CE 0123 IVD

REF Q-3

qLabs® ElectroMeter

User's Manual
For Self-Testing Use

MICROPOINT

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1 Introduction

1.1 Before You Start

Before using the qLabs® ElectroMeter to test Prothrombin Time (PT) and International Normalized Ratio (INR), read the entire User's Manual carefully.

1.2 Intended Use

The qLabs® PT-INR monitoring system is used for quantitative measurement of Prothrombin Time in fresh, capillary whole blood samples. The qLabs® PT-INR monitoring system is intended for in vitro diagnostics and is not intended to be used for screening purposes.

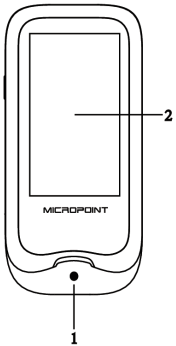
1.3 Test Principle

The qLabs® PT-INR monitoring system consists of the qLabs® ElectroMeter and Prothrombin Time (PT)-International Normalized Ratio (INR) test strips. The qLabs® ElectroMeter automatically detects the insertion of a qLabs® PT-INR test strip and heats the strip to a preset operating temperature. When a drop of blood is added to the sample well of the strip, the blood flows through the test channels to two reaction zones: a Test Zone and a Control Zone. In these zones the blood reacts with pre-printed reagents and begins to coagulate. Each reaction zone contains a pair of electrodes to which a constant voltage is applied by the qLabs® ElectroMeter. As the coagulation of the blood proceeds, the current monitored across the two electrodes changes. The qLabs® ElectroMeter detects the change of the current and determines the PT and INR results.

1.4 Packaging

The qLabs® ElectroMeter is packed individually.
Upon receiving the package, please open and remove the packaging materials. Place the qLabs® ElectroMeter on a flat surface and connect the power adapter.
Do not keep the qLabs® ElectroMeter in direct sunlight, near a high heat source, or near an area with a strong magnetic field.

2 Product Overview



Front View
1.Test Strip Guide
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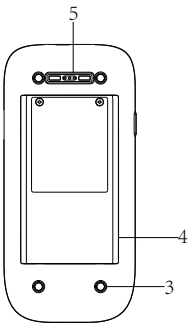

Back View
3.Footpad
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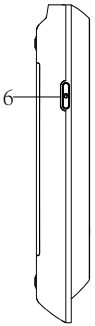
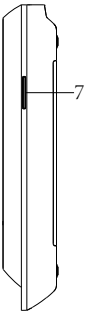
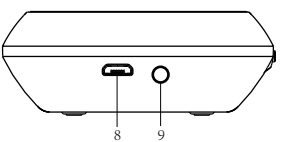


Left View
6.Power Button



Right View
7. Codechip Slot



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8.Data Port
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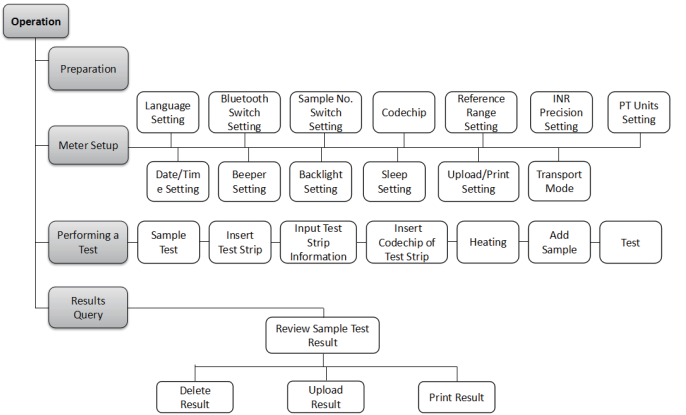
3 Operation Summary



4 Before Testing

Before using the qLabs® monitoring system to do a test, you will need:

- qLabs® PT-INR Test Strips
- Power supply
- Puncture proof container

Testing fingerstick blood sample:

- Alcohol Pads and Gauze
- Lancet Device

5 Precautions, Limitations and Warnings

The qLabs® PT-INR monitoring system is intended for in vitro diagnostics use only. Before using this system to test PT and INR, take special note of CAUTIONS throughout this User's Manual.

5.1 Care of Your qLabs® ElectroMeter

- The qLabs® ElectroMeter is a delicate instrument and should be handled with care. Dropping or other mishandling may cause malfunction of the qLabs® ElectroMeter.
- The qLabs® ElectroMeter should be transported in a carrying case or a secure container.
- DO NOT spill any liquid on the qLabs® ElectroMeter. If this should occur, immediately contact your local distributor from Micropoint Biotechnologies Co., Ltd.
- DO NOT store the qLabs® ElectroMeter below -10 ºC or above 40 ºC.
- DO NOT use the qLabs® ElectroMeter for any other types of test strips not provided by Micropoint Biotechnologies Co., Ltd.
- This instrument should be used in an environment free from high-frequency vibrations.
- When connecting the power supply of the instrument or any other external power, care should be taken to avoid electric shock.
- When the instrument is turned on for the first time, the battery must be fully charged.
- Make sure the instrument is fully charged before testing, or the system will indicate that the battery is running low.

  Do not perform other operation during the test.
- Do not disassemble the instrument.

5.2 Patient Health Status

Current patient health status may cause inaccurate or unexpected test results. It is important to take certain health factors into consideration when interpreting the test results and deciding on a course of action for your patients. Failure to do so may lead to an incorrect interpretation of the PT-INR result.

5.3 Performing a Test

- The qLabs® ElectroMeter should be operated on a level surface that is free of vibration. Testing on an uneven or unstable surface may cause inaccurate results. DO NOT hold the qLabs® ElectroMeter in your hands during the testing.
- Strictly follow the test procedure specified in the manual to perform the test.
- DO NOT move or touch the qLabs® ElectroMeter during testing.
- Do not use expired or damaged test strips.
- The blood sample must be applied to the test strip immediately after collection. Otherwise, the blood sample may begin clotting, causing inaccurate results.
- Do not add the sample until the system prompts you to start adding sample.
- The sample should be added in one continuous operation, do not reapply additional sample.
- Do not use the instrument for unintended purposes, which may cause unexpected test results.
- Use the correct sample to perform the test, failure to do so may cause inaccurate result.
- Do not use the test results to diagnose unintended conditions.
- Do not use the test results for unstated clinical purposes.

5.4 Collecting a Fingerstick Blood Sample

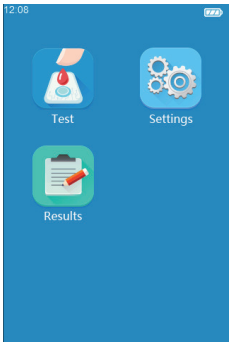
- Sanitize the site of the fingerstick with alcohol wipe before testing.
- Use a fresh capillary fingerstick blood sample for testing.
- Squeezing the fingerstick site excessively (milking) may release interstitial fluid into the blood sample, which may lead to inaccurate results.
- The site of the fingerstick must be completely dry. If any alcohol remains on the finger, it may cause hemolysis, which may lead to inaccurate results.

5.5 Electromagnetic Compatibility

- This equipment has been tested and found to comply with applicable EMC emission requirements as specified in EN 61326-1: 2013 and EN 61326-2-6: 2013, immunity to electrostatic discharge as specified in IEC 61000-4-2, and immunity to radio-frequency interference at the frequency range and test levels specified in IEC 61000-4-3. The emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.
- Do not use this instrument in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment. This may cause incorrect operation or damage to the device. The recommended humidity operating range for qLabs® ElectroMeter is 10% to 90%.
- Do not use this instrument near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the instrument.

6 Power On/Off

6.1 Power On



(2-1)

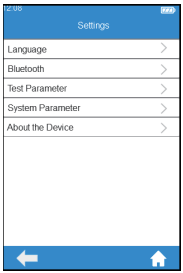
Turn on this instrument by pressing and holding the Power button for 1 second, and enter the main menu screen (Figure 2-1). When the instrument is turned on for the first time, the battery must be fully charged. If the battery is running low, please don't turn on the instrument until the power adapter provided with the instrument is inserted into the power jack and connected to the external power supply. If the instrument is in sleep mode, just press and hold the Power button for 1 second or insert a test strip to wake it up.

6.2 Power Off

Press and hold the Power button for 1 second to turn it off.
If auto sleep function is enabled, the meter will automatically shut down after the idle time reaches the sleep waiting time.
When the battery power of the meter is exhausted, it will automatically shut down.

7 Settings

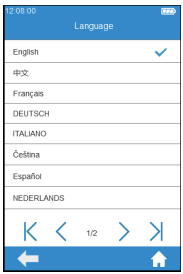
7.1 Enter Settings Screen



(3-1)

Click the "Settings" icon from the main menu screen (Figure 2-1) to enter the Settings screen (Figure 3-1).

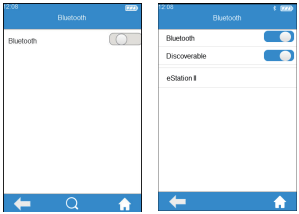
7.2 Language



(3-2)

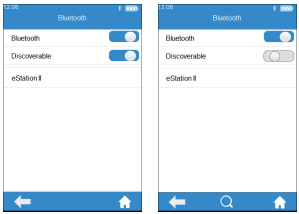
Click "Language" from the Settings screen (Figure 3-1) to enter the screen that prompts the user to select a language (Figure 3-2). The user can select different language by touching the desired one. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

7.3 Bluetooth



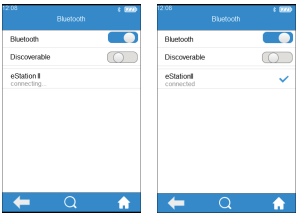
(3-3)

Click “Bluetooth” from Settings menu (see figure3-1) to enter the Bluetooth menu (see figure 3-3). When the Bluetooth button is displayed in blue, it means Bluetooth is turned on; when the Bluetooth button is grayed out, it means Bluetooth is turned off. Once Bluetooth is turned on and connected successfully, the Bluetooth icon on the upper right corner of the menu is highlighted. However, if Bluetooth is turned on but fails to connect, the Bluetooth icon is grayed out. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.



(3-4)

"Detectable" option pops up automatically when Bluetooth is set to On. When "Detectable" option is displayed in blue, it means Detectable Mode is opened, and the meter can be searched by other Bluetooth devices. However, the meter cannot search other Bluetooth devices actively in the mode. If "Detectable" option is grayed out, it means Detectable Mode is closed.



(3-5)

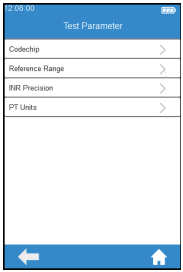
When Bluetooth is set to On and Detectable Mode is closed, the meter automatically searches for the connectable base. Touch one of the bases in the search result list after completing the search, the screen then displays “connecting...”, and the meter displays "connected" after the connection is completed. Touch " Q " to manually search for the connectable Bluetooth devices. Touch the connected Bluetooth device, and the system prompts whether to disconnect, then touch OK to disconnect the current connection.

Bluetooth can be used to connect the meter to eStation II and a specific mobile APP. Once connected to eStation II, the test results can be transferred to eStation II for printing. The test results can also be transferred to DMS, LIS or HIS system via eStation II. After connecting with a specific mobile APP, Micropoint cloud can be accessed to upgrade and maintain the meter’s software when necessary.

(3-6)

When Bluetooth is disconnected or failed to connect during operation, the system pops up a box and prompts the user to reconnect. In such case, please turn on Bluetooth again and then reconnect.

7.4 Test Parameter



(3-7)

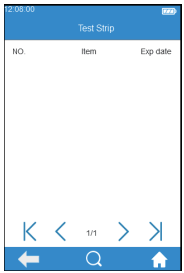
Click "Test Parameter" from the Setting screen (Figure 3-1) to enter the screen (Figure 3-7) that prompts the user to set the parameters.

7.4.1 Sample No.

(3-8)

Click "Sample No." from the Test Parameter screen (Figure 3-7) to enter the screen (Figure 3-8) that prompts the user to set the sample No. If the sample No. button is grayed out, then the sample does not need to be numbered. If the sample No. button is blue, the sample can be numbered manually or automatically. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

7.4.2 Codechip



(3-9)

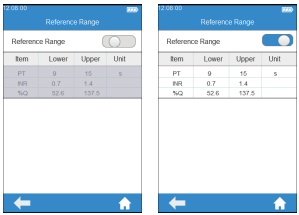
Click "Codechip" from the Test Parameter screen (Figure 3-7) to enter the screen (Figure 3-9) that shows the Codechip information. The user can view the information of the test strip. A new strip Codechip can also be installed by inserting the strip Codechip into the Codechip slot (see the right figure on P5). Please make sure the side with the arrow is facing up and the Codechip is inserted into the end. If the Codechip has not been installed, the Codechip is automatically installed into the meter and displayed in the list. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

In addition to being installed from Codechip menu, a Codechip can also be installed during the test. When testing with a test strip or control with a Codechip installed, the installation operation is no longer required during the test; otherwise, the system enter the prompt menu which enables the user to install the desired Codechip accordingly.

The Codechip provides the meter with important information that it needs to perform the coagulation test. The chip contains information about the test strip code, the lot number, and the expiration date. The Codechip is required, whenever a new test strip lot is used, so that the meter can read and store the lot information about that particular lot of test strips.

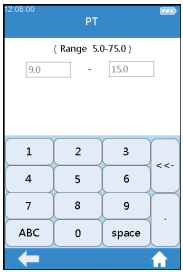
- Do not forget to use the test strip Codechip that is supplied with each pack of test strips before you perform the first test with these strips. We recommend that you leave the Codechip in the meter to protect the electrical contacts in the meter from becoming dirty.
- Each Codechip belongs to a particular lot of test strips. Only remove the Codechip when you are testing with test strips taken from a new pack.
- Protect the Codechip from moisture and equipment that produces magnetic fields.

7.4.3 Reference Range



(3-10)

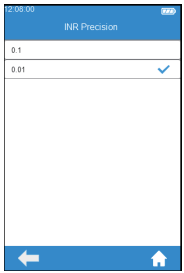
Click "Reference Range" from Test Parameter screen (Figure 3-7) to enter the screen (Figure 3-10) that prompts the user to set the reference range switch. Grey button indicates the reference range function is disabled and blue button indicates the reference range is enabled.



(3-11)

Click any value in the Reference Range table to automatically enter the menu which allow the user to modify the value, and the user can re-modify the upper and lower limits (see figure 3-11) within the given setting range. After the value range is modified, if the test result is below the lower limit, "↓" then displays in the result menu; if the test result is above the upper limit, "↑" then displays. Touch "✓" to return to the previous menu.

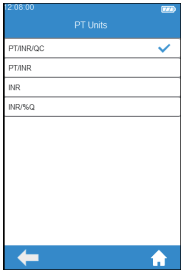
7.4.4 INR Precision



(3-12)

Click "INR Precision" from Test Parameter menu (see figure 3-7) to enter the INR Precision menu (see figure 3-12). The INR accuracy displayed can be set as needed. When 0.1 is selected, the INR value is displayed as one decimal place. When 0.01 is selected, the INR value is displayed as two decimal places. Click "←" to return to the previous screen and click " ⌂ " to return to the main menu.

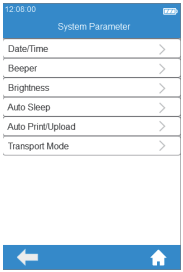
7.4.5 PT Units



(3-13)

Click “PT Units” from Test Parameter menu (see figure 3-7) to enter the PT Units menu (see figure 3-13). The display format of the PT test result can be set as required. The available display formats are: PT/INR/QC, PT/INR, INR, INR/%Q. After selecting a format, PT test result is displayed accordingly. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

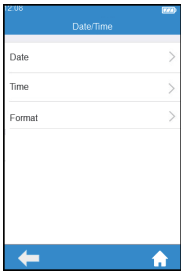
7.5 System Parameter



(3-14)

Click "System Parameter" from the Settings screen (Figure 3-1) to enter the screen (Figure 3-14) that prompts the user to set the system parameter. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

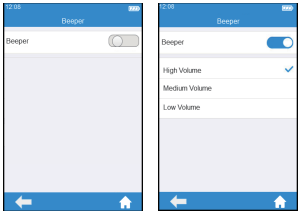
7.5.1 Date/Time



(3-15)

Click "Date/Time" from the System Parameter screen (Figure 3-14) to enter the screen (Figure 3-15) that prompts the user to set the date and time. The user can set the date, time, and even their display format respectively. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

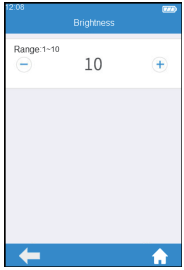
7.5.2 Beeper



(3-16)

Click "Beeper" from the System Parameter screen (Figure 3-14) to enter the screen (Figure 3-16) that prompts the user to set the beeper. The beeper is turned off when the beeper button is grayed out.The beeper is turned on when the beeper button is blue, and the user can set different volume: high, medium and low. After the beeper is turned on, it will “beep” in any of the following circumstance: the instrument is turned on, the test strip is inserted successfully, the heating is completed, the sample is added, the test is completed, and the instrument enters sleep mode.

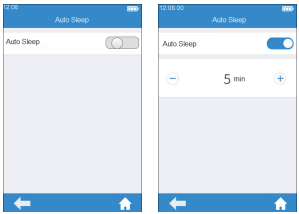
7.5.3 Brightness Adjustment



(3-17)

Click "Brightness" from the System Parameter screen (Figure 3-14) to enter the brightness adjustment screen (Figure 3-17). The adjustment range is between 1 and 10. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

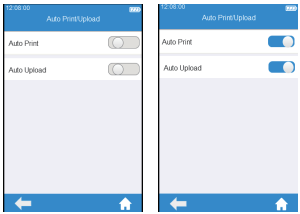
7.5.4 Sleep Setting



(3-18)

Click "Auto Sleep" from the System Parameter screen (Figure 3-14) to enter the sleep setting screen (Figure 3-18). The auto sleep function is turned off when the button is grayed out.The auto sleep function is turned on when the button is blue, and the user can set the idle time value before the instrument enters auto sleep mode.Insert the test strip or re-power the instrument to wake it up from the sleep mode.

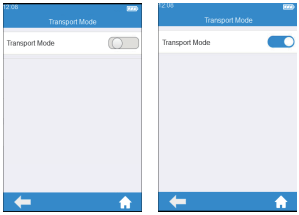
7.5.5 Print and Upload



(3-19)

Click "Auto Print/Upload" from the System Parameter screen (Figure 3-14) to enter the print upload setting screen (Figure 3-19). The auto print/upload function is disabled when the button is grayed out. The auto/print upload function is enabled when the button is blue. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

7.5.6 Transport Mode



(3-20)

Click “Transport Mode” from System Parameter menu (see figure 3-14) to enter Transport Mode menu (see figure 3-20). When the button is in blue, Transport Mode is turned on; when the button is grayed out, Transport Mode is turned off. Transport Mode is set to On by default to extend the storage period of the battery. When using the meter for the first time, please connect the external power supply, and the transport mode then turns off automatically after booting. After Transport Mode is turned on and the power is turned off, the system time will be reset. Please set the correct system time after the next boot. Click "⬅" to return to the previous screen and click " 🏠 " to return to the main menu.

7.6 About the Device

(3-21)

Click "About the Device" from Settings screen (Figure 3-1) to enter the screen that displays the system information (Figure 3-21). The user can check the version and log information. Click "⬅" to return to the previous screen and click " 🏠 "to return to the main menu.

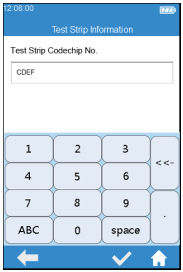
8 Sample Test

8.1 Insert a Test Strip

(4-1)

Enter the strip insertion screen, then insert the test strip in the direction shown in Figure 4-1. Keep inserting the strip from the right direction until the sample well on it is align with the dot on the instrument. If the test strip is already inserted, please skip the strip insertion screen and enter the next screen to input the test strip information.

8.2 Input Test Strip Information



(4-2)

After the test strip is inserted, please enter the test strip information screen (Figure 4-2), and input the Codechip number of the test strip, then click "✓" to save. The package of the test strip bears the Codechip number of the test strip. The Codechip number of the test strip must be input, or the system will deliver a warning message indicating that the input is invalid when you click Save.

8.3 Install Codechip

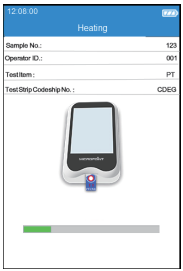
(4-3)

Insert the test strip Codechip into the chip slot (see Section 1.3 for position details), then the specific Codechip information will display (Figure 4-3).

When the input Codechip number of the test strip does not match the Codechip information, the system will deliver a warning message indicating that the Codechip information does not match.

When the input Codechip number of the test strip has expired, the system will deliver a warning message indicating that the Codechip has expired.

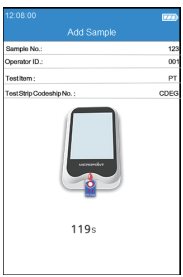
8.4 Heating



(4-4)

After the test strip is inserted and its Codechip is installed, the instrument will enter the heating state, and the screen will display the heating progress (Figure 4-4).

8.5 Add Sample



(4-5)

The system will count down and prompt the user to add sample (Figure 4-5) upon the completion of heating, and the sample must be added within 120 seconds. Do not move the instrument or your fingers during sample adding. If the sample is not added properly within 120 seconds, the system will deliver an error message indicating sample adding is timeout.

8.5.1 Getting a Fingerstick Sample

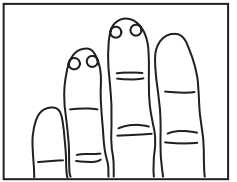
Proper fingerstick technique is beneficial to both the professional user and the patient. A proper fingerstick will ensure minimal discomfort for the patient and accurate test results for the user. Please sanitize the site of the fingerstick with alcohol wipe before testing.

1. Maximize Blood Circulation

1) If needed, briefly warm the hand in warm water or with a

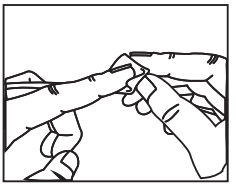
heating pad.

2) Massage the finger with a downward motion several times before performing the fingerstick.
3) Lower the hand to below the heart level when collecting the blood drop.

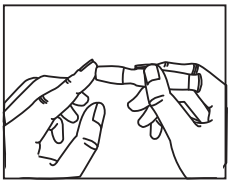


2. Identify a site on the finger to puncture

1) On one of the middle fingers of either hand.
2) Near the top of the finger on either side.
3) Away from any calluses or scars.



3. Clean the selected area with 70% isopropyl alcohol, or an alcohol pad. Dry thoroughly with cotton or gauze.



4. Puncture the finger following the instructions for the lancet that you are using.

5. Apply gentle, continuous pressure until a large, hanging drop of blood forms.

6. Add blood sample. Apply the blood directly on the sample well of the strip. The minimum sample volume is 10 μL.

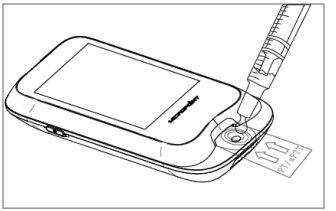
8.6.2 Collect fresh venous whole blood samples

1. Clean the venipuncture site with alcohol and allow it to air-dry

completely.

2. Collect > 0.1 mL of venous blood into 1.0mL syringe.

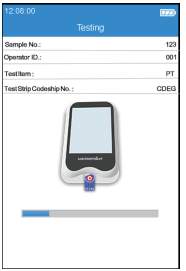
3. Discard the first four drops of blood collected. Then immediately apply one drop of blood (at least 10 μL) directly onto the strip for testing.



NOTES:

Do not exceed 30 seconds from venipuncture to adding blood sample.

8.6 Perform a Test

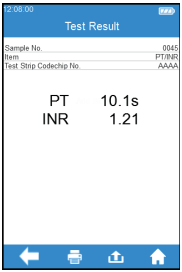


(4-6)

After the sample is added properly, the system will start the test automatically and display the test progress (Figure 4-6). Do not perform other operations during testing.

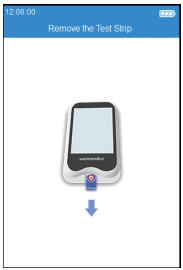
8.7 Test Results

Please check the strip insert for the results and explanation.



(4-7)

The system will display the test results after the test is completed (Figure 4-7). The test results can be printed or uploaded, provided that the instrument is properly connected to the printer or server. When the result is out of the normal range, the system will prompt that the result is ↑ (high) or ↓ (low).



(4-8)

If the test strip has not been removed after the test is completed, please click " ⌂ " from the test result screen to go to the strip removal screen (Figure 4-8), and remove the test strip in the direction shown in the figure. If the test strip is removed from the test result screen after the test is finished, the screen will directly jump to the Main screen.

9 Quality Control

The qLabs® ElectroMeter also measures the clotting time in the Quality Control (QC) zone. If the QC result fails to fall within a predetermined range, the qLabs® ElectroMeter will display an error code rather than give a possible erroneous PT-INR result.

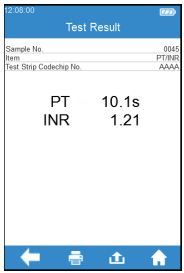
This safety measure guards the user against situations in which the qLabs® PT-INR Test strip may have been subjected to very high temperatures or humidity (which could happen if the foil pouch is torn or punctured).

10 Results

When the storage amount of the sample result reaches 80% of the total amount of the meter, the user will be prompted to upload data. If the user does not upload the data, the sample results will automatically overwrite the oldest records after the total amount exceeds the limit.

(5-1)

Click the "Result" icon from the main menu screen (Figure 2-1) to enter the result query screen (Figure 5-1).If there are multiple test results, please scroll through the display for all results. Click " 🗑 " in the test result screen to clear all test results.



(5-2)

To view the detailed test result information (Figure 5-1), please click a result from the test result query screen (Figure 5-2), information can be uploaded, printed or deleted separately. You can also delete the test result information individually.

11 Maintenance

11.1 Care and Cleaning of Your qLabs® ElectroMeter

Follow these steps for cleaning the qLabs® ElectroMeter:

11.1.1 Cleaning Frequency

1. Clean the meter after every patient and when there are signs of visible soil and/or organic material prior to disinfecting. soil and/ or organic material prior to disinfecting. Also follow any facility disinfection SOPs.
2. The exterior of the meter and test strip guide area should be cleaned and disinfected before being used between each patient.
3. The exterior of the meter and test strip guide area should be cleaned and disinfected if too much blood (> 20 uL) has been applied to the strip in the case of sampling the same patient.
4. Disinfect the meter when it is soiled, and per your facility's guidelines.
5. Routine cleaning should be performed a minimum of once a month when the meter is in regular use or per any facility SOP.

11.1.2 Areas to be cleaned and/or disinfected

1. The area around the test strip insert port
2. The meter display
3. The meter housing (front and back)
4. The button area on the face of the meter

11.1.3 Precautions to avoid moisture

1. Make sure that no liquid enters the meter. If moisture enters the meter it may cause a malfunction of the meter.
    1.1. Ensure the meter is turned off
    1.2. Never spray anything onto the meter
    1.3. Never immerse the meter in liquid
    1.4. Do not use cloths or swabs that are saturated. Remove any excess solution before wiping the surface of the meter.

11.1.4 Recommended cleaning/disinfecting solutions

1. Disposable wipes containing a quaternary ammonium compound up to 0.5% (single compound or mixture) in isopropyl alcohol up to 55%.
2. Do not use other disinfectants or cleaning solutions on the meter.
3. Recommended cleaning cloths are listed in table 1
4. The button area on the face of the meter

Table 1. Recommended Cleaning cloths.

Name	Disinfectant	Size
PDI SaniCloth Plus®	Quaternary/low-alcohol formula (14.85% IPA).	8" x 14", or 6" x 6.75
Cavi Wipes®	Quaternary/low-alcohol formula (17.2% IPA).	9” x 12 ", or 6” x 6.75"

11.1.5 Cleaning and disinfecting the meter housing

1. Use the recommended cloth in table 1 to clean and disinfect the meter exterior.
2. Remember to apply the solutions and allow a contact time of 2 minutes.
3. Turn the meter off.
4. Pre-clean: Using a clean cloth, gently remove any gross debris and wipe the entire surface of the meter.
5. Disinfecting: Using a new cloth, gently wipe the meter housing surfaces. Wipe the entire meter housing including the LCD screen, sample, and button areas.
   5.1. Wipe the meter twice top to bottom, then twice left to right. With the cleaning cloth in the palm of your hand, hold the meter with the LCD screen side up (battery side on the cloth) and wipe the meter twice top to bottom, then left to right. Wipe each of the sides of the meter twice from top to bottom then from left to right.
   5.2. Next wipe the sample area in an up and down motion, and repeat. Do not insert or press the cloth into the Test Strip Guide, Data Port or Power Supply Jack areas.
   5.3. Do not let liquid accumulate near any opening, make sure no

liquid enters the meter.
5.4. Leave meter “wet” for 2 minutes or the recommended time.

5.5. With a fresh dry cloth (like a **Kimwipe®**) remove any residual moisture.
5.6. Once the meter is dried with the Kimwipe it is ready for use.

11.1.6 Visually verify that no residual moisture is on the meter or sample area.

11.2 Precautions for Lithium-ion Battery

When the instrument is turned on for the first time, the battery must be fully charged.
Fully charge the meter prior to storage or extended non-usage.
For storage greater than three months, recommend recharge every three months to avoid battery capacity discharge and decay.

11.3 Servicing

No user serviceable components. All service and adjustment must be performed by Micropoint Biotechnologies Co., Ltd

12 Troubleshooting

When you receive an error code, please retest. If you receive a second error code, then contact your local distributor and test the patient with a laboratory method. Do not interpret an error code as a patient result in any case.

ERROR CODE	DESCRIPTION	CORRECTIVE ACTIONS
E001	Low battery.	Please use power adapter or the base as a power source.
E002	Heating has timed out.	Please adjust the ambient temperature to 10 °C ~ 35 °C, and turn off the meter for 5 minutes, then turn on the meter and restart the test. If the problem recurs, please contact the relevant technical staff.
E003	The ambient temperature is too high or too low.	Please ensure that the meter is used in an environment of 10 ° C ~ 35 ° C.
E004	The added sample is insufficient.	Please retest with a new test strip and ensure that the added blood is sufficient for the test.
E005	Internal QC failed.	Please use an unexpired test strip and enter the correct test strip Codechip number.
E006	External QC failed.	Please ensure that the test strip and control are within the expiry period, and enter the correct test strip Codechip number and control Codechip number.
E007.x	PT calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

ERROR CODE	DESCRIPTION	CORRECTIVE ACTIONS
E009	The sample may not suitable for qLabs testing.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E010	The operation of sample adding has timed out.	Make sure the sample adding is completed before the end of the countdown.
E011	The sample is added too early or the strip is a used one.	Please use the new test strip to re-test and add the sample after the meter prompts the user to add sample.
E012	APTT calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E013	The strip is defective or the sample is added improperly.	Please retest with a new test strip and add the sample strictly as specified in the insert.
E014	The HCT of the sample is out of range.	Please ensure that the HCT value of the sample is between 30% and 55%.
E015	Bluetooth error.	Please turn off the meter and reboot it. If the problem recurs, please contact the relevant technical staff.
E016	FIB calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.
E017	TT calculation error.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

ERROR CODE	DESCRIPTION	CORRECTIVE ACTIONS
E018	The strip is placed improperly.	Do not remove the test strip during the test.
E019	The temperature of the meter is too high.	Please adjust the ambient temperature to 10 °C ~ 35 °C, and turn off the meter for 5 minutes, then turn on the meter and restart the test. If the problem recurs, please contact the relevant technical staff.
E031	The strip is inserted inversely.	Make sure the test strip is facing up before inserting it into the meter.
E032	Print error.	Make sure that the meter is properly communicating with the base and that printing paper at the base is installed correctly and that there is sufficient paper.
E033	Codechip reading error.	Please unplug the Codechip and reinsert it, and make sure the Codechip is inserted in place. If the problem recurs, please contact the relevant technical staff.
NO COAG	No sample coagulation is detected.	Please retest with a new test strip. If the problem recurs, please contact your local dealer and use the laboratory method to perform the test.

13 Symbols

SYMBOLS	EXPLANATION	SYMBOLS	EXPLANATION
IVD	In Vitro Diagnostics		Expiry Date
	Caution. Read Carefully		Fragile
	Keep Dry		Biological Risk
	Separate Collection		DO Not Reuse
	Temperature Limitation		Manufacturer
EC REP	Authorized Representative in the European Community		Consult Instructions For Use
REF	Catalogue Number	SN	Serial Number
CE 0123	CE Marking	LOT	Lot Number

14 Operating Condition and Product Specifications

14.1 Operating Condition

Temperature	10ºC ~ 35ºC / 50ºF ~ 95ºF
Humidity	10% ~ 90% (No condensation)
Maximum altitude	4300 m (14,000 feet)

14.2 Product Specifications

Processor	32-bit ARM Cortex-M4
Display	320mm×480mm LCD
Touch screen	Capacitive touch screen
Power	External power supply: 100-240V~50/60Hz±5Hz, 0.4A Max Internal power supply: DC3.7V (lithium polymer)
Size	148mm×70mm×26mm (L×W×H)
Weight	199g
Warranty	2 years

15 Special storage conditions and methods

Storage environment temperature: -10 °C ~ +40 °C; relative humidity 10%~90%.

16 Warranty

Use of the qLabs® ElectroMeter

The qLabs® ElectroMeter (the "Meter") is designed for use in monitoring patients on oral anticoagulant therapy. Proper adherence to the instructions in the User's Manual and package insert is critical to proper operation.

WARNING: Failure to comply with the user manual could lead to inaccurate results and incorrect medication dosing which could result in injury or death.

Limited Warranty

Micropoint Biotechnologies Co., Ltd. guarantees to the original purchaser of the Meter that the Meter is free from material defects in material and workmanship for two years from the date of purchase. This warranty does not guarantee the uninterrupted operation of the meter.

Micropoint Biotechnologies Co., Ltd.'s only liability and purchaser's only remedy under this warranty is that during the warranty period Micropoint Biotechnologies Co., Ltd. shall replace or repair, at no charge, any Meter component with defects in material or workmanship. MICROPOINT BIOTECHNOLOGIES CO., LTD. MAKES NO OTHER WARRANTIES AND EXPRESSLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR USE.

Tampering with any other portion of the Meter, abusing the Meter or using the Meter in a manner inconsistent with its user manual will void this warranty. This warranty does not apply to any component that is damaged by improper storage or accident or that is subject to alteration, misuse, tampering or abuse. Before returning any defective components, you must obtain a "Return Material Authorization" number and return instructions from Micropoint Biotechnologies Co., Ltd. Technical Support

by emailing customerservice@micropointbio.com or calling +86 755 86296766.

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qLabs®

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P/N 630-00172 Rev. A2 2019-10