wellion®

BONA HbA1c ANALYZER



MANUAL

ABOUT THIS MANUAL

Thank you for your purchase of Wellion® BONA HbA1c Analyzer. This User Manual contains all the information needed to use the analyzer and keep it ready to operate. Please read this User Manual carefully before using. Also read the package insert of the test kits to be used for the planned test.

Also, be sure to refer to the additional guides and read the package insert of the test kits to be used for the planned test.

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ANALYZER INTRODUCTON AND INSTALLATION

Intended use

This analyzer is for use with Wellion BONA Glycohemoglobin Test Kit to measure the long-term blood glucose (HbA1c) in human capillary blood or venous blood (by healthcare professionals only). It is intended for measurement by medical professionals and for self-testing by people over the age of 18. This analyzer is not applicable for the diagnosis of diabetes.

Testing principle

The analyzer adopts Boronate Affinity Chromatography to measure the percentage of HbA1c in total hemoglobin. A solid phase separation matrix is implemented as a membrane that has been chemically modified to contain both negatively charged groups and boronate groups. When buffer A, which is acidic, flows through the matrix membrane, positively charged hemoglobin (including Glycohemoglobin HbA1c and non-glycohemoglobin) binds to the negatively charged groups. When buffer B flows through and the pH turns basic, hemoglobin loses its positive charge and is released from the matrix.

However, cis-diols of glycohemoglobin can bind with the boronate group thus glycohemoglobin stays on the matrix. The analyzer uses an optical reflectance measurement technique to quantify the optical intensity in A and B phase respectively, thus to calculate the ratio of the glycohemoglobin to the total hemoglobin. This Wellion BONA HbA1c analysis system, using the boronate affinity chromatography method, is traceable to the IFCC Reference Measurement Procedure and traceable to the Diabetes Control and Complications Trial Reference method.

Analyzer components

The analyzer is composed of testing module, AD conversion module, data processing module, display module, Bluetooth module, power module, and button control module. The shell is made of medical grade ABS and PC material. The accessories along with the analyzer includes: lithium battery, charging cable, user manual, quick start guide, cleaning guide.

Note: (1) The rated working supply voltage for analyzer is 3.7V.

(2) Please use the lithium battery provided by the manufacturer, and install it according to the positive and negative sign in the battery slot.

Battery installation

Install the battery to analyzer before use.

Open the battery slot by pushing the battery cover downward.

Place BL-5C (3.7V Li-ion 800mAh) battery into the battery slot. Make sure the battery is placed in the correct way.

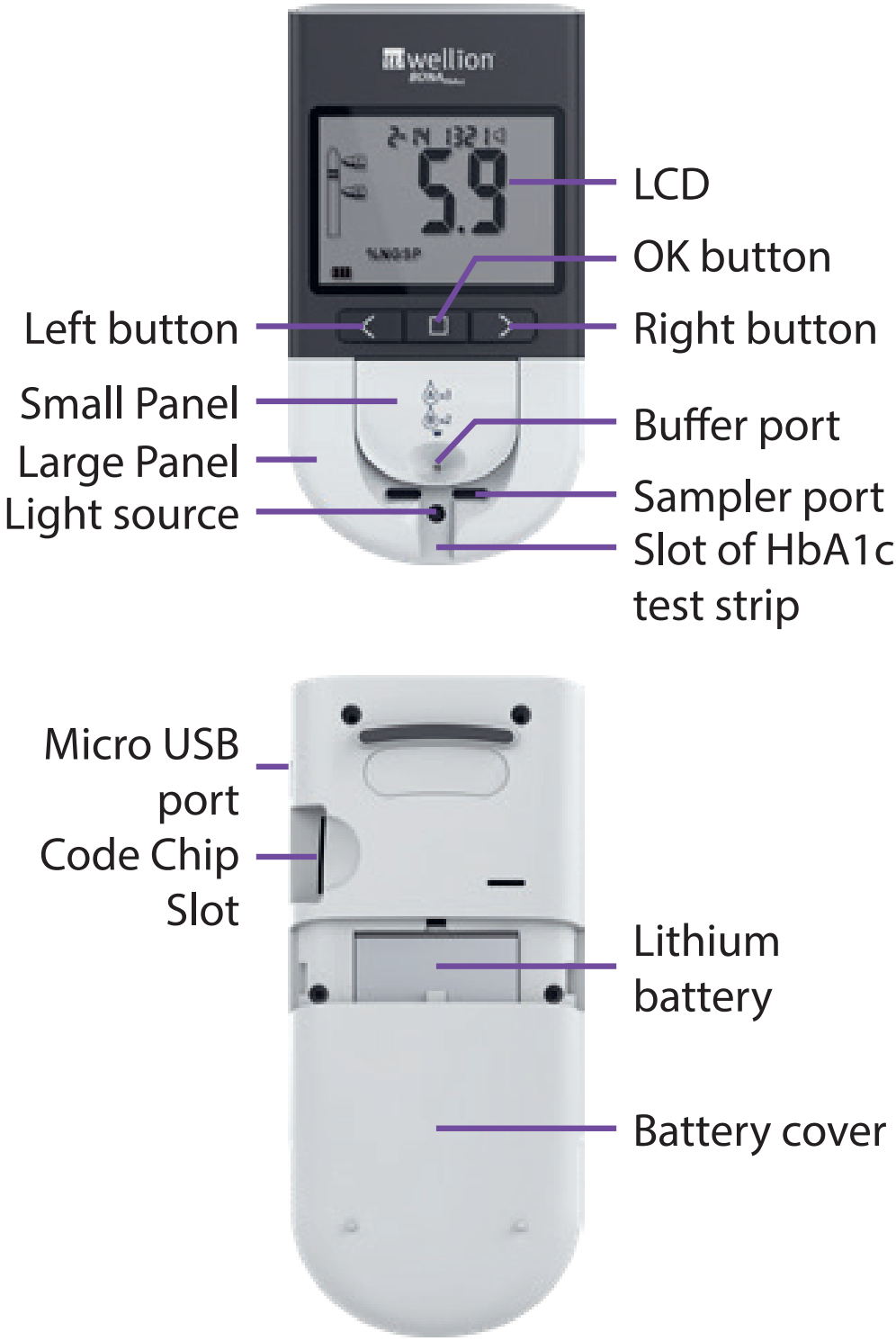


The analyzer will turn on automatically when the battery is installed, and the setting mode will be initiated. Please refer to the "SETTING THE ANALYZER" section for detailed information.

Note: 1. The rechargeable battery should be charged if the battery symbol is low.
2. Dispose the used battery according to local regulations.

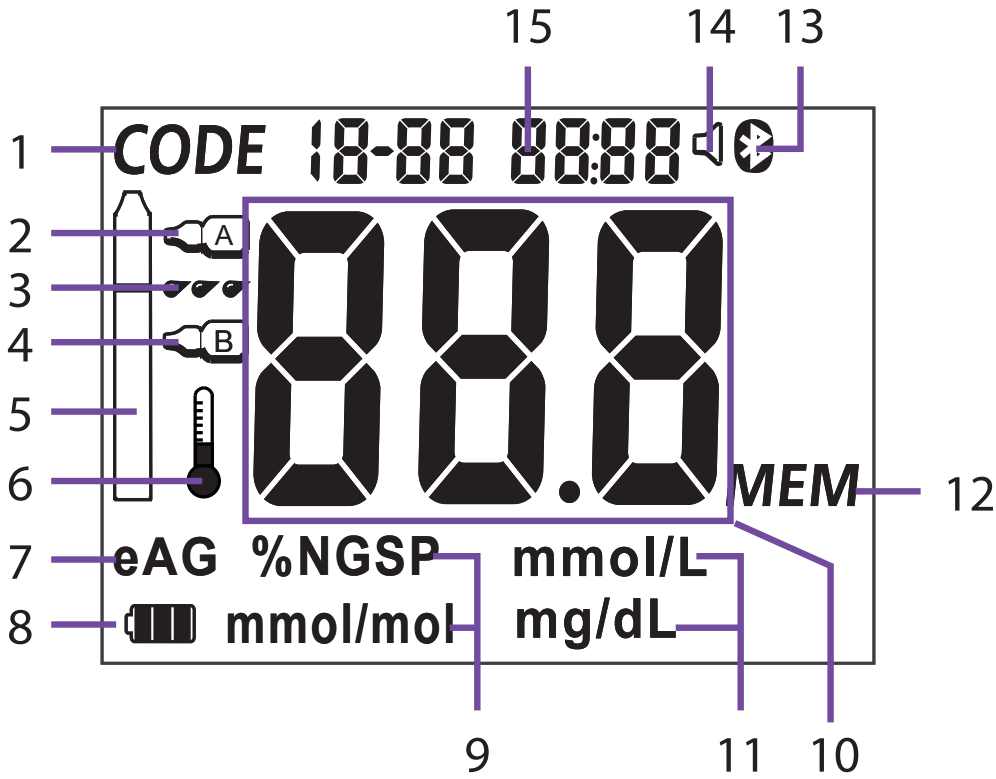
Overview of Analyzer

Please refer to the following sketches to get an overview of the analyzer.



Display of Analyzer

When the analyzer is turned on, the following digital symbols will appear on the display:



1. Code
2. Add buffer A
3. Add blood sample
4. Add buffer B
5. HbA1c test strip
6. Environment temp.
7. eAG
8. Power usage
9. HbA1c units
10. Testing result
11. eAG units
12. Memory data
13. Bluetooth ON/OFF
14. Voice function ON/OFF
15. Date and time

EMC preventive Warnings

The analyzer has been tested and complies with the EN/IEC 61326-1 & EN/IEC 61326-2-6

standards. Do not use in environment where there is a chance of a severe electrostatic discharge, which may damage the analyzer and produce incorrect results.

The analyzer has been tested and complies with the EN/IEC 61326-1 & EN/IEC 61326-2-6 standard for electromagnetic radiation and immunity interferences. Do not use the analyzer near a strong radiation source (for example, non shielded radio source).

It is recommended to evaluate the electromagnetic environment before using the analyzer.

The analyzer has been tested and complies with the IEC/CISPR 11:2010 for Class B equipment. The analyzer may cause some radio interference in a residential environment.

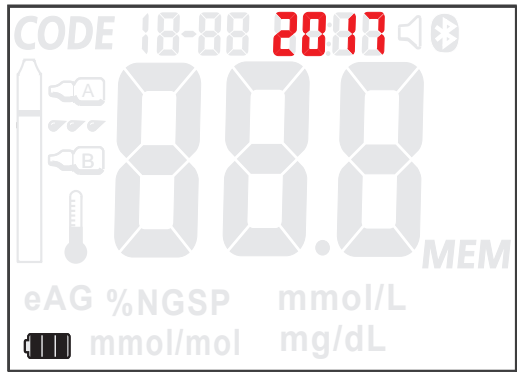
SETTING THE ANALYZER

Analyzer Settings after Battery Installation

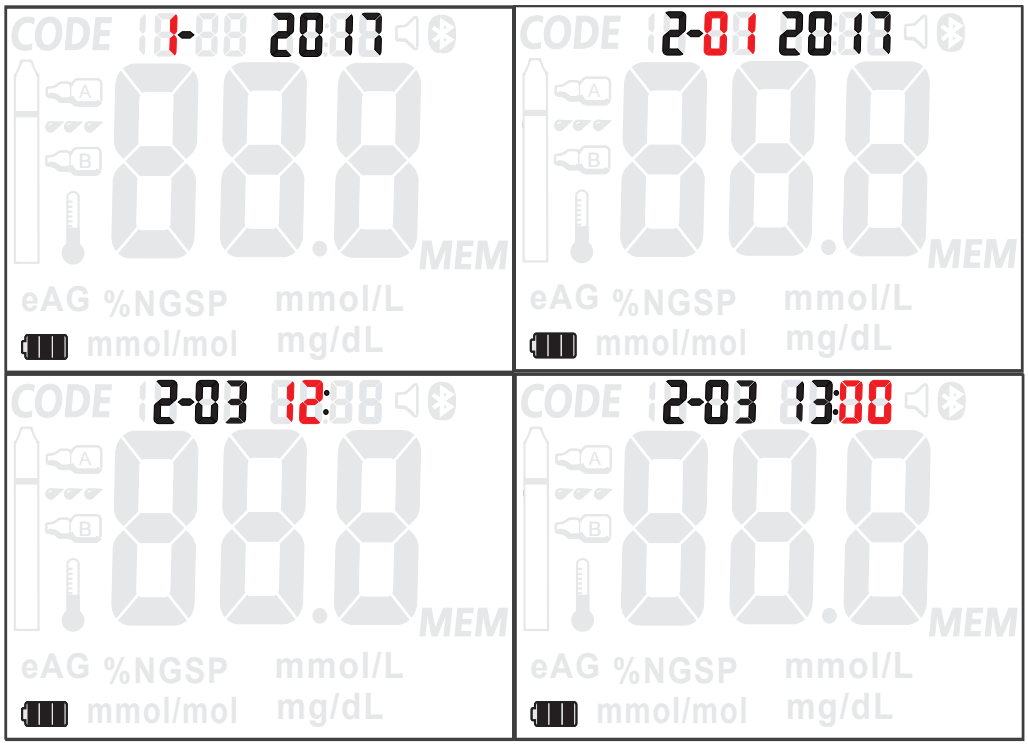
After the initial installation of battery, the analyzer enters the setting mode. The sequence of parameters setting is “year-month-day-hour and minute”. The system default time format is the 24-hour time format.

Year setting:

Press the LEFT button and RIGHT button to set the year from 2017 to 2036, and then press the OK button to confirm.



Other time-settings:
Repeat the above steps to set the month, day, hour and minute accordingly, as shown below:



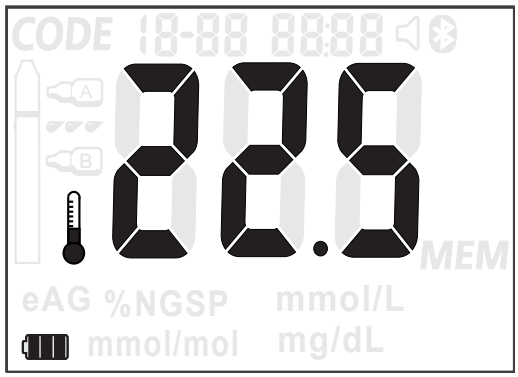
Enter Setting Mode

When the analyzer is ON, press the LEFT button and RIGHT button together to enter analyzer setting mode. The sequence of parameters setting or display is “year – month – day – hour – minute – temperature display – voice function ON/OFF – Bluetooth ON/OFF – measurement unit – HbA1c testing amount – software version”.

Please refer to “Analyzer Settings after Battery Installation” section for time settings.

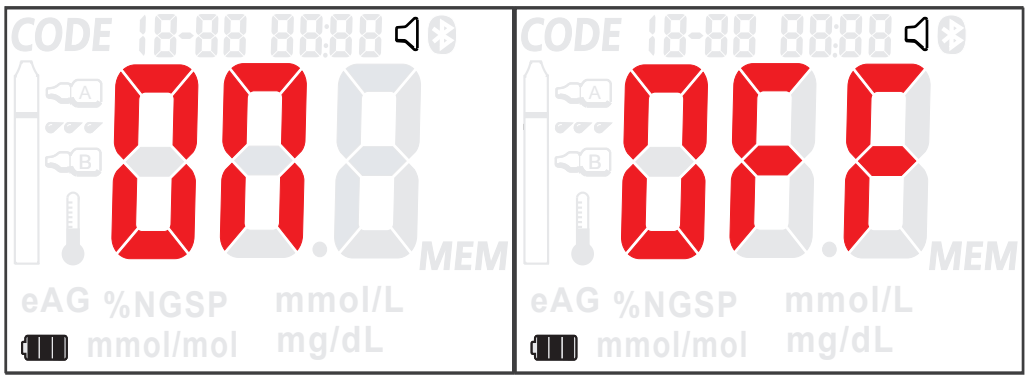
Temperature display:

After the time settings, press the OK button, the analyzer will display the real-time temperature, as shown below:



Voice function ON/OFF setting:

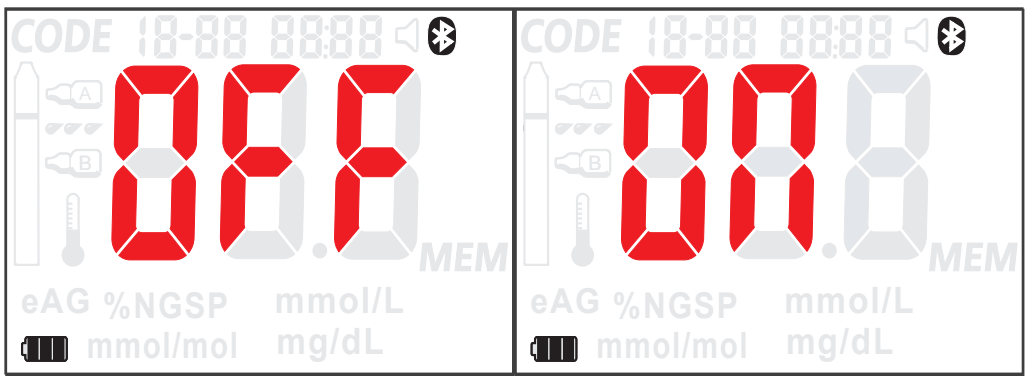
After the temperature display, the analyzer will enter the voice function ON/OFF setting. Press the LEFT or RIGHT button to select ON or OFF, and then press the OK button to confirm, as shown below:



If the voice function is set to OFF, audible tones will still prompt the user if an action is required in addition to displayed symbols on the screen.

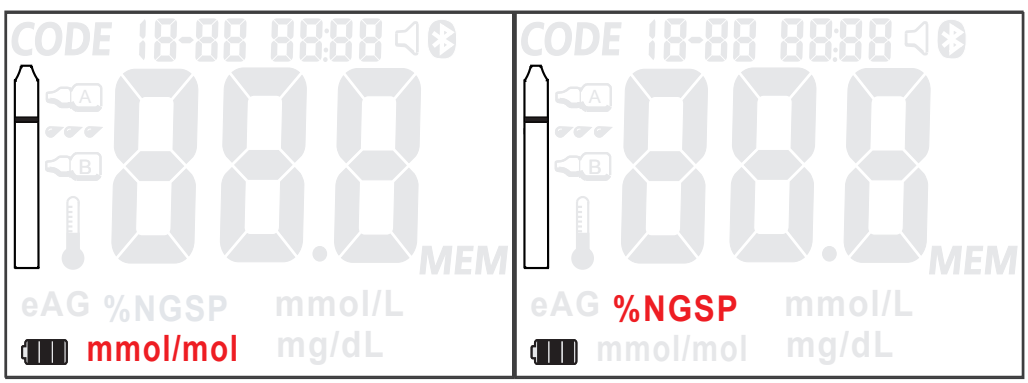
Bluetooth setting:

The analyzer will enter the Bluetooth setting after the voice function ON/OFF setting. For the analyzer equipped with Bluetooth function, this function defaults to ON. To turn off Bluetooth function, press the RIGHT button to select OFF, and then press the OK button to confirm, as shown below:



Measurement units setting:

The analyzer will enter the measurement units setting after the Bluetooth setting, the symbol of HbA1c test strip will display. Press the LEFT or RIGHT button to select the measurement unit %NGSP or IFCC mmol/mol for HbA1c, and then press the OK button to confirm, as shown below:

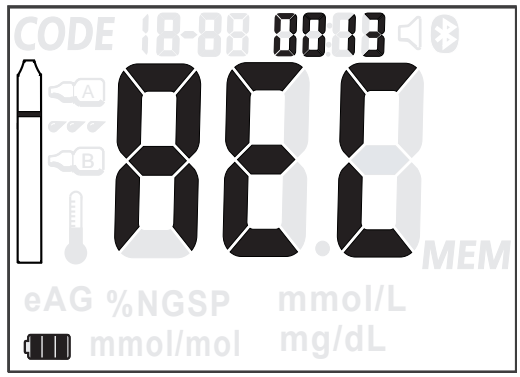


After setting the HbA1c units, the meter proceeds to setting the Estimated Average Glucose (eAG) units of measurement. Press the LEFT or RIGHT button to select the measurement unit mmol/L or mg/dL for eAG, and then press the OK button to confirm, as shown below:



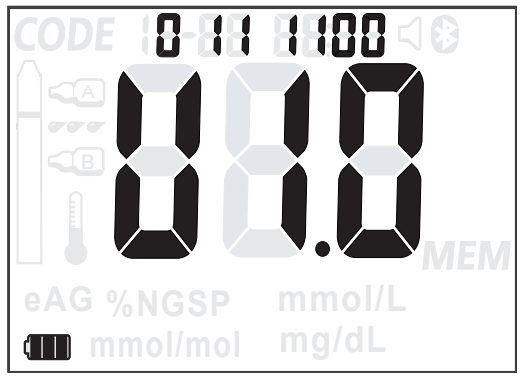
HbA1c test amount:

The analyzer will display the HbA1c test amount after the measurement units setting. The number displayed represents the HbA1c testing times conducted in total, as shown below:



Software version:

The analyzer will enter software version display after the HbA1c test amount display. As shown below:



The parameters now are all set and the analyzer is ready for performing test.

Note: The analyzer will turn off automatically if no operation conducted over five minutes. Or user can turn off manually by pressing OK button for 2 seconds.

PERFORMING TEST

Performing a HbA1c test

Preparation:
Please note that all flashing symbols on display graphics are shown with **red** color.

1. **Materials preparation**
   Get followings ready before testing: analyzer, HbA1c test strip, dry cotton swabs, medical alcohol (or alcohol pad), safety lancet.
2. **Blood collection preparation**
   Get the safety lancet ready. Wash and dry the hands thoroughly.

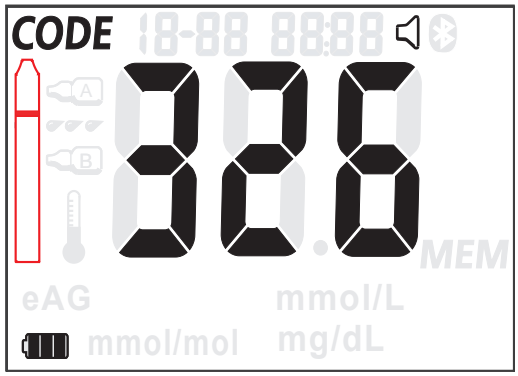
Insert the calibration code chip:
When use a new kit of HbA1c test strips, remember to insert the calibration code chip packed with the strips.

(1) Take out the calibration code chip from the HbA1c test kit. Compare the code number of the chip with that on the vial of strips. If these two codes number are inconsistent, please contact your local distributor.

(2) Insert the calibration code chip to the code chip slot (the chip can be inserted either when analyzer is ON or OFF). If analyzer

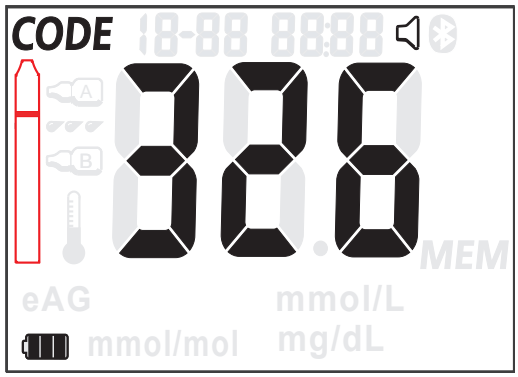
and voice function is ON, it will prompt "*Please insert the correct calibration code chip*".

(3) After calibration code chip is inserted, code number will be displayed with the voice prompt "*Please confirm the calibration code number is correct*". If the code number is inconsistent with that on the chip, please contact your local distributor.



Insert the HbA1c strip:

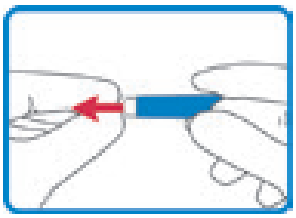
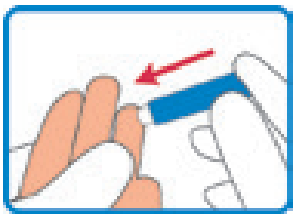
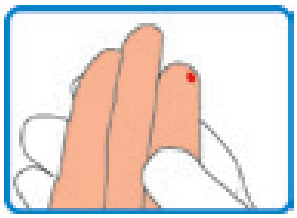
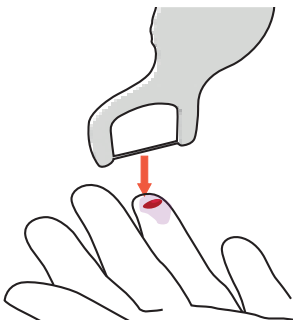
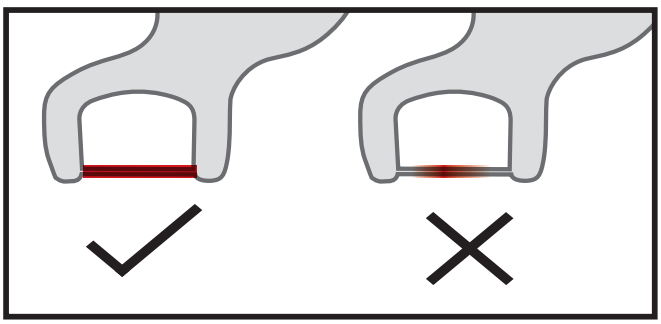
Turn on the analyzer by pressing the OK button and insert the HbA1c test strip. If the HbA1c test strip is not inserted or improperly inserted, the test strip symbol will unceasingly blink on the display. As shown below:



If the voice prompt is ON, there will be a voice prompting as "*Please insert the test strip*". If there is still no correct test strip inserted, the voice will prompt again after 30 seconds.

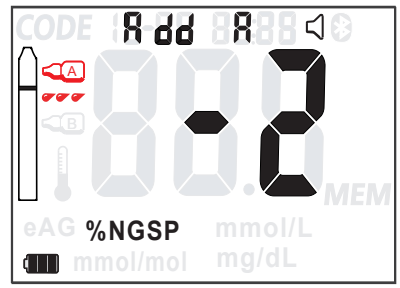
Step 1: Collect the blood sample

Tear sampler package, take out the sampler and put aside for ready. Use medical alcohol swab or alcohol pad to disinfect the fingertip. Put the safety lancet against the fingertip to prick the finger. Rub the finger from base to top to get a blood drop. Use the sampler to absorb the blood drop, wait until the cotton thread becomes fully red.

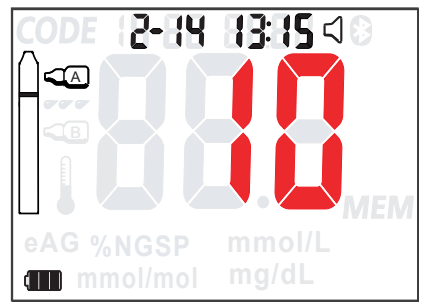
Step 2: Add buffer A

When the test strip is inserted, the analyzer will prompt *"Collect the blood sample and add three drops of buffer A to the buffer port"*. The buffer A symbol and the blood sample symbol will blink, "-2" and "Add A" will be displayed, which indicates the testing procedure enters the step 2, as shown below. Add 3 drops of buffer A vertically and continuously to the buffer port.



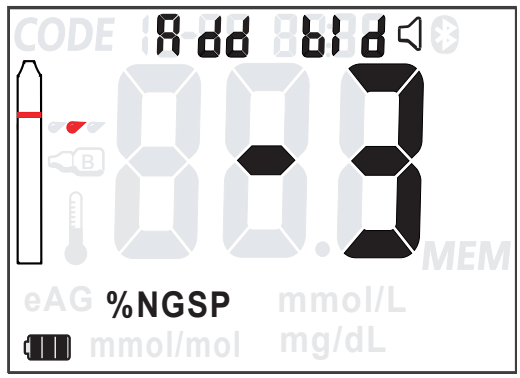
After adding buffer A, the analyzer will detect buffer A automatically. When buffer A is detected successfully, analyzer will start a countdown of 10 seconds. As shown below:

If buffer A is not detected (e.g. if inserted an used HbA1c strip) or not added, the buffer A symbol and the blood sample symbol will unceasingly blink, and the voice will prompt for buffer A addition and blood sample collection after about 25 seconds of first prompt again. If still no buffer A is detected, voice will prompt twice again every two minutes, then analyzer turns off automatically.

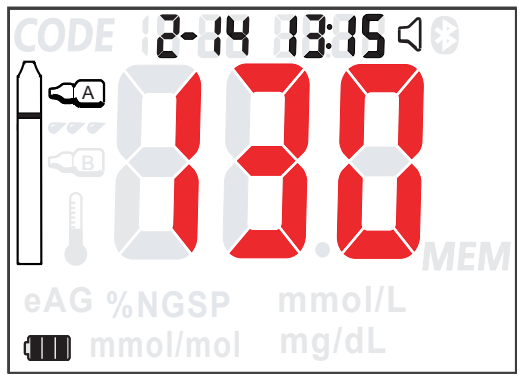


Step 3: Apply the blood sample

After 10 seconds countdown, the analyzer will prompt to apply the blood sample "*Please apply the blood sample*". The blood sample symbol will also blink, "-3" and "Add bld" will be displayed, which indicates the testing procedure enters the step 3, as shown below. Apply the sampler with collected blood sample to the sampler port, and contact the sampler to test strip for 3 seconds.

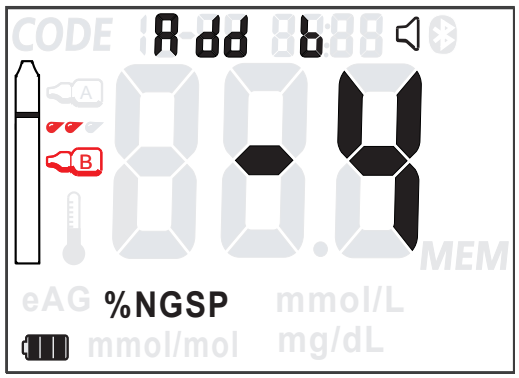


After applying the blood sample, the analyzer will detect the sample automatically. When the blood sample is detected successfully, the analyzer will start a countdown of 130 seconds. As shown below:

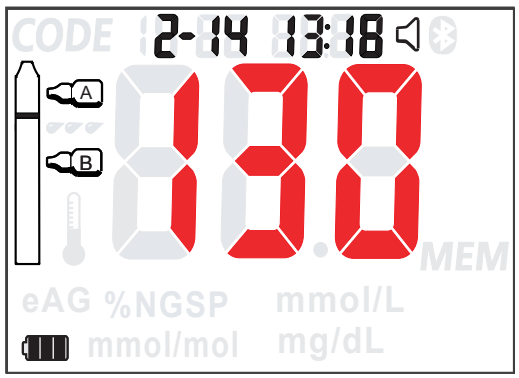


Step 4: Add buffer B

After the 130 seconds' countdown, the analyzer will prompt to add 2 drops of buffer B "*Please add two drops of buffer B to the buffer port*". The buffer B symbol and the blood sample symbol will blink, "-4" and "Add b" will be displayed, which indicates the testing procedure enters the step 4, as shown below. Add 2 drops of buffer B vertically and continuously to the buffer port.

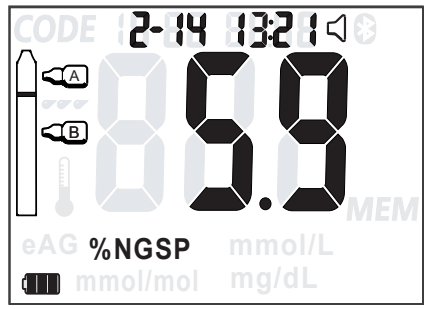


After adding buffer B, the analyzer will detect buffer B automatically, which will take 20 to 50 seconds. When buffer B is detected successfully, analyzer will start a countdown of 130 seconds. As shown below:



Read the result

The analyzer will give a “beep” tone when the countdown is finished. The HbA1c result will be shown in either %NGSP or mmol/mol unit as preset. Additionally, if voice function is ON, there will be a voice output ”*Result is* ....“ for the HbA1c-test result.



Note: **1.** The average blood glucose (eAG) result can be viewed by long pressing the RIGHT button.

2. After the tested strip is removed from the analyzer, the analyzer will immediately start the next round of testing. If the tested strip remains on the analyzer without remove, the result will remain for 5 minutes, and then analyzer will turn off automatically.

Discard the used test strips and all other consumables properly according to the local regulations.

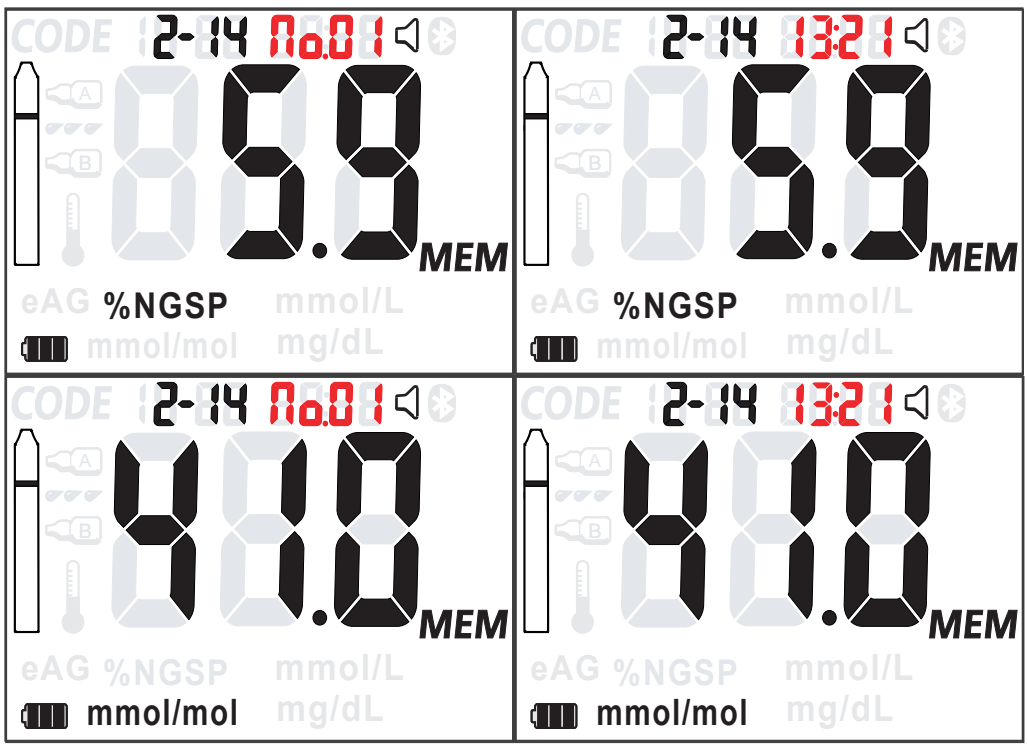
MEMORY AND DATA MANAGEMENT

Displaying the stored data

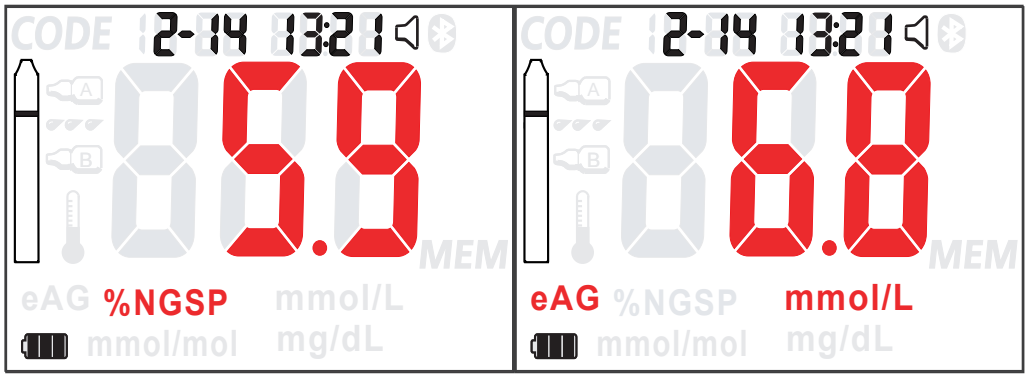
The analyzer can store 1000 test results with information of date and time. When the memory reaches to 1000, the earliest data will be replaced by the latest one.

In the power-off or test standby mode, press LEFT or RIGHT button to enter the data management mode. In this mode, the result will be displayed with corresponding test number and test time. Press LEFT or RIGHT key to view the stored results.

The stored HbA1c test results are shown as follows:



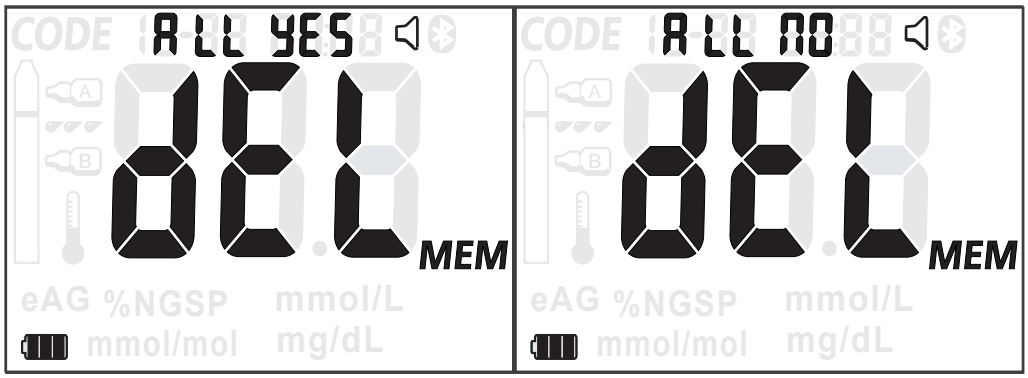
In this mode, eAG result can be viewed by long pressing the RIGHT button. As shown below:



Deleting the data

When deleting all data is needed, long press RIGHT button in the power-off mode. A “beep” sound indicates analyzer entering the “All data delete” mode with the voice prompt *“Memory delete mode enabled, proceed with care“*, as shown below. User can choose YES or NO, to delete all the data or keep them.

After selection of YES or NO, user has to press the OK-key for confirmation of data deletion. If YES is selected, some seconds after pressing the OK key, symbols „---„ and „MEM“ will be displayed which indicate successful deletion of all data. If no action was performed after selection of YES or NO, device will turn off after about five minutes.



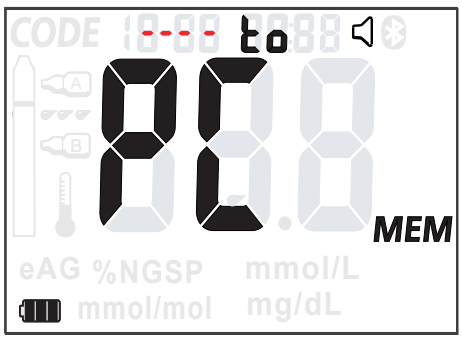
DATA TRANSFER

The data can be transferred to PC or mobile phone with corresponding software by Bluetooth.

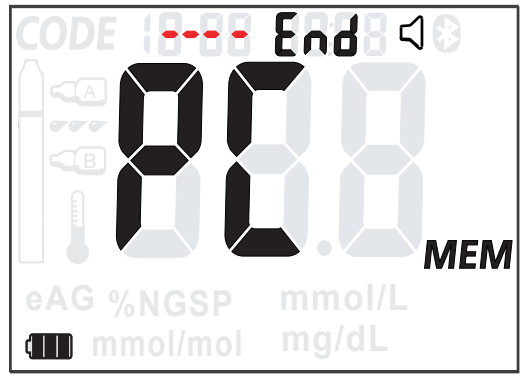
For supplementary data management service, please contact the manufacturer (or service provider) or visit the Wellion website (www.wellion.at) to get more information.

Uploading a single data record

In the data management mode, long press LEFT button, a “beep” will sound, indicating analyzer enters the single data record transfer mode and will start the data transfer, as shown below:



Note: Open the corresponding software on PC or mobile phone before data transfer. If connection is in normal function, data will start to be uploaded after the "beep" sound.



When transfer is finished, display will show as below.

Uploading all data records

In the data management mode, long press the LEFT and RIGHT button at the same time until hearing "beep". The analyzer will enter the "all data records transfer" mode and start the data transfer. The rest is the same with that of "Uploading a single data record" mode.

PRINT (EXTERNAL THERMAL PRINTER)

Connection to Analyzer

The analyzer is compatible for external thermal printer which is not included and can be purchased separately.

Note: Please disable the Bluetooth connection of HbA1c analyzer to other devices before

using the printer, or the result will be printed as unreadable codes.

Printing operation using external thermal printer (not included): Connect the power supply to the compatible port of the printer and plug the power supply into a suitable electrical outlet.Power on the printer by long-pressing “P” button of the printer. If operation was successful, a prompt tone is given and a blue blinking light appears on the printer. Adjust the printing paper properly. If necessary, paper can be moved forward by pressing “F” button. Connect the included BONA USB cable to the compatible USB-port of the external thermal printer and to the compatible USB-port of the HbA1c-Analyzer.

Printing the result

There are two options to print the test result.

A. Directly after HbA1c-test performance: Printer is ON and connected. After conduction of HbA1c-test, test result will be printed automatically once the test is finished.

B. Print stored data: Printer is ON and connected. Enter the data management mode by pressing LEFT or RIGHT button of analyzer (OFF-modus) and select the test result. Then, long press the LEFT button of the analyzer to print the result.

QUALITY CONTROL

Control solution test

Quality control test is usually conducted in the form of control solution test. It is important to perform control tests with more than one level of control to assure your system is working properly.

Why to do a control solution test

Control solution is used to check that the analyzer and the test kits are working together as a system and that the test is performed correctly and the result is accurate.

Choose your control products

Only control products supplied by MED TRUST can be used.

When to conduct a control test

- When the strip vial is not closed or not closed tightly for a long time.
- When user wants to check the system's performance.
- When the storage temperature or humidity is out of permissive condition.
- When the analyzer is dropped.
- When user doubts the test result.

Conduct the control test

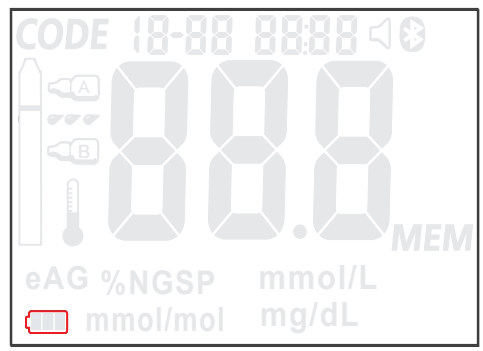
Check the expiration date of the control products. Mark the opening date on the container label. For HbA1c control test, the test procedure is same with that of blood sample HbA1c test. Once the control results are given, please compare them with the target value and control range provided on the quality control product, to decide the measures to be taken next. Please read the package inserts of control products for detailed information.

MAINTENANCE

The accessories used for the analyzer must be obtained from manufacturer or authorized distributors, otherwise analyzer's performance might be affected. In order to continually ensure the accurate results, the analyzer should be regularly maintained. Routine maintenance programs are as follows.

Battery charging

When the low battery symbol appears with blink, it means the power of battery is too low to conduct test. Under these circumstances, user should recharge it as soon as possible. Note that during charging process no HbA1c-test or other operation can be performed.



Please note that as soon as the analyzer detects the insertion of test strip, the low power alarm will be turned off even though the battery power is under the threshold.
Battery is the consumable component of the analyzer for routine use. Please contact the local distributor or manufacturer if battery cannot be normally charged.

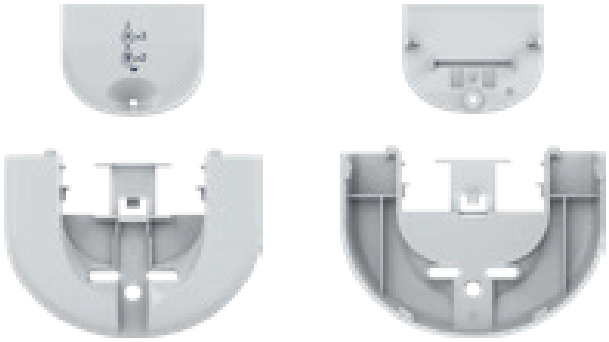
Note: 1. Please make sure the analyzer is turned off before replacing the battery.
2. Pay attention to the correct direction when installing the battery.
3. After the battery is replaced, please check and set the parameters accordingly.
4. If the lithium battery is damaged or not functioning properly, please contact the local distributor or manufacturer.

Analyzer Cleaning

In order to get accurate test results, clean your analyzer after testing. Use a dry cotton swab or cotton swab dipped with 75% alcohol to wipe the surface of the analyzer. Disassemble the small and large panels from the analyzer according to the instruction shown below, then use a cotton swab dipped with 75% alcohol to wipe both sides of panels as well as the light source area and it's surrounding area. After cleaning, reinstall the small and large panels back to the analyzer.



Disassemble the panels



Clean the small and large panels



Clean the light source area

Note: 1. The sequence for panels disassembly: first disassemble the large and small panels as a whole from the analyzer, and then remove the small panel from the large panel.

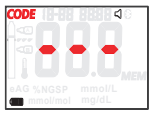
2. Do not use organic solvent such as gasoline or paint thinner for cleaning, which may cause chemical damage to the analyzer.

3. Do not soak the analyzer in water or any other liquid for cleaning.

TROUBLESHOOTING

In certain circumstances, error codes may appear on the display. Generally, user should first try the solutions suggested for the respective error by below form. If problem persists, please contact the local distributor for further support.

Error Code	Possible cause	Solution
	Software problem	Contact distributor
	Hardware problem	Contact distributor
	Improper working temperature	Change testing environment to a proper one
	Code chip used more than 27 times	Please replace the code chip when using a new test kit.
	Delay in applying the blood sample	Apply the blood sample timely after the prompt
	Delay in adding buffer B	Add buffer B timely after the prompt
	Low battery power	Recharge battery

	No calibration code chip inserted	Insert the corresponding calibration code chip
	Test result is higher than the measurement range of analyzer	Test with a new strip again. If the result still shows 'HI', please contact the medical professional for advice.
	Test result is lower than the measurement range of analyzer	Retest. If the result still shows 'Lo', retest after an interval. If the result still shows 'Lo', contact the medical professional for advice.

PRECAUTIONS AND LIMITATIONS

The user should follow the proper safety principles when using this analyzer.

This meter is for in vitro diagnostic use only (i.e. the measurement is outside the body) by people aged 18 and over. Please use the analyzer in accordance with the purposes described in the user manual.

Do not use the analyzer over large temperature fluctuation. When taking the analyzer to the environment of large temperature difference, please wait for at least half an hour until the analyzer reaches the temperature equilibrium.
Do not use the analyzer for testing serum or plasma sample. For HbA1c testing, please use finger capillary blood sample or EDTA anticoagulated venous blood sample.

Do not use the accessories that are not provided or recommended by the manufacturer.

Do not use the analyzer if it has been damaged or appears abnormal, such as dropping damage, continuing fault alarm, submersion into water or water splashed into the analyzer.

Do not use this analyzer under direct sunlight.

Do not use this analyzer when being charged.

Self-protective features of the analyzer are likely to fail if the analyzer is used incorrectly.

Do not splash liquid on the analyzer or use the analyzer near liquids.

This analyzer must be handled with care during transportation, avoid intensive vibration; it is strictly prohibited to roll or place heavy objects on the analyzer, and avoid transporting in high temperature and humidity. Refer to the Index symbols for a better understanding.
Dispose of used batteries, test strips, blood samples and other related waste should be strictly in accordance with local regulations.

Do not use the analyzer in overheated environment or surface.

The compatible battery model for the analyzer is BL-5C (3.7V Li-ion 800mAh). It may damage the analyzer or cause fire if the wrong models are used.

Avoid buffer A and buffer B directly contacting

the skin or eyes.

This product is a portable low voltage meter. The product is not in direct contact with the test part of human body. Therefore it will not bring adverse effects to the people being tested. And this product does not contain ingredients or accessories that may cause side effects.

Do not disassemble the analyzer, warranty service is not provided for unauthorized disassembly of analyzer.

MANUFACTURER´S WARRANTY

The producer warrants Wellion BONA HbA1c analyzer against defects in materials and workmanship for a period of two years from the date of purchase. The warranty is lost if the instrument is misused, poorly maintained or is tampered with.

Liability under this warranty is limited to the repair of defective parts or - at the discretion of the producer - to the replacement of the instrument. The right to rescind the purchase agreement exists only if the replacement is also found to be defective. Claims other than these will not be dealt with.

The warranty is not valid if the damage results from misuse, maltreatment, tampering, human error and the use of extreme.

The warranty period is not to be extended by any claim made under this warranty.

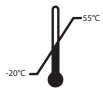
TECHNICAL INFORMATIONS

Performance	Technical index
Principle	Boronate affinity chromato-graphy
Test item	HbA1c
Measurement range, NGSP: Measurement range, IFCC:	4.0% - 14.0% 20 mmol/mol - 130 mmol/mol
Sample requirement	Capillary blood or venous blood (venous: exclusively by medical professionals and EDTA anticoagulated)
Sample volume	About 3µl
Test time	5 ± 1 minutes
Result unit	NGSP %; IFCC mmol/mol; eAG mmol/L (mg/dL)
Working condition	Temperature: 10 - 40° C Humidity: 30% - 75% Atmospheric pressure: 700 hpa - 1060 hpa
Calibration	Calibrated by code chip and no extra calibration required during use.
Temperature cor-rection	Corrected automatically by the temperature sensor

Voice function	Voice prompt available during whole operation process
Data storage	1000
Port	Micro USB port
Wireless transmission	Bluetooth
Power supply	3.7V(⎓), lithium battery (rechargeable)
Battery life	Battery full-charge support = 800 tests (regular use)
Dimension (mm)	125 x 65 x 22 mm
Screen size	54.6 x 40.2 mm
Weight	98.0g
Storage and transportation condition	Temperature: -20 to 55°C Humidity: <80%; Atmospheric pressure: 700hpa - 1060hpa
Certifications	IFCC: Certified HbA1c Analysis System, traceable to the IFCC Reference Measurement Procedure. NGSP: Certified HbA1c Analysis System, traceable to the Diabetes Control and Complications Trial Reference method.

INDEX OF SYMBOLS

	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
	DATE OF MANUFACTURE
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
	DO NOT DISCARD WITH HOUSEHOLD GARBAGE
	FRAGILE, HANDLE WITH CARE
	KEEP AWAY FROM SUNLIGHT
	BIOLOGICAL RISKS
	BLUETOOTH
	USE BY
CODE	CODE NUMBER
REF	CATALOGUE NUMBER

	TEMPERATURE LIMITATION: -20 - 55°C
SN	SERIAL NUMBER
	UPSIDE
	KEEP DRY
	DO NOT REUSE
	SUFFICIENT FOR
	STORAGE HUMIDITY<80%
	CAUTION
CE 0197	CE CERTIFIED
IFCC certified	Certified HbA1c Analysis System, traceable to the IFCC Reference Measurement Procedure.
NGSP certified	Certified HbA1c Analysis System, traceable to the Diabetes Control and Complications Trial Reference method.

Manufacturing date: please refer to the package.

wellion®

BONA HbA1c ANALYZER

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W16-32EN 20220316

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THE MEDICAL SERVICES COMPANY

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CE 0197

IVD In Vitro Diagnostic Medical Device