ZBT-ESR®

USER MANUAL

Version: 04.2026.01

Sterile Safequip & Chemicals Limited

Safe, Smart & Quality Analyser

Sterile Safequip & Chemicals Limited
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Preface

Thank you for purchasing the **ZBT-ESR Analyzer** manufactured by **Sterile Safequip & Chemicals Limited**.

This manual provides detailed information regarding installation, operation, maintenance, and troubleshooting of the analyzer. It is intended for trained laboratory personnel and should be read thoroughly before operating the device.

The ZBT-ESR Analyzer is designed to provide accurate, reliable, and automated ESR measurement with minimal operator intervention.

Product Name: ZBT-ESR Analyzer

Model: ZBT-ESR DT10

Contents

1. EXPLANATION OF SYMBOLS: PRODUCT AND PACKAGE LABEL & PICTOGRAMS

The following symbols are used on the product and packaging:

	**Biohazard Symbol** Indicates potential biological risk. Follow all safety precautions when handling blood samples.
	**Warning Symbol** Indicates potential risk of injury or hazardous condition.
	**Hot Surface Symbol** Indicates surfaces that may become hot during operation.

1.1. ABBREVIATIONS

Abbreviation	Meaning
ESR	Erythrocyte Sedimentation Rate
PID	Patient Identification
FIFO	First In First Out
LIS	Laboratory Information System
Min	Minute
Hr	Hour

2. CONTENT DISCLAIMERS

- All images and screenshots are for illustration purposes only
- Display values shown may differ from actual device output
- Product specifications are subject to change without prior notice
- Each device has a unique serial number for identification

3. INTRODUCTION

The **ZBT-ESR Analyzer** is an automated diagnostic instrument designed to measure the **Erythrocyte Sedimentation Rate (ESR)** using the **Westergren method**, which is the globally accepted reference method for ESR determination.

The analyzer allows simultaneous processing of up to **10 K3 EDTA tubes (samples)**, ensuring high throughput and efficiency in laboratory environments.

The system performs:

- Automatic tube detection
- Blood level sensing
- Sedimentation tracking
- Temperature monitoring
- Result calculation (Room Temperature & 18°C corrected)

4. INTENDED USE

The ZBT-ESR Analyzer is intended for the **quantitative determination of ESR (mm/hr)** in anticoagulated human blood samples collected in EDTA tubes.

It is designed for use in:

- Clinical laboratories
- Diagnostic centers
- Hospitals

5. WHO SHOULD READ THIS USER MANUAL

This manual is intended for:

- Laboratory technicians
- Clinical operators
- Biomedical engineers

The device should only be used by trained and qualified personnel.

6. DANGER & FIRST AID

6.1. DANGER

- Use only test tubes approved by local regulatory authorities (in the USA, only US FDA-approved tubes).
- Always wear laboratory-grade PPE, including gloves, safety goggles, and a face mask, when operating the analyzer or handling blood samples to prevent exposure to contamination.
- Follow the manufacturer's Instructions for Use (IFU), including cleaning and packaging procedures.

- Operate the ZBT-ESR Analyzer only within the environmental conditions specified in this manual.
- Do not reuse or use damaged test tubes.
- In case of tube breakage inside the device, avoid contact, immediately switch off the unit using the main circuit breaker, and contact Sterile Safequip & Chemicals Limited or authorized service personnel.
- In case of analyzer malfunction, contact Sterile Safequip & Chemicals Limited or authorized service personnel immediately.
- It is the responsibility of the user's facility management to ensure that all personnel are properly trained and authorized to operate the analyzer.

6.2. FIRST AID

- **Skin or clothing contact with patient's sample blood:** Wash with soap immediately. Remove contaminated clothing and wash clothing before reuse. If signs/symptoms develop, seek medical attention.
- **Eye contact:** Immediately seek medical attention.
- **Inhalation/Ingestion:** Immediately seek medical attention.

7. SAFETY

I. The ZBT-ESR Analyzer complies with the following standards:

a. IEC 61010-1:2010 + AMD1:2016
b. IEC 61010-2-010:2019
c. IEC 61010-2-040:2020
d. IEC 61326-1:2020 (3rd Edition) for laboratory use.
e. CFR 47, FCC Part 15B (ANSI C63.4:2014).

II. This equipment complies with the limits for a Class A digital device under FCC Part 15, providing reasonable protection against harmful interference in a medical laboratory environment.

III. Always wear laboratory-grade safety goggles, gloves, and a face mask when operating the analyzer or handling blood samples to prevent exposure to contamination.

IV. Ensure proper positioning of the test tube and secure placement of the cap to prevent tube breakage or blood spillage during operation.

V. It is the responsibility of the user's facility management to ensure that all personnel operating or maintaining the equipment are properly trained in its operation and safe use, and that all required safety inspections are completed. For safety guidance, contact Sterile Safequip & Chemicals Limited or its authorized service personnel.

8. PRINCIPLE OF OPERATION

The ZBT-ESR Analyzer operates on the **Westergren sedimentation principle**, where red blood cells settle under gravity over time.

Working Process

1. Blood sample is placed in a vertical tube
2. Red blood cells gradually settle down
3. Serum rises to the top
4. Distance travelled by RBCs in 1 hour is ESR

In ZBT-ESR Analyzer

- Measurement time = **20 minutes**
- Result extrapolated to standard ESR value
- Temperature correction applied to **18°C (Manley's correction)**

9. SYSTEM OVERVIEW

The analyzer consists of:

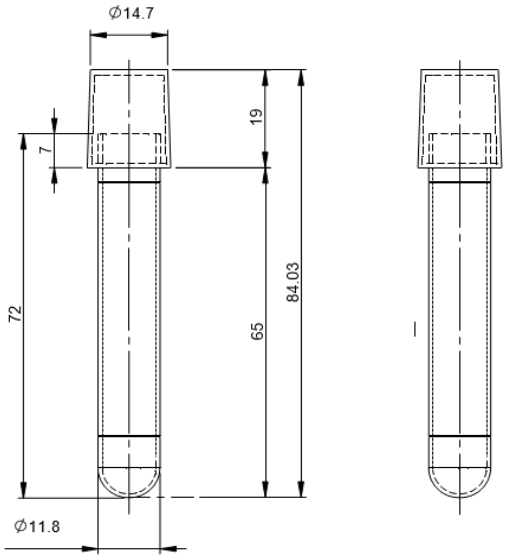
- 10-channel tube holder
- Touchscreen display
- Internal sensors for level detection
- Thermal printer interface
- LIS communication port

10. TUBE DETAILS

ZBT-ESR Analyzer can be used with certain fixed size of tube which contain K3 EDTA as per below details. No other tube which has different size or other than below described details can be used. These tubes need to be filled with blood sample with certain volume and kept in the ZBT-ESR Analyzer's tube slot to measure ESR.

Tube specification: Standard 4.0 mL K3 EDTA

Tube Usable Volume: 2 ml Blood



Tube Blood Sample volume: 2ml

Tube Inner diameter: 10.4 mm

Tube Outer diameter: 12.2 mm

Tube Total height: 75 mm

11. SPECIFICATIONS

11.1. Power Specifications

Electrical Power	**Operating Condition**
Voltage Range	24 VDC ± 5%
Frequency	50 Hz
Phase	Single
ZBT-ESR	2.5 Amps

11.2. Device Specifications

Analysis time	20 min (0~±3%)
ESR measurement method	Westergren method mm/hr. Auto compensation to 18°C (Manley table)
Measurement range	1~140mm/hr.
Height Reading resolution	0.1mm
Accuracy in height reading	±1mm
Reproducibility	C.V<5%
LIS	RS-232, D type 9 pin male connector, HL7
Barcode scanner interface	USB type
Sample code entry	16 Alpha/ numeric digit Manual entry & also with Barcode scanning
Test tube	As per above "10.0 Tube details"
Temperature compensation	15~30℃
Dimension	189mm(L) X282mm(W)X231mm(H)
Weight	4 Kg
Loading pattern	Random access
Memory	9999 Sample Results
Sound level	(Min) 41 dB – (Max) 44 dB
Standard & Regulations	ISO 13485, USFDA Registered, CDSCO Registered, CE Certified IEC 61010-1:2010/AMD 1:2016, IEC 61010-1:2010, IEC61010-2-101:2018, IEC 61326-1:2020, IEC61326-2-6:2020

11.3. Operating Environment Specification

Environmental Condition	**Operating Condition**
Operating Temperature	15-30℃
Operating Relative Humidity	20-70% (non-condensing)
Altitude	1800 Meters
Installation/ Transient over voltage	Category II
Pollution Degree	2
Ventilation	Keep air exchange to ensure good air circulation
Electromagnetic Wave	Keep the ZBT-ESR Analyzer away from electric-brush motors, flashing fluorescent and electric-contact equipment, which is switched on/off frequently.

12. PREPARING TEST TUBES FOR ESR MEASUREMENT

1. Blood can be collected in K3 EDTA directly as per standard blood collection method.
2. Blood also can be collected in Standard EDTA tubes and can be used with the instrument.
3. Tube must be mixed by inverting (do not vigorously mix tube).
4. Test must be performed within 4 hours from the collection of the blood.

This analyzer requires a specific type of test tube as detailed in Fig. 1 (Tube Specifications). Remove the cap and dispense approximately 2 mL of blood; volumes above or below this range may result in inaccurate ESR readings. Mix the sample by gently inverting the tube for at least 3 minutes to ensure uniform distribution of blood from one end to the other. Insert the tube into the device. Upon insertion, tube detection may take 1–2 minutes, depending on the sensing cycle. During this time, blood may settle along the inner surface toward the bottom. Once the tube is detected, the corresponding slot on the display will initiate lap timing.

13. METHOD OF TUBE PLACEMENT

The ZBT-ESR Analyzer is designed for sample tubes with a single secondary label placed as close as possible to the lavender EDTA cap, leaving one side free of labelling (Fig. 1). During loading, ensure the label-free side is aligned with the arrow on the insertion ring (Fig. 3), positioning it toward the rear of the analyzer (Fig. 2). This alignment is essential for proper sample handling and accurate analysis within the system.

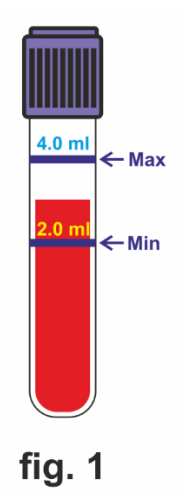


fig. 1

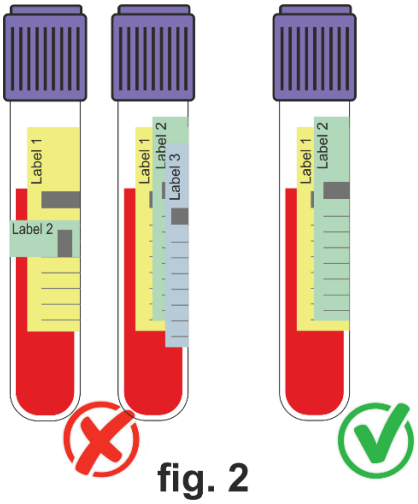


fig. 2

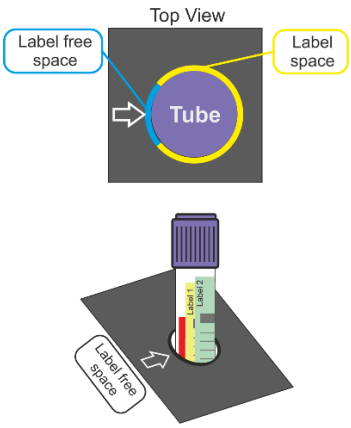


fig. 3

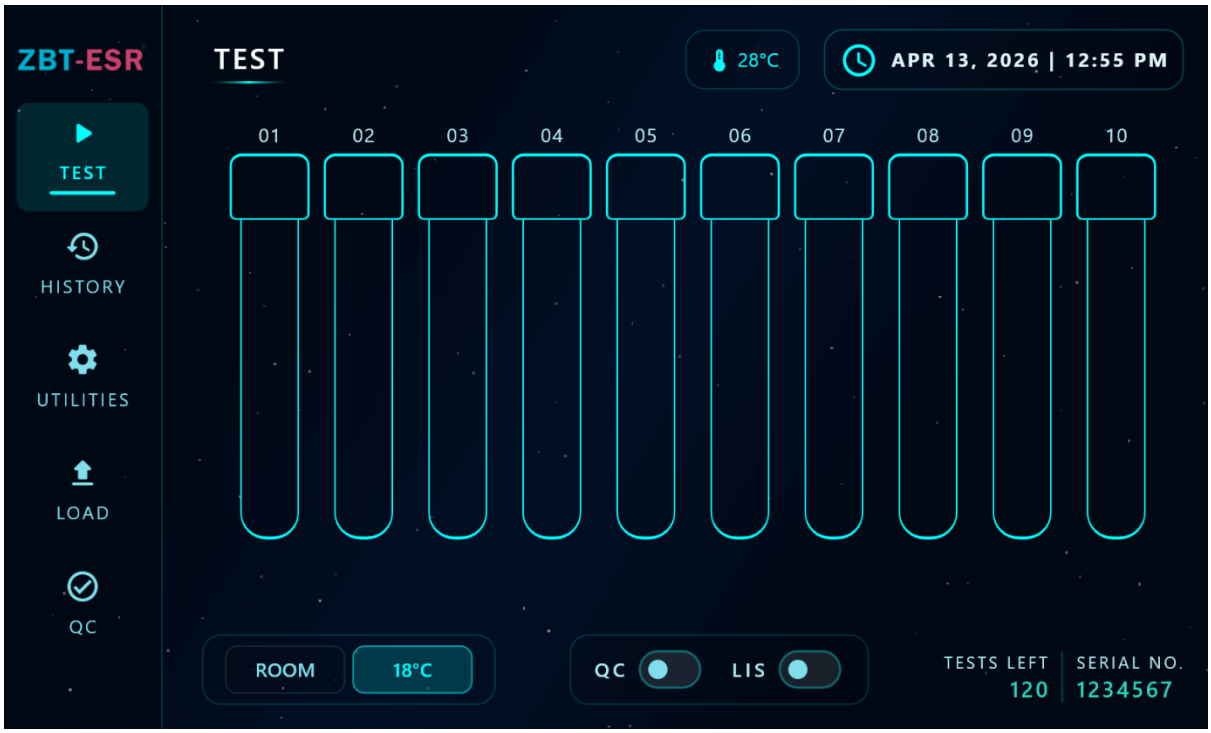
1. Ideal blood volume. (fig-1)
2. Allow tube with a single secondary label only. (fig-2)
3. Label-free space with the arrow marked on the insertion ring (fig-3).

14. USER INTERFACE OVERVIEW

The system uses a **touchscreen interface with side navigation panel**.

14.1. Test Screen (Main Operation Screen)

This is the primary working screen where all tests are performed.



Display Elements

- 10 tube slots (Channel 1–10)
- ESR result display
- Remaining timer per channel
- Blood level indication
- Serum separation visualization
- Current temperature
- Serial Number
- Remaining test count
- LIS toggle (ON/OFF)
- QC toggle (ON/OFF)
- Test Mode (Room Temperature / 18 ° C)

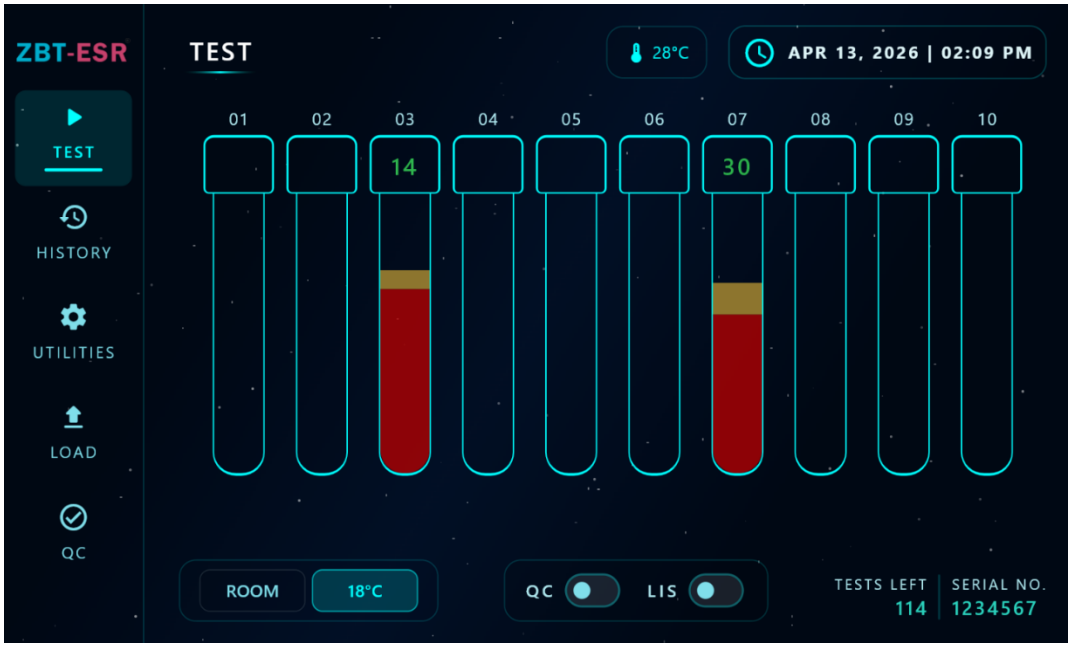
Tube Slot Behaviour

Each tube slot shows:

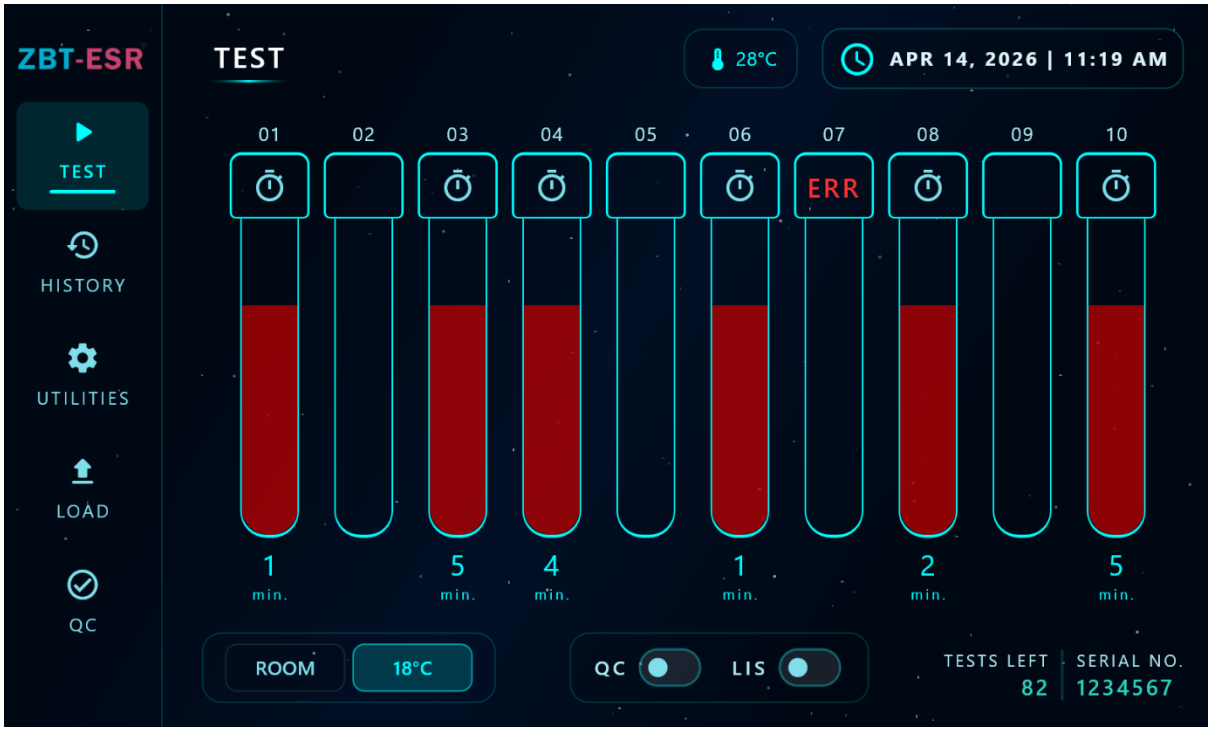
STAGE	DISPLAY
Empty	Blank
Tube Detected	Blood Level
Running	Countdown Timer
Completed	ESR Result
Error	ERR

TEST RUNNING

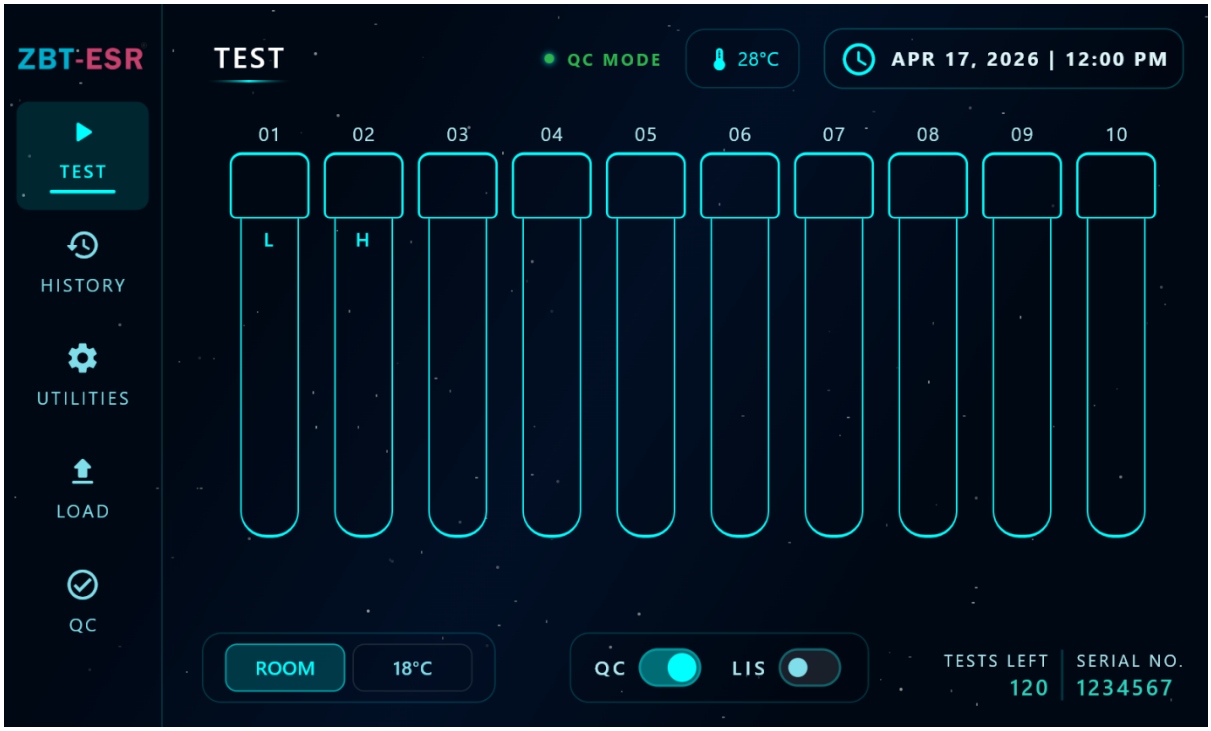
ESR RESULT DISPLAY



ERROR INDICATION



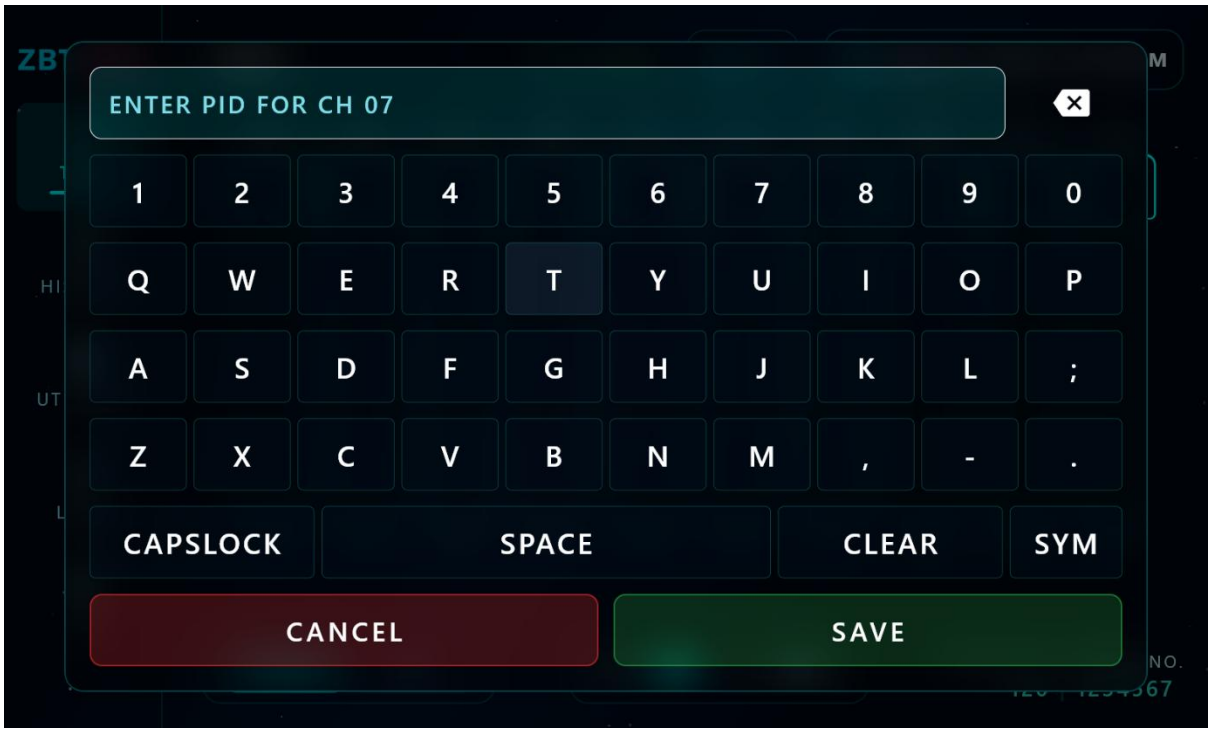
QC MODE ON



LIS INTEGRATION

- LIS toggle on Test screen
- When enabled:
  - Data sent automatically after test

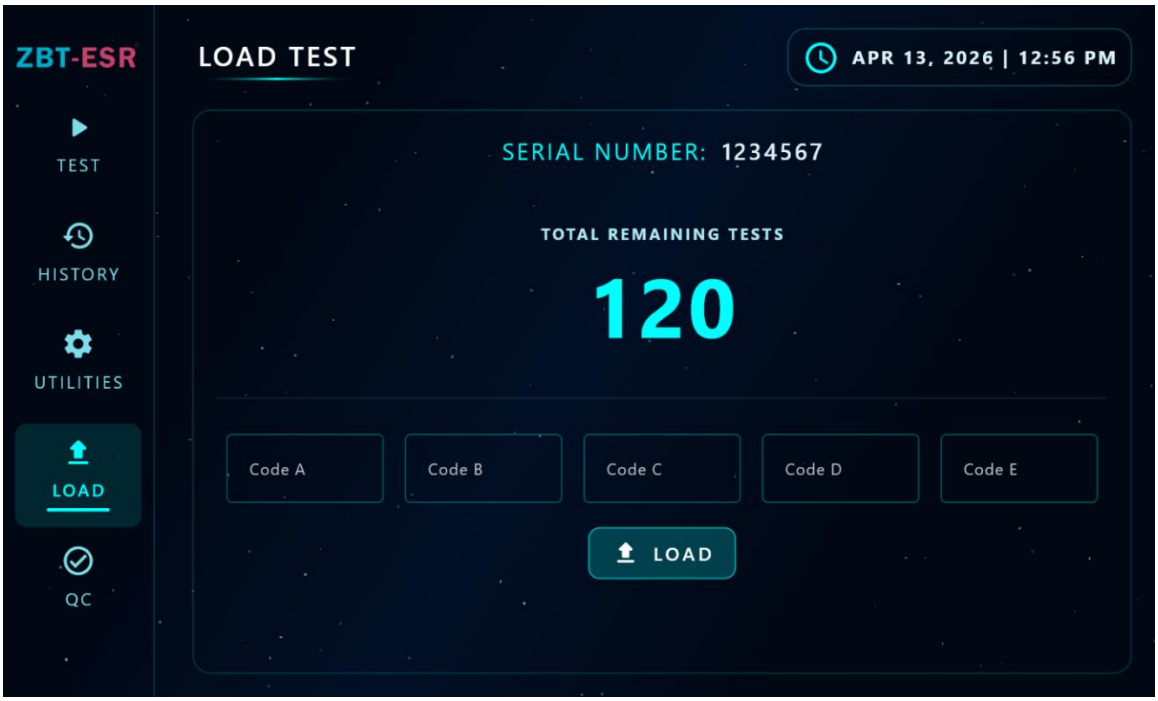
14.2. PATIENT ID (PID) ENTRY



- Tap any tube slot
- On-screen keyboard appears
- Barcode scanner supported
- PID is optional
- To view Patient ID tap on that tube slot when test is running or when result is displayed

⚠ If PID not entered → test still runs

14.3. LOAD SCREEN - TEST COUNT MANAGEMENT



- Enter Codes A–E
- Load test count
- Count reduces automatically after each test
- If count < 50 → Warning
- If count ≤ 0 → No new test allowed

14.4. HISTORY SCREEN

Features

- View all test records
- Filter by date range

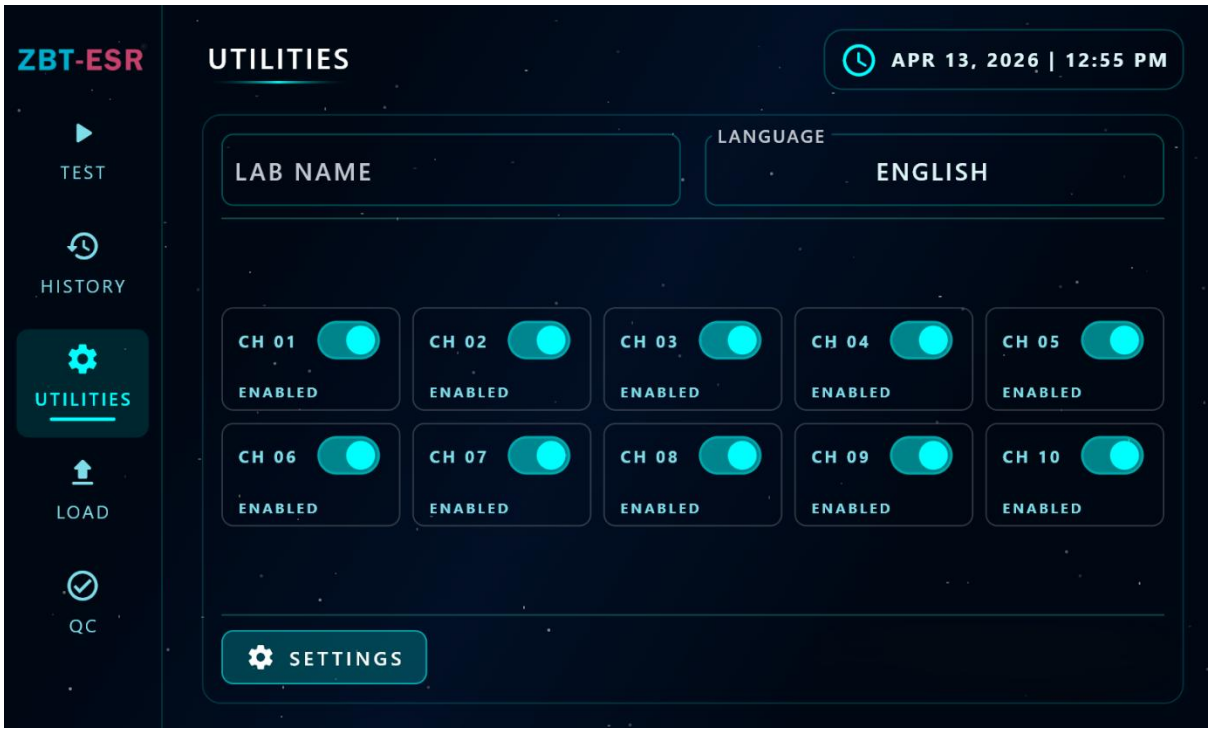
Export Options

- No selection → Export all / filtered data in PDF
- Selected row → Export single test in PDF

Printing

- Reprint any test

14.5. UTILITIES SCREEN



Always Available on Screen

- Set Lab Name
- Change Language

Available when No Test Running

- Enable / Disable Channels
- Settings for Service

Channel Disable

- Disabled channel shown dim on Test Screen.
- No detection occurs.

14.6. QC SCREEN

QC Types

- QC Low → Channel 1
- QC High → Channel 2

Features

- Stored separately
- Exportable as PDF

15. OPERATING PROCEDURE

The ZBT-ESR Analyzer is designed for fully automated operation with minimal user intervention. Before starting the analysis, ensure that the device is properly powered ON using the main power switch. Once switched ON, the system initializes automatically and loads the Test screen, where all operational parameters, including tube slots, temperature, and test count, are displayed.

The operator may optionally assign a Patient Identification (PID) before inserting the sample tube. This can be done by tapping the desired tube slot on the Test screen, which opens an on-screen keyboard for manual entry or allows barcode scanning if a scanner is connected. Although PID entry is recommended for proper sample tracking, the analyzer allows testing even without PID entry.

For analysis, a properly prepared EDTA blood sample tube must be inserted vertically into any available tube slot, ensuring correct positioning. Once inserted, the analyzer automatically detects the presence of the tube within approximately one minute. During this detection

phase, the system identifies the blood level and initializes the test cycle. Upon successful detection, the test starts automatically without requiring any manual intervention.

The analyzer performs ESR measurement using a fixed analysis time of 20 minutes. Multiple samples can be processed simultaneously across all available channels. During the test, the system continuously monitors the blood level and sedimentation process using its internal sensing mechanism. The progression of each test is displayed on the screen with a countdown timer and graphical indication of blood level separation.

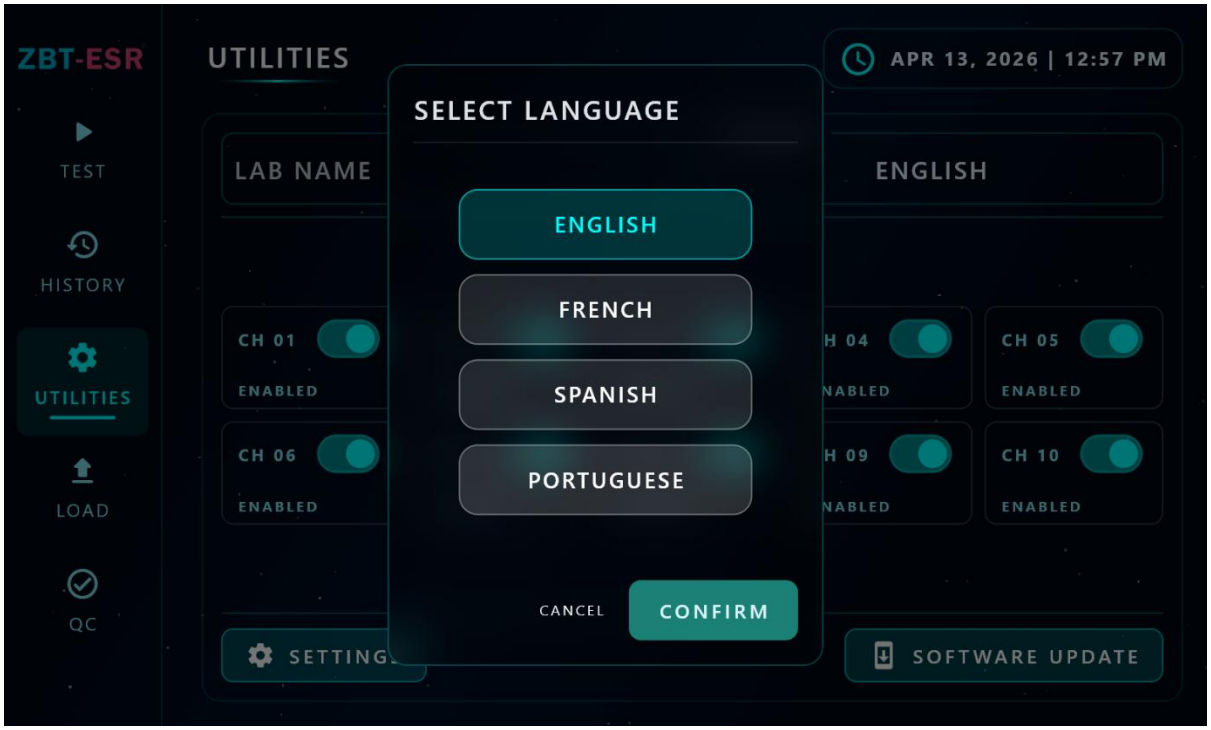
Upon completion of the analysis cycle, the ESR result is automatically calculated and displayed on the respective tube slot. The result remains visible on the screen until the tube is removed. If printing is enabled, the result is automatically printed with all relevant details.

After completion of the test, the operator can remove the tube from the slot. Once the tube is removed, the system automatically clears the result from the display within approximately 30 to 60 seconds, and the slot becomes available for the next test.

It is important to ensure proper test conditions during operation. If a tube is removed before detection is completed, the test will not be initiated. Incorrect placement of the tube or improper alignment may result in no detection or display of an error condition. Additionally, if the blood volume is insufficient (below the required level), the analyzer will display an "ERR" message instead of a valid ESR result.

Furthermore, the analyzer operates based on a test count system. If the available test count is less than or equal to zero, the analyzer will not initiate any new tests until additional test count is loaded into the system.

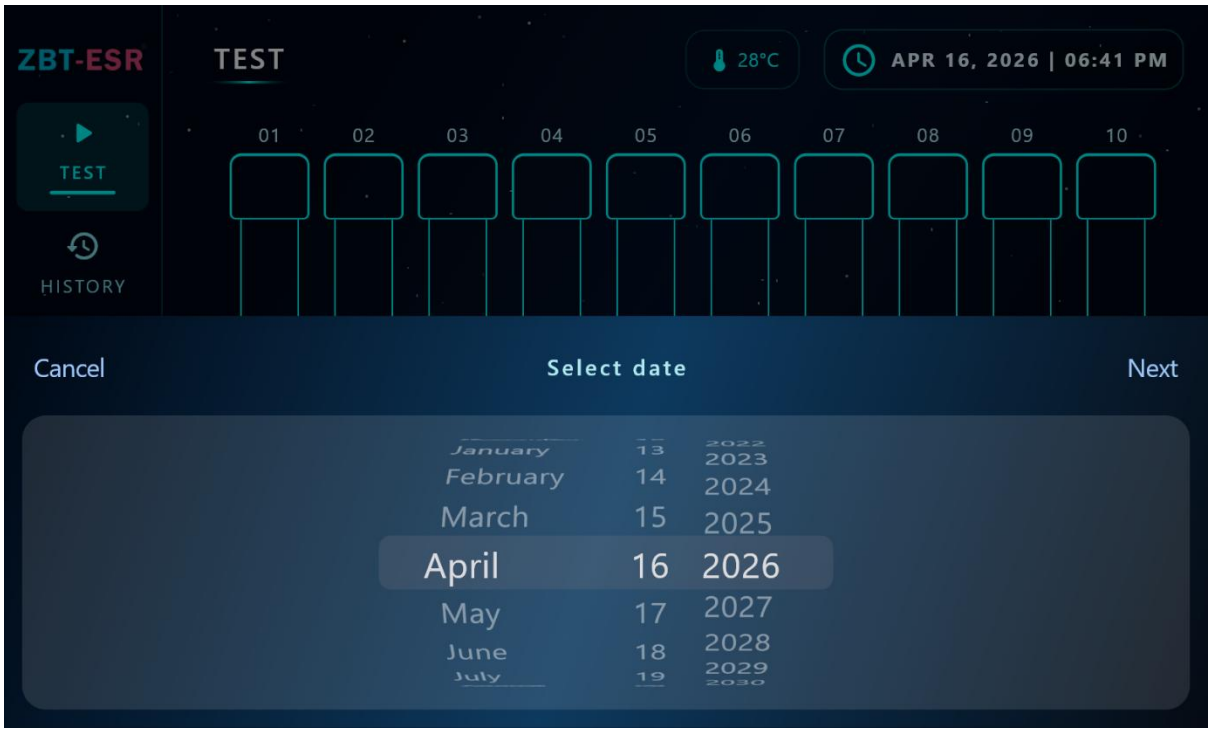
16. LANGUAGE SUPPORT



Supported languages

- English
- French
- Spanish
- Portuguese

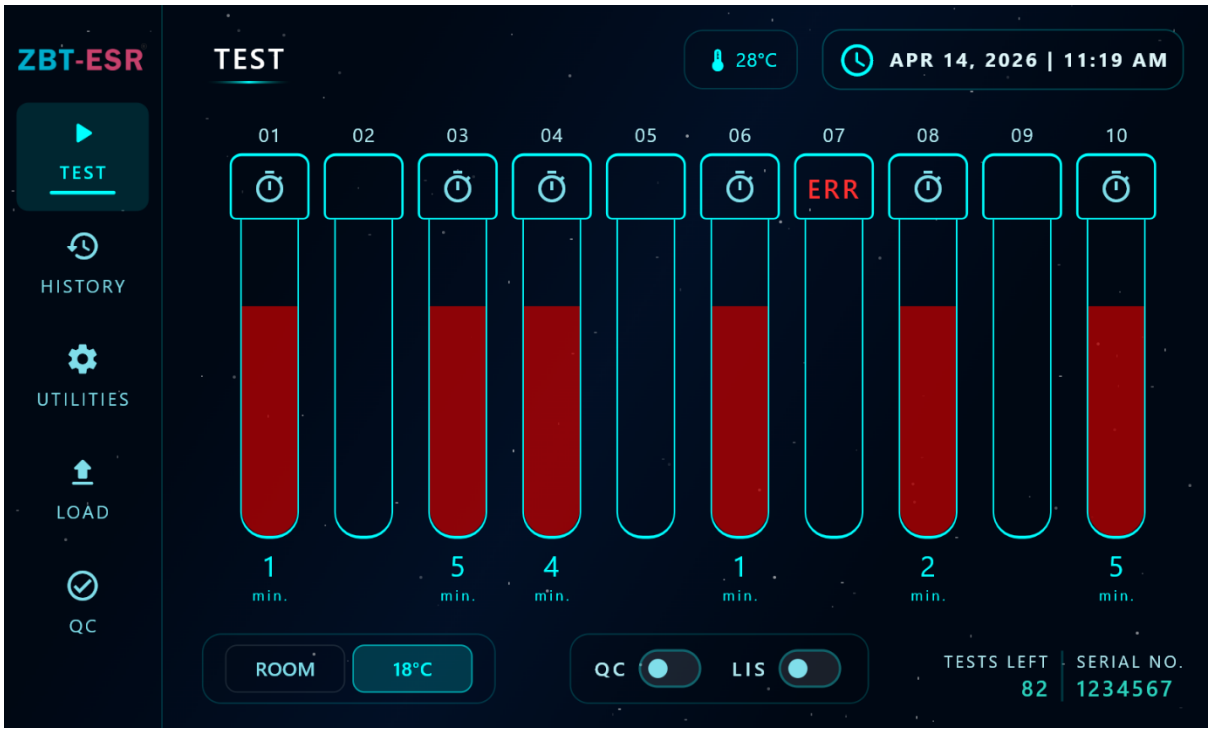
17. CHANGE DATE & TIME



Change Date & Time

- Tap on Date & Time Panel
- Select Date
- Click Next
- Select Time
- Click Done
- Click Set to Confirm
- Date & Time will be updated after the machine is shutdown
- Turn On the machine

18. ERROR LIST



ERROR	DESCRIPTION
ERR	Low Blood Volume
ERR	Incorrect Tube
No Detection	Improper Insertion
Test Blocked	Count ≤ 0

19. POWER FAILURE

- All running tests are lost
- No recovery after restart

20. MAINTENANCE

- Clean with dry cloth
- Avoid liquids
- Keep dust-free
- Ensure stable placement

21. PRINTER

- Automatic print after test completion

Print Format

****

LAB: LAB NAME

****

Auto ESR analyzer

Test Time: 20 min

Date (DD/MM/YYYY): 10/04/2026

Time (HH:MM): 13:16

Patient ID: 1234567891012345

Channel: 3

Temperature: 27 ℃

1 HR ESR at RT = 59

1 HR ESR at 18℃ = 50

****

Here in print out format
"**LAB**": will represent end user institution or laboratory as per entered at power screen
"**Test Time**" will represent the total time of test
"**Patient ID**" will represent PID which was enter respectively
"**Channel**" will represent respective slot number
"**Temperature**" will represent instrument temperature in ℃
"**ESR at RT**" will represent ESR result at Room Temperature
"ESR at 18℃" will represent ESR result at 18℃.

22. TRANSPORTATION AND PACKAGING INSTRUCTION

Packing, Storage and Handling

All markings and labels must remain clearly visible, durable, and tamper-resistant. The instrument shall be securely packed using stretch film, bubble wrap, and thermocol or sponge cushioning to protect the touchscreen and all external connections from damage. The packaged unit must then be placed inside a corrugated box clearly marked with "FRAGILE" and "THIS SIDE UP" indicators.

Storage and Transport Environment

The device must be stored and transported under the following environmental conditions:

- Temperature: 10°C to 40°C
- Relative Humidity: ≤ 50% RH (non-condensing)

Handling for ZBT-ESR Analyzer

Due to its lightweight design, the ZBT-ESR Analyzer can be safely handled and relocated manually. Care should be taken during movement to avoid impact, vibration, or improper handling.

23. REPAIR AND REPLACEMENT

Sterile Safequip & Chemicals Limited assumes responsibility for defects arising from manufacturing faults or malfunction during normal and intended use within the warranty period. The company disclaims all other liabilities beyond the stated warranty conditions.

For service support or warranty claims, contact the authorized service representative, dealer, or the service center at:

Sterile Safequip & Chemicals Limited
Unit 31, Panchratna Industrial Estate,
Inside Pirana Gate, Ghoda Circle,
Ode Village, Ahmedabad – 382425, Gujarat, India
Email: Service2@ssq.com

24. COMPLIANCE AND REFERENCE STANDARD

Device Safety Compliance

The ZBT-ESR Analyzer complies with the following safety standards:

- **IEC 61010-1:2010 + AMD1:2016 (Edition 3.1)** – General safety requirements for laboratory equipment
- **IEC 61010-2-010:2019** – Particular requirements for laboratory equipment for heating materials
- **IEC 61010-2-040:2020** – Particular requirements for sterilizers and washer-disinfectors

Electromagnetic Compatibility (EMC) Compliance

The ZBT-ESR ESR complies with the following EMC standard.

- **IEC 61326-1:2020 (Third Edition)** – EMC requirements for electrical equipment for measurement, control, and laboratory use

25. WARRANTY

The ZBT-ESR Analyzer is warranted to be free from defects in design, materials, and workmanship under normal use and service conditions, in accordance with the applicable warranty policy.

1. The warranty period for the **ZBT-ESR DT10** (main unit only) is 12 months from the date of purchase.
2. The warranty does not cover accessories supplied with the device.
3. Damage caused by transportation, mishandling, or improper use is not covered.
4. The warranty applies only to manufacturing defects identified during the warranty period.
5. Any unauthorized modification or tampering voids the warranty.
6. A valid purchase invoice is required for all warranty claims.
7. Warranty is not applicable for products purchased from unauthorized dealers or distributors.
8. Warranty claims must be processed through the authorized dealer or distributor.
9. The company reserves the right to repair or replace the product at its discretion.
10. Warranty is valid only if the product is registered with Sterile Safequip & Chemicals Limited within **seven (7) days** of purchase via email submission of the invoice to Service2@ssqllp.com .