wellion®

CLEVER HbA1c ANALYZER



MANUAL

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About this manual

Thank you for your purchase of Wellion® CLEVER 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 the related products. Also read the package insert of the test kits to be used for the planned test.

ANALYZER INTRODUCTON AND INSTALLATION

Intended use

Wellion CLEVER HbA1c analyzer is for use with the Wellion CLEVER HbA1c Test Kit to quantitatively measure the HbA1c in human capillary blood or venous blood.

This analyzer is intended for HbA1c measurement and monitoring performed by health-care professionals as clinical professionals or pharmacists. This analyzer is not applicable for the diagnosis of diabetes.

Testing principle

The Wellion CLEVER 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) bind to the negatively charged groups. When buffer B flows through and the pH turns alkaline, hemoglobin loses its positive charge and is released from the matrix. However, cis-diols of HbA1c glycohemoglobin still bind with the boronate group thus HbA1c 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 calculates the ratio of the HbA1c glycohemoglobin to the total hemoglobin.

This Wellion CLEVER HbA1c analysis system, using the boronate affinity chromatography method, is traceable to the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) 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 material. The accessories along with the analyzer include: power cord with removable plug, Type B-USB cable, User manual, Quick start guide, Cleaning and maintenance guide, one set of additional panels (one large and one small panel).

Note:

The analyzer is equipped with a rechargeable internal lithium battery DC 5.0V(⎓), 2A, $3.7^{+0.5}_{-0.1}$V(⎓), 3600mAh. Please use only the power adapter provided from the manufacturer. The usage of the wrong power adapter could lead to analyzer damage and fire hazard.

Installation

Please ensure the following conditions met before use:

- Dust-free without direct sunlight
- Working temperature is between 10 °C to 40 °C
- Horizontal platform without vibration
- Power source condition: 100–240V~, 10VA, 50–60Hz ± 1Hz.

Overview of Analyzer



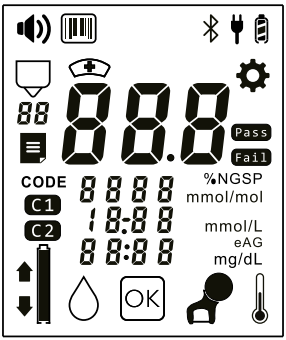
1	Display	2	Dust cover
3	⏻ Power button, ⚙ Setting button, ≪ Left button, ≫ Right button, OK OK button		
4	Buffer kit holder	5	Small & large panel
6	Sampler slot	7	Test strip slot



8	Code chip slot	9	Mini-USB interface (can be connected to external printer)
10	Type B USB interface (can be connected to PC)	11	RS232 interface (can be connected to barcode reader)
12	Power adapter interface		

Display of Analyzer

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



	Voice function symbol (Voice function ON/OFF)
	Setting mode symbol
	Operator ID symbol 1. Under data record mode, it indicates the sample has a corresponding operator ID input. 2. Under the standby mode, it indicates an operator ID has been input for the following tests.

	Patient ID symbol 1. Under data record mode, it indicates the data result has a corresponding patient ID input 2. Under the standby mode, it indicates a patient ID has been input for the next test.
	OK button symbol Signal for pressing OK button (blinking)
CODE	Code chip symbol (shown next to calibration code chip number) Blinking = no calibration code chip inserted
	Bluetooth symbol (Bluetooth ON/OFF)
	Temperature symbol When this symbol is ON, it indicates the number on the screen represents the current working temperature.
	Power plug symbol When this symbol is ON, it indicates the analyzer is connected to the external power source.
	Battery symbol Indicates battery charge status Here: full battery / low battery
	Data record mode symbol
	Sampler symbol When this symbol blinks, it signals that it`s time to apply the blood sample.

	**Buffer kit symbol** 1. When this symbol (without the number below) blinks, it indicates the analyzer is under buffer kit operation mode (installation or uninstallation). 2. When this symbol is normally ON, it indicates the analyzer is installed with a buffer kit. The number below indicates the remaining number of tests with the current installed buffer kit.
	**Blood drop symbol** When this symbol blinks, it signals that it`s time to prepare the blood sample (absorb the blood sample with the sampler-thread).
	**Test strip symbol** When this symbol blinks, it signals the user to insert the test strip or to remove the used test strip (upwards / downwards arrow).
mmol/L eAG mg/dL	**eAG (estimated average glucose) units**
%NGSP mmol/mol	**HbA1c units** % for NGSP, mmol/mol for IFCC
C1	**Quality Control Level 1**
C2	**Quality Control Level 2**
Pass	**Quality control test passed**
Fail	**Quality control test failed**

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 (e.g. non-shielded radio source).

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

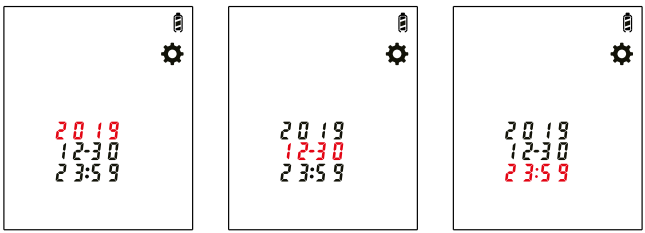
The analyzer has been tested and complies with the IEC/CISPR 11:2015+A1: 2016 for Class B equipment. The analyzer may cause some radio interference in a residential environment.

SETTING THE ANALYZER

The analyzer has factory settings with related parameters already set. User can use the analyzer directly or user can press the setting button to enter the setting mode to set related parameters. Setting mode can be entered in OFF or ON (standby) modus.

Date and time setting

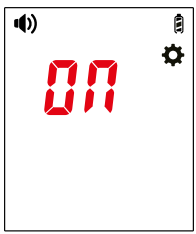
Press the setting button in OFF or standby mode to set year, month, day, hours and minutes respectively, press the LEFT button or the RIGHT button to adjust the parameter and press the OK button to go to the next setting parameter.



Voice function ON/OFF setting

Press the LEFT button ≪ or the RIGHT button ≫ to turn ON/OFF the voice function and press the OK button OK to confirm and enter the next setting parameter (language of the voice output).

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



Voice language setting

After Voice function ON/OFF setting, the language of the voice function can be selected. User can choose between 12 different languages including English, French, German, Greek, Italian, Portuguese, Slovenian, Slovak, Swedish, Bulgarian, Croatian and Czech. The default language of factory settings is English. Once one language was selected and confirmed, it will be the permanent operation language of the analyzer until user sets the language again. The languages will be displayed as abbreviations (alphabetic segment codes) and in the sequence as shown below:

No.	Language	Abbreviation and Display code
1	English	eng: 
2	French	fra: 
3	German	ger: 

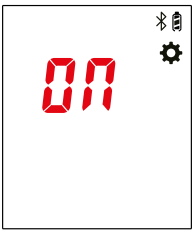
4	Greek	gre: 
5	Italian	ita: 
6	Portuguese	por: 
7	Slovenian	slo: 
8	Slovakian	svk: 

9	Swedish	swe: 
10	Bulgarian	bul: 
11	Croatian	cro: 
12	Czech	cze: 

By pressing the LEFT button ≪ or RIGHT button ≫ user can switch between the twelve languages, and confirm selected language by pressing the OK button OK.

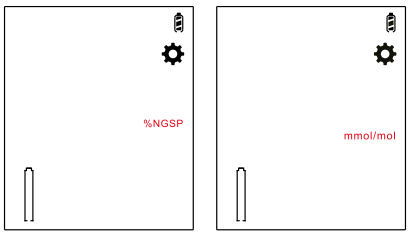
Bluetooth ON/OFF

Press the LEFT button ≪ or the RIGHT button ≫ to turn ON/OFF the Bluetooth function and press the OK button OK to confirm and enter the next setting parameter.

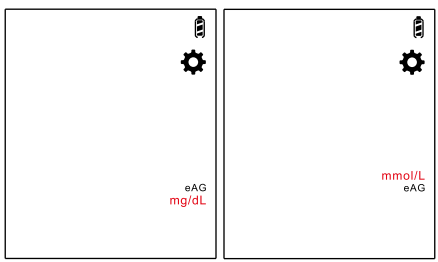


HbA1c and eAG units setting

The default main HbA1c unit of factory setting is % NGSP. Press the LEFT button ≪ or the RIGHT button ≫ to switch between % NGSP and mmol/mol IFCC units. Press the OK button OK to confirm and enter the next setting parameter.

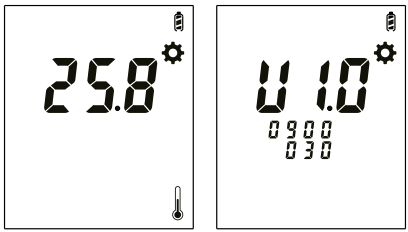


The default eAG (estimated average blood glucose) unit of factory setting is mg/dL. Press the LEFT button ≪ or the RIGHT button ≫ to switch between eAG unit mmol/L and mg/dL. Press then the OK button OK to go to the next setting parameter.



Display of working temperature and software version

After units setting is finished, the real-time working temperature and software version will be displayed in sequence by pressing the OK button OK.



After the display of the software version and the pressing of the OK button OK, the analyzer will display the "CODE" symbol and the corresponding calibration code chip number if a code chip is inserted. After about three seconds, the analyzer automatically enters the standby modus. If no buffer kit is installed, analyzer will prompt now for buffer kit installation by displaying the blinking buffer kit symbol and by voice output *"Please install the buffer kit"* (see section *"Buffer kit installation and rinse operation"*).

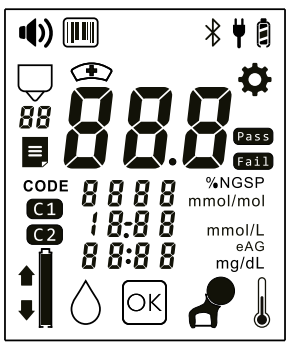
PERFORMING A TEST

Power on the analyzer

User can connect the analyzer to power source for power supply during use.

The analyzer is equipped with an internal lithium battery; when the analyzer is connected to the power source, the battery will be charged spontaneously. Fully charged battery can support about 100 tests.

Press the Power button ⏻ to turn ON the analyzer. All symbols on the screen will be displayed for a few seconds.



Buffer kit installation and rinse operation

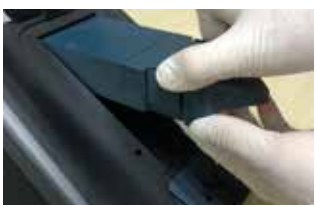
1. After powering on the analyzer, the buffer kit symbol will blink with voice prompt *"Please install the buffer kit"*. Uplift the dust cover and then the buffer kit holder, and install the buffer kit onto the holder. Then, take off the sealed cap on the buffer kit.



Uplift the buffer kit holder



Install the buffer kit onto the holder - I



Install the buffer kit onto the holder - II



Take off the sealed cap on the buffer kit

Important:

Make sure to take off the sealed cap on the buffer kit before the conduction of the rinse operation or before a test performance. Otherwise, test will be failed.

2. Rinse operation: After the buffer kit is installed on the buffer kit holder, the analyzer will prompt for the rinse operation step with the voice output *"Please take off the panels and insert the rinse card"*. Then, take off the small and large panel together and insert the rinse card in the right direction. Lay down the buffer kit holder and press the OK button OK according to the voice prompt *"Please press the OK button to start the buffer rinse"* to start the rinse process. Wait for around one minute till the rinse process is finished, and then remove the rinse card according to the voice prompt *"Buffer rinse completed, please remove the rinse card and install the panels back"*. After that, uplift the buffer kit and install the panels back, and then carefully push down the buffer kit for the following test operation.
   After the rinse operation, analyzer will directly enter the next functional step and prompt for the insertion of the calibration code chip (audible tone or voice prompt *"Please insert the correct code chip"*).



Take off the panels.



Insert the rinse card.



Lay down the buffer kit for rinse operation.



Remove the rinse card.



Install the panels back.

Note:

1. One rinse operation is required after installation of a new buffer kit. The rinse card is included in the test kit. The rinse card is disposable - Please do not keep it after the rinse operation is finished.
2. Newly installed buffer kit can support 25 tests.
3. If buffer kit is expired before 25 tests are conducted, please refer to the *"Buffer kit replacement"* section to uninstall the unconsumed buffer kit.
4. If no test is conducted following the rinse operation, please cover back the sealed cap onto the buffer kit to prevent buffer liquid from crystallization.

Insert the calibration code chip

After installation of a new buffer kit, remember to insert the calibration code chip packed with the corresponding HbA1c test kit.

The calibration code chip can be inserted in the OFF or ON modus. Whenever the analyzer is turned ON, there will be an initial prompt for the removal of the sealed cap before the code chip number is displayed (four striking audible tones or voice output *"Please take off the sealed cap on buffer kit before test"* accompanied by a blinking buffer kit symbol on display). After this, the calibration code chip insertion and code chip number confirmation is required, as described below.

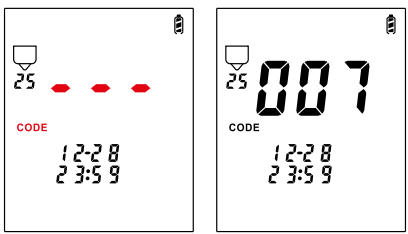
1. Take out the calibration code chip from the HbA1c test kit. Compare the code number of the chip with that imprinted on the vial of the test strips. If these two code numbers are inconsistent, please contact your local distributor.

2. Insert the calibration code chip into the code chip slot. The chip can be inserted in ON or OFF modus. When analyzer is ON, device will prompt with audible tone or voice output *"Please insert the correct code chip"*.



Insert the calibration code chip
into the code chip slot.

3. After calibration code chip is inserted, code number will be displayed on the screen. If voice function is ON, there will be a voice output *"Please confirm the code chip number is correct"* after insertion of the code chip. If the code number on the display is inconsistent with that one on the chip, please contact your local distributor.
   If no calibration code chip is inserted, "---" and "CODE" will be blinking on the analyzer screen and audible tones/voice function will prompt for correct code chip insertion (*"Please insert the correct code chip"*) every minute again. After five minutes without operation or code chip insertion, device will automatically turn off.



Barcode reader connection - Operator ID & Patient ID input

(optional - user can skip this step if not necessary)

Barcode reader is not included in this product and has to be purchased separately. If user purchases barcode reader on the market, please note that the barcode reader should meet the following specifications:

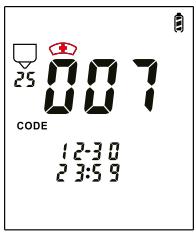
Interface type: RS-232
Power supply: 5V, 300mA
Scanning speed: 160 times/second
Target barcode: one dimensional code

Make sure the barcode reader is connected to the analyzer (if not, then turn OFF the analyzer and connect the barcode reader to the analyzer).

Operator ID input

(optional - user can skip this step if not necessary)

In the standby mode, long press the setting button ⚙ and then the analyzer will enter the operator ID-input mode with the Operator ID-symbol 👁 blinking on the screen.



Use the barcode reader to scan the operator ID barcode. Once the barcode is successfully scanned and detected by the analyzer, the barcode reader will give a *"beep"* sound with the Operator ID symbol 👁 continuously displayed on the analyzer screen. Then, press the OK button OK to exit the operator ID input-mode and to go back to the standby mode. The Operator ID symbol 👁 will continuously stay on the screen now, indicating that all following tests will be marked with this particular operator ID.

If user wants to change the operator ID, go to the operator ID input mode and scan a new ID barcode.

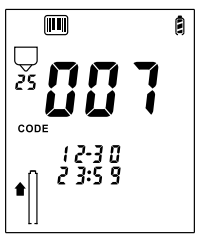
Note:

1. The scanned operator ID will not be displayed on the screen, and will only be shown on the printing report (compatible printer- or PC software-output).
2. Once the analyzer is OFF, the operator ID will get invalid, and the user needs to scan the operator ID again after powering on the analyzer next time.

Patient ID input

(optional - user can skip this step if not necessary)

Before one test is started (standby mode), scan the patient ID of the test sample with the barcode reader (not included). Once the barcode is successfully scanned and detected by the analyzer, the barcode reader will give a *"beep"* sound with the Patient ID symbol continuously displayed on the screen.



Note:

1. The scanned patient ID will not be displayed on the screen and will only be shown on the printing report

(compatible printer- or PC software- output) and only with the corresponding test result.

2. Once the testing process is initiated, it´s not possible to input a patient ID.
3. If the test procedure is stopped accidently, the user needs to scan the patient ID again before retesting the same sample.

Insert the test strip

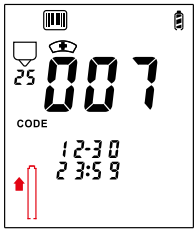
In the standby mode, the test strip symbol with upwards arrow blinks on the screen with the voice prompt *"Please insert the test strip"*. To start a test, take one test strip from the test strip vial, close the vial immediately afterwards, and insert the test strip into the test strip slot. Make sure that the arrow-imprinted side of the test strip is up and that the index line on the strip is horizontal to the bottom line of the large panel.



Insert the test strip.

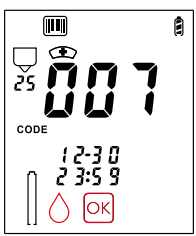
If the HbA1c test strip is not inserted or improperly inserted, the test strip symbol will unceasingly blink on the display, accompanied by four audible tones or the voice

output prompting for test strip insertion every minute.



Prepare the blood sample

When the analyzer detects that an appropriate test strip is inserted, the blood drop symbol and the OK button symbol are blinking on the screen, accompanied by audible tones / voice prompt *"Please prepare the blood sample, then press the OK button, and wait"*.



A. Collect a capillary blood sample

Tear sampler package, take out the sampler and put aside for ready. Collect the capillary blood sample - use the sampler to absorb the blood drop, wait until the cotton thread becomes fully red.

Notes:

- Patients hands and testing site on finger should be completely clean and dry - wash hands thoroughly with soap plus warm water and dry well before pricking the finger.
- Disinfection: Use medical alcohol swab or alcohol pad to disinfect the fingertip. Fingertip has to be completely dry and no alcohol or liquid shall remain on the skin.
- Usage of a safety lancet for pricking the fingertip is recommended.
- After pricking, gently massage your hand and finger towards the puncture site. Do not “milk” or squeeze around the puncture site.





B. Collect a venous blood sample

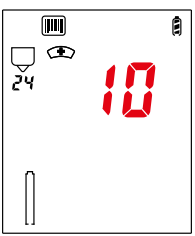
The venous blood sample should be collected and stored properly according to the standard venous blood collection procedures. Only use EDTA as anticoagulant. Make sure to have a homogenous sample in the sample tube before test (shake the tube properly before the test). Use a blood collector (not included) to get one drop of venous blood (~3 microliter) from the tube. Hold the blood collector (slot of the collector) to the thread of the blood sampler and let the thread absorb the blood sample until it becomes fully red.





Initiate the test

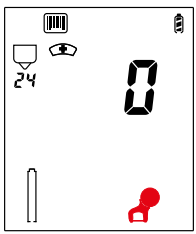
After the blood sample is collected, press the OK button (OK) to start the test procedure. Then, the test procedure will be initiated (vibrating sound) and a 10-second-countdown starts on the display. During this step, buffer A is added automatically.



Note:
Do not apply blood sample during the 10-second-countdown.

Apply the blood sample

After the 10-second-countdown, the analyzer will prompt for blood sample application by a blinking blood sampler symbol on the screen and by the voice output *"Please apply the blood sample"*.



Apply and hold the thread of the blood sampler to the sampler slot for three seconds (the analyzer will also give three striking audible tones *"Ding, Ding, Ding"* to prompt the user to hold for 3 seconds). A few seconds later, analyzer will enter into the countdown mode till the result is given.



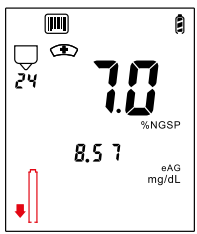
Apply the blood sample

Note:

1. If it is failed to apply the blood sample in time, the analyzer will give a striking sound and the voice output *"Failed to apply the blood sample in time" – "Please clean the light source area"*. Additionally, the error code number "E-7" is displayed on the screen. In this case, please use a cotton swab to absorb the buffer residual in the buffer port before removing the test strip, and repeat the test with a fresh blood sample.
2. There will be two rounds of countdown after the blood sample application, each round is around 130 seconds. Between these two rounds of countdown, there will be a short time interval without countdown, which is normal for this operational step. Please do not take any action during the interval.

Read the test result

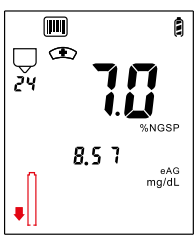
After the second countdown, the HbA1c result (in large letters) and the eAG will be displayed in the pre-set units (NGSP% or IFCC mmol/mol, eAG: mg/dL or mmol/L) with the voice output *"Please read the test result now on the display".*



Note:
In the data record mode, the result will also only be shown in the current preset unit form. For example, if the main HbA1c unit is %NGSP in the analyzer settings, all recorded results will also only be shown in %NGSP unit in the data record mode.

When the test is finished, remove the tested strip and discard the used test strip and accessories in proper containers, according to your standard laboratory procedures and local regulations.

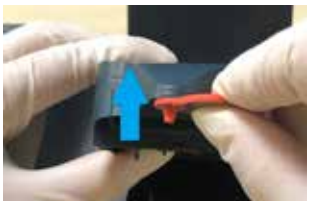
After test performance, the test strip symbol with the backwards-arrow will blink on display and the analyzer will prompt with the voice output *"Please remove the test strip"* for removal of the test strip.



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

Important:

1. If no further test is conducted, cover back the sealed cap on the buffer kit to prevent buffer liquid from crystallization.



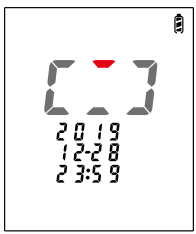
Cover back the sealed cap onto the buffer kit after use.

2. Before the analyzer turns OFF, it will prompt for the covering back the sealed cap onto the buffer kit with a blinking buffer kit symbol on the screen and the voice output *"Please cover back the sealed cap on buffer kit after use"*.

Buffer Kit Replacement

1. Replace the buffer kit after 25 tests

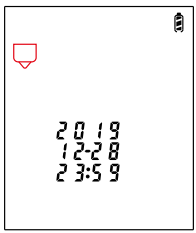
Each new test kit can support 25 tests. Once the 25th test is ended, the buffer kit will be unloaded and deinstalled from the buffer kit holder automatically with the voice prompt *"Please wait"*. This unloading procedure takes several seconds with the symbols "--" rotating on the screen and is accompanied by sound.



Note:

Do not conduct any operate during the unloading procedure.

After the buffer kit is unloaded from the holder, the buffer kit symbol ⛉ blinks on the screen with the voice prompt *"Please replace the buffer kit"*.



Then, user should disassemble the buffer kit from the holder, install a new buffer kit and conduct the rinse operation (please refer to the section above *"Buffer kit installation and rinse operation"*).



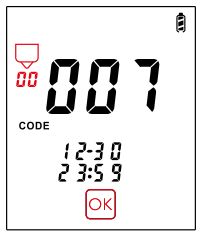
Disassemble the buffer kit from the holder

2. Replace the buffer kit before 25 tests

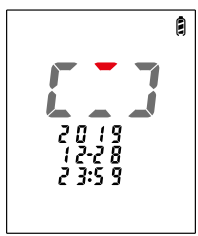
Under some special circumstances, if user wants to replace the buffer kit before 25 tests are used up, buffer kit deinstallation can be initiated through the user. For this

operation, please follow the instructions below:

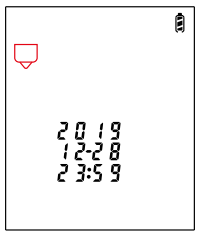
- In the stand-by mode, long-press the OK button (OK). Then, the buffer kit symbol and the OK button symbol (OK) will blink on the screen with the voice prompt *"Please confirm to replace the buffer kit, and press the OK button again"*.



- Press the OK button (OK) and then the analyzer will start to unload the buffer kit from the buffer kit holder with the voice prompt *"Please wait"* and with the symbols "--" rotating on the screen, accompanied by vibration sound.



- Several seconds later, the buffer kit symbol will blink on the screen with the voice prompt *"Please replace the buffer kit"*. Then, disassemble the buffer kit from the holder, install a new buffer kit and conduct the rinse operation (Please refer to the part above *"Buffer kit installation and rinse operation"*).



Note: Once a buffer kit is de-installed, it cannot be installed again for a second-time use. Please proceed with care.

MEMORY AND DATA MANAGEMENT

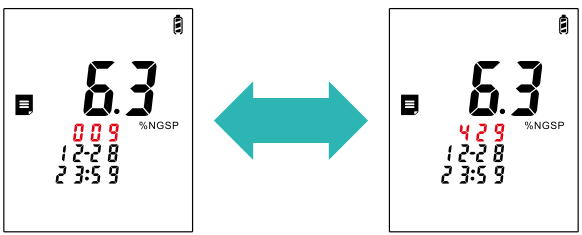
The analyzer can store 1000 HbA1c test results with information of number, date and time. When the memory reaches 1000 results, the oldest data will be replaced by the latest one.

Display the stored data

In the OFF or standby mode, press the LEFT button ≪ or the RIGHT button ≫ to enter the data record mode and view the test results. Press the LEFT button ≪ or the RIGHT button ≫ to switch between the results.

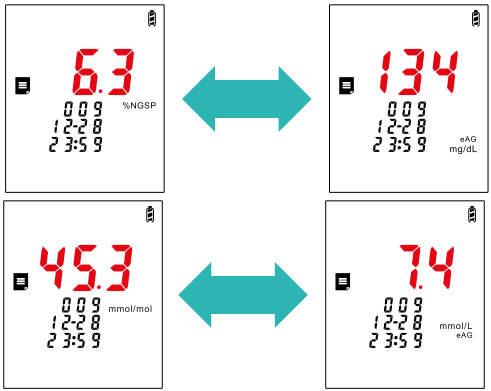
For each record, the

- Test number alternately switches between the daily test number and the number of total conducted tests



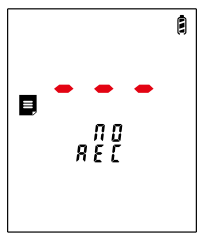
and the

- Test result value unit alternately switches between HbA1c unit (%NGSP or mmol/mol IFCC) and eAG (mg/dL or mmol/L).



To change the HbA1c or eAG unit output of the data record mode, user has to enter the setting mode and set the units accordingly.

If no data was recorded, in the data record mode "---" and "NO REC" will be displayed.



Press the Power button ⏻ to quit the data record mode.

Delete the stored data

1. Delete one record

Under the data record mode, select the test result and long press the RIGHT button ≫. Then, "dEL" and the test number among total tests will be displayed on the screen, with the voice prompt *"Memory delete mode enabled, proceed with care"*.



Select "YES" or "NO" by pressing the LEFT button ≪ or the RIGHT button ≫. Then, press the OK button OK to confirm the data deletion. If "YES" has been selected, the selected data will be deleted.

2. Delete all records

Under the power OFF mode, long press the RIGHT button ≫. Then, "dEL" and "ALL" will be displayed on the screen, with the voice prompt *"Memory delete mode enabled, proceed with care"*. Select "YES" or "NO" by pressing the LEFT button ≪ or the RIGHT button ≫ and, then, press the OK button OK to confirm. If "YES" has been selected, all data recorded will be deleted.



DATA TRANSFER

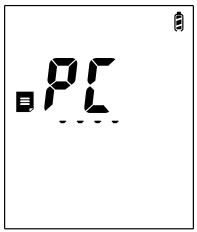
The data can be transferred to PC with corresponding software or mobile phone (if corresponding APP is available) by Bluetooth or type-B USB cable (only for PC). For supplementary data management service, please contact the manufacturer or service provider.

Note:
Open the corresponding software on PC or mobile phone APP (if available) before data transfer. Make sure to have a proper Bluetooth connection / USB cable connection before upload is initiated.

The following two methods are the active ways for data transfer, for which the command is sent from the analyzer.

1. Uploading a single data record

In the data record mode, long press the LEFT button ≪. Then, a "beep" will sound, indicating analyzer enters the single data record transfer mode and will start the data transfer, as shown in the screen illustration below.



If connection is in proper function, data upload will be started after the "beep" sound.

When transfer is finished, display will show as in the figure below:



2. Uploading all data records

In the data record mode, long press the LEFT button ≪ and the RIGHT button ≫ at the same time until hearing a "beep" sound. The analyzer will enter the "all data records transfer" mode and will start the data transfer. After successful upload of data, analyzer will turn OFF automatically.

LIS/HIS connectivity

The CLEVER HbA1c analyzer can be connected to a LIS (laboratory information system) or HIS (hospital information system) system for data management purpose. For detailed connectivity protocol, please contact the manufacturer or service provider.

PRINT (EXTERNAL THERMAL PRINTER)

Connection to Analyzer

The analyzer is compatible for an external thermal printer. The printer is not included in this product and can be purchased separately.

Note:

1. Please disable the Bluetooth connection of the HbA1c analyzer to other devices before using the printer, or the result will be printed as unreadable codes.
2. Make sure to correctly connect the printer cable (mini USB – mini USB cable, included in the printer set): Cable Interface A is for the printer and Interface B is for the CLEVER analyzer.

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. If operation was successful, a prompt tone is given and a blue blinking light appears. Adjust the printing paper properly.

If necessary, paper can be moved forward by pressing "F" button. Connect the compatible mini – mini USB cable of the external printer product (included in the printer set) with the USB-Interface "A" to the external thermal printer

and with the USB-Interface “B” to the printer port of the CLEVER HbA1c-Analyzer according to the labels “A” and “B” on the cable. Make sure not to interchange and misconnect the cable interfaces.

Printing the result

There are two options to print the test result:

- Directly after HbA1c-test performance: Printer is ON and connected. After conduction of the HbA1c-test, the test result will be printed automatically once the test is finished.
- Print stored data: Printer is ON and connected. Enter the data record mode and select the test result. Then, press the OK button of the analyzer to print the result.

QUALITY CONTROL

Quality control (QC) test

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

Why to do a quality control test

A Quality control test is used to check that the analyzer and the test kits are working together as a system and that the produced results are accurate.

Choose your quality control products

Only quality control products of MED TRUST can be used for the evaluation of this HbA1c-analyzing system. Error or incorrect result will be generated if other quality control products are used.

When to conduct a quality control test

Frequency and indications

Quality control test should always be performed according to your laboratory/institution`s quality assurance standards to ensure proper performance of the analysis system.

Additional indications for performing a quality control test are:

- When the strips vial was 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 was out of the permissive condition.
- When the analyzer has been dropped.
- When user doubts the test result.

Conduct a quality control test

1. Set the range of quality control product

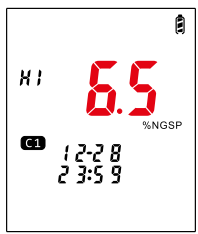
In the standby mode, long press the RIGHT button ≫ to enter the quality control range setting interface. Then, follow the instructions below to set lower and upper limit of both quality control levels. The sequence of the quality control limit-setting is: Level 1-lower limit, Level 1-upper limit, Level2-lower limit and Level2-upper limit. Press the LEFT button ≪ or the RIGHT button ≫ to set the limit and the OK button OK to confirm and go to the next Level-limit.

Note: The factory default ranges for the quality control (QC) are 4.3–6.5% for QC Level 1 and 7.8–11.6% for QC Level 2. User can adjust them according to the corresponding QC LOT. The valid **Control Range (%)** and **Target Value (%)** are provided on your quality control product.

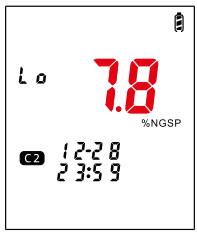
Set the lower limit value of Level 1 quality control. Press the LEFT button ≪ or the RIGHT button ≫ to adjust corresponding numerical value, and press the OK button OK to confirm and continue.



Set the upper limit value of Level 1 quality control. Press the LEFT button ≪ or the RIGHT button ≫ to adjust corresponding numerical value, and press the OK button OK to confirm and continue.



Set the lower limit value of Level 2 quality control. Press the LEFT button ≪ or the RIGHT button ≫ to adjust corresponding numerical value, and press the OK button OK to confirm and continue.



Set the upper limit value of Level 2 quality control. Press the LEFT button ≪ or the RIGHT button ≫ to adjust corresponding numerical value, and press the OK button OK to confirm and continue.

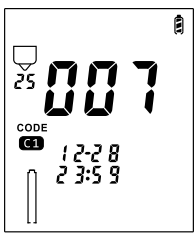


2. Enter the quality control testing mode and conduct the quality control test

On the standby mode, after insertion of the test strip, long press the LEFT button. Then, the Quality Control Level-1

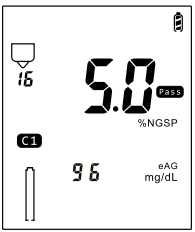
symbol "C1" will be displayed on the screen, indicating entering into the QC testing mode. Press the LEFT button ≪ or the RIGHT button ≫ to switch between "C1"-Level 1 and "C2"-Level 2 quality control level test, and, then, press the OK button OK to confirm and to start the quality control test.

The quality control test procedure is the same as the one of analyzing a capillary/venous human blood sample (see section *"Performing a test"*) except that the prepared quality control solution is applied to the blood sampler instead of the human blood sample. Additionally in the quality control testing mode, an adapted voice output will prompt the user to prepare the quality control sample with the voice prompt *"Please prepare the quality control, then press the OK button, and wait"* after test strip insertion; and to apply the quality control solution prompting *"Please apply the quality control"* after the 10-second-countdown.



3. Read the Quality control test result

The quality control test result will be marked with “C1”+ “Pass”, “C1” + “Fail”, “C2” + “Pass” or “C2” + “Fail”, respectively. The quality control test result will also be stored in the data record mode.



CLEANING AND MAINTENANCE

The accessories used for the analyzer must be obtained from the manufacturer of the device or authorized distributors, otherwise analyzer's performance might be affected. In order to continually ensure the accurate results, the analyzer should be regularly maintained and cleaned. Routine maintenance and cleaning should be performed according to the following instruction:

1. Power OFF the analyzer.
2. Lift up the buffer kit holder.
3. Disassemble the small and large panels from the analyzer according to the instruction shown below.



Disassemble the small and large panels



Disassemble the small panel from the large panel

4. Use a cotton swab dipped with distilled water (or 75% alcohol if necessary) to wipe both sides of panels as well as the light source area and its surrounding area. Ensure that components are properly dried.



Clean the surfaces of large panel



Clean the surfaces of small panel



Clean the light source area

5. After cleaning, reinstall the dried small and large panel back to the analyzer and lay down the buffer kit holder.

Note:

1. The sequence of panel's disassembly: first disassemble the large and small panel as a whole from the analyzer and, then, remove the small panel from the large panel.

2. Do not use organic solvents like gasoline, paint thinner or other solvents which may cause chemical damage to the analyzer.
3. Do not soak the analyzer in water or any other liquid.

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	Suggested solution	Voice prompt
Failed to power on	Battery was damaged or low battery power	Connect the analyzer to power source. Contact local distributor if error persists.	-
E-1	Hardware error	Contact local distributor.	-
E-2	Improper working temperature	Change testing environment to a proper one.	-
E-3	Improper blood sample applied or blood sample not properly applied.	1. Check if the blood sample has clotted, if yes, re-test with a fresh blood sample. 2. Check if the blood sample on sampler thread is enough, please ensure the cotton thread on the sampler becomes fully red. 3. Re-test of a fresh blood sample is recommended.	-

E-4	Buffer kit is not properly installed	Re-install the buffer kit.	-
E-5	Communication fault	Contact local distributor.	-
E-6	Buffer A not detected	1. Check if the sealed cap is removed. 2. Clean the small/ large panel and the light source area. 3. Re-test with a new test strip.	*"Failed to apply Buffer A in time" – "Please clean the light source area".*
E-7	Delay in applying the blood sample	1. Use a cotton swab to absorb residual buffer in the buffer port (hole in the small panel), clean the small/ large panel and clean the light source area. 2. Re-test with a new test strip and apply the blood sample timely.	*"Failed to apply the blood sample in time" – "Please clean the light source area".*
E-8	Buffer B not detected	1. Use a cotton swab to absorb residual buffer in the buffer port (hole of the small panel), clean the small/ large panel and clean light source area. 2. Re-test with a new test strip and apply the blood sample timely.	*"Failed to apply Buffer B in time" – "Please clean the light source area".*
E-9	Code chip used more than 25 times	Please replace the code chip when using a new test kit. Only use the calibration code chip provided in the corresponding test kit.	-

	Low battery power	Connect the analyzer to the power source and charge the battery	*"Please charge up the battery".*
	Test result is higher than the measurement range of the analyzer	Re-test. If the result still shows 'HI', take appropriate medical measures.	*"The result is too high".*
	Test result is lower than the measurement range of the analyzer	Re-test. If the result still shows 'Lo', take appropriate medical measures.	*"The result is too low".*

PRECAUTIONS AND LIMITATIONS

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

Any object that comes in contact with human blood is a potential source of infection (See Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Third Edition; CLSI document M29-A3, 2005). During the test, the analyzer itself will be in contact with blood, therefore, the analyzer has the risk of infection. When the analyzer is used in the medical field, the medical staff should follow the infection control procedures, such as wearing gloves or other personal protection.

This analyzer and the related components are for in-vitro diagnostic professional use only. 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 an environment with 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. Please use only finger capillary blood sample or EDTA-anticoagulated venous blood sample.

Do not use 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, falling into the water or if liquid got splashed into the analyzer.

Do not use this analyzer under direct sunlight.

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 any liquids.

This analyzer must be handled with care. During transportation, avoid intensive and violent vibration. It is strictly prohibited to roll or place heavy objects on the analyzer. Avoid transporting the analyzer in high temperature or humidity. Refer to the "INDEX OF SYMBOLS" for a better understanding.

Disposal of 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 product is not in direct contact with the test part of the human body. Under this condition 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 the Wellion CLEVER 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 chromatography
Target	HbA1c Glycated hemoglobin
Measurement range, NGSP: Measurement range, IFCC:	4.0% – 14.0% 20 mmol/mol – 130 mmol/mol
Sample requirement	Capillary blood or venous blood (EDTA anticoagulated)
Sample volume	About 3µL
Test time	~5 minutes
Result unit	NGSP %; IFCC mmol/mol; eAG: mmol/L; mg/dL
Working conditions Temperature: Humidity: Atmospheric pressure:	 10 °C to 40 °C 30% – 75% 700 hpa – 1060 hpa
Calibration	Calibrated by code chip and no extra calibration required in during use.
Temperature correction	Corrected automatically by the integrated temperature sensor.
Voice function, languages	Voice function available during whole operation process Languages: English, French, German, Greek, Italian, Portuguese, Slovenian, Slovak, Swedish, Bulgarian, Croatian, Czech
Data storage	1000
Ports	RS232 / Type-B USB / Mini USB / DC5V,2A
Wireless transmission	Bluetooth

Power supply Adapter input: Adapter output: Internal lithium battery (rechargeable):	 100–240V~, 10VA, 50–60Hz±1Hz DC 5.0V(⎓), 2A $3.7^{+0.5}_{-0.1}$V(⎓), 3600mAh
Full-charge battery support	About 100 tests
Dimension	250±5mm ×195±5mm × 100±5mm
Screen size	94±3mm × 80±3mm
Weight	1.2±0.2 kg
Storage and transportation condition Temperature: Humidity: Atmospheric pressure:	 -20 °C to 55 °C <80% 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 to -55°C
SN	SERIAL NUMBER
	UPSIDE
	KEEP DRY

	DO NOT REUSE
	SUFFICIENT FOR
	STORAGE HUMIDITY<80%
	CAUTION
	Certified HbA1c Analysis System, traceable to the IFCC Reference Measurement Procedure.
	Certified HbA1c Analysis System, traceable to the Diabetes Control and Complications Trial Reference method.

wellion®

CLEVER HbA1c ANALYZER

MED TRUST
THE MEDICAL SERVICES COMPANY

AUSTRIA

MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
AUSTRIA
www.medtrust.at

CE

IVD In Vitro Diagnostic Medical Device

W17-32EN RevA / 2020-10

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