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ZellCLOT®

Blood Coagulation Analyser

Precision at, every clot.

Semi-automated optical coagulometer for routine clinical haemostasis

RoHS compliant

ISO 13485:2016

USFDA Registered

CDSCO Registered

CE

- Safe
- Simple
- Quality

ZellCLOT

Blood Coagulation Analyzer

USER MANUAL

Model: ZellCLOT-M (Mechanical)

Designed for multiple types of haemostasis analyses on a single device.

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Contents

1 Document Information 4
1.1 Copyright 4
1.2 Manufacturer 4
1.3 Warranty 4
2 Introduction 4
3 Description of Symbols 5
3.1 Signal words used in this manual 5
4 Hazards 5
4.1 Electrical hazards 5
4.2 Chemical hazards 6
4.3 Biohazard 6
5 Intended Use 6
6 Specimen Requirements 7
6.1 Sample type 7
6.2 Blood collection 7
6.3 Centrifugation 7
6.4 Storage 7
6.5 Interferences 7
6.6 Important considerations 7
7 Measurement Principle 8
7.1 Mechanical detection (ZellCLOT-M) 8
8 Safety Information 8
8.1 General 8
8.2 Avoiding risk to health 8
8.3 Service and maintenance 9
8.4 Electrical and EMC safety 9
9 Disposal and Recycling 10
10 Installation 10
10.1 Unpacking 10
10.2 Operating environment specification 11
10.3 Transport and storage 11
10.4 Setup 11
10.5 Thermal printer connection 12
10.6 Barcode scanner connection 12
11 Operation 13
11.1 Device settings 13
11.2 Patient ID 17
11.3 Test Selection and Parameter Settings 17
11.4 Running a measurement 19
12 Cleaning, Maintenance, and Decontamination 20
12.1 Cleaning 20
12.2 Decontamination 21
12.3 Routine maintenance 21
13 Technical Data 21

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1 Document Information

1.1 Copyright

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The software incorporated within SSQLTD products is the exclusive intellectual property of SSQLTD, and SSQLTD retains all inherent rights regarding its use. Upon purchase of an SSQLTD ZellCLOT instrument, the purchaser is granted a non-exclusive licence to use the associated software solely in conjunction with the operation of the ZellCLOT instrument.

1.2 Manufacturer

Sterile Safequip & Chemicals Limited
Unit 31, Panchratna Industrial Estate, Off SP Ring Road, Inside Pirana Gate, Ode Village, Paldi Kankaj, Ahmedabad – 382425, Gujarat, India.
Website: www.ssqllc.com

1.3 Warranty

The ZellCLOT is under warranty for one year from the invoice date. The warranty covers manufacturing defects only. It does not cover physical damage or damage caused by over- or under-voltage fluctuation.

The warranty becomes void in the event of failures caused by:

- Accidents, lack of proper maintenance, improper care, or misuse.
- Use of unauthorised reagents, consumables, or replacement parts.
- Unauthorised repairs or services. All repairs and maintenance must be carried out by authorised personnel only.

> **NOTE:** This manual applies to the Mechanical model (ZellCLOT-M).

2 Introduction

The ZellCLOT Blood Coagulation Analyzer is a sophisticated diagnostic instrument designed for the in vitro quantitative and qualitative determination of coagulation factors in human blood samples. It is intended for use by trained laboratory professionals.

The ZellCLOT-M uses a magnetic steel ball to monitor the change in the sample's viscosity during the coagulation process, providing accurate and reliable test results. This manual provides comprehensive instructions for the installation, operation, maintenance, and troubleshooting of the ZellCLOT.

ATTENTION: The ZellCLOT Blood Coagulation Analyzer must only be operated in strict accordance with the instructions in this Operator's Manual. Failure to do so may result in damage to the instrument, inaccurate test results, and potential harm to patients or operators. SSQLTD assumes no liability for any damage, injury, or consequence arising from use of the ZellCLOT in a manner inconsistent with this manual.

3 Description of Symbols

The following symbols appear on the analyzer and throughout this manual.

Symbol	Meaning
	Warning — Attention — consult the instructions for use. The specific meaning is described where the symbol appears.
	Hot surface — Attached on or close to parts that become hot when the instrument is switched on. Keep fingers and other body parts clear.
	Pinch point — Fingers and other body parts can be pinched where this label appears. Keep clear of the pinch point.
	Biohazard — The contents of the marked container are a biological hazard and are potentially infectious. Shown on waste bottles.
	Separate collection (WEEE) — At end of life, the analyzer must be collected separately in accordance with European Directive 2002/96/EC.
	Electrical safety warning — Indicates a risk of electric shock from live electrical parts.

3.1 Signal words used in this manual

WARNING: Failure to follow the information in a warning could lead to serious personal injury and/or damage to the analyzer.

ATTENTION: Failure to follow the information in an attention message could lead to damage to the analyzer.

NOTE: Notes contain additional information related to the surrounding text.

4 Hazards

4.1 Electrical hazards

WARNING: To prevent the risk of electric shock and/or damage to the instrument, operators must not open the covers over live (electrical) parts. Only authorised personnel, such as service technicians, may open the instrument for maintenance or repair. Touching live parts while the power is on may cause severe injury or death.

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4.2 Chemical hazards

The operator is responsible for taking all necessary precautions against hazards associated with clinical laboratory chemicals. Specific recommendations for each reagent are normally found on the manufacturer's package inserts or product information sheets. Wipe up any reagent spillage on the instrument immediately.

4.2.1 Additional precautions

Consult the reagent manufacturer for information on concentrations and other toxic constituents in each reagent. Avoid direct body contact with reagents and cleaning solutions, as this may cause irritation or skin damage. Refer to the manufacturer's reagent kit box, package inserts, or product information sheets for specific instructions.

4.3 Biohazard

> **BIOHAZARD:** Patient samples, controls, calibrators, and liquid waste are potentially infectious. They must be handled in accordance with national and international laboratory safety regulations.

Patient samples, controls, calibrators, and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens. Handle these substances in accordance with established laboratory safety regulations to minimise risk to laboratory staff, including wearing gloves and personal protection. Avoid contact with skin and mucous membranes. This also applies to all components of the instrument exposed to these substances. If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant.

Waste disposal is regulated differently in various countries. Refer to local sources for additional information on correct waste disposal.

5 Intended Use

The ZellCLOT-M Blood Coagulation Analyzer is designed for in vitro diagnostic use to perform a range of blood coagulation tests, including:

- **Prothrombin Time (PT)** — specimen: plasma; clot method.
- **Activated Partial Thromboplastin Time (APTT)** — specimen: plasma; clot method.
- **Thrombin Time (TT)** — specimen: plasma; clot method.
- **Fibrinogen (FIB)** — specimen: plasma; clot method.

This instrument is intended for operation in laboratory or clinical settings by trained laboratory professionals only. The ZellCLOT-M Blood Coagulation Analyzer provides quantitative and qualitative results to aid in the diagnosis and monitoring of haemostasis disorders.

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6 Specimen Requirements

The ZellCLOT analyzers are designed for use with human citrated plasma. Proper specimen collection, preparation, and storage are crucial for obtaining accurate, reliable results. Follow the guidelines below.

6.1 Sample type

- Human citrated plasma.

6.2 Blood collection

- Perform venipuncture using standard techniques.
- Collect blood into tubes containing 3.2% (0.105 M) sodium citrate as the anticoagulant in a 1:10 ratio (1 part citrate to 9 parts blood). Ensure the citrate tube is filled to the proper level to obtain the correct blood-to-citrate ratio.

6.3 Centrifugation

- Centrifuge the collected blood at 1500 × g for 10 minutes to obtain platelet-poor plasma.

6.4 Storage

- Analyse plasma samples as soon as possible after collection and centrifugation.
- If immediate analysis is not possible, store plasma at room temperature (15–30 °C) for a maximum of 4 hours.

6.5 Interferences

- **Bilirubin:** levels above 50 mg/dL may interfere with results.
- **Haemoglobin:** levels above 9000 mg/L (9 g/dL) may interfere with results.
- **Triglycerides:** levels above 2500 g/L (25000 mg/dL) may interfere with results.

> **NOTE:** Haemolysed, icteric, or lipemic samples should be avoided whenever possible, as they may lead to inaccurate results.

6.6 Important considerations

- Always follow your institution’s established protocols and guidelines for specimen collection, handling, and storage.
- Refer to the specific test reagent package inserts for detailed information on specimen requirements and potential interferences.
- Inadequate mixing of blood with anticoagulant, or improper centrifugation, can lead to erroneous results.
- Ensure the centrifuge is properly calibrated and maintained for optimal performance.

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7 Measurement Principle

7.1 Mechanical detection (ZellCLOT-M)

The ZellCLOT-M series uses a small magnetic steel ball placed in the sample to monitor the change in viscosity as the sample clots. As the clot forms, it traps the ball, and the ball's movement is monitored by a sensor. As the blood clots and becomes more viscous, the movement of the ball is impeded; this change is detected to determine the clotting time.

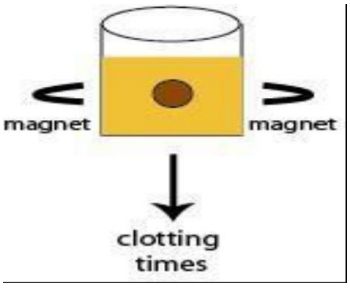

Figure 1. Mechanical (magnetic) detection principle.

8 Safety Information

8.1 General

WARNING: Always use new cuvettes; do not reuse or re-wash cuvettes, as this may cause errors or incorrect results.

Do not spill reagent on the ZellCLOT, as this may damage the instrument.

Regularly validate the ZellCLOT by running control readings to verify performance, and always use cuvettes supplied by SSQLTD. Calibrate the pipette used for plasma or reagent dispensing.

The ZellCLOT must be operated only by trained laboratory personnel. Read this manual carefully before use to avoid malfunction; failure to do so may affect the warranty.

Do not use any reagent or material after its expiry date, as this can lead to incorrect results.

8.2 Avoiding risk to health

8.2.1 Bleeding or thrombosis

Any false coagulation result may lead to a wrong diagnosis, which can in turn lead to critical bleeding or thrombosis. A faulty instrument, reagent, or calibration data increases this risk. To mitigate it:

- Perform quality control regularly — before patient sample testing, when changing a reagent vial or bottle, and after any calibration — to detect malfunction of the instrument, reagent, or calibration data.
- Calibrate the pipette on a regular basis (every 6 or 12 months) and label it with the calibration expiry date.
- Always run inter-laboratory quality-control standards.
- Always use highly purified water.
- Do not use any reagent or material after its expiry.

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- Always recheck with a different instrument if an abnormal result appears during patient sample testing.

8.2.2 Biohazard / infection risk

Any surface or material in direct contact with a blood sample, plasma sample, or other biological liquid is a likely contamination or infection hazard.

- Always use medical-grade personal protective equipment such as eyewear and protective gloves. Use hand disinfectant and wash your hands carefully. Do not reuse any personal protective equipment.
- Dispose of used cuvettes, reagent bottles, plasma cuvettes, liquid waste, and any infectious material in accordance with local regulatory guidelines.

8.3 Service and maintenance

Perform only the maintenance, repair, and replacement tasks specified in this Operator's Manual. Improper handling of the device can void the manufacturer's liability and may require service calls, which could incur additional charges not covered under warranty. Servicing must be carried out exclusively by authorised Customer Service personnel using only original replacement parts. Before starting any service work, ensure all potentially contaminated parts are thoroughly disinfected.

WARNING: Before removing the instrument from the laboratory for disposal or servicing, it must be decontaminated. This process is described in the "Cleaning, Maintenance, and Decontamination" chapter and must be carried out only by authorised, well-trained personnel who follow all required safety precautions.

Instruments returned for service must be accompanied by a decontamination certificate authorised by the laboratory manager. If this certificate is not provided, the returning laboratory will be responsible for any costs arising from the instrument being refused.

BIOHAZARD: Treat all surfaces and materials that may have come into contact with plasma or other biological fluids as potentially contaminated with infectious substances.

8.4 Electrical and EMC safety

WARNING: Prevent liquids from spilling into the system. If a spill occurs, disconnect the system from the power supply immediately, then clean and dry all affected parts.

- Always disconnect the power cord before opening the instrument.
- Avoid touching any electronic components during operation.
- Ensure the system is properly positioned for use.
- Never intentionally disrupt protective ground connections.
- Do not remove housing panels, protective covers, or secured structural components, as this could expose live electrical parts.
- Ensure the floor and workbench surfaces are dry while operating the device.
- Regularly inspect electrical equipment and promptly replace any damaged leads or sockets.

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- The instrument is classified as a portable Class II device and does not require a safety connection to electrical ground.
- Verify that the operating voltage is set correctly before connecting the device to the mains. Refer to the “Installation” chapter for electrical requirements.
- Ensure the power cord remains easily accessible during regular use.
- The ZellCLOT-M Series is designed for use in clinical and industrial settings.

9 Disposal and Recycling

BIOHAZARD: Before removing the instrument from the laboratory for disposal as electrical waste, it must be decontaminated.

The instrument must be recycled in accordance with local government regulations and guidelines for electronic waste disposal. Ensure proper recycling practices are followed to comply with environmental standards.

10 Installation

10.1 Unpacking

Inspect the box for damage and confirm the contents. In case of any damage or missing parts, inform your supplier. Retain the original packing material.

10.1.1 Packing list — ZellCLOT-M

No.	Item description	Qty.
1	Main unit	1
2	Thermal printer	1
3	Printer paper roll	1
4	Thermal printer connection cable	1
5	Power adaptor	1
6	Steel ball	100
7	Warranty certificate	1
8	Operational manual	1
9	QC report	1
10	Cuvette	100
11	Micro-volume pipette	1
12	Barcode scanner	1

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10.2 Operating environment specification

Parameter	Specification
Operating temperature	15–30 °C
Operating relative humidity	20–70% (non-condensing)
Elevation above sea level	< 3000 m
Dust	Free of dust — Grade 2
Impact resistance	According to IEC 61010-1
Electrical conditions	110–240 V AC, 50/60 Hz, no earthing required (Class II)
Electrostatic discharge (ESD)	No special requirements for ESD protection
Storage conditions	5–50 °C, max. 12 months in original package
Transport conditions	No special conditions; general transport regulations apply

ATTENTION: Do not install the device near sources of vibration, in direct sunlight, or in the direct path of air conditioning.

10.3 Transport and storage

ATTENTION: Always store the analyzer in an environment between 20 °C and 45 °C.

10.4 Setup

1. Unpack the device and confirm that the operating environment matches the specifications above.
2. Plug in the power adaptor.
3. The booting screen appears on the display.
4. After a few seconds, the home screen appears.

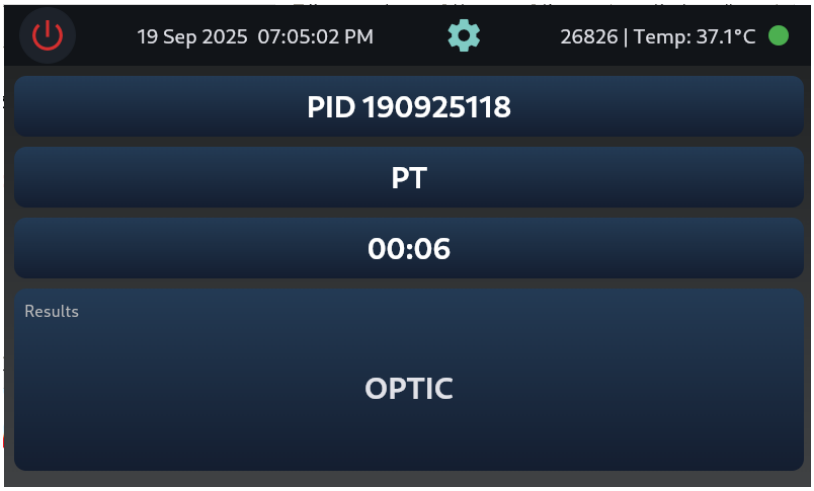

Figure 2. Home screen.

WARNING: Always store the original packing material.

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10.4.1 Preheat time

The ZellCLOT requires time to heat up to 37 °C (default setting) or the configured temperature. The temperature shown on the upper-right of the screen is the surface temperature of the heating block. If the displayed temperature does not reach the set value within 30 minutes, contact an authorised agency or SSQLTD for assistance.

10.4.2 Power off

To power off the device, press the power button at the upper-left of the display, enter the password ("1234"), and press "Yes" to begin shutdown. Once the screen goes blank, turn off the power-adaptor switch and disconnect the power adaptor.

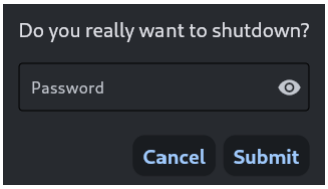

Figure 3. Shutdown confirmation screen.

10.5 Thermal printer connection

Parameter	Specification
Connector	Serial RS-232 D-type (the ZellCLOT has a female D-type connector)
Power supply	5 V DC, 3 A
Connection cable	1 m length, D-type 9-pin connectors at both ends
Communication protocol	9600 baud, 8-N-1

10.5.1 Setup instructions

1. Connect one end of the cable to the ZellCLOT and the other end to the printer.
2. The printer's power LED begins to blink, indicating a successful connection.
3. Ensure the paper roll is correctly fitted in the printer.
4. No additional software configuration is required for the printer connection.

WARNING: Do not connect any other brand of printer; doing so may damage the ZellCLOT.

10.6 Barcode scanner connection

Parameter	Specification
Interface type	USB
Power supply	Powered directly through the USB connection

10.6.1 Setup instructions

1. Connect the barcode scanner to either of the two USB ports on the ZellCLOT.
2. No additional software configuration is required for the barcode scanner connection.

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11 Operation

After power-up or reboot, the home screen appears. From the home screen you can enter the Patient ID, select the test type, start the incubation timer, and view the result. The screen header shows the date and time, the settings icon, the reference value, and the heating-block temperature.

Figure 4. Home screen with Patient ID, test type, incubation timer, and result area.

11.1 Device settings

Press the settings icon on home screen and enter the password “1234” to open the Settings screen.

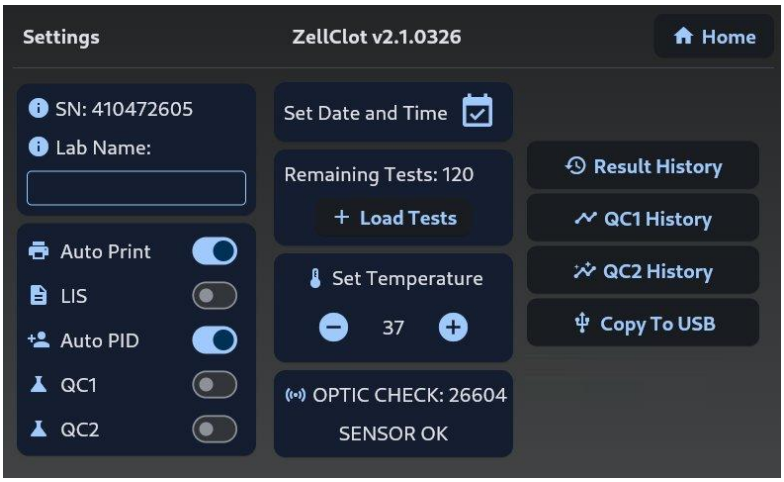

Figure 5. Settings screen.

SN: Displays Serial Number of the machine.

Lab Name: Enter Lab Name

Auto Print: When enabled, the printer automatically prints the results after each test is completed.

LIS: When enabled, LIS will be turned on.

Auto PID: When enabled, the Patient ID increments automatically after each test using the default ID format. When disabled, the operator must enter the Patient ID manually before each test or can use the external barcode scanner if they choose to do so for manual PID entry.

QC1: When enabled, all processed results are categorised as low QC and stored accordingly.

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QC2: When enabled, all processed results are categorised as high QC and stored accordingly.

Remaining Tests: Indicates the number of tests remaining on the ZellCLOT. When this reaches zero, no further tests can be performed until tests are reloaded.

Load Tests: Opens the voucher-code screen used to reload tests (see below).

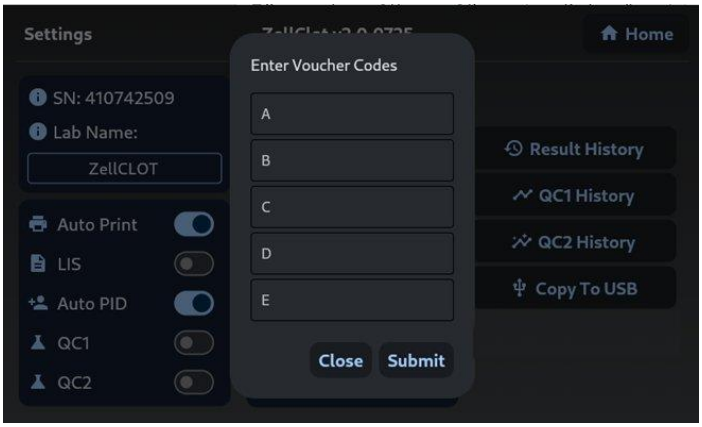

Figure 6. Load Tests (voucher code) screen.

Enter the values for “A”, “B”, “C”, “D”, and “E” obtained from the dealer or the SSQLTD recharge website, then press “Submit”. Once all values are entered correctly, the ZellCLOT is reloaded with tests.

11.1.1 Set Temperature

On the Set Temperature screen, adjust the surface temperature of the heating block using the + and – buttons. Once the desired value is set, the heating block then maintains the set temperature.

Figure 7. Set Temperature screen.

11.1.2 Set Date / Time

Select the date from the calendar and press OK, then select the time and press OK. Press Save and Shutdown to apply the selected date and time. Once the device powers off, wait a few seconds and switch it back on — the new date and time take effect on restart.

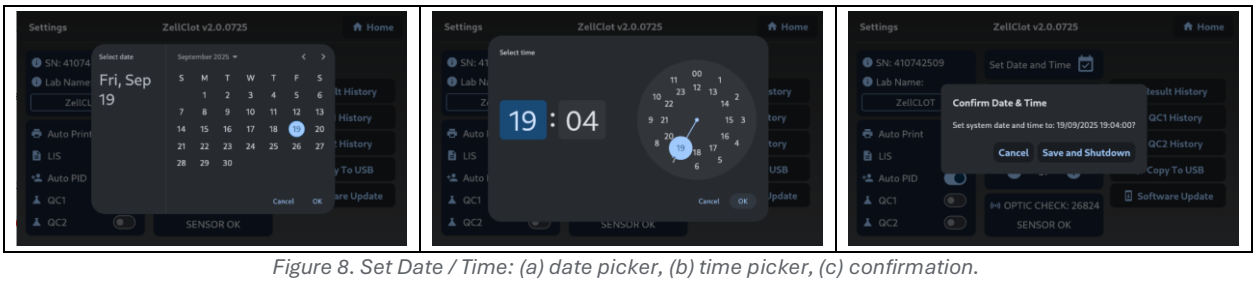

Figure 8. Set Date / Time: (a) date picker, (b) time picker, (c) confirmation.

> **NOTE:** If the device is not restarted, the new date and time settings take effect only after the next restart.

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11.1.3 Result History

The Result History screen shows the history of results, with the most recent at the top and the earliest at the bottom. The ZellCLOT can store up to 9999 results. Press the print button to print the selected result on the thermal printer. Select the From and To dates, then press Filter to display tests within the chosen date range.

Figure 9. Result History screen.

11.1.4 QC1 History and QC2 History

The QC1 History and QC2 History buttons on the Settings screen open the quality-control records for the two control levels: QC1 (low control) and QC2 (high control). After opening either screen, select the test — PT, APTT, TT, or FIB — to view the QC configuration and records for that test. The two screens are identical in layout and differ only in the control level they manage.

For the selected test and control level, the following fields can be defined and reviewed:

- **QC Name —** the name or identifier of the control material.
- **QC Batch —** the batch (lot) number of the control material.
- **QC Expiry —** the expiry date of the control material.
- **QC Target High —** the upper limit of the acceptable range.
- **QC Target Low —** the lower limit of the acceptable range.
- **QC Mean —** the expected mean (target) value of the control.

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Figure 10. QC1 History screen (PT shown).

Figure 11. QC2 History screen (PT shown).

11.1.5 Levey–Jennings graph (QC Graph)

Press QC1 Graph or QC2 Graph to display the Levey–Jennings chart for the selected test and control level. The chart plots the recorded quality-control results against the configured mean and target limits, allowing analytical performance to be monitored and trends or shifts to be detected over time.

Figure 12. Levey–Jennings graph with the Export to USB option (no data shown).

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Press “Export to USB” to save the displayed graph to a connected USB drive.

> **NOTE:** The Levey–Jennings graph displays data from the last 30 days only. If no results are available for that period, the screen shows “No QC data available.”

11.1.6 Copy to USB

Press “Copy to USB” button on settings screen to export the history data and audit logs to a connected USB drive.

11.2 Patient ID

Pressing the PID button on home screen opens the Patient ID entry screen. The Patient ID (up to 16 characters) can be entered manually, or — if a barcode scanner is attached — by tapping the designated area and scanning the code. The PID is then shown on screen. Press Save to store the PID; the screen closes and returns to the home screen.

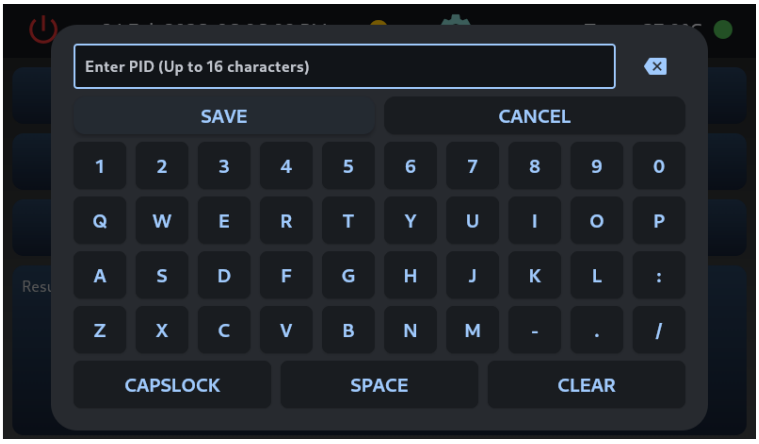

Figure 13. Patient ID entry screen (tap the indicated area when using a barcode scanner).

> **NOTE:** Patient ID entry is not mandatory when Auto PID mode is enabled. Otherwise, if the PID field is left empty, the Patient ID entry prompt appears.

11.3 Test Selection and Parameter Settings

Pressing the test button on home screen opens the Test Selection / Parameter Setting screen. All available tests — PT, APTT, TT, and FIB — are displayed; the selected test is highlighted in sky blue. Tap the corresponding button to select a test, and the related parameters appear below.

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Figure 14. Select Test / parameter screen (PT shown).

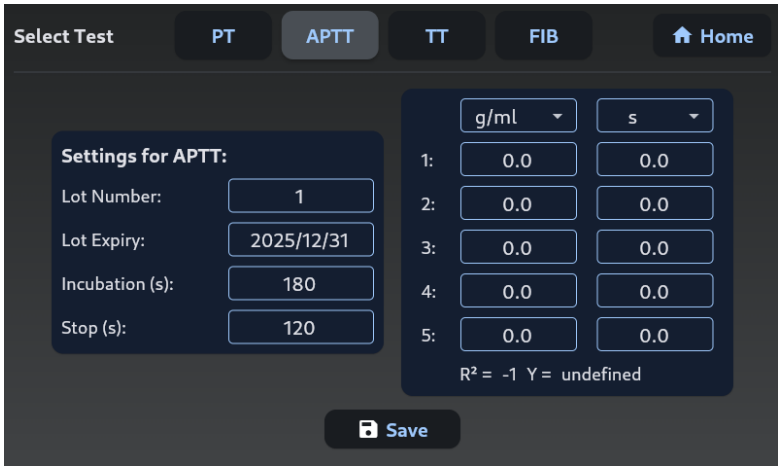

Figure 15. Parameter screen for APTT.

Figure 16. Parameter screen for TT.

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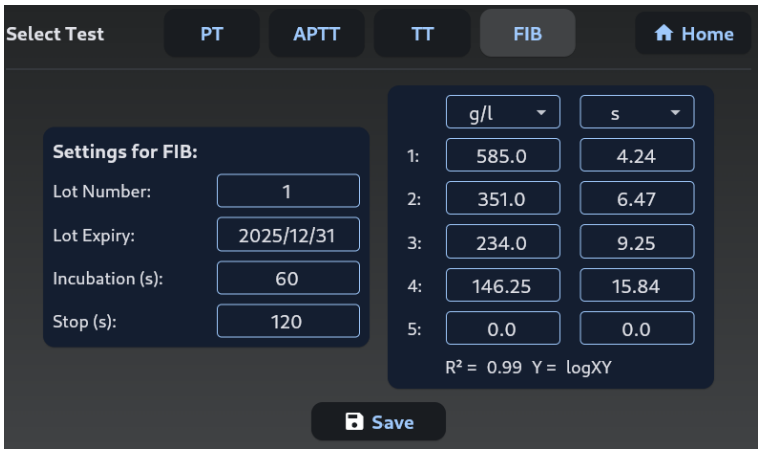

Figure 17. Parameter screen for FIB.

> **NOTE:** Tapping any data-entry field opens the on-screen keyboard, allowing data to be entered for that parameter.

11.3.1 Parameter glossary

Parameter	Description
Lot	A batch of reagent production that aids traceability.
Expiry	The date beyond which a product (reagent or consumable) is no longer guaranteed to meet its specified quality or performance.
Unit	The standardised measurement in which a parameter or substance is expressed, ensuring consistency and accuracy in reporting.
Incubation	Maintaining specific conditions, such as temperature, for a defined period to promote the chemical/analytical reaction.
Stop	For samples that do not clot, the instrument halts measurement after the specified stop time and indicates that no clot was detected.
Calibration curve	Established by entering calibration points (minimum 2, maximum 5) to define the calibration range for accurate measurement.
Normal	The reference value for normal clotting time, such as the MNPT for PT.
ISI	International Sensitivity Index of the PT reagent, provided with the reagent to standardise results.

R^2 (coefficient of determination): Indicates the linearity of the calibration, which determines the interpolation method used:

- **R^2 < 0.5:** not linear — uses Y = LIN (linear interpolation).
- **R^2 < 0.9:** moderately linear — uses Y = 1/X (reciprocal linear interpolation).
- **R^2 >= 0.9:** highly linear — uses Y = logXY (double-logarithmic interpolation).

11.4 Running a measurement

The measurement procedure for the ZellCLOT-M is described below.

11.4.1 Mechanical model (ZellCLOT-M)

1. Prepare the cuvette: Load the reagent into the cuvette.

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2. Place the cuvette: Insert it into the well.
3. Start the incubation timer: The timer counts down from the set incubation time, and the countdown is displayed during incubation.
4. End of incubation: When incubation is complete, a “Ready” message appears.
5. Add reagent: Add the reagent to the cuvette when prompted. Addition is detected when the pipette is pressed, via a switch attached to the pipette. The pipette must be connected to the right-hand side of the machine; when it is pressed, the indicator turns green. If reagent addition is not detected automatically, tap “Ready” to start the test.
6. Start measurement timer: The timer increments to measure reaction time. The frequency of the metal ball rotating in the cuvette is shown on the screen, and the frequency and result are displayed when the metal ball stops rotating and sample gets clot in the result window.
7. Completion: When measurement is complete, the system displays the result.
8. Result display: The screen shows the final result in the designated format.

WARNING: Always maintain a minimum volume of 150 µl in the cuvette. Mix the reagent according to the manufacturer’s standard procedure; any deviation may result in inaccurate results. Always perform quality control each day before testing patient samples to confirm the device’s working status.

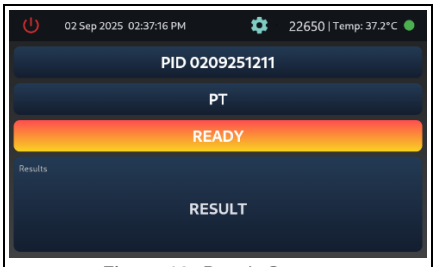

Figure 18. Ready Screen

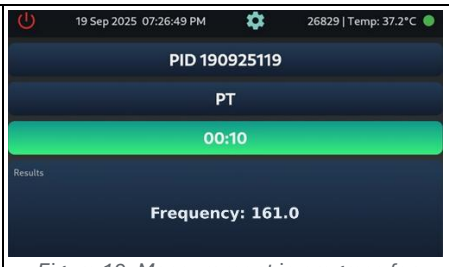

Figure 19. Measurement in progress for mechanical model

Figure 20. Result screen (clotting time and derived value).

12 Cleaning, Maintenance, and Decontamination

12.1 Cleaning

General: Gently clean the device using a lint-free cotton cloth or cleaning stick to avoid scratches or damage.

Prevent liquid contact: Do not pour or spill liquids into the working area or onto the touch display, to prevent malfunction.

Maintain cleanliness: Keep the device clean, dry, and free from dust and moisture to ensure proper functioning.

Screen: Clean the screen with a microfibre cloth only; avoid using any liquids.

Spill cleanup: Clean and wipe up spills in the working area using a 5–10% diluted bleach detergent solution or water.

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12.1.1 Handling spills

- If the device comes into contact with liquid, wipe it quickly with an absorbent cloth.
- If liquid enters the measurement channel, turn off the power immediately, then carefully clean the channel using a pipette and a lint-free cloth.

12.2 Decontamination

Disinfectant: Use a 30% diluted bleach solution or a commercial disinfectant for decontamination.

Working area: Ensure thorough decontamination of the working area.

> **ATTENTION:** Do not apply liquids directly onto the display, to avoid damage.

12.3 Routine maintenance

12.3.1 ZellCLOT-M

- No routine maintenance is required.
- Perform a temperature check daily or before use to ensure optimal performance.

> - **BIOHAZARD:** Treat all surfaces and materials that come into contact with plasma or other biological liquids as potentially contaminated with infectious substances.

> **WARNING:** Avoid any direct contact with decontaminants or disinfectants.

13 Technical Data

Specification	ZellCLOT-M
Global coagulation tests	PT, APTT, TT, FIB
Real-time clock	Yes
Display	4" colour touchscreen
Material of construction	ABS plastic
Product dimensions	275 × 140 × 80 mm (D × W × H)
Interface	Thermal printer, barcode reader
Humidity	20–80% (without condensation)
Power supply	110–230 V AC, 50/60 Hz
Power Adaptor	12V
Packing dimensions	390 × 225 × 160 mm (D × W × H)
Storage conditions	0–50 °C, max. 12 months in original package
Accessories	Thermal printer, micro-volume pipette, ball dispenser

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