not discard with household garbage		Up sign

	Fragile, handle with care		Keep dry
	Keep sunlight from direct irradiation		Do not use two times
	CE representative		Storage humidity < 80%
	Bio-hazard		

Manual updated at March 2nd, 2017