

element COAG+

Veterinary Analyzer Product Manual



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1. Introduction

1.1 Before Starting

Before using the Element COAG+ Analyzer, carefully read the Product Manual as well as the package inserts for all relevant consumables.

1.2 Intended Use

The Element COAG+ Analyzer system, which consists of Element COAG+ Test Strips, is intended for quantitative determination of Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) in fresh venous blood and citrated whole blood. The Element COAG+ Analyzer is only for veterinary use in cat, dog and other animals.

1.3 Test Principle


The Element COAG+ Analyzer automatically detects the insertion of a test strip and heats the strip to a preset operating temperature. After a drop of blood is applied to the strip, the sample channel automatically carries the blood sample into the reaction zone through capillary action, where the blood mixes with pre-printed reagent and starts coagulation process. As the blood coagulates, conductivity across the test strip changes. The system measures this electrical change and calculates the development of a clot. The values are then displayed.

1.4 Packaging

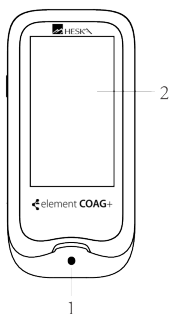
The Element COAG+ Analyzer is packed individually. Upon receipt of the device, please open and remove the packaging materials, then place the Element COAG+ Analyzer on a flat surface and connect the power adapter to make it ready for testing.

Do not keep the Element COAG+ Analyzer in direct sunlight, near a high heat source, or near an area with a strong magnetic field.

If you find any damage that may be caused by transportation, please inform Heska's Technical Support Services.

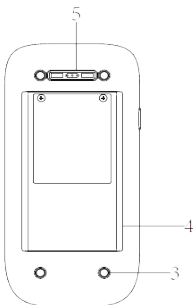
Please pay attention to content where the symbol “” appears in the manual.

2. Product Overview



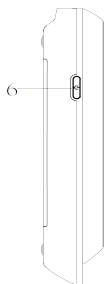
Front View

- 1. Test Strip Guide
- 2. Touchscreen

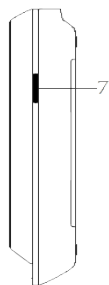


Back View

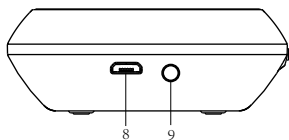
- 3. Footpad
- 4. Battery Cover with Label
- 5. Magnetic Charging Port



Left View
6. Power Button

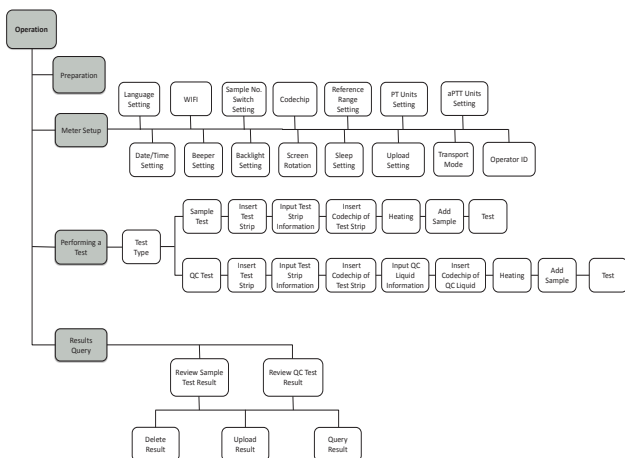


Right View
7. Codechip Strip Slot



Top View
8. Micro USB Data Port
9. DC 5V Power Supply Jack

3. Operation Summary



4. Before Testing

Materials provided:

- Element COAG+ Analyzer
- Power supply
- USB disk (Manual)

Materials required (but not provided):

- Element COAG+ Analyzer test strip
- Puncture-resistant container for medical sharps
- Sterile alcohol
- Disposable gloves

Testing fresh venous blood samples:

- 21-gauge needle or larger and syringe
- Sterile band aid

Testing citrated whole blood samples:

- Element COAG+ Re-Calcification Reagent
- 100 μ L pipette and pipette tips
- 1.8 or 2.7 mL 3.2% (w/v) sodium citrate venous collection tube

5. Precautions, Limitations and Warnings



The Element COAG+ Analyzer is for in vitro diagnostic use only. Some environmental factors and incorrect operation may cause the Element COAG+ Analyzer to not work effectively or to report inaccurate results. Please read the following warnings carefully before use and strictly follow them.

As with all diagnostic tests, Element COAG+ Analyzer's test results should be analyzed and interpreted by combining the condition, medical history, current and possible treatment of a specific animal. Any results exhibiting inconsistency with the clinical status should be repeated or supplemented with additional test data or repeated with other testing methods.

5.1 Element COAG+™ Analyzer Care

- DO NOT spill any liquid on the Element COAG+ Analyzer. In this case, immediately contact Heska's Technical Support Services.
- The Element COAG+ Analyzer is a delicate instrument and should be handled with care. Dropping or mishandling may cause malfunction of Element COAG+ Analyzer.
- The Element COAG+ Analyzer should be transported in a carrying case or a secure container.
- DO NOT store the Element COAG+ Analyzer below 14°F or above 104°F (-10°C or above 40°C).
- DO NOT use the Element COAG+ Analyzer with any other test strips not provided by Heska.

5.2 Test Environment Requirements

- The temperature should be maintained between 50°F-95°F (10°C and 35°C).
- This equipment has been tested and found to comply with applicable EMC emission requirements as specified in EN 55032. 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 static discharges in a dry environment. That may cause incorrect operation or damage to the device. The recommended humidity operating range is 10% to 90%.

- Do not use this instrument near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the instrument.

5.3 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 test result.

5.4 Performing a Test

- The analyzer should be placed on a level surface that is free of vibration. Testing on an uneven or unstable surface may cause inaccurate results. DO NOT hold the analyzer 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 analyzer during testing.
- After inserting the test strip, please confirm the codechip. Failure to do so may cause inaccurate test result.
- Do not add the sample until the system prompts you to start adding sample.
- When using fresh whole blood, the blood sample must be applied to the test strip immediately after collection. Otherwise, the blood sample may begin clotting and cause inaccurate results.
- The sample should be added in one continuous operation; do not reapply additional sample.
- Do not use the device for unintended purposes, failure to do so may cause unexpected test results.

5.5 Collecting Sample

- Use fresh venous whole blood and citrated whole blood. Do not use plasma.
- The drop of blood must be a minimum of 10 μ L.

5.6 Warning Information on Built-In Lithium Battery

- The Element COAG+ has a built-in lithium battery, which cannot be removed by any user.
- The user must use the matching 5V special charger provided by Heska to charge.
- Do not bring the analyzer close to a high-temperature heat source.
- Do not allow the analyzer to be hit or exert heavy pressure on the analyzer.
- If it is found that there is leakage from the battery cover on the back of the analyzer, direct skin contact should be avoided as much as possible. In case of accidental contact with skin due to battery leakage, please rinse with water. If your eyes come into contact with battery liquid, you should also seek medical care.
- The battery should be disposed of with the analyzer in accordance with local regulations.

6. Power ON/OFF

6.1 Battery and Charging

When turning on the analyzer for the first time after unpacking, please connect the adapter for power supply and turn off the transportation mode. You do not need to repeat this operation for subsequent reboot.

Ensure the analyzer is fully charged (Approximately 3.5 hours to fully charge) before using for the first time.

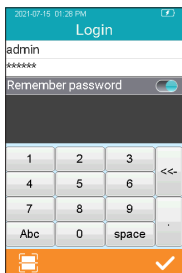
When the screen displays E001, the adapter should be connected immediately for charging. If the battery charge display shows only one bar, it is recommended that the user connect the power adapter to charge as soon as possible.

When the analyzer automatically shuts down due to insufficient power, the user should charge the analyzer within 7 days. Otherwise the time and date will require a reset.

The test results and all settings of the analyzer will be permanently stored in the memory except the time and date.

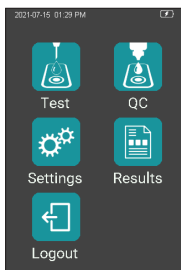
6.2 Power ON

When the instrument is turned on for the first time, the battery must be fully charged. If the battery is low, do not turn the instrument on 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 power off mode, short press the Power button and wait 2 seconds to power on. If the instrument is in sleep mode, short press the Power button or insert a test strip and wait 2 seconds to wake it up.



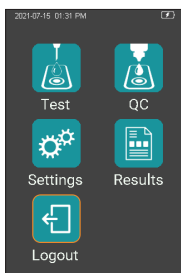
If Operator ID is set to On, the analyzer automatically enters Operator ID menu (Figure 1-1) after it is turned on. Manually input Operator ID and Password or obtain by scanning (The default Operator ID is "**admin**" and **all must be lower case**. The default password is "**123456**".) and touch "✓" to enter main menu.

Please set Operator ID function according to Section 7.7 of this manual.



1-2

Once Operator ID is On, the Log out icon in main screen will be enabled and displayed in teal (Figure 1-2). To switch between operators, please return to the screen for inputting the Operator ID by pressing the Log out icon, and then re-enter the Operator ID.



1-3

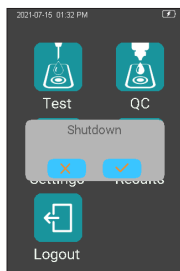
If Operator ID is Off, the Log Out icon on main screen will be disabled and displayed in teal with orange frame (Figure 1-3), and the analyzer will return to main screen after it is turned on.

6.3 Sleep Mode

After a short press and release of the Power button, the screen will be off and enter sleep mode. The sleep mode is a low power mode to save battery power. Short press the Power button or insert a test strip and wait 2 seconds for device start-up.

If auto sleep function is enabled, the analyzer will automatically shut down after the allotted idle time.

6.4 Power OFF



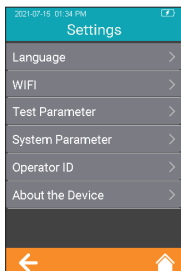
1-4

After depressing the Power button for 3 seconds, the system will deliver a message. Press "✓" to power off the instrument, or press "✗" to cancel the operation (Figure 1-4).

When the battery power of the analyzer is exhausted, it will automatically shut down.

7. Settings

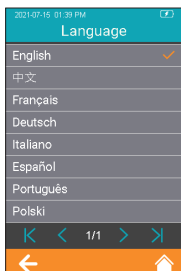
7.1 Enter Settings Screen



2-1

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

7.2 Language

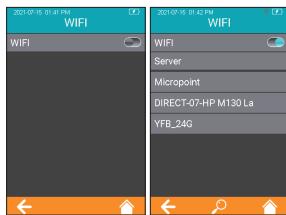


2-2

Click "Language" from the Settings screen (Figure 2-1) to view and select a language (Figure 2-2). Click "←" to return to the previous screen and click "🏠" to return to the main menu.

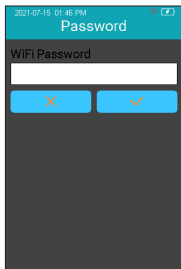
7.3 WIFI

WIFI connectivity allows the analyzer to connect with Practice Information Management Software (PIMS) and can be used for data transmission.



2-3

Click "WIFI" from Settings menu (Figure 2-1) to enter the WIFI menu (Figure 2-3). When the WIFI button is displayed in teal, it means WIFI is turned on; when the WIFI button is grayed out, it means WIFI is turned off. Once WIFI is turned on and connected successfully, the WIFI icon on the upper right corner of the menu is highlighted. However, if WIFI is turned on but fails to connect, the WIFI icon is grayed out. Click "←" to return to the previous screen and click "🏠" to return to the main menu.



2-4

The system will search for nearby hotspots and list automatically. Click the hotspot name to enter the password to connect successfully. The system will remember the password and connect to the last connected hotspot automatically.

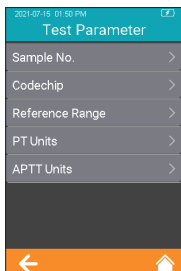


2-5

The server is used for wireless data transmission with the specific Practice Information Management Software. Click “Server” to enter the server IP address and port number, and click “✓” to save. Set the instrument’s IP address and port number to be consistent with PIMS.

The loss of signal or access to bandwidth of one particular client may vary depending on one or more of the following situations: the type and number of other clients, the performance of the Access Point, the presence of electromagnetic disturbances, and other potential interfering factors, e.g., concrete walls.

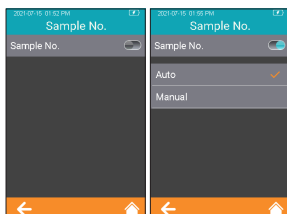
7.4 Test Parameter



2-6

Click "Test Parameter" from the Settings screen (Figure 2-1) to set the parameters (Figure 2-6).

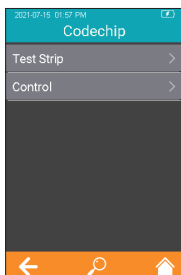
7.4.1 Sample No.



2-7

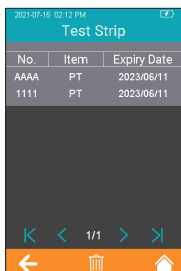
From the Test Parameter screen (Figure 2-6), click Sample No. to set the Sample number (Figure 2-7). If the Sample No. button is grayed out, then the sample does not need to be numbered. If the Sample No. button is teal, the sample can be numbered manually or automatically. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

7.4.2 Codechip Strip



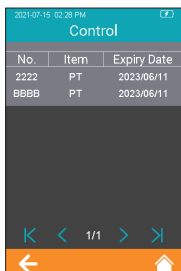
2-8

Click "Codechip" from Test Parameter menu (Figure 2-6) to enter Codechip menu (Figure 2-8). Touch "Q" to search and view the corresponding Codechip information displayed based on the search criteria. Click "←" to return to the previous screen and click "🏠" to return to the main menu.



2-9

Click "Test Strip" from Codechip menu (Figure 2-8) to enter Test Strip menu (Figure 2-9). The Codechip information of the installed strip is displayed in this menu. A new strip Codechip can also be installed by inserting the strip Codechip into the Codechip slot (See the right figure in Section 2 Product Overview). Please make sure the side with the arrow is facing up and the Codechip is inserted completely. If the Codechip has not been installed, the Codechip should be manually entered into the analyzer and displayed in the list. Click "←" to return to the previous screen and click "🏠" to return to the main menu.



2-10

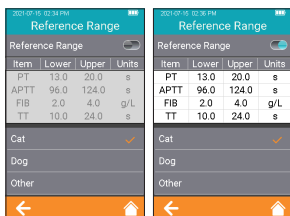
Click "Control" from Codechip menu (Figure 2-8) to enter Control menu (Figure 2-10). The Codechip information of the installed control is then displayed in this menu. A new control Codechip can also be installed by inserting the control Codechip into the Codechip slot (See the right figure on Section 2 Product Overview). Please make sure the side with the arrow is facing up and the Codechip is inserted completely. If the Codechip has not been installed, the Codechip should be manually entered into the analyzer and displayed in the list. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

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

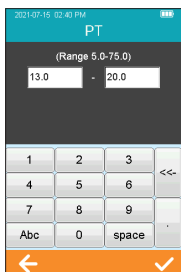
The Codechip provides the analyzer with important information to perform the coagulation test. The chip contains information about the test strip code, the lot number, and the expiration date. The Codechip is required, whenever a new test strip lot is used, so that the analyzer can read and store the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

- Do not forget to load 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 analyzer to protect the electrical contacts in the analyzer 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



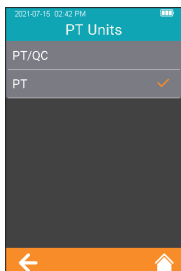
Click "Reference Range" from Test Parameter screen (Figure 2-6) to enter the screen (Figure 2-11) that prompts the user to set the reference range switch. Gray button indicates the reference range function is disabled and teal button indicates the reference range is enabled.



2-12

Click any value in the Reference Range table to automatically enter the menu which allows the user to modify the value, and the user can re-modify the upper and lower limits (Figure 2-12) within the given setting range. After the value range is modified, if the test result is below the lower limit, a popup will prompt, "Illegal Input". Click "←" to return to the previous screen.

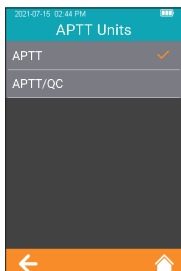
7.4.4 PT Units



2-13

Click "PT Units" from Test Parameter menu (Figure 2-6) to enter the PT Units menu (Figure 2-13). Default format is PT. The display format of the PT test result can be set as required. The available display formats are: PT/QC and PT. 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.

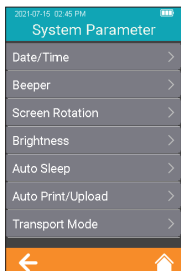
7.4.5 aPTT Units



2-14

Click "APTT Units" from Test Parameter menu (Figure 2-6) to enter the APTT Units menu (Figure 2-14). Default format is APTT. The display format of the APTT test result can be set as required. The available display formats are: APTT and APTT/QC. After selecting a format, APTT test result is displayed accordingly. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

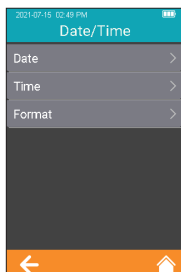
7.5 System Parameter



2-15

Click "System Parameter" from the Settings screen (Figure 2-1) to enter the screen (Figure 2-15) that prompts the user to set the system parameters. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

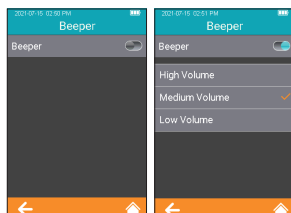
7.5.1 Date/Time



2-16

Click "Date/Time" from the System Parameter screen (Figure 2-15) to enter the screen (Figure 2-16) 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.

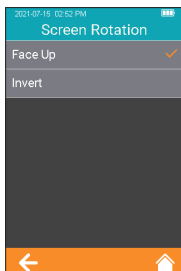
7.5.2 Beeper



2-17

Click "Beeper" from the System Parameter screen (Figure 2-15) to enter the screen (Figure 2-17) 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 teal, and the user can set different volumes: high, medium and low. After the beeper is turned on, it will "beep" in any of the following circumstances: the instrument is turned on, the test strip is inserted successfully, scan is performed successfully, the heating is completed, the sample is added, the test is completed, and the instrument enters sleep mode.

7.5.3 Screen Rotation



2-18

Press "Screen Rotation" from the System Parameter screen (Figure 2-15) to enter the screen for selecting screen rotation (Figure 2-18). Change the settings and rotate the screen for 180°, then the text direction is adjusted automatically. The test strip is inserted from the lower part by default. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

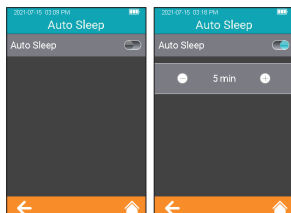
7.5.4 Brightness Adjustment



2-19

Click "Brightness" from the System Parameter screen (Figure 2-15) to enter the brightness adjustment screen (Figure 2-19). The adjustment range is between 1 and 10. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

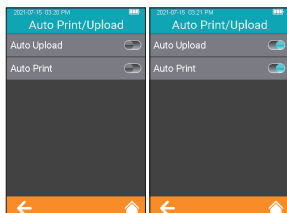
7.5.5 Sleep Setting



2-20

Click "Auto Sleep" from the System Parameter screen (Figure 2-15) to enter the Sleep Setting screen (Figure 2-20). The Auto Sleep function is turned off when the button is grayed out. The Auto Sleep function is turned on when the button is teal, 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.

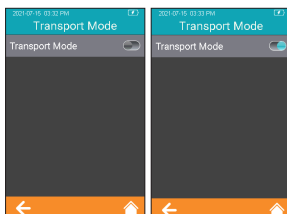
7.5.6 Auto Upload



2-21

Click "Auto Print/Upload" from the System Parameter screen (Figure 2-15) to enter the print/upload setting screen (Figure 2-21). The Auto Upload function is disabled when the button is grayed out. The Auto Upload function is enabled when the button is teal. Click "←" to return to the previous screen and click "🏠" to return to the main menu. Auto Upload function can be worked when the analyzer is connected to PIMS software.

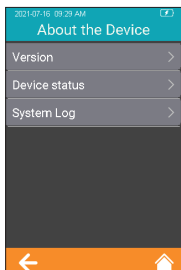
7.5.7 Transport Mode



2-22

Click "Transport Mode" from System Parameter menu (Figure 2-15) to enter Transport Mode menu (Figure 2-22). When the button is teal, 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 analyzer for the first time, please connect the external power supply, and the transport mode then turns off automatically. After Transport Mode is turned on and the power is turned off, the system time will be reset. Please set the correct system time during the next reboot. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

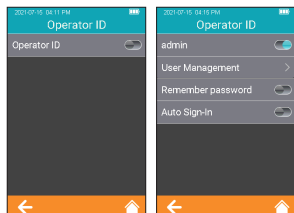
7.6 About the Device



2-23

Click "About the Device" from Settings screen (Figure 2-1) to enter the screen that displays the system information (Figure 2-23). The user can check the version and log information. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

7.7 Operator ID

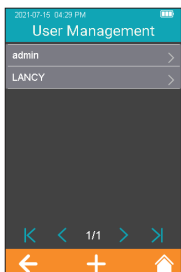


2-24

Touch "Operator ID" from Settings screen (Figure 2-1) to enter the screen for setting the Operator ID (Figure 2-24). The operator ID is enabled when displayed in teal and it is disabled when displayed in gray. There is no limit on operator ID under the status of "Disabled". Touch "←" to return to the previous screen, and touch "🏠" to return to the main menu.

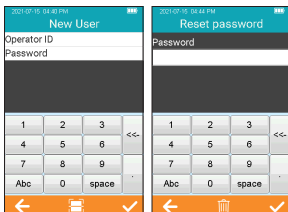
When Operator ID is enabled, use the Administrator account "**admin**" (**all lower case**), and input administrator password. The initial password is "**123456**".

Administrator account is allowed to create and manage accounts, and set all function of Operator ID. The analyzer can remember the password. After the function is enabled, the user can check, "Remember Password" checkbox to save the password. Automatic login is also supported. Once the function is enabled, the user can automatically login with the last used account number and password.



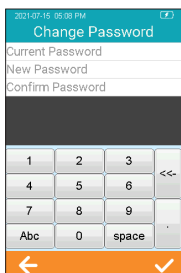
2-25

After touching "User Management" from the Operator ID screen (Figure 2-24), the administrator can enter the screen and view the created user list (Figure 2-25). To create a new user account, please touch "+" at the bottom of the screen. The number of user accounts should not exceed 50. If the upper limit is exceeded, "Maximum number of account exceeded" will be prompted. An account must be removed before creating a new account. The historical results of the old account will be retained. The character length of the operator ID and password is between 1 and 16 digits. The Operator ID can be input manually or by scanning the barcode or QR code.



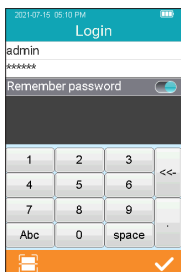
2-26

The password reset screen will appear when the administrator touches the created account (Figure 2-26). The password of an user account can be reset from the screen, please touch "✓" to save the settings after the password is reset. The user account can be removed by touching the "🗑️" at the bottom of the password reset screen (Figure 2-26). Users can only change the passwords of their own accounts.



2-27

To change the password, the user needs to provide the current password, the new password, and confirm the new password (Figure 2-27). If a user forgets their password, contact the administrator to reset the user password. If the administrator forgets the password, please contact Heska's Technical Support Services.

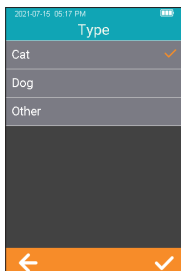


2-28

The user can log in to any existing account from the Login screen. Enter the correct password and log into the screen to perform the relevant operation. After entering the ID and password, please touch “✓”. If it is prompted that the user does not exist, or the password is incorrect, please use the administrator account to log in and create a new account to reset the password.

8. Sample Test

8.1 Choosing Test Type



3-1

In the Test Type interface, select the test type. The available test types include: cat, dog and other. Click "←" to return to the previous screen and click "🏠" to return to the main menu.

8.2 Input Sample No.

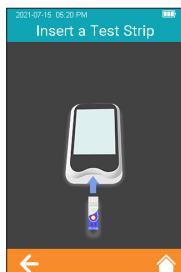
When the Sample No. switch is turned off, skip the step of inputting the Sample No. and insert the test strip directly. When the Sample No. switch is turned on, the sample can be numbered manually or automatically. If auto numbering is selected, please enter the screen for inserting the test strip directly after entering the sample test channel. The system then generates a Sample No. automatically; if manual numbering is selected, please input the Sample No. manually and save it after entering the sample test channel (as shown in Figure 3-2), then enter the strip insertion screen.



3-2

Click the "Sample Test" icon from the main menu (Figure 1-1) to enter the Sample Information screen (Figure 3-2). Manually enter the sample number, which consists of numbers, uppercase and lowercase letters, and spaces. The character length should be between 1-20, Click "✓" to save.

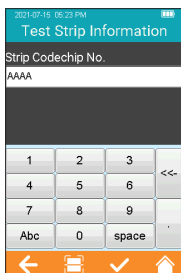
8.3 Insert Test Strip



3-3

Once the Insert a Test Strip screen appears on the analyzer, insert the test strip in the direction shown (Figure 3-3). Keep inserting the strip as directed until the sample well is aligned 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.

8.4 Input Test Strip Information



3-4

After the test strip is inserted, please enter the Codechip number of the test strip (Figure 3-4). The Codechip number may be entered manually by clicking "✓" to save, or by scanning the barcode on the package of the test strip. 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 Save is clicked.

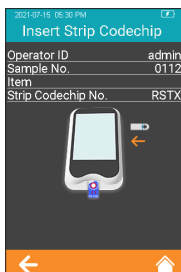
When using the barcode scanner, the white area in the rectangular light field is the sensing area. When scanning, the scan port should be aligned with the barcode, and the position, distance, and angle between the barcode and scan port should be adjusted according to the light field.

Location: The barcode should be placed in the white sensing area with the barcode direction aligned with the long axis of the white sensing area.

Distance: Adjust the distance between the barcode and analyzer scan port to make sure the barcode fits completely within the white sensing area.

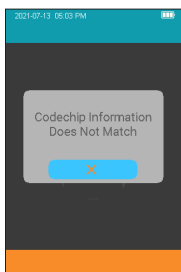
Angle: The light field should be as perpendicular to the barcode plane as possible, and the vertical deviation should have the highest recognition rate within $\pm 5^\circ$.

8.5 Install Codechip



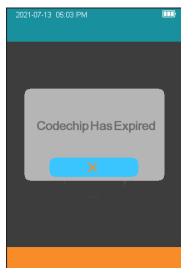
3-5

Insert the test strip Codechip into the chip slot (see Section 1.3 for position details), then the specific Codechip information will display (Figure 3-5). Codechip number and arrow side should be face up.



3-6

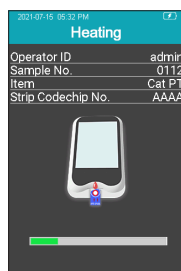
When the input Codechip number of the test strip does not match the Codechip information, the system will deliver a warning message indicating that the Codechip information does not match.



3-7

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

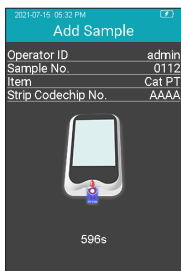
8.6 Heating



3-8

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 3-8).

8.7 Add Sample



3-9

The system will count down and prompt the user to add sample upon the completion of heating (Figure 3-9). The sample must be added within 10 minutes. Do not move the instrument when adding the sample. If the sample is not added properly within 10 minutes, the system will deliver an error message indicating that sample adding has timed out.

8.8 Collecting a Sample

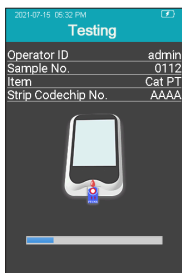
After the heating is complete, collect whole blood sample and run test. Refer to the test strip insert for detailed sample collecting procedures.

NOTE:

- To avoid mechanical hemolysis of the blood sample, nonheparinized syringe with 21 gauge needle or larger is highly recommended.
- Since the interstitial fluid (thromboplastin) will accelerate the clotting process, vascular puncture action is preferably a one-time action so as to minimize the interstitial fluid from entering into the blood sample.
- Excitement of the patient should be minimized when collecting the sample. The clotting reaction and test results will be affected when the patient is extremely excited. Sedatives and analgesics can also affect the blood clotting process.
- When collecting the sample, follow the guidelines and procedures for blood collection as instructed by the veterinary clinic.

8.9 Performing the Test

Discard the first drop of blood, then apply a total of approximately 10-20 microliters of blood to the sample well of the strip. Make sure to apply the blood sample directly on the sample well of the strip. DO NOT move the analyzer while adding the blood to the strip.

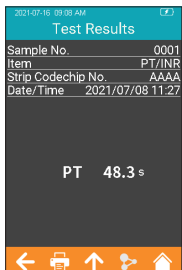


3-10

After the sample is added properly, the system will start the test automatically and display the test progress (Figure 3-10). Do not perform other operations on the analyzer during testing.

8.10 Test Results

Please check the test strip insert for an explanation of the results.



3-11

The system will display the test results after the test is completed (Figure 3-11). The test results can be uploaded, provided that the instrument is properly connected to the server. When the result is out of the normal range, the system will prompt that the result is ↑ (high) or ↓ (low), if Reference Range function has been enabled.



3-12

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 3-12), and remove the test strip in the direction shown in the figure. If the test strip is removed after the test is finished, the screen will directly jump to the main screen.

9. Quality Control

● Onboard QC Test

The Element COAG+ utilizes a number of internal quality methods to ensure proper operation. The built-in quality control of the instrument automatically monitors critical conditions before and during the testing period. The onboard quality control of the test strip detects the signal characteristics of two channels. By identifying possible problems such as test strip defects and operational issues, we are able to ensure the accuracy of the test results.

Failure of Quality Control test will result in the instrument displaying an error code. Please repeat the test utilizing a new test strip.

● Liquid QC Test

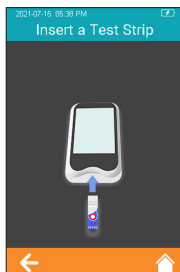
Optional liquid controls are available for use on the Element COAG+ Analyzer and are to be used with Element COAG+ Test Strips to verify performance. It is recommended that two levels of liquid controls be used.



Only use qualified Element COAG+ Controls for QC testing.

The specific procedure for external QC test are as follows.

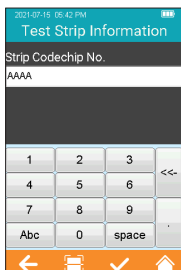
9.1 Insert Test Strip



4-1

Click the "QC Test" icon from the main menu screen (Figure 1-1) to start the QC test, and insert the test strip in the direction as indicated by Figure 4-1. Keep inserting the strip until the sample well is aligned 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.

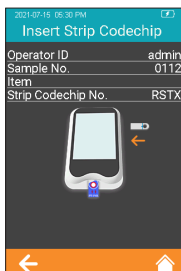
9.2 Input Test Strip Information



4-2

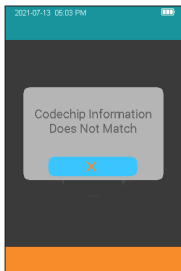
After the test strip is inserted, please enter the Test Strip Information screen, and input the Codechip number of the test strip (Figure 4-2). The Codechip number can be manually entered and then click "✓" to save, or by scanning the barcode on the package of the test strip. The package of the test strip bears the Codechip number of the test strip. The Codechip number of the test strip must be entered, or the system will deliver a warning message indicating the input is invalid when Save is clicked.

9.3 Install Test Strip Codechip



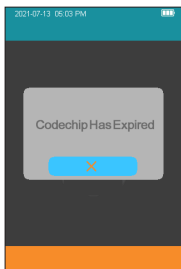
4-3

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).



4-4

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



4-5

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

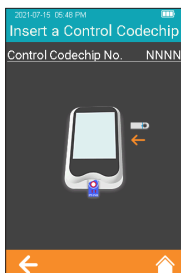
9.4 Input QC Information



4-6

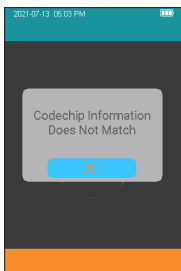
After the Codechip is installed, enter the Codechip number of the QC liquid (Figure 4-6). (See outer package for details.) The Codechip number can be entered manually and then click "✓" to save, or by scanning the barcode on the package of the test strip. The Codechip number of the QC liquid must be entered, or the system will display a warning message indicating that the input is invalid when Save is clicked.

9.5 Install QC Liquid Codechip



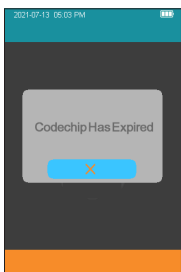
4-7

The screen will display the specific Codechip information of the QC liquid (Figure 4-7) after inputting the Codechip information of the QC liquid.



4-8

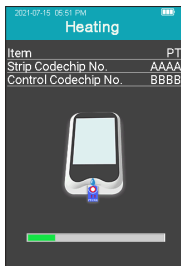
When the input Codechip number of QC liquid does not match the Codechip information, the system will provide a warning message indicating that the Codechip information does not match.



4-9

When the input Codechip number of QC liquid has expired, the system will provide a warning message indicating that the Codechip has expired.

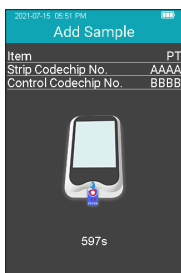
9.6 Heating



4-10

After the test strip is inserted and Codechip is installed, the instrument will enter the heating state, and the screen will display the heating progress (Figure 4-10).

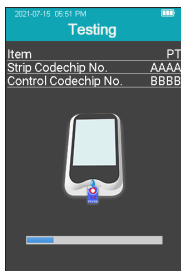
9.7 Add Sample



4-11

The system will count down and prompt the user to add sample (Figure 4-11) upon the completion of heating. The sample must be added within 10 minutes. Please strictly follow the requirements of the QC liquid insert during sample adding. Do not move the instrument when adding sample. If the sample is not added properly within 10 minutes, the system will deliver an error message indicating sample adding has timed out.

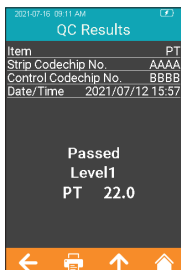
9.8 QC Test



4-12

After the QC liquid is added, the system will start the QC test automatically and display the test progress (Figure 4-12).

9.9 QC Test Results



4-13

The system will display the QC test results after the test is completed (Figure 4-13). The test results can be uploaded, provided that the instrument is properly connected to the server.



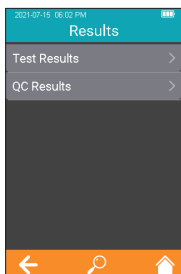
4-14

If the test strip has not been removed after the QC test is completed, please click "🏠" from the Test Result screen to go to the strip removal screen (Figure 4-14), and remove the test strip. If the test strip is removed after the QC test is finished, the screen will directly jump to the main screen.

10. Results

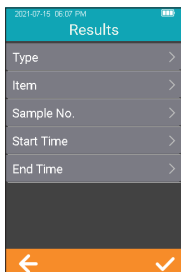
When the storage amount of the sample result reaches 80% of the total amount of the analyzer, the user will be prompted to upload data. If the user does not upload the data, the sample results will automatically overwrite the oldest records after the total amount exceeds the limit.

10.1 Results Channel



5-1

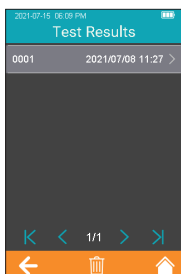
Click the "Results" icon from the main menu screen (Figure 1-1) to enter the Results query screen (Figure 5-1).



5-2

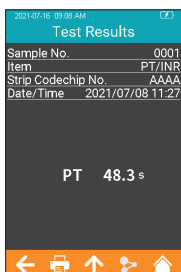
From the Results Query screen, touch "Q" to view the information by specific criterion. Both test results and QC results can be viewed by Type, Item, Sample No., Start Time, or End Time.

10.2 Test Results



5-3

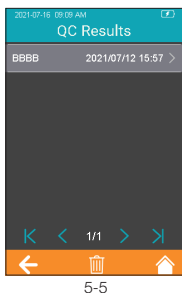
Click "Test Results" from the Results screen (Figure 5-1) to enter the test results query screen (Figure 5-3). If there are multiple test results, please scroll through the display for all results. Click "🗑️" on the Test Results screen to clear all test results.



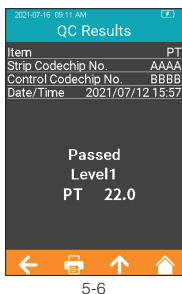
5-4

To view the detailed test result information (Figure 5-3), please click a result from the test results query screen (Figure 5-4), the results can be uploaded.

10.3 QC Results



Click "QC Results" from the Results screen (Figure 5-1) to enter the QC Results query screen (Figure 5-5). If there are multiple QC test results, please scroll through the display to list all results. Click "🗑️" in the test results screen to clear all test results.



To view the detailed QC Results information (Figure 5-5), please click a result from the QC Results query screen (Figure 5-6). The results can be uploaded.

11. Maintenance

11.1 Screen Care and Cleaning

Follow these steps for cleaning the analyzer:

11.1.1 Cleaning Frequency

1. Clean the analyzer after every patient and when there are visible signs of soil and/or organic material prior to disinfecting. Also follow any facility disinfection SOPs.
2. The exterior of the analyzer and test strip guide area should be cleaned and disinfected before being used between each patient.
3. The exterior of the analyzer 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 analyzer when it is soiled, and per your facility's guidelines.
5. Routine cleaning should be performed a minimum of once a month when the analyzer 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 analyzer display.
3. The analyzer housing (front and back).
4. The button area on the face of the analyzer.

11.1.3 Precautions to Avoid Moisture

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

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 analyzer.
3. Recommended cleaning cloths are listed in Table 1.

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"
CaviWipes®	Quaternary/low-alcohol formula (17.2% IPA).	9" x 12" or 6" x 6.75"

11.1.5 Cleaning and disinfecting the analyzer housing.

1. Use the recommended cloth in Table 1 to clean and disinfect the analyzer exterior.
2. Remember to apply the solutions and allow a contact time of 2 minutes.
3. Turn the analyzer off.
4. Pre-clean: Using a clean cloth, gently remove any gross debris and wipe the entire surface of the analyzer.
5. Disinfecting: Using a new cloth, gently wipe the analyzer housing surfaces. Wipe the entire analyzer housing including the LCD screen, sample, and button areas.
 - 5.1. Wipe the analyzer twice top to bottom, then twice left to right. With the cleaning cloth in the palm of your hand, hold the analyzer with the LCD screen side up (battery side on the cloth) and wipe the analyzer twice top to bottom, then left to right. Wipe each of the sides of the analyzer 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 analyzer.
 - 5.4. Leave analyzer "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 analyzer is dried with the Kimwipe it is ready for use.

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

11.2 Precautions for Lithium-Ion Battery

Element COAG+ Analyzer has a built-in lithium-ion battery, which cannot be removed by any user. For battery replacement, please contact Heska's Technical Support Services.

If you plan not to use the analyzer for more than one month, please fully charge the analyzer. Turn on the transportation mode in the Settings screen, and then turn off for storage. Please charge the analyzer for 3.5 hours before using.

When stored for more than 3 months, it is recommended to turn on the transportation mode after charging every 3 months to avoid battery discharge and capacity attenuation.

11.3 Servicing

No user serviceable components. All service and adjustments must be performed by Heska Corporation.

12. Troubleshooting



When you receive an error code, please retest. If you receive a second error code, then contact Heska's Technical Support Services 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.
E001.1	Battery failure.	Please turn off the analyzer and restart it. If the problem recurs, please contact Heska's Technical Support Services.
E002	Heating has timed out.	Please adjust the ambient temperature to 50°F–95°F (10°C–35°C), and turn off the analyzer for 5 minutes, then turn on the analyzer and restart the test. If the problem recurs, please contact Heska's Technical Support Services.
E003	The ambient temperature is too high or too low.	Please ensure that the analyzer is used in an environment of 50°F–95°F (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.

Error Code	Description	Corrective Actions
E008	Scanning error.	Please turn off the analyzer and reboot. If the problem recurs, please contact Heska's Technical Support Services.
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 analyzer prompts the user to add sample.
E012	aPTT calculation error.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services 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 within specification of strip insert.
E016	FIB calculation error.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E018	The strip is placed improperly.	Do not remove the test strip during the test.

Error Code	Description	Corrective Actions
E019	The temperature of the analyzer is too high.	Please adjust the ambient temperature to 50°F–95°F (10°C–35°C), and turn off the analyzer for 5 minutes, then turn on the analyzer and restart the test. If the problem recurs, please contact Heska's Technical Support Services.
E020	The coagulation reaction of PT and/or aPTT is not activated.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E021	PT calculation error.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E022	No sample coagulation of aPTT is detected.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E023	aPTT result extremely high and unreliable.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E024	PT result extremely high and unreliable.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.

Error Code	Description	Corrective Actions
E025	PT result is above reportable range.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E026	PT result is below reportable range.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.
E030	The analyzer is vibrating or shaking.	Do not move, vibrate, or shake the analyzer during the test and ensure that the analyzer is used in an environment away from high frequency vibrations.
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 Heska's Technical Support Services.
NO COAG	No sample coagulation of PT is detected.	Please retest with a new test strip. If the problem recurs, please contact Heska's Technical Support Services and use the laboratory method to perform the test.

13. Symbols

Symbols	Explanation	Symbols	Explanation
	Consult Instructions For Use		Expiry Date
	Caution. Read Carefully		Fragile
	Keep Dry		Biological Risk
	Separate Collection		Do Not Reuse
	Temperature Limitation		Manufacturer
	Catalogue Number		Serial Number
	Laser Radiation Risk		Lot Number
	CE Marking		

14. Operating Conditions and Product Specifications

14.1 Operating Conditions

Temperature	50°F - 95°F (10°C - 35°C)
Humidity	10% - 90% (No condensation)
Altitude	14,000 feet (4,300 m)

14.2 Product Specifications

Processor	32-Bits V2 ARM Cortex-M4
Display	320 × 480 LCD
Touch screen	Capacitive touch screen
Bar code module	QR code scanning module (QR code, Code 39, Code 128, UPC, PDF417, Data Matrix)
Memory	Stores up to 2,000 patient records and 500 raw data
Power	External power supply: 100 - 240 V ~ 50/60 Hz ± 5 Hz, 0.4 A Max Internal power supply: DC3.7V (lithium polymer)
Size (LxWxH)	5.82 in x 2.76 in x 1.03 in (148 mm × 70 mm × 26 mm)
Weight	7.16 oz (203 g)

15. Special Storage Conditions & Methods

- 1). Environment temperature: 14°F–104°F (-10°C - 40°C);
- 2). Relative humidity: $\leq 90\%$ (no coagulation).

15.1 Use of the Element COAG+ Analyzer

Proper adherence to the instructions in the Element COAG+ Analyzer Product Manual and Package Insert is critical to proper operation.



WARNING: Failure to comply with the Element COAG+ Analyzer Product Manual could lead to inaccurate results and incorrect medication dosing which could result in injury or death.



For further assistance, please call Heska's Technical Support Services at 800.464.3752, option 3.

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