



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: SOP for Operation, Calibration and Monitoring of Stability Walk In Chamber (30±2°C/75±5 RH)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

- 1.1 To lay down the procedure for Operation, Calibration and monitoring of Stability Walkin Chamber.

2.0 SCOPE:

- 2.1 This SOP is applicable to operation, calibration and monitoring of Stability Chambers (Make-Thermo-Lab) in quality control department. The instrument details are:

Name of Instrument	Stability Walk In Chamber
Model /Serial No.
Manufacturer	Thermolab
Location	Stability Room
Instrument ID No.

3.0 RESPONSIBILITY:

- 3.1 Analyst & Executive / trained person shall be responsible for operation as per the procedure and making entries in the relevant records.
- 3.2 Head-QC are responsible for effective implementation of this SOP.

4.0 REFERENCE:

- 4.1 In-House

5.0 DEFINITION:

- 5.1 NA

6.0 PROCEDURE:

6.1 Operation of Chamber:

- 6.1.1 Ensure that instrument is clean and free from dust and the water supply should be connected to its boiler tank and also check the all power connections.



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6.1.2 Switch on the mains of the chamber and allow at least half an hour to stabilize the inner environment of chamber and keep it on for continuous maintaining of set temperature and humidity

6.1.3 Display of HMI should be as shown below.

Main Screen:

- It shows the **Set Point (SP)** and **Process value (PV)** of the controlling sensor at top of the screen.
- **AT** the Top-Right of the Set point window indicates the **Auto tuning** Status for Temperature and Humidity
- **REFRIGERATION SYSTEM** Indicates which refrigeration system is running.
- **HUMIDITY SYSTEM** Indicates which humidity system is running.
- **CHAMBER STATUS** Indicates chamber status with countdown time. e.g. OFF MODE, RUNNING MODE, STABILIZATION etc.
- **TEMPERATURE SENSOR** Indicates which temperature sensor is in control MAIN OR STANDBY.
- **HUMIDITY SENSOR** Indicates which humidity sensor is in control MAIN OR STANDBY
- The alarm button blinking in red and blue indicates that active alarm are present in the system. Alarm button in red colour indicate alarms are acknowledged but not rectified

6.1.4 SWITCH ON THE CHAMBER THROUGH TO PLC: When Start button is pressed to start the chamber, system should only start main contractor. Refrigeration system should start only after 2 mins. After starting of Refrigeration system, with delay of around 30 seconds, Air heater and healthy humidity system should start with the PID action (soft start).

6.1.5 STARTING THE CHAMBER WITH REGULAR SYSTEMS: If START button on HMI is pressed to start the main contractor, only if any one water level is present with door is closed, safety thermostat temperature contact closed & safety thermostats in humidity tank are closed and mains power supply is present, at least one sensor of both temperature & humidity should not be open (i.e. it should be closed) then PLC will switch ON the mains contractor after 5 sec.

6.1.6 SET TEMPERATURE ON HMI: To set temperature select Menu button from the main page, which will navigate to the page shown below.



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6.1.7 Select **TEMPERATURE SETTINGS** button from the Main Menu Page which will navigate to the page shown below.

6.1.8 TEMPERATURE SETTINGS page allows to do the following settings in temperature.

- In this page user can set the parameters for temperature controlling sensor and temperature scanners.
- In this page user can also start the temperature auto tuning by pressing the A. TUNE button which is given on the screen.
- After the required settings are made press the save button on the HMI to save the settings made.

6.1.9 SET HUMIDITY ON HMI: Select **HUMIDITY SETTINGS** button from the Main Menu Page which will navigate to the page shown below.

HUMIDITY SETTINGS page allows to do the following settings in humidity.

- In this page user can set the parameters for humidity controlling sensor and humidity scanners.
- In this page user can also start the humidity auto tuning by pressing the A. TUNE button which is given on the screen.
- After the required settings are made press the save button on the HMI to save the settings made.

6.1.10 CHECK SCANNER READING: A scanner of 16 channels is provided inbuilt in PLC with 8 sensors for temperature mapping & 8 sensors for humidity kept at different locations. One can download the scanned data on the Stability Control System software and same can be printed on inkjet printer.

- **TEMP 1 to TEMP 8:** Displays the current process value of channel 1 to 8 temperature sensors. Value with Red background indicates out of range from upper limit. Value with Blue background indicates out of range from Lower limit. **(Note: If the 4 sensors are present in the chamber then only 4 channels will be display in this page for temperature)**
- **HUMI 1 to HUMI 8:** Displays the current process value of channel 1 to 8 humidity sensors. Value with Red background indicates out of range from upper limit. Value with Blue background indicates out of range from Lower limit. **(Note: If the 4 sensors are present in the chamber then only 4 channels will be display in this page for humidity)**

Note: Door Access is optional; hence DOOR button will only be visible in this screen if purchased.



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6.1.11 Check Graph:

6.1.12 Select GRAPH VIEW button from the Main Menu Page, select Temperature Graph button to view temperature graph & select Humidity Graph to view humidity graph.

6.1.13 TEMPERATURE GRAPH:

6.1.14 HUMIDITY GRAPH

6.1.15 **CHECK SYSTEM SETTINGS FROM HMI:** On touching the SYSTEM SETTINGS Button on Main Menu page will navigate to the below page.

6.1.16 **SET SAFETY THERMOSTAT:** The safety thermostats with the range of 0°C to 120°C is provided in the control panel. The Safety Thermostat is provided as an extra safety to safeguard the inside test samples from exposure to high temperature. It is a safety precaution where by it cuts off the Mains Contactor after 7 minutes through PLC with text indication on HMI and alarm if the set temperature overshoot by accident.

6.1.17 **SET HUMIDITY SAFETY THERMOSTAT:** The safety thermostat with the range of 0°C to 150°C is provided in each Humidity tank. Set the safety thermostat at 110°C temperature. On humidity safety thermostat cut off, the PLC will switch off the running humidity system and changeover to standby humidity system.

Note:

- Before the chamber is started by pressing **START** button, please keep the chamber door open for 1 hour.
- After the chamber is stopped by pressing **STOP** button, please keep the chamber door open for 1 hour

6.1.18 If the stability chamber's preset condition overshoot or under shoot shall deviate from its acceptance criteria, then audio alarm blown at stability area and security gate.

6.1.19 Visual Alarm: Red light of indicator lamp shall beep sound on attached with display board whenever temperature and Humidity overshoot or under shoot.

6.1.20 Audio Alarm: Burger shall be blown at security main gate whenever temperature and Humidity overshoot and other or under shoot.

6.1.21 SMS Alert: Any shoot out in Temperature and Humidity than immediately SMS will go to Head Stability, Engineering head/Designee and QA head/Designee.

6.1.22 After noticing the chamber's disturbance Immediately stop the alarm by pressing "Mute" key and identify the reason.

6.1.23 Depending upon the problem immediately inform to maintenance department or Breakdown Maintenance Intimation request to Company's Service Engineer.



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- 6.1.24 If any problem, take corrective action as per the system operation.
- 6.1.25 Rectify Any type of problem within 24 hours.
- 6.1.26 Record the temperature and humidity displayed on each chamber twice in a day as per Annexure-I.
- 6.1.27 All the chamber related activities like charging or withdrawing of samples, cleaning or any other activity should be recorded as per annexure-II.
- 6.1.28 If stability chamber of any condition is not in use, then it can be put on shutdown and prior to use it can be monitoring up to 24 hrs. for particular condition set the preset condition as per Annexure-V
- 6.1.29 The temperature and Humidity shall be monitored at the interval of 30 minutes.

6.2 Operation of Software:

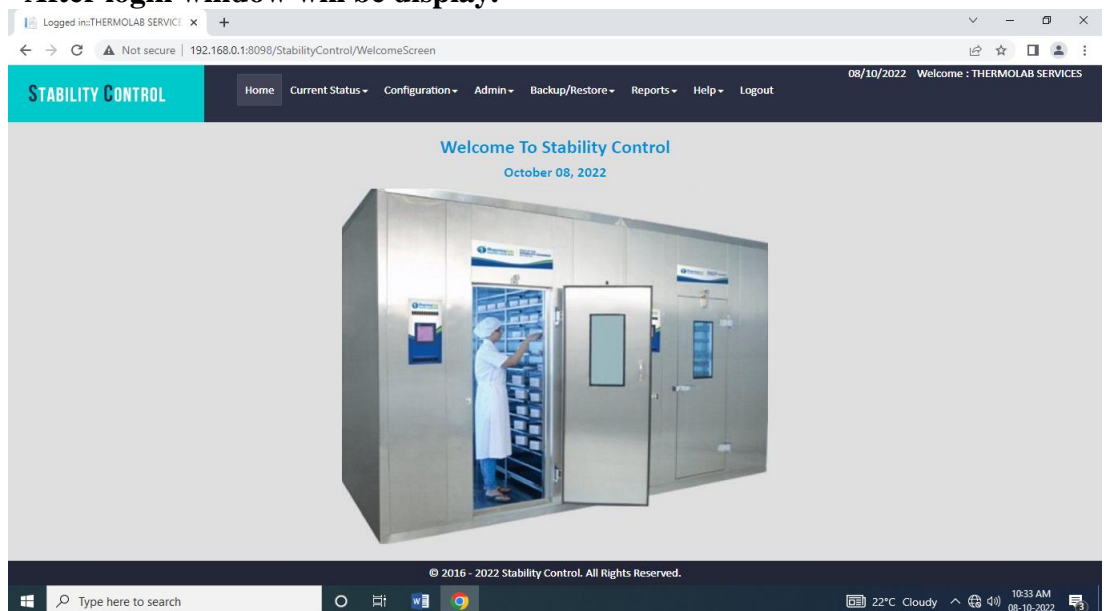
6.2.1 Stability Control System Software (Version 1.3 Lite):

6.2.2 Switch on the mains of PC.

6.2.3 Double click on the Stability software icon to login the stability software viewed on the monitor.

6.2.4 After opening of Stability chamber monitoring system a login screen will be displayed. Login by enter valid user name and password.

6.2.5 After login window will be display.



6.2.6 Then click on the reports section to open the reports by following given the display.



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6.2.7 Select the report type as shown the below display.

6.2.8 Than selects the Instrument ID than display screen below.

6.2.9 Fill the date and time from and to and click on the view report shown on the below screen.

6.2.10 To follow e-signature, click on the sigh button to generate the report as shown below screen.

6.2.11 To follow the e-signature, click on the send to review button for review as shown below screen.

6.2.12 To follow the e-signature, click on the review button shown as below screen.

6.2.13 To follow the e-signature, click on the sign and send to approve button shown as the below screen.

6.2.14 To follow the e-signature, click on the approve button for the approved the reports as shown below screen.

6.2.15 To check the report, click on the view report button as shown below screen.

6.3 Printing the report and log out the software:

6.3.1 To prints the report, click on the print report button as below shown the screen.



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6.4 CALIBRATION:

6.4.1 Calibration is done by outside agency.

6.4.2 **FREQUENCY:** Once in year

Note: If the results of the calibration and temperature are not satisfactory call the service engineer/ engineering department immediately. affix “OUT OF ORDER” label on the instrument as per below mention label.

OUT OF ORDER	
INSTRUMENT NAME	:
INSTRUMENT ID.	:
SIGNATURE	:
DATE	:

6.5 Precaution:

6.5.1 The outer surface of instrument should be cleaned by lint free dry cloth daily and occasionally use mild detergent to clean.

6.5.2 Also ensure that the water supply to its boiler tank is proper and this should be monitored on daily basis.

6.5.3 Do not keep the chamber near the back wall. At least 2 feet clear distance should be provided from all sides of chamber.

6.5.4 Do not disturb the internal parameter of the controller, which might change the calibration.

6.5.5 Users on operating software are created by IT or Administrator & privileges are assigned as per annexure-III respectively.

6.5.6 Password resetting and user creation/Up-gradation shall be done by IT or administrator.



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7.0 ANNEXURES:

ANNEXURE No.	TITAL OF ANNEXURE	FORMATE No.
Annexure-I	Stability Chamber Temperature and Humidity Record	
Annexure-II	Stability Chamber Activity Record	
Annexure-III	User Privileges on stability Software (Version 1.3 Lite)	
Annexure-IV	Stability Chamber Start/Shutdown Record	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Quality Control

9.0 ABBREVIATION:

SOP	Standard Operating Procedure
QC	Quality Control
HMI	Human Machine Interface.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date



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ANNEXURE-III

USER PRIVILEGES ON STABILITY CONTROL SYSTEM SOFTWARE

The privilege groups are as follows:

I. General (Analyst)	II. Master (Reviewer& Approval)	III. Administrator
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Privilege groups →			
Privileges ↓	General	Master	Administrator
Login	√	√	√
Current Status	√	√	√
Current Status - Current Status	√	√	√
Current Status - Status Details	X	X	√
Current Status - Chamber Report	√	√	√
Current Status - Chamber - Graph	√	√	√
Current Status - Chamber – Graph - Generate Graph	√	√	√
Current Status - Data LOG - Table	√	√	√
Current Status - Data LOG - Graph	√	√	√
Current Status - Data LOG – Graph- Generate Graph	√	√	√
Current Status - Event Alarm	√	√	√
Current Status - Audit Trail	X	X	√
Current Status – Door Access	√	√	√
Current Status – GSM Report	X	√	√
Current Status – Email Report	X	X	√
Current Status – Current Status – Start/Stop	X	√	√
Current Status – Current Status – Mute / Accept	√	√	√
Configuration	X	X	√



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Privilege groups →			
Privileges ↓	General	Master	Administrator
Configuration – Chamber Setting	X	X	√
Configuration – Report Setting	X	X	√
Admin – Chambers	X	X	√
Admin – Assign Chambers	X	X	√
Admin – Chamber Event Config	X	X	√
Admin – Auto Backup Setting	X	X	√
Admin – Role Master	X	X	√
Admin – User Master	X	X	√
Admin – Right Assignment	X	X	√
Admin – System Setting	X	X	√
Admin – Activate Licence	X	X	√
Backup/Restore	X	X	√
Backup/Restore – Restore Database	X	X	√
Backup/Restore – Restore Main Database	X	X	√
Backup/Restore – Manual Backup	X	X	√
Report – Generate – Chamber Report	√	√	√
Report – Generate – Chamber Alarm Report	√	√	√
Report – Generate – Event Alarm Report	√	√	√
Report – Generate – Data Logger Report	√	√	√
Report – Generate – Data Logger Alarm Report	√	√	√
Report – Generate – Email Report	X	X	√
Report – Generate – Door Access Report	√	√	√
Report – Generate – GSM Report	√	√	√
Report – Generate – MKT Report	√	√	√



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Privilege groups →			
Privileges ↓	General	Master	Administrator
Report – Generate – Audit Trial Report (Chamber Wise)	X	X	√
Report – Generate – Audit Trial Report (User Wise)	X	X	√
Report – Generate – Audit Trial Common Report	X	X	√
Report – Generate – Lux-UV Report	X	X	√
Report – Generate – Chamber Report	√	√	√
Report – Review – Chamber Alarm Report	X	√	√
Report – Review – Event Alarm Report	X	√	√
Report – Review – Data Logger Report	X	√	√
Report – Review – Data Logger Alarm Report	X	√	√
Report – Review – Email Report	X	X	√
Report – Review – Door Access Report	X	√	√
Report – Review – GSM Report	X	√	√
Report – Review – MKT Report	X	√	√
Report – Review – Audit Trial Report (Chamber Wise)	X	X	√
Report – Review – Chamber Graph	X	√	√
Report – Review – Data Log Graph	X	√	√
Report – Review – Audit Trial Report (User Wise)	X	X	√
Report – Review – Audit Trial Common Report	X	X	√
Report – Review – Lux-UV Report	X	X	√
Report – Approve – Chamber Report	X	√	√
Report – Approve – Chamber Alarm Report	X	√	√
Report – Approve – Event Alarm Report	X	√	√
Report – Approve – Data Logger Report	X	√	√
Report – Approve – Data Logger Alarm Report	X	√	√



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Privilege groups →			
Privileges ↓	General	Master	Administrator
Report – Approve – Email Report	X	X	√
Report – Approve – Data Access Report	X	√	√
Report – Approve – GSM Report	X	√	√
Report – Approve – MKT Report	X	√	√
Report – Approve - Audit Trial Report (Chamber wise)	X	X	√
Report – Approve - Audit Trial Report (User wise)	X	X	√
Report – Approve - Audit Trial Report (Chamber wise)	X	X	√
Report – Approve - Audit Trial Report (User wise)	X	X	√
Report – Approve - Audit Trial Common Report	X	X	√
Report – Approve – Lux-UV Report	X	√	√
Report – Approve – Chamber Graph	X	√	√
Report – Approve – Data Log Graph	X	√	√
Report – View Report	√	√	√
Report – Print Report –Chamber Report	√	√	√
Report – Print Report –Chamber Alarm Report	√	√	√
Report – Print Report –Event Alarm Report	√	√	√
Report – Print Report –Data Logger Report	√	√	√
Report – Print Report – Data Logger Alarm Report	√	√	√
Report – Print Report –Email Report	X	X	√
Report – Print Report –Door Access Report	√	√	√
Report – Print Report –GSM Report	√	√	√
Report – Print Report –MKT Report	√	√	√
Report – Print Report –Audit Trial Report (Chamber wise)	X	X	√



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Privilege groups →			
Privileges ↓	General	Master	Administrator
Report – Print Report – Audit Trial Report (User wise)	X	X	√
Report – Print Report – Audit Trial Common Report	X	X	√
Report – Print Report – Lux-UV-Report	X	X	√
Report – Print Report – Chamber Graph	√	√	√
Report – Print Report – Data Log Graph	√	√	√

Note: Privileges which are not assigned to user level are marked as “X” and privileges which are assigned to user level are marked as “√”.

