📘 User Manual

Walk-In Stability Chamber with External AHU & Steam Humidification

Model: SCH-13000L
Manufacturer: Kavoshteb Co. (CELLOGEN)

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1. Introduction

This manual provides comprehensive instructions for operating, maintaining, and understanding the Walk-In Stability Chamber (SCH-13000L) equipped with an external AHU (STM-AHU 100) and steam humidifier. The system is designed for long-term stability testing under controlled temperature and humidity per ICH guidelines.

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2. System Overview

- **Chamber Volume:** 13,000 Liters
- **Control Type:** Siemens S7-1200 PLC with Delta HMI
- **Humidification:** Hot Steam Generator
- **Cooling/Heating:** 1.0 HP compressor with hot gas bypass & electric heaters
- **Air Handling Unit (External):** STM-AHU 100, 1,000 CFM capacity
- **Compliance:** FDA 21 CFR Part 11, EU GMP Annex 15, ICH Q1A

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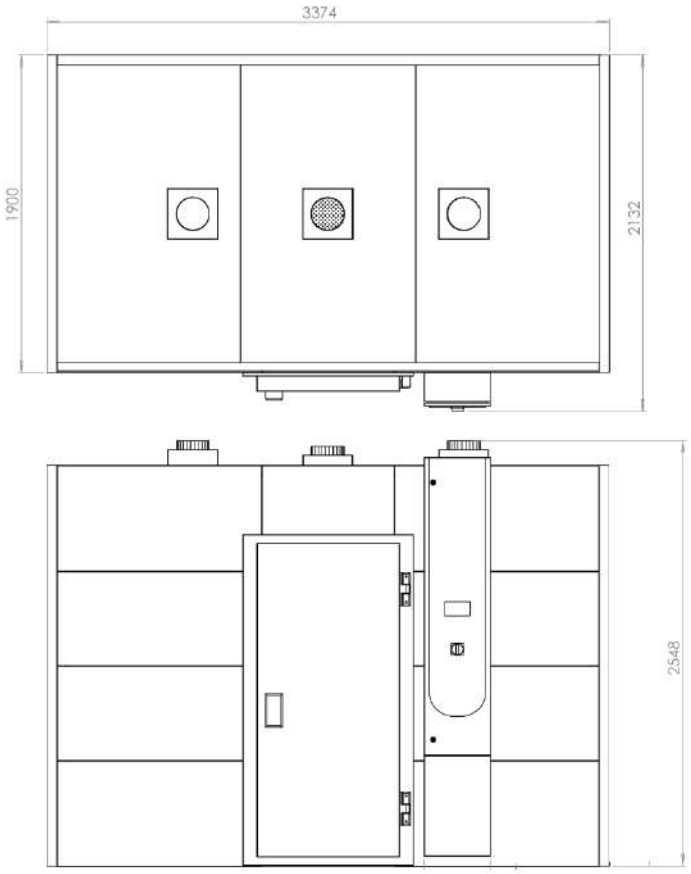
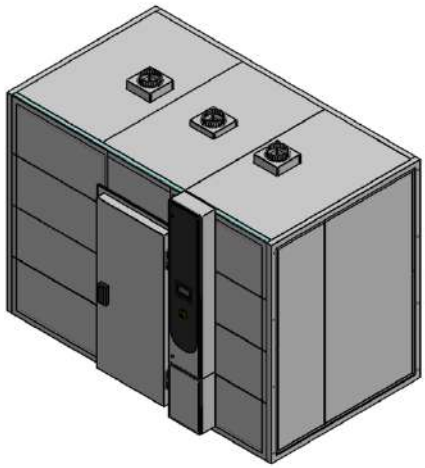
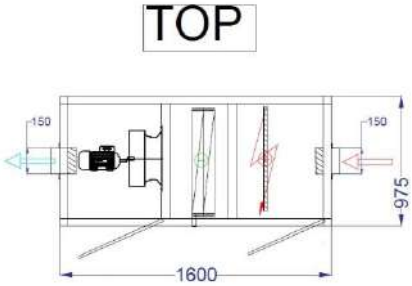
3. Physical Specifications

Feature	Description
Chamber Size	4.0m (L) × 1.7m (W) × 2.16m (H)
Floor	Stainless steel 304L with rounded corners
Wall Panels	PU foam sandwich Panels + Electrostatic Powder coating
Doors	Magnetic lock with internal emergency release
Shelves	SS 304, load capacity 50kg each





4. Air Handling Unit (AHU)



Feature	Specification
Model	STM-AHU 100
Flow Capacity	1,000 CFM (Return Air)
Cooling Coil	DX Cooling (26,000 BTU/h)
Heating	Heating Element Box (2kw),
Compressor	Copeland, Scroll1HP
Fan	Plug fan, backward curved, 0.77kW, 1450 RPM
Motor Protection	IP54, Class F
Filters	Washable Aluminum G2 (Primary)
Casing & Insulation	25mm PU foam, stainless steel internal surface

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5. Control & Monitoring

- **PLC:** Siemens S7-1200
- **HMI:** Delta 7-inch touchscreen
- **Features:**
    - 3-level access control
    - Audit trail (21 CFR Part 11)
    - Data logging on USB (6 months)
    - Real-time display of temperature & RH
- **Login Interface** (Fig. 1):
    - Authentication screen with username/password fields
    - Displays: **ESPAD** (Client) and **KAOSHTEB** (manufacturer)
    - Supports 3-level access control (Admin/Technician/Operator)

Fig. 1

- **Main Dashboard** (Fig. 2):
    - **Current User**: Display (e.g., "ALI HASHEMI")
    - Navigation menu:
        - *Overview*: Real-time parameter monitoring
        - *Diagnostics*: Component status check (Fig. 4)
        - *System Setting*: Configuration and calibration (Fig. 5)
        - *Calibration*: Sensor offset adjustment (Fig. 8)
        - *Trends*: Historical data graphs
        - *Access Level*: User permission management

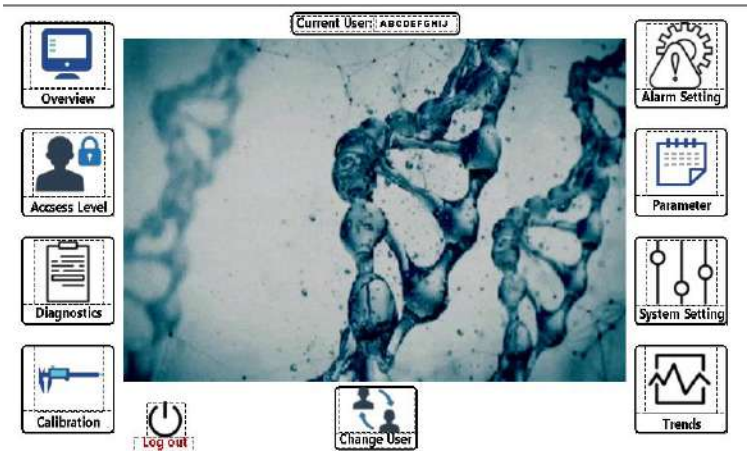

Fig. 2

6. Sensors & Safety

- **Temperature:** IC sensors
- **Humidity:** Integrated capacitive sensors
- **Alarms:**
  - Door open
  - High/low temp/RH
  - Power failure
  - Steam generator/PW line failure
- **Emergency Features:**
  - Manual override from inside
  - Independent over-temperature protection

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7. Operating Conditions

Parameter	Range
Temperature	25°C to 40°C
RH Range	40% to 75%
Uniformity (Temp)	±1.0°C (target), ±2.0°C (tolerance)
Uniformity (RH)	±2.0% RH

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8. Operating Instructions

1. **Start-Up**
   - Ensure main power (400V AC, 3-phase) is on.
   - Power on HMI and follow screen instructions.
2. **Set Conditions**
   - Navigate to Setpoints.
   - Input desired Temperature and RH.
3. **Monitoring**
   - Use HMI to observe current conditions.
   - Verify stable conditions before sample loading.
4. **Stop**
   - Navigate to **Run/stop** menu on HMI.
   - Power off only after fan and compressors stop.

🟥 Main Display Panels (Fig. 3)

There are **two blue panels** representing real-time values for:

Fig.3

1. Top Panel – Temperature Monitoring

Item	Description
PV 12.3	**PV = Process Value** – the current temperature inside the chamber.
SP 12.3	**SP = Setpoint** – the desired temperature set by the user.
🔔 **Alarm (Thermometer Icon)**	Indicates **temperature Hi/Lo Limit**. Conditions could include: – Temperature Hi Limit setpoint – Temperature Lo Limit setpoint – Lo-temperature or Over-temperature safety trigger

2. Bottom Panel – Humidity Monitoring

Item	Description
PV 123	Current relative humidity in percentage (e.g., 123% is abnormal and just it is an example).
SP 12.3	Setpoint for relative humidity.
🔔 **Alarm (Icon Drop with %)**	Indicates a **humidity Hi/Lo Limit**. Possible causes: – Humidity Hi Limit setpoint – Humidity Lo Limit setpoint – Lo- Humidity or Over- Humidity safety trigger

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🕹️ Control Buttons (Bottom Row)

Icon	Function
🏠 **Home**	Returns to the main menu or home screen.
▶️ **Start/Run**	Starts the chamber cycle (activates heating/cooling/humidity control systems).
💡 **Lighting**	Toggles internal chamber lights on/off.
🚪 **Door Control**	Magnetic lock and door monitoring.
⚠️ **Alarm Log / Acknowledge**	View current alarm list or acknowledge/reset alarms.

📝 Best Practices

- Always monitor both **PV and SP** values to ensure stability.
- Address any red **alarm indicators** immediately; they could affect sample integrity.
- Use appropriate **user credentials** for actions that require elevated access (e.g., modifying SP or silencing alarms).

Control Parameters (Fig. 4)

- **Temperature Control**:

  PID Settings: P [Value], I [Value], D [Value]

  Control Variable (CV): [Value]

- **Humidity Control**:

  ON/OFF Toggle, Setpoint (SP): [Value]% RH

- **Fan Control**:

  Speed Setpoint: [Value]%

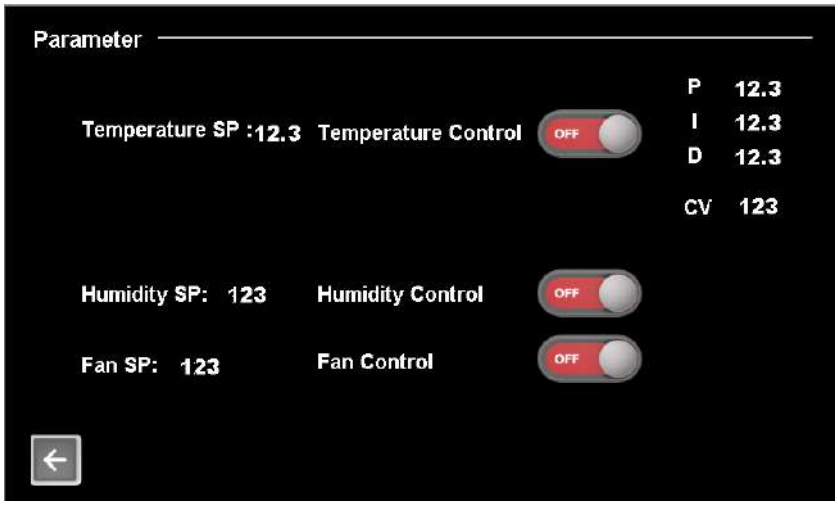

Fig. 4

Alarm Configuration (Expanded) (Fig. 5)

. Temperature Alarms:

High Limit: [Set Value] °C, Low Limit: [Set Value] °C

- **Humidity Alarms**:

  High Limit: [Set Value] % RH, Low Limit: [Set Value] % RH

- **Alarm Acknowledgment**: Manual reset required

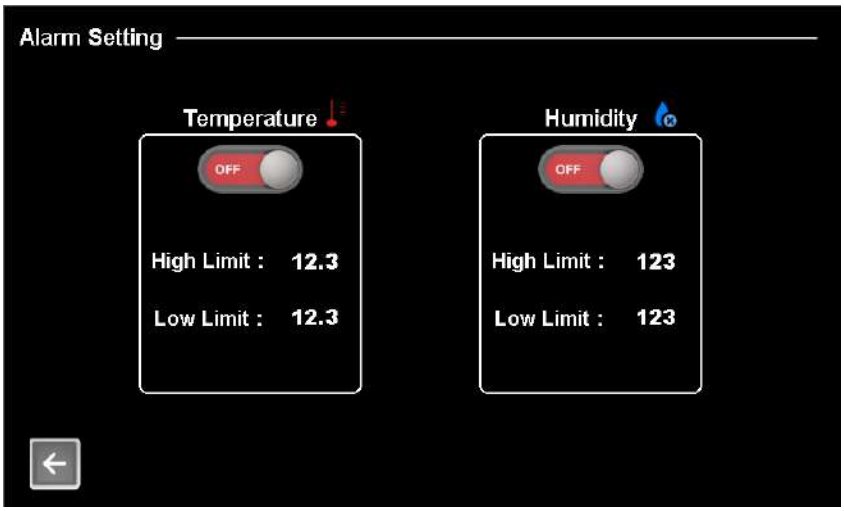

Fig.5

Calibration Menu (Fig. 6)

1. **Sensor Calibration** (Fig. 8):

Chamber Sensors:

- Temperature: PV [Current Value] ± OFFSET [Adjustment]
- Humidity: PV [Current Value] ± OFFSET [Adjustment]

AHU Sensors:

- Separate calibration for temperature/humidity

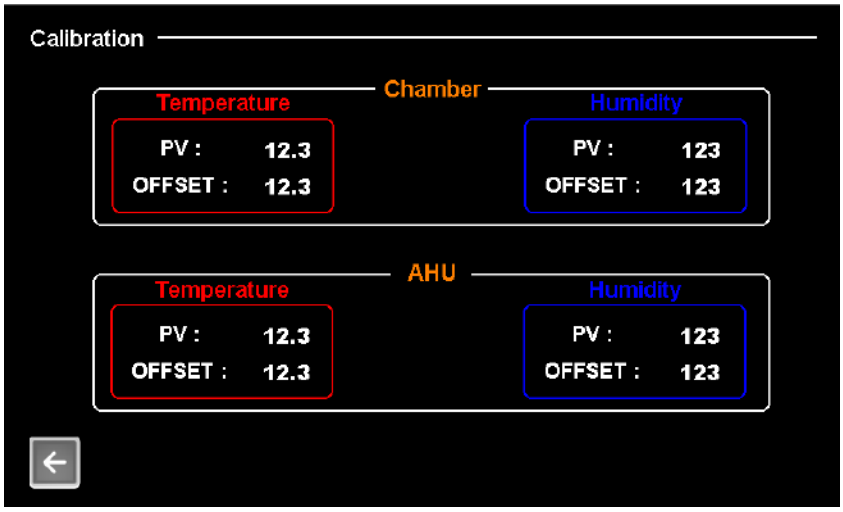

Fig. 6

Audit Trail (Fig. 7):

- Automatic event logging in format: hh: mm: ss mm/dd/yy
- Tracks: User logins, parameter changes, alarm events

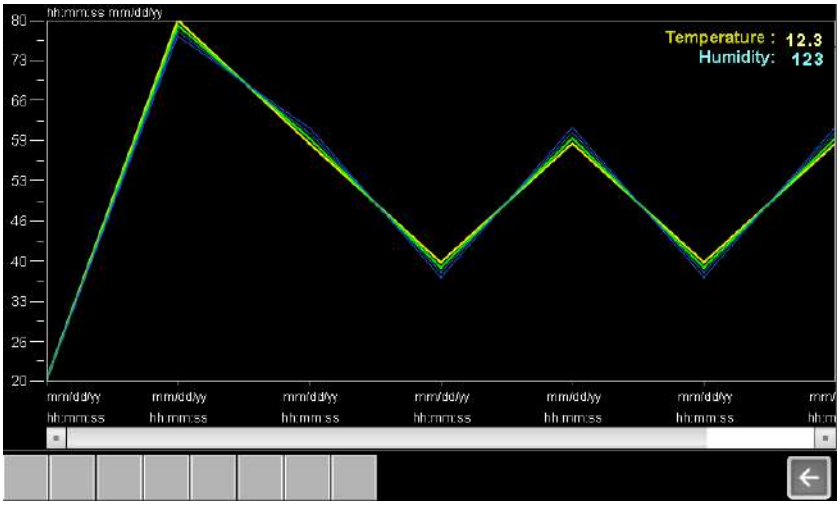

Fig. 7

Diagnostics Screen (Fig. 8):

Component	Status Indicators
Door Safety	Open Switch, Limit Switch, Magnet
Humidifier	Low/High Level, Valve, Element
AHU	Compressor, Diffuser Valve, Heating Element
Emergency Controls	Emergency Switch, Alarm Tower (Buzzer/Red Light)
Power Safety	3-Phase Monitor, Heating Safety Switch

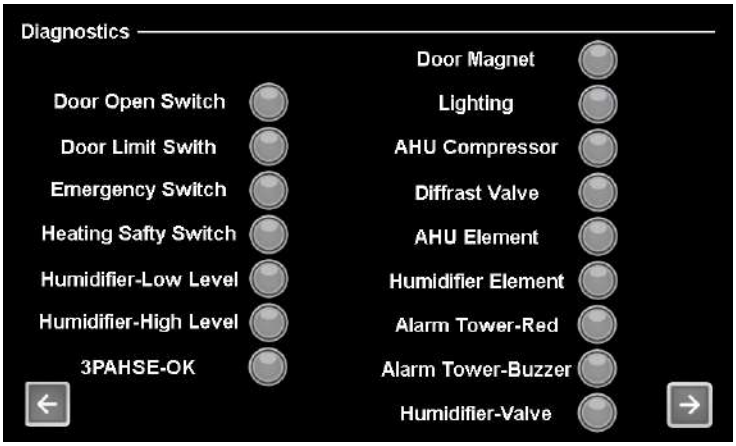

Fig. 8

System Menu (Fig.9)

- Brightness adjustment
- Date/Time synchronization
- Storage management (data export)
- Device information access (Fig. 6)

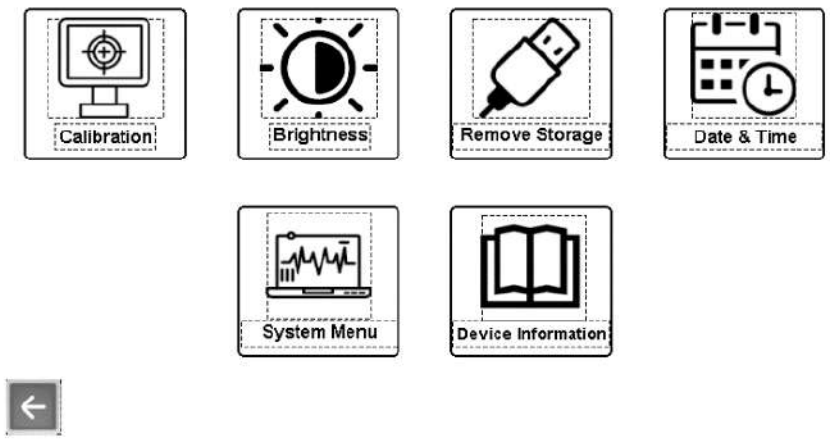

Fig.9

Device Information (Fig.10)

- **Identification**:
  - Model: [Displayed on HMI]
  - S/N: [Displayed on HMI]
  - Manufacture/Expiry Dates
- **Manufacturer**:

  Kavoshteb Co. (CELLOGEN)

  No 04 - Second East Alley - North Motahari Blvd., Safa-Dasht Tehran, IRAN

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Fig.10

9. Maintenance

Task	Frequency	Notes
Clean filters (AHU)	Monthly	Replace if damaged
Inspect steam generator	Monthly	Check water line and alarms
Verify sensor calibration	Every 12 months	As per SOP
Visual chamber inspection	Weekly	Look for condensation/leaks

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10. Troubleshooting

Symptom	Possible Cause	Action
No temp/RH control	Power failure, PLC error	Restart system
High temp alarm	Heater fault, sensor error	Check heater, recalibrate
Humidity not increasing	Steam generator failure	Check PW line, restart
Door open alarm	Door not closed properly	Inspect seal & lock

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11. Documentation & Qualification

The system has passed:

- **Installation Qualification (IQ)**
- **Operational Qualification (OQ)**
- Including:
  - Physical inspection
  - Sensor & control verification
  - Temperature & RH mapping
  - Alarm tests
  - Power failure recovery
  - Data integrity checks

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12. Regulatory Compliance

- **ICH Q1A (Stability Testing Guidelines)**
- **EU GMP Annex 15**
- **21 CFR Part 11 (Electronic Records & Signatures)**

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13. Manufacturer Contact

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