InCoag

Automated Coagulation Analyzer

User's Manual

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RoHS

FOR VETERINARY USE ONLY

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Important User Information

Disclaimer

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Caution

- If the InCoag Automated Coagulation Analyzer is used in any way other than described in this manual, the device may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard.
- Animal blood is a potential source of zoonotic diseases. We recommend wearing personal protective equipment when handling animal blood or devices used for measuring animal blood.
- Be sure to follow local occupational health and safety regulations.
- Read all instructions before using the InCoag Automated Coagulation Analyzer.
- Attempting to open or dismantle the analyzer may cause electric shock and will void the warranty.
- Protect the analyzer from liquids, including exposure to wet locations.
- Check power supply and power cord for damage before usage.
- Never use a damaged power cord or power supply.
- Always power the device off before disconnecting the power supply.
- Do not place objects on top of the analyzer.
- Do not place the analyzer near centrifuges.
- It is strongly recommended to inspect the device regularly for damages. If damaged, disconnect immediately and contact your local technical support.
- If the InCoag Automated Coagulation Analyzer is accidentally dropped, immediately contact Technical Support. No tests should be performed until the unit has been serviced by authorized personnel.
- Handle and dispose all reagents and samples as biohazardous material or follow disposal guidelines as defined by your local regulatory agency.

Table of Contents

Symbols

Symbol	Meaning
	Caution To indicate that caution is necessary when operating the device or control close to where the symbol is placed. To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. On the health app quality label: to indicate that the health app requires approval from a health professional for use.
	Serial number
	Use by date
	Date of manufacture at country of manufacturing China
	Manufacturer of the device
	Temperature limit
	CE marking
	SGS Q mark
	RCM mark
	To indicate the identity and address of the Importer
	Importer
	Distributor
	Operator's manual

	Indicates that separate collection for waste of electric and electronic equipment (WEEE) is required
	Keep away from rain
	Fragile, handle with care
	This way up
	Stacking limit by number
	Do not roll
	Keep away from sunlight
	Universal Serial Bus (USB), port/plug
	Direct current
	Computer network
	Model Number
	Catalogue Number
	Electronic instructions for use
	For indoor use only
	Biological Risk
	This device is only for veterinary use
RoHS	With reference to RoHS Directive (EU) 2015/863 amending 2011/65/EU.

Introduction

This manual comes with a detailed description of the purpose, function, and operation of the InCoag Automated Coagulation Analyzer. Please read this manual before operating the Automated Coagulation Analyzer and follow all safety precautions.

Intended Use

The InCoag Automated Coagulation Analyzer is intended for veterinary use only, particularly in cats and dogs, to assess blood clotting function. The analyzer measures Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT), aiding in the detection of abnormalities caused by acquired or congenital coagulopathies, liver dysfunction, or the use of medications. The system is compatible with sodium-citrated whole blood samples.

How the InCoag Automated Coagulation Analyzer Works

The InCoag Automated Coagulation Analyzer is intended for veterinary use only. It measures the clotting time of blood samples through coagulation tests. Supported tests include Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT).

The analyzer uses a mechanical coagulation method to detect the coagulation time of animal blood. During the testing process, the analyzer's air pump connects to the micro-flow channel in the test cartridge, driving the blood into the test channel where it comes into contact with the coagulation-activating reagent. The blood is then circulated and oscillated within the test channel. Before coagulation occurs, the oscillation frequency and pressure in the flow channel change according to physical principles. Once blood begins to clot, both the frequency of oscillation and the pressure in the flow channel change significantly. The system monitors these changes to determine the solidification time of the target sample. The InCoag Automated Coagulation Analyzer combined with coagulation testing reagents are used to test the hemagglutination index of animals, including prothrombin time (PT) and activated partial thromboplastin time (aPTT). The acceptable sample type is sodium citrated whole blood.

Blood coagulation involves three main pathways: the extrinsic (PT), intrinsic (aPTT), and common clotting pathways. The extrinsic pathway is activated by tissue factor, which is exposed when the vessel wall is damaged. TF binds with Factor VII, forming a complex that activates Factor X to Xa. Factor Xa, together with Factor Va, converts prothrombin into thrombin. Thrombin then converts fibrinogen into fibrin, forming a fibrin network to stop bleeding.

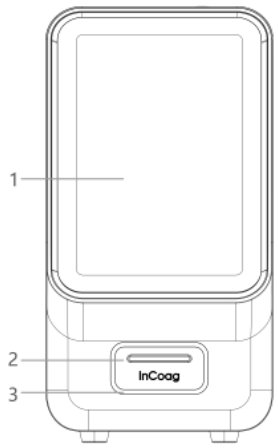
Clotting indicators are commonly used to diagnose diseases related to blood clotting and to monitor the effects of drugs, such as those affecting liver function or anticoagulant medications. The liver is the primary site for synthesizing clotting factors. When liver function is impaired, it can affect the levels of clotting factors in the blood, leading to abnormal clotting indicators. Anticoagulant drugs like heparin and warfarin prolong clotting time by inhibiting the synthesis of certain clotting factors or reducing their activity.

Specifications

Analyzer Conventional Parameter	Display screen	8 inch color touch display capacitive screen, resolution 800x1280
	Power Adapter specification	INPUT：100-240VAC, 50/60Hz, 1.0-0.5A
		OUTPUT：12V ⎓ 3.34A,40W MAX
	Instrument Input specification	12V ⎓ 3.34A,40VA
	Communication specification	Net interface：TCP/IP protocol， Ethernet connection
	Size	L×W×H：182×148.5×284.5 mm
	Weight	About 2kg
	Use environment	Indoor use only Ambient temperature：10-35℃ Relative humidity：≤90% (No condensation）
		Atmospheric pressure：80KPa-106KPa
		Overvoltage category：Class II
		Pollution degree：2
	Storage and transport-ation environment	Ambient temperature：-20-55℃； Relative humidity：≤90% (No condensation)
		Atmospheric pressure：80Kpa-106KPa
		Stack no more than 5 layers
	Operating noise	The analyzer's maximum operating noise shall not exceed 60 decibels
	External interface	Two, 2.0 USB ports, one Ethernet port
	Software interface	Graphical interface
Test Parameter	Test channel	4-channel
	Coagulation endpoint test	Mechanical solidification
	Test	Activated partial thromboplastin time (aPTT)
		Prothrombin time (PT)
	Test time	≤6min
	Complementary reagent	Disposable test cartridge consumables
	Sample size	100μL

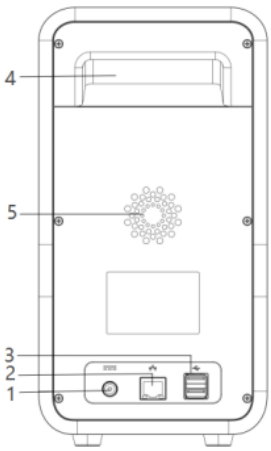
System Overview

Front



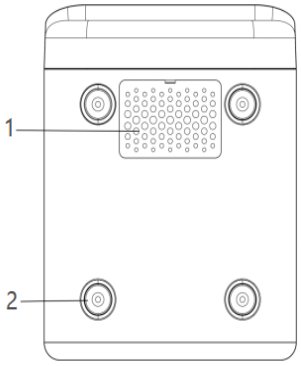
1. Touch display
2. Cartridge slot
3. LED light

Back



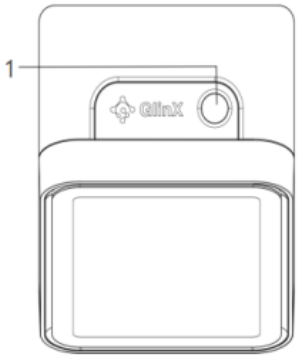
1. Power
2. Ethernet port
3. USB2.0 port
4. Handle position

Bottom



1. Air inlet
2. Foot pad

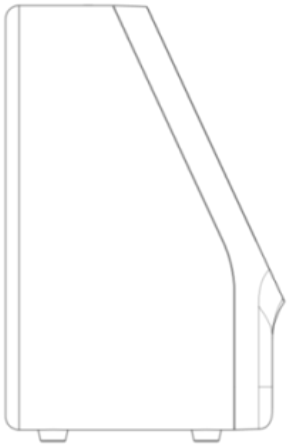
Top



1. On-off key

Left

Right



Setting Up the InCoag Automated Coagulation Analyzer

The InCoag Automatic Coagulation Analyzer is only suitable for indoor installation and use. The analyzer requires a voltage of 100-240V AC and a power supply frequency of 50-60HZ. Improper use of the power supply may damage the analyzer's wiring system and cause a fire.

The analyzer should be placed in the relative humidity ≤90% (no condensation), a temperature of 10-35℃, and atmospheric pressure of 80KPa-106KPa. Ensure that the area is well ventilated, clean, dry, and free of dust, smoke, and corrosive and explosive gases.

Place the analyzer on a dry, clean, flat, horizontal surface, away from direct sunlight, mechanical vibration, or strong electromagnetic field interference.

- **VERIFY THAT THE INPUT VOLTAGE MEETS THE REQUIREMENTS.**
- **DO NOT USE IN AN ENVIRONMENT WITH AIR PRESSURE GREATER THAN THE ANALYZER'S RATING.**
- **IF THE INSTRUMENT IS USED IN ANY WAY OTHER THAN DESCRIBED IN THIS MANUAL, THE ANALYZER MAY NOT OPERATE AS INTENDED, MAY PRODUCE INACCURATE OR NO RESULTS, AND MAY POSE A SAFETY HAZARD.**
- **TO PREVENT POWER SURGES OR DRAIN, DO NOT PLUG THE ANALYZER INTO THE SAME CIRCUIT AS A CENTRIFUGE OR ANY OTHER HIGH-CURRENT DEVICE. IF THIS IS NOT POSSIBLE, USE AN ANCILLARY POWER CONDITIONER OR UPS.**

Installation Environment	Requirements
Place	• The ground should be smooth, and the operating table must be stable and sturdy. • The environment should be free from dust, mechanical vibrations, heat, pollution, direct sunlight, major noise sources, and power interference.
Space	• Maintain a clearance of at least 10 cm between the left and right sides of the analyzer and the wall. • Ensure a minimum distance of 10 cm between the back of the analyzer and the wall. • Provide sufficient space on the operating surface and beneath the main unit for inspection tools. • Position the analyzer close to a power outlet, ensuring there are no obstructions, to allow easy unplugging when power is not required.
Power Connection	• The analyzer host connects to the power supply via an adapter.
Ventilation	• Ensure proper air exchange with the outside environment, smooth air circulation, and no direct wind sources blowing at the analyzer.
Electromagnetic Environment	• Assess the laboratory's electromagnetic environment before operating the analyzer to ensure proper functionality. • Avoid placing the analyzer near sources of strong electromagnetic interference to prevent disruptions in its operation. • Keep the analyzer away from brush motors, flashing fluorescent lamps, and electrical contact devices that are frequently switched on and off.
Consumable Treatment	• Follow medical waste requirements when disposing of consumables.
Installation Personnel Requirements	• The installation must be authorized by professional personnel
Damage Inspection	The analyzer is thoroughly inspected before packaging and shipping. Upon receiving the analyzer, carefully examine the packaging for any of the following issues before opening the box: • The outer package is inverted or deformed. • The outer package shows visible signs of water damage. • The outer package has noticeable impact marks. • The outer package appears to have been opened. If you notice any of the above damage, notify the after-sales service team immediately. If the outer package is in good condition, proceed to open it and perform an unpacking inspection: • Verify that all components are present according to the packing list included in the box. • Inspect the appearance of all components carefully for cracks, indentations, or deformations.

- **MAKE SURE TO PLUG THE ANALYZER INTO A GROUNDED OUTLET.**
- **DO NOT REPLACE A REMOVABLE GRID POWER CORD WITH AN IMPROPERLY RATED CABLE.**
- **WARNING: USE ONLY THE POWER**

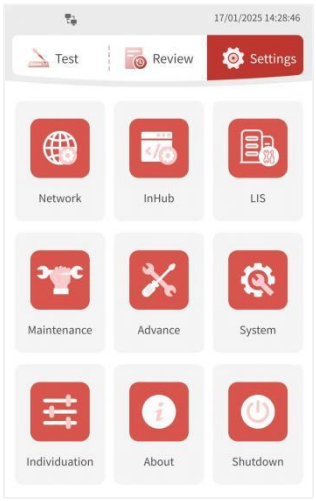
ADAPTER SUPPLIED WITH THIS INSTRUMENT. ANY OTHER POWER ADAPTER WILL DAMAGE THE INSTRUMENT AND VOID THE WARRANTY.

Turn on the Analyzer

Once the analyzer is placed on a suitable surface (see above), turn it on by pressing and holding the power button.

Analyzer Settings

The analyzer settings can be accessed by tapping **Settings**.



Settings screen

Network , InHub and LIS

Network ,InHub and LIS features are not supported with this analyzer.

Maintenance

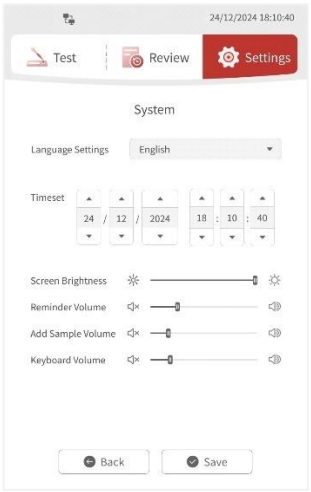
For maintenance instructions, please refer to the Maintenance section of this manual.

Advance

The functions in this area are for professional and technical personnel only.

System

Tap **System** to adjust the Language Settings, Screen Brightness, Reminder Sound Volume, Add-Sample Reminder Volume, and Keyboard Sound Volume.



System setting interface

Language

To change the language:

1. Tap **Settings** > **System**.
2. Tap and scroll to choose a language from the **Language Settings** drop-down box.
3. Tap **Save**.

Date and Time

To change the date and time:

1. Tap **Settings** > **System**.
2. Use the up and down arrows to adjust the **date** (DD/MM/YYYY format) and **time** (24-hour format).
3. Tap **Save**.

Screen Brightness

To change the screen brightness:

1. Tap **Settings** > **System**.
2. Locate the **Screen Brightness** slider.
3. Tap the slider:
   a. Tap left to decrease brightness.
   b. Tap right to increase brightness.

Screen brightness bar set to maximum brightness

4. Tap **Save**.

Adjust Reminder Sound Volume

To change the reminder volume:

1. Tap **Settings** > **System**.
2. Locate the Reminder **Sound Volume** slider.
3. Tap the slider:
   a. Tap left to decrease the volume.
   b. Tap right to increase the volume.

The Reminder Sound Volume is set to medium

4. Tap **Save**.

Adjust Add-Sample Sound Volume

To change the add-sample reminder sound volume:

1. Tap **Settings** > **System**.
2. Locate the **Add-Sample Sound Volume** slider
3. Tap the slider:
   a. Tap left to decrease the volume.
   b. Tap right to increase the volume.

The Add Sample Sound Volume is set to medium

4. Tap **Save**.

Adjust Keyboard Sound Volume

To change the sound volume on the touchscreen keyboard:

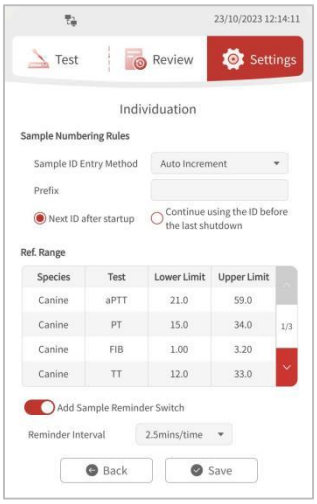
1. Tap **Settings** > **System**.
2. Locate the Keyboard Volume slider.
3. Tap the slider:
   a. Tap left to decrease the volume.
   b. Tap right to increase the volume.

The Keyboard Sound Volume is set to medium

4. Tap **Save**.

Individuation

Use this area to edit sample numbering rules, reference ranges, and add-sample reminders.



Individuation Screen

Sample Numbering Rules

The Sample Numbering Rules determine the input and numbering of the samples.

Sample ID Entry Method

To change the Sample ID Entry Method:

1. Tap **Settings** > **System**.
2. Tap Individuation.
3. Tap and scroll to choose Manual Entry or Auto Increment from the drop-down box.
   - When the sample number is set to **Manual Entry**, the sample number must be manually entered for each test.
   - When the sample number is set to **Auto Increment**, a sample number is automatically

generated for each test. The automatically generated sample number cannot be modified.

i. Use the **Prefix** field to set a minimum length for the sample number. If you enter 4, for example, the first sample will be numbered 0001.
ii. Select either the “Next ID after startup” or “Continue using the ID before the last shutdown” option.
    - **Next ID after startup** – This option re-starts the sample numbering every time you start up.
    - **Continue using the ID before the last shutdown**: This option resumes numbering after the last sample number after startup.

4. Tap **Save**.

Reference Ranges

Ref Range (Reference Range) allows users to set an upper and lower limit to the reference range for coagulation parameters for aPTT and PT tests.

Please Note: This analyzer has been validated for use with feline and canine species ONLY. Use of the "Other " button will provide results with no reference ranges displayed. Please note that off-label use is not supported by Zoetis and is at your own risk.

Users can change the reference range according to the reference range of the test card or their own actual test results.

To change the reference range for a test:

1. Tap **Settings > System > Individuation**.
2. Tap  to scroll to the coagulation index to be set.
3. Tap the appropriate Lower Limit or Upper Limit box and enter the reference range of the test cartridge or the upper or lower limit value of your actual test results. The lower and upper limits only support numbers.
4. Tap **Save**.

- THE LOWER LIMIT OF THE REFERENCE RANGE SHOULD NOT BE LESS THAN THE LOWER LIMIT OF THE REPORTABLE RANGE (SYSTEM RANGE) AND THE UPPER LIMIT OF THE REFERENCE RANGE SHOULD NOT BE GREATER THAN THE UPPER LIMIT OF THE REPORTABLE RANGE (SYSTEM RANGE). IF THE NUMBER EXCEEDS THESE LIMITS, YOU WILL SEE THE PROMPT "THE LOWER LIMIT INPUT CANNOT BE LESS THAN XX" OR "THE UPPER LIMIT INPUT CANNOT BE GREATER THAN XX".

System Ranges are specified in the table below.

Test	**System Range**
aPTT	7.0 – 120.0s
PT	7.0 – 90.0s

Change Add-Sample Reminder

- Use the **Add-Sample Reminder** switch to enable or disable sample reminders.
- Turning the switch on unlocks options for setting reminder.
- Tap the Reminder Interval drop-down menu to adjust how frequently the reminder prompt is repeated.

Reminder Interval choices for reminders

- Turning the switch off disables the add-sample reminders.

About

Tap **Settings > About** to display the Name, Model, Application, Motion Module, SN, and Manufacturer of the analyzer.

About Interface

Shutdown

To shut down the analyzer:

1. Tap **Settings** > **Shutdown**. The “Confirm to shutdown?” question appears.

Shutdown question

2. Tap **OK** to turn off the analyzer, or tap **Cancel** to exit without shutting it down.

Running a Test

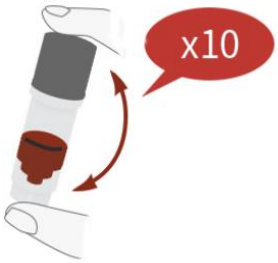
Acceptable Sample Types:

- **Citrated Whole Blood**

Citrated Whole Blood Sample Collection

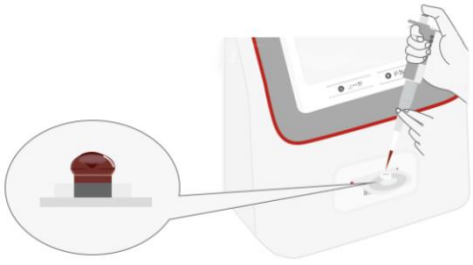
The correct sample volume and collection procedure are crucial for accurate coagulation testing. Follow these guidelines during the collection process:

1. Calm the animal before collection. Excitement can increase blood circulation and enhance coagulation activity, potentially affecting test outcomes.
2. Ensure that any alcohol disinfectant has fully evaporated before collecting the sample.
3. Use a syringe that has an appropriate gauge needle to avoid mechanical hemolysis while obtaining the sample to collect whole blood.
4. Ensure a minimum of 300µL of venous blood is collected to provide sufficient quantity.
5. Immediately after collection, transfer 270µL of the sample to the anticoagulant tube within 30 seconds. When using the syringe to transfer the sample, ensure the amount added reaches the marked scale line to maintain the proper ratio of anticoagulant to blood. Gently invert the tube 10 times to mix.



Mixing sample

3. Transfer the citrated whole blood sample to the sample well using a pipette.



Citrated whole blood Sample addition

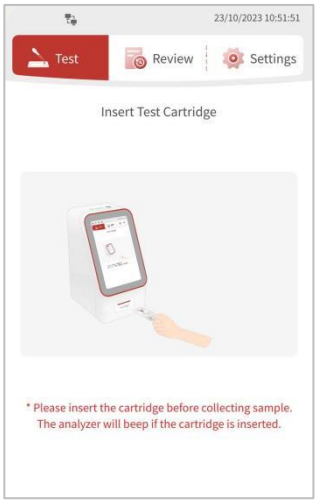
The citrated whole blood samples collected can be used at room temperature for 1h. The samples collected can be stored at 2-8°C for 4h. The sample should be brought to room temperature for 10 minutes before use.

Test Procedure

1. **Turn on the device**. After the Automatic Coagulation Analyzer is plugged in, long press the power button to start the device. The device should enter the main test interface by default. If it is not in the main test interface, tap the **Test** button.

2. **Take the test cartridge out of the kit.** Confirm the foil bag has no air leakage or damage, the sample types are consistent with the test, and the QR code has no obvious defects. If the test cartridge is taken out of the cold storage, it should be brought to room temperature for 10 minutes before use.

3. **Insert the cartridge**. Remove the cartridge from the foil pouch and insert it horizontally into the slot with the QR code facing up. **Insert the cartridge before the sample**. The analyzer will beep when the cartridge is inserted.



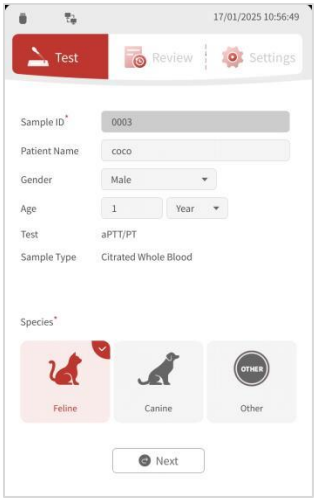
Insert test cartridge screen

4. **Verify cartridge information**. After inserting the cartridge, the analyzer will automatically verify the cartridge information.

Verify cartridge information screen

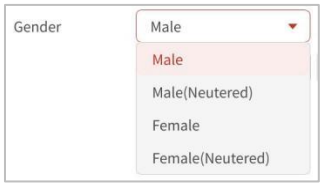
- IF AN ERROR POPS UP, REFER TO APPENDIX B: ERRORS.
- BE SURE THE CARTRIDGE IS INSERTED HORIZONTALLY, NOT AT AN ANGLE.

5. **Enter the sample information**. **Sample ID** and **Species** are required. Other fields are optional. Tap **Next**.



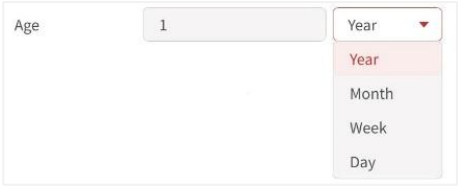
Sample information input screen

- **Gender**: To select a gender, tap the pet gender drop-down and select Male, Male (Neutered), Female, or Female (Neutered).



Gender of pet drop-down list

- **Age**: Only numbers, up to three digits, can be entered in the pet age input box. Use the pet age drop-down to specify whether the age is in years, months, weeks, or days.

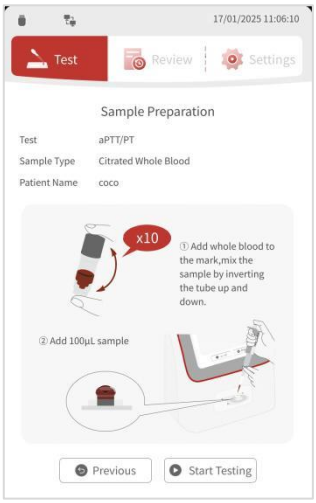


Age of pet drop-down list

6. **Heat the cartridge**. It takes between 10 seconds and 1 minute for the analyzer to automatically heat the cartridge. The length of heating time depends on the ambient temperature. After the heating is completed, the analyzer will automatically jump into the loading interface.

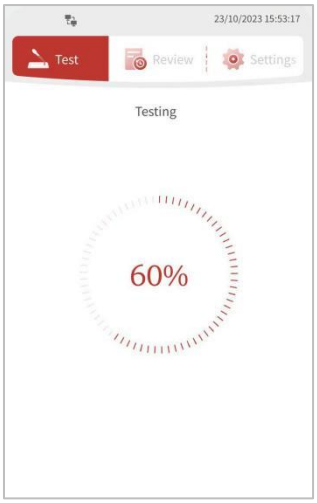
Citrated whole blood heating screen

7. **Prepare and Transfer the Sample**. Follow the instructions in the Sample Collection section above for Citrated Whole Blood. Depending on the cartridge type, ensure the cartridge is filled with the required sample volume.



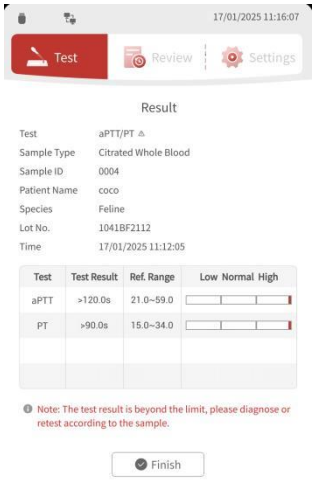
Citrated whole blood Sample Preparation screen

8. **Run the test.** Tap the **Start Testing** button on the screen. The analyzer will complete the test within 6 minutes. The progress bar shows the ratio of the current test time to the maximum allowed completion time. The automated coagulation analyzer performs real-time testing. Once the system detects the coagulation endpoint, it will automatically switch to the test result display screen.



Testing interface

9. **View results**. Sample result screens are shown below.

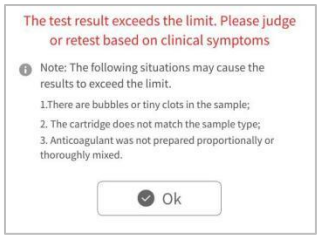


Citrated whole blood test result screen

10. **Dispose of testing materials.** After the test is complete, remove the cartridge. The cartridge, syringes, and disinfectant pads should be regarded as hazardous materials and disposed of according to the local medical waste disposal regulations.

Test Result Exceeds the Limit

When the result exceeds the upper or lower limit of the analyzer's reporting, the analyzer will show the message "The test result exceeds the limit. Please judge or retest based on clinical symptoms."



Test result exceeds the limit message

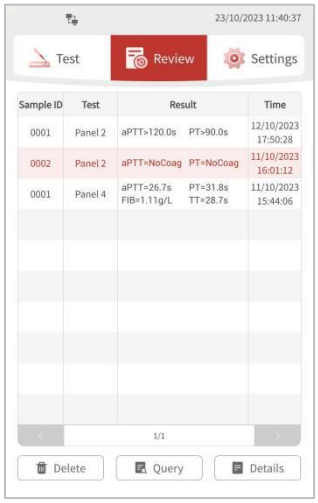
Tap the **OK** button to clear the message and display the test result.

The following user errors may inadvertently cause the results to exceed the limit:

1. Presence of bubbles or tiny clots in the sample.
2. The cartridge does not match the sample type.
3. Anticoagulants were not prepared proportionally or thoroughly mixed.

Reviewing Previous Results

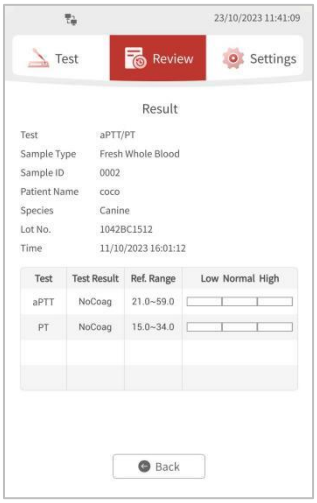
Tap **Review** to view all test records stored in the system.



Review screen

For each result, Sample ID, Test, Result, and Time are displayed. The analyzer can store up to 2000 test results. Tap **<** or **>** to turn the page and browse the review list.

To view a specific test result, tap the test result, then tap the **Details** button. The test result details interface opens.



Test result details interface

Tap the **Back** button to return to the review list interface.

Delete Test Result

To delete a test result permanently, tap the test result, then the **Delete** button. You will be asked to confirm the deletion. Tap **OK** to confirm or **Cancel** to exit.

Confirm deletion box

A TEST RESULT CANNOT BE RETRIEVED ONCE IT IS DELETED.

Search for Result

You can search for specific test results using Species, Sample ID, Test, Starting Time, and End Time as search criteria.

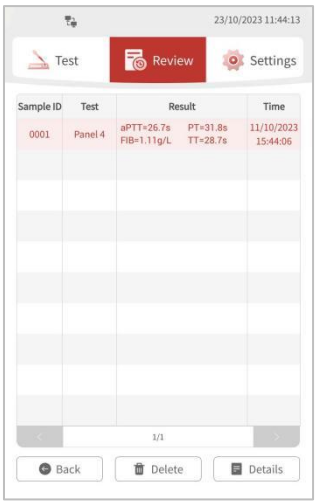
1. Tap **Review**.
2. Tap **Query**. The search/query screen opens.

Query screen

3. **Enter** your search criteria. You can combine one or more search conditions when executing a query:
   - Tap the **Species** drop-down to select the species.
   - Tap in the **Sample ID** field to enter and search for a sample number. The sample number supports error-tolerant and precise query. Tap outside of the Sample ID field to exit the keyboard.
   - Tap the **Test** drop-down to select Panel 2 or Panel 4.
   - Tap in the **Starting Time** and/or **End Time** field to select a starting and/or ending date for when the test was run.

Select a start or end date for your search, using the calendar

4. To start your search, tap **Query**. Your query results are shown.

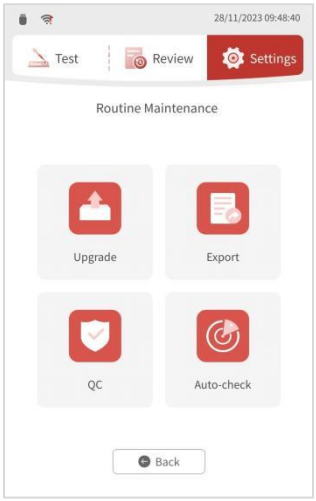


Query results

5. If there are more than 10 results, tap the < and > buttons to browse the results.
6. Tap **Back** to return to the query interface.

Maintenance

Access Routine Maintenance functions by taping **Settings** > **Maintenance**. Routine maintenance functions include Upgrade, Export and Auto-check.



Routine Maintenance screen

Software Upgrade

To upgrade your software version, tap **Settings** > **Upgrade**. The version information and the version information to be upgraded to is displayed.

Version information interface

Tap the **Upgrade** button to upgrade.

Tap the **Back** button to return to the Maintenance screen.

Version upgrade

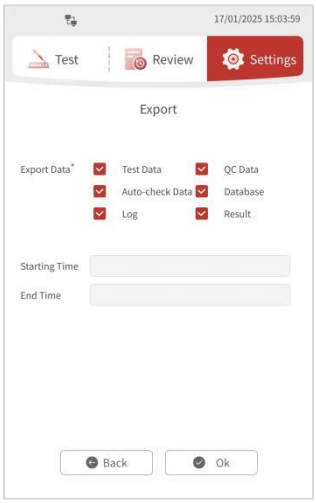
1. Tap **Settings** > **Upgrade**.
2. Insert the **USB flash drive** containing the upgrade file into the analyzer USB port and verify that is displayed in the upper-left corner of the analyzer.
3. Tap the **Upgrade** button at the bottom right-hand side of the screen.
4. While the analyzer is being upgraded, a progress bar is displayed.
5. When the upgrade progress bar displays 100%, you will be asked if you want to restart the analyzer. If you tap **OK**, the device will restart and the version will upgrade. If you tap **Cancel**, the analyzer will not restart and the version will not upgrade.

⚠

- **UPGRADE DOES NOT SUPPORT VERSION ROLLBACK.**
- **ANALYZER UPGRADES REQUIRE A USB STICK WITH THE NEW VERSION OF THE INSTALLER FROM THE DEALER.**

Export

To export data, tap **Settings** > **System > Export**. Check the boxes next to all data field to be exported (Test data, QC data, Auto-check data, Database, and Log). The export interface displays optional Export Data, Starting Time, and End Time.



Export screen

1. Insert the **USB flash drive** into the analyzer USB port and confirm that is displayed in the upper-left corner of the analyzer.
2. Tap each check box in front of any of the following fields to select the export data:
   - Test Data
   - QC Data
   - Auto-check Data

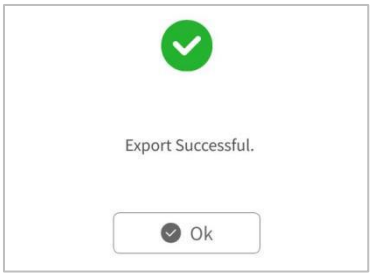
- Database

- Log
- Result

3. Select the **Start Time** and **End Time**.
4. Tap the **OK** button. The export progress bar will appear.

Export progress

5. When the progress bar reaches 100%, a dialog box is displayed indicating that data was exported successfully.



Export successful

6. Tap the **OK** button to close the dialog.

- IF THE USB FLASH DRIVE DOES NOT HAVE ENOUGH CAPACITY FOR THE EXPORTED DATA, THE DATA IS NOT EXPORTED AND THE EXPORT FAILED MESSAGE IS DISPLAYED.

Quality Control (QC)

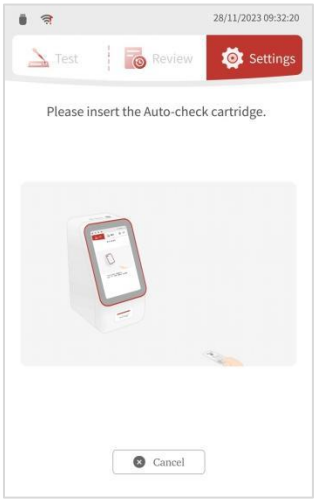
The Quality Control feature is currently not supported with this analyzer.

Auto-Check (Auto-check)

The Auto-Check evaluates the functionality of the analyzer's camera, cartridge port, thermal system, optics, and pump to ensure proper operation.

Please note: the Auto-Check cartridge is **not** a single-use cartridge, but can be used again any time an Auto-Check is indicated. Please do not dispose of it after use; **store it for future use** instead.

1. Tap **Settings** > **Maintenance** > **Auto-Check**. The "Please insert the auto-check cartridge" screen will be displayed.



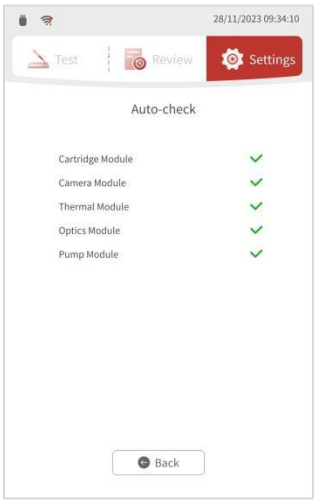
Please insert the auto-check cartridge screen

2. **Insert** the Auto-check cartridge with the QR code facing up horizontally into the cartridge slot until it cannot be pushed in any further. The Auto-check automatically starts after the cartridge is verified.

⚠

MAKE SURE THE QR CODE OF THE CARTRIDGE IS COMPLETE BEFORE INSERTING IT. IF THE QR CODE IS INCOMPLETE, IT WILL NOT BE RECOGNIZED AND THE NEXT TEST CANNOT BE PERFORMED.

3. When the Auto-check is complete, the Auto-check result screen will be displayed.



Auto-check result screen

The Auto-check results are described in the following table：

Symbol	**Interpretation**
	Test in progress
	Test failed
	Test passed

4. Tap **Back** to return to the **Auto-check** screen.
5. Take out the Auto-check cartridge and **store it for future use**.

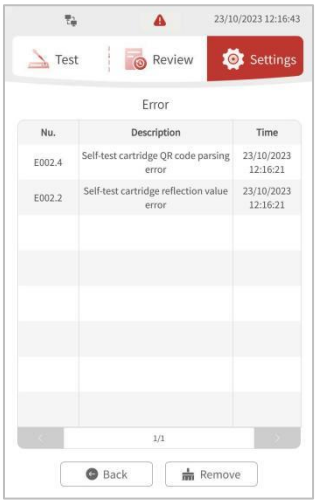
Appendix A: Troubleshooting

Zoetis Resources

For product support, please contact your local **Zoetis Customer Service Team**.

Errors

When there is an error in the analyzer, a flashing triangle will appear in the top center of the screen and the analyzer indicator light will remain red. Tap the to enter the error list, which displays the analyzer's current errors, including error number, error description, and time.



Error screen

Error Codes

System prompt	Description of the problem	Solution
No Coag	Test Error	Please strictly follow the blood collection instructions for sample collection and use a new cartridge. If the problem reoccurs, please contact Zoetis customer service.
E002	Ambient temperature is out of service range	Ensure that the instrument is used in an environment between 10°C - 35°C (50 – 95°F).
E003	Ambient pressure is too low	Ensure that the instrument is used in the environment below 2000m altitude.
E004	QR code parsing error	Please try again or use another cartridge.
E005	This is an Auto-check cartridge, please change the cartridge.	Please replace with correct cartridge or select the correct test.
E006	Insufficient sample	Use a new cartridge and ensure sufficient sample volume.
E007	Excessive sample	Use a new cartridge and ensure sufficient sample volume.
E008	Expired cartridge	Please use a cartridge within dating.
E009	Expired Quality control liquid	N/A
E010	Quality control liquid code is invalid	N/A
E011	Add sample timeout	Please try again or use another cartridge.
E013	Used cartridge or pressure value error	Please try again or use another cartridge.
E014	Sample coagulated or HCT is out of range	If the sample flow is abnormal, please strictly follow the blood collection instructions for sample collection and use a new cartridge for testing. If the problem still occurs, please contact customer service.
E015	The cartridge is removed during the instrument test	Do not pull out the cartridge before the test is completed.
E017	Heating timeout	Please try again or contact customer service.
E018	Cartridge reflectance error	Please try again or use another cartridge.
E019	No sample	Make sure the sample is added before testing.
E020	The cartridge leaking	Please use a new cartridge and test again. If the problem still occurs, please contact customer service.
E001.1	Real-time voltage of pump error	Please tap the【Remove】button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.2	Real-time sample of Optical system error	Please tap the【Remove】button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.3	Startup pressure error	Please tap the【Remove】 button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.4	QR code parsing error	Please tap the【Remove】button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.5	Communication in the internal system of the instrument error	Please tap the【Remove】 button below the error list to restart the instrument. If the problem still exists, please contact customer service.

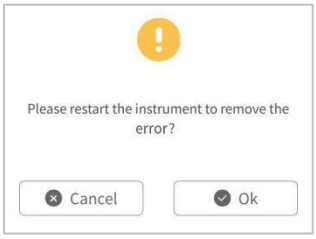
E001.6	Status light error	Please tap the【Remove】 button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.7	Heater temperature out of range	Please tap the【Remove】 button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E001.8	Real-time environment parameters readings error	Please tap the【Remove】 button below the error list to restart the instrument. If the problem still exists, please contact customer service.
E002.1	Auto-check cartridge pressure value error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E002.2	Auto-check cartridge reflection value error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E002.4	Auto-check cartridge QR code parsing error	Please confirm whether the QR code of the Auto-check cartridge is complete and free of stains. After restarting the instrument, use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E002.7	Temperature rise of heating module error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E003.1	Real-time voltage of pump error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E003.2	Real-time sample of Optical system error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.
E003.3	Real-time pressure readings error	Please tap the【Remove】button below the error list and press the prompt to use the Auto-check cartridge to conduct the instrument Auto-check. If the problem still exists, please contact customer service.

Resolving an Error

To resolve an error, tap **Remove**. The analyzer will prompt the user to restart or do a Auto-check depending on the type of error.

Restart to Resolve Error

1. If the analyzer determines a restart is necessary, the user will be prompted to restart the instrument to resolve the error.

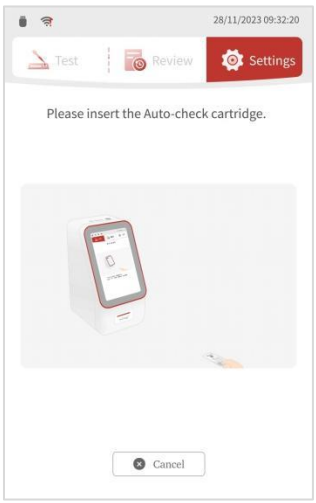


Restart to remove the error screen

2. Tap **OK** to restart the instrument and remove the error.
3. If the error is resolved, the analyzer light turns white and the triangle error  disappears.
4. If the error still exists, contact Zoetis customer service.

Auto-check to Resolve Error

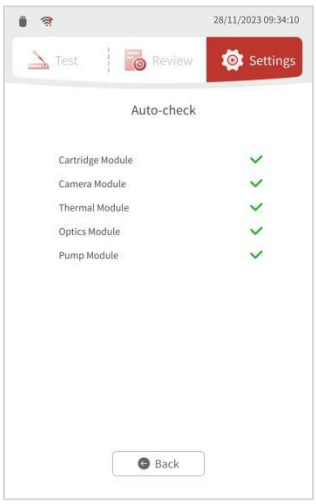
1. If the analyzer determines a Auto-check is necessary, the user will be prompted to insert the Auto-check cartridge to resolve the error.



Insert Auto-check cartridge screen

2. **Insert** the Auto-check cartridge into the slot horizontally, with the QR code facing up, following the cartridge animation displayed on the instrument. Push it in until it stops. The Auto-check will automatically begin once the cartridge is verified.

3. The interface will display the Auto-check results on the screen.



Auto-check result interface

4. Tap **Back**. Take out the Auto-check cartridge and store it for future use.
5. If the instrument asks the user to restart, tap **OK**.
6. If the error is removed, the analyzer light turns white and the triangle error  disappears.
7. If the error still exists, contact Zoetis customer service.

Appendix B: Maintenance

- Equipment maintenance must be performed by qualified professionals.
- Ensure proper ventilation around the equipment during use.
- If the automatic coagulation analyzer will not be used for an extended period, unplug it from the power source.
- When disconnecting the power cord, hold the plug to remove it—do not pull the cable itself.
- Clean the equipment, wipe down accessories, and cover them with a dust cover.
- Store the equipment in a cool, dry environment. Mobile equipment should be handled carefully to avoid violent vibrations.
- Do not immerse the equipment in cleaning agents during cleaning. Always disconnect the equipment from the power supply before cleaning its enclosure. It is recommended to use 75% alcohol for cleaning, following these guidelines:

If hazardous substances leak on the surface of the equipment or into the inside of the equipment, the following measures should be taken：

Scenes Requiring Disinfection	**Disinfection procedure**
Accidental Events: Sputtering or splashing of items such as samples, quality control products, calibrators, reagents, or waste liquid onto the instrument's surface.	①Remove Contaminants: Use 75% alcohol to remove contaminants from the instrument's surface. If the contaminant has dried, wipe the area repeatedly with 75% alcohol until the residue is gone. ②Clean with Water: Wipe the instrument's surface with clean water to remove any remaining disinfectant or alcohol. Dry the Surface: ③Use a dry, disposable rag to thoroughly dry the instrument's surface.
Before moving or handling instruments	Wipe the surface of the instrument with 75% alcohol, then wipe with water to remove residual alcohol, and finally use a dry disposable rag to dry the surface of the instrument.

1）Do not use dangerous cleaning agents or disinfectants that chemically react with equipment parts or materials contained in the equipment.

2）If there is any doubt about the compatibility of the disinfectant or cleaning agent with the parts of the equipment or the materials contained in the equipment, the manufacturer or its agent should be consulted.

Appendix C: Transportation

- During transportation, the equipment should be placed in the transportation packing box provided with the equipment.
- This product must be firmly positioned in the box, with appropriate thickness of soft cushion to prevent loosening or friction during transportation.
- The accessories should be firmly fixed in the box without falling off or colliding with each other.
- The packaged products should be stored in a room with no corrosive gases and good ventilation.
- As the instrument is precision equipment, it is important to consider the space and position during transportation to prevent severe impacts, vibrations, moisture, and rain. This will help avoid damage to critical components, such as optical parts.
- Do not put the equipment in an unstable position, handle carefully during the process, avoid collision, prevent instrument damage and personal injury.
- Please check the outer packaging of the equipment before opening the box. If there are any defects, collisions, or water immersion marks, please contact our company in time.
- Open the outer package to take out the host, according to the packing list to check the products and accessories, if there is no conformity, please contact our company in time.

Appendix D: Proper Disposal of Related Wastes

1) Wastes, such as used (contaminated) disposable experimental consumables and reagents, shall be disposed reasonably. Please wear gloves and other protecting facilities during the disposal and prevent contacting them directly. Dispose them reasonably following related laws about disposal of relevant medical wastes. Prevent harms to human health and environment.

2) This instrument belongs to electrical equipment. Discarded instruments shall not be disposed of as municipal or domestic waste and shall be disposed of in accordance with all applicable local or national regulations and must be recycled separately.

- **Wearing protective clothing**

1) Please wear safety glasses, gloves, masks, and other protective clothing during disposal of specimens, wastes or calibrators to prevent infection. If any part of the body comes into contact with contaminated consumables, immediately rinse the contaminated area thoroughly under running water and then disinfect it with 75% ethanol. Seek medical attention if necessary.

2) Leakage of the reagent into the Automated Coagulation Analyzer may result in short circuit or poor insulation or electric shock.

3) Users should comply with laboratory safety regulations and wear personal protective equipment (such as laboratory protective clothing, gloves, masks, etc.) when handling reagents in the laboratory. Once the reagent comes into contact with the skin, rinse immediately with plenty of water and seek medical treatment if necessary. As soon as the reagent comes into contact with eyes, rinse immediately with plenty of water. Seek medical attention if necessary.

Appendix E: Description of Electromagnetic Compatibility (EMC)

- The automated coagulation analyzer meets the requirements of emission and immunity specified in the part of IEC61326-1, IEC61326-2-6.
- Users shall have the responsibility to ensure the electromagnetic compatibility environment for the automated coagulation analyzer for normal work.
- It is recommended to evaluate the electromagnetic environment before using the Automated Coagulation Analyzer.
- The automated coagulation analyzer meets the requirements of Class A of Group I of CISPR 11.
- Users shall install and use the automated coagulation analyzer according to the electromagnetic compatibility information provided in the accompanying document.
- The portable and mobile RF communication device may affect the performance of the automated coagulation analyzer, so keep the Automated Coagulation Analyzer away from strong electromagnetic interference during use, such as mobile phone, microwave oven, etc.

Warning

- The automated coagulation analyzer shall not be used close to or stacked with other devices. If it must be used close to or stacked with other devices, it shall be observed and verified could work properly under the configuration in which it is used.

- The automated coagulation analyzer shall be designed and detected meeting the requirements for Class A device of CISPR 11. The automated coagulation analyzer may cause radio interference in a residential environment, so protective measures are needed.

- Do not use the automated coagulation analyzer near a strong radiation source (e.g. unshielded RF source), otherwise the radiation source may interfere with the normal operation of the automated coagulation analyzer.

The test items, standards and requirements on electromagnetic compatibility for the environment are shown in the table below.

Emission Test	Compliance	
RF emissions CISPR Ⅱ	Group 1	
RF emissions CISPR Ⅱ	Class A	
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation and flashing IEC 61000-3-3	N/A	
Immunity Test	Test Level	Performance Criterion
Electrostatic discharge (ESD)IEC61000-4-2	contact discharge：±8kV air discharge：±2kV、±4kV、±8kV、±15kV	A A
Electromagnetic field IEC61000-4-3	3 V/m (80 MHz to 2.0 GHz) 80%AM	A
Power frequency magnetic fields (50/60Hz)(PFMF)	3A/m, 50/60Hz	A

IEC 61000-4-8		
Voltage dips and interruptions IEC 61000-4-11	0% of U+ (Supply Voltage) for 0.5T, 1T & 250/300T 70% of U+ (Supply Voltage) for 25/30T	A A
Electrical fast transient(EFT) IEC 61000-4-4	±2 kV 100kHz repetition frequencye	A
Surge IEC 61000-4-5	Line-to-line: ±0.5kV、±1kV Line-to-ground: ±0.5kV、±1kV、±2kV	A A
Conducted RF IEC 61000-4-6	3V 0.15MHz - 80MHz 6V in ISM bands and amateur radio bands between 0.15MHz and 80MHz 80%AM at 1kHz	A

Appendix F: Regulatory

USA

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

CANADA

CAN ICES-3 (A)/NMB-3(A)

EUROPEAN UNION

Declaration of Conformity
Directives covered by this Declaration:
• EU RoHS2 Directive 2011/65/EU including amendments by Directives 2015/863/EU and 2017/2102/EU
• EU LVD Directive 2014/35/EU
The manufacturer hereby declares under his sole responsibility that this device complies with the Low Voltage Directive 2014/35/EU and the RoHS2 Directive 2011/65/EU including amendments by Directives 2015/863/EU and 2017/2102/EU.

Rev. 1.0