



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Quality Assurance

**SOP No.:**

**Title:** OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### 1.0. OBJECTIVE:

To lay down a procedure “Operation and Calibration for walk in type stability chamber (Make : Thermolab scientific)”.

### 2.0. SCOPE:

This SOP is applicable for the procedure of “Operation and Calibration for walk in type stability chamber (Make: Thermolab scientific) ID No.:....., in quality control department of .....

### 3.0. RESPONSIBILITY:

- 3.1 Concerned Officer/Executive
- 3.2 Department Head or his designee
- 3.3 Head Quality Assurance or his designee

### 4.0 ACCOUNTABILITY:

Head- Quality Control

### 5.0 DEFINITION:

Not Applicable

### 6.0 PROCEDURE

#### 6.1 To Start the Chamber

- 6.1.1 Put ON the mains switch on the control panel and show on Display of HMI should be as shown below.

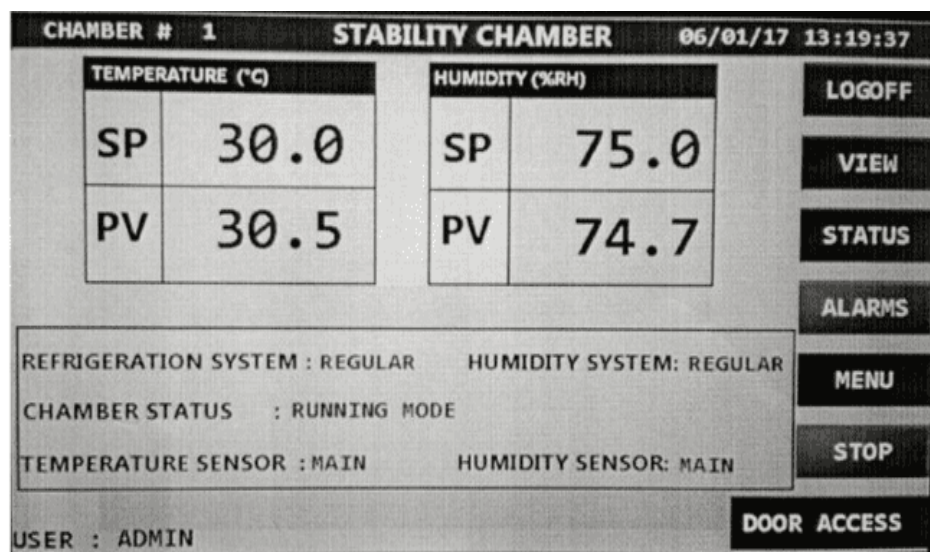


# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



### 6.2 Main Screen

- 6.2.1 It shows the Set Point and Process value of the controlling sensor at top of the screen
- 6.2.2 At the top-Right of the Set point window indicates the Auto tuning Status for temperature and humidity.
- 6.2.3 Refrigeration System indicates which refrigeration system running.
- 6.2.4 Humidity system indicates which humidity system is running.
- 6.2.5 Chamber status indicates chamber status with countdown time. E.g. Off mode, Running mode, Stabilization etc.
- 6.2.6 Temperature sensor indicates which temperature sensor is in control Main or Standby.
- 6.2.7 Humidity sensor indicates which humidity sensor is in control Main Or Standby.
- 6.2.8 The alarm button blinking in red and blue indicates that active alarm are present in the system, Alarm button in red color indicate alarms are acknowledged but not rectified.  
Note : If independent Biometric is used for door access then the “DOOR ACCESS” button won’t be visible in HMI main screen.

### 6.3 Switch on the Chamber Through PLC :



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

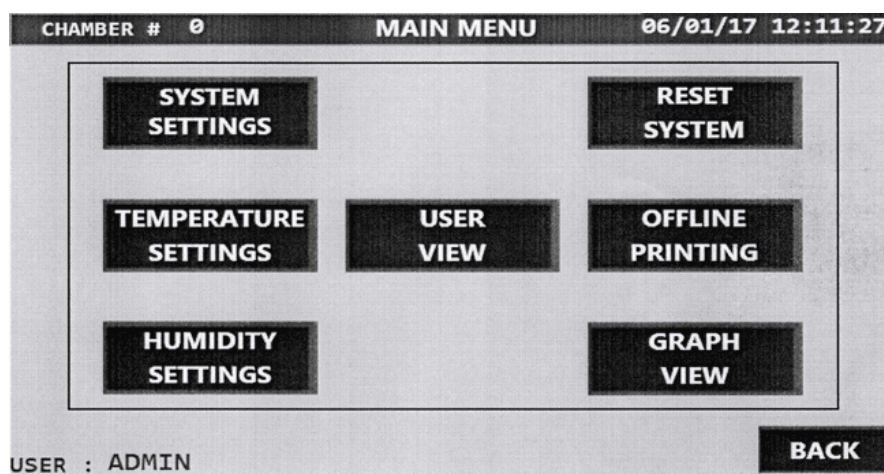
6.3.1 When Start button is pressed to start the chamber, system should only start main contactor. Refrigeration system should start only after 2 mins. After starting of Refrigeration system, with delay of around 30 seconds, Air heater and healthy humidity system should start with the PID action (soft start).

### 6.4 Starting the Chamber with Regular System :

6.4.1 If Start button on HMI is pressed to start the main contactor, 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 contactor after 5 second.

### 6.5 Set Temperature on HMI :

6.5.1 To set temperature select Menu button from the main page, which will navigate to page shown below.



6.5.2 Select TEMPERATURE SETTING button from the main menu page which will navigate to the page shown below



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

CHAMBER # 1		TEMPERATURE (°C)		06/01/17 12:47:05	
SET POINT	30.0	O/P	+0.0 (%)	P VALUE	5.0
STANDBY CHANGEOVER LIMIT	2.0	PV	0.0 (°C)	I VALUE	240
SAFETY CONTROLLER LIMIT	5.0			D VALUE	60.0
CONTROLLER LOWER LIMIT	1.0				
CONTROLLER HIGHER LIMIT	1.0				
SCANNER LOWER LIMIT	2.0				
SCANNER HIGHER LIMIT	2.0				
GRAPH WIDTH LOWER	0.0				
GRAPH WIDTH HIGHER	100.0				

USER : ADMIN

6.5.3 Temperature Settings page allows to do the following settings in temperature.

6.5.4 In this page user can set the parameters for temperature controlling sensor and temperature scanners.

6.5.5 In this page user can also start the temperature auto tuning by pressing the A. TUNE button which is given on the screen.

6.5.6 After the required settings are made press the save button on the HMI to save the settings made.

## 6.6 Set Humidity on HMI

6.6.1 Select HUMIDITY SETTINGS button from the Main menu page which will navigate to page shown below.

CHAMBER # 1		HUMIDITY (%RH)		06/01/17 13:04:19	
SET POINT	70.0	O/P	+0.0 (%)	P VALUE	5.0
STANDBY CHANGEOVER LIMIT	5.0	PV	OPEN (%RH)	I VALUE	240
SAFETY CONTROLLER LIMIT	10.0			D VALUE	60.0
CONTROLLER LOWER LIMIT	3.0				
CONTROLLER HIGHER LIMIT	3.0				
SCANNER LOWER LIMIT	4.0				
SCANNER HIGHER LIMIT	4.0				
GRAPH WIDTH LOWER	0.0				
GRAPH WIDTH HIGHER	100.0				

USER : ADMIN



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

6.6.2 HUMIDITY SETTING page allows to do the following settings in humidity.

6.6.3 In this page user can set the parameters for humidity controlling sensor and humidity scanners.

6.6.4 In this page user can also start the humidity auto tuning by pressing the A. TUNE button which is given on the screen.

6.6.5 After the required settings are made press the save button on the HMI to save the settings made.

### 6.7 Check Scanner Reading :

6.7.1 A scanner of 16 channels is provided inbuilt in PLC with 8 sensors for temperature mapping & 8 sensors for humidity kept at different locations with printer and PC interface facility available through HMI. One can download the scanned data on the Stability Control System software and same can be printed on inkjet printer.

6.7.2 One can view scanner readings by selecting VIEW button from the main page which will navigate to the page shown below.

CHANNELS	TEMPERATURE (°C)	HUMIDITY (%RH)
CHANNEL 1	30.5	74.8
CHANNEL 2	30.2	74.4
CHANNEL 3	29.7	74.2
CHANNEL 4	28.4	74.6
CHANNEL 5	30.0	73.8
CHANNEL 6	29.5	74.9
CHANNEL 7	30.8	75.1
CHANNEL 8	30.4	74.2

CHAMBER # 1      VIEW      06/01/17 13:28:32

DOOR      EVENT      AUDIT      BACK

USER : ADMIN

6.7.3 **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 limits.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

(Note : If the 4 sensors are present in the chamber then only 4 channels will be display in this page for temperature)

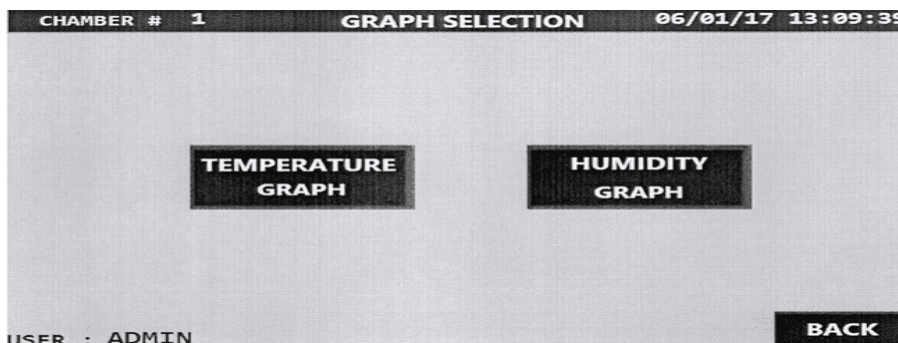
6.7.4 **HUMI 1 to HUMI 8** :Displays the current process value of channel 1 to 8 humidity sensors. Value with Red background indicates out of range from upper limit. Value with Blue background indicates out of range from lower limits.

(Note : If the 4 sensors are present in the chamber then only 4 channels will be display in this page for humidity)

(Note : If independent biometric is used for door access then the “DOOR ACCESS” button won’t be visible in HMI main screen).

### 6.8 Check Graph :

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



6.8.2 **Temperature graph :**

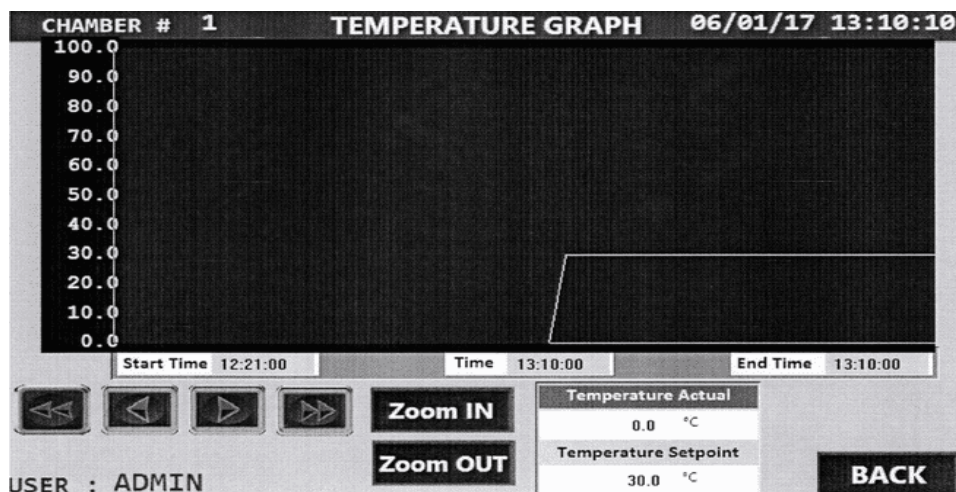


# DECODING PHARMA

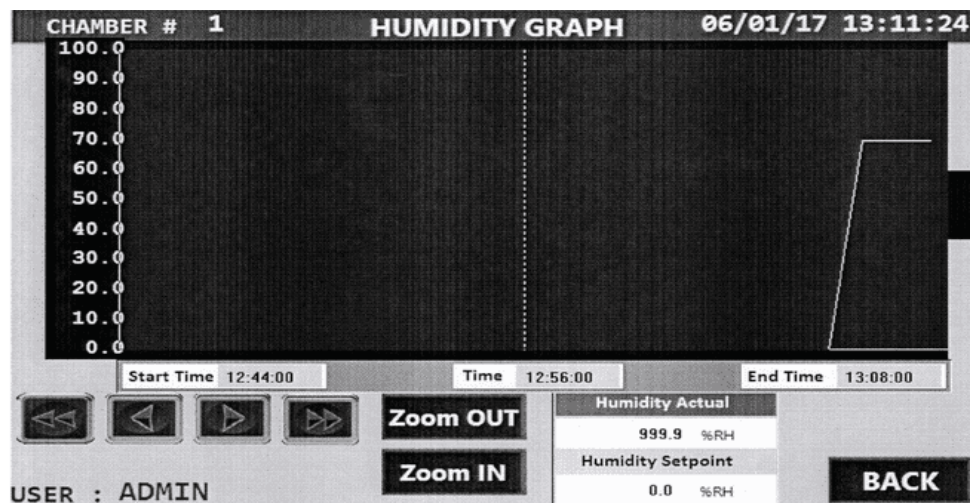
QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



### 6.8.3 Humidity Graph :



### 6.9 Log in :

- 6.9.1 Open Chamber Software (Stability Control System Software Version 1.3).
- 6.9.2 Login Screen is loaded as soon as the application is started. Enter the initial User Id as thermolab and password as stability to login:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



- 6.9.3 User has to go in System Settings screen and enter details of:
- 6.9.4 Dongle Serial No in Enter Serial Number section to register the license (Mandatory).
- 6.9.5 Host Address, Enter From Address and Enter Email Signature in E-mail settings (Optional, if require E-mail notifications).
- 6.9.6 Report folder path for saving encrypted reports (Mandatory).
- 6.9.7 Tick or untick button for Enable password complexity (Optional, as per each organization policy).
- 6.9.8 Tick or untick button for Enable Email (Optional, if require E-mail notifications).
- 6.9.9 Tick or untick button for Enable GSM (Optional, if require SMS notifications from GSM modem).
- 6.9.10 Tick or untick button for Enable SSL Certificate (Required as per domain configuration for E-mail notifications)
- 6.9.11 Upload image for all report header logo settings.
- 6.9.12 Press Save button for saving all details.





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

The screenshot shows the 'System Settings' page in the STABILITY CONTROL software. The interface includes a navigation menu on the left with options like Main Options, Security, and System Settings. The main content area contains various configuration fields: 'Enter Serial No\*' (5100000375), 'SMTP Host Address' (SMTP.GMAIL.COM), 'Enter From address' (TESTMAIL@GMAIL.COM), 'Enter Email Signature' (TEST NAME), 'Report Folder Path\*' (D:\REPORTPATH), 'Username' (TEST), 'Password' (masked), and 'Domain' (TEST). There are also checkboxes for 'Enable Email', 'Enable GSM', 'Enable SSL certificate', and 'Enable password complexity'. A 'Company Logo' section shows the 'thermolab' logo with a 'Remove Logo' button. At the bottom, there are 'Edit', 'Save', and 'Cancel' buttons. A file upload section is also present, showing a table with columns for File Name, Status, Size, and Progress, and buttons for 'Select File' and 'Upload'.

6.9.13 User can use User Master Screen for creating new users and also editing details of selected user. Every new user has default password as Operator (This password can never be used to login in the software)

Note: Once the new user is created under Admin role, the default user ID thermolab with password stability gets disabled permanently. It is the responsibility of user created under Admin role to control the software. In case the user created under Admin role forgets the password, software needs to be reinstalled and old backup files will only be visible by restoring it to restore database.

The screenshot shows the 'User Master' screen in the STABILITY CONTROL software. The interface includes a navigation menu on the left with options like Main Options, Security, Auto Backup Setting, Role Master, User Master, RightsAssignment, and System Settings. The main content area displays 'User Detail' for a user named 'admin'. Fields include 'Login ID' (admin), 'First Name' (ADMIN), 'Middle Name' (TEST), 'Title' (TEST), 'Email Id' (test@gmail.com), 'Description' (TEST), 'Password' (masked), 'Middle Name' (TEST), 'Role' (ADMIN), 'Phone No' (8511105804), 'Last Name' (ID), 'ExpiryDay' (365 (in days)), 'Valid From' (04/01/2016), and 'Valid To' (Enter date). A 'Record saved successfully' message is visible at the top right. At the bottom, there is a copyright notice: '© 2015-2016 Stability Control. All rights reserved.'



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

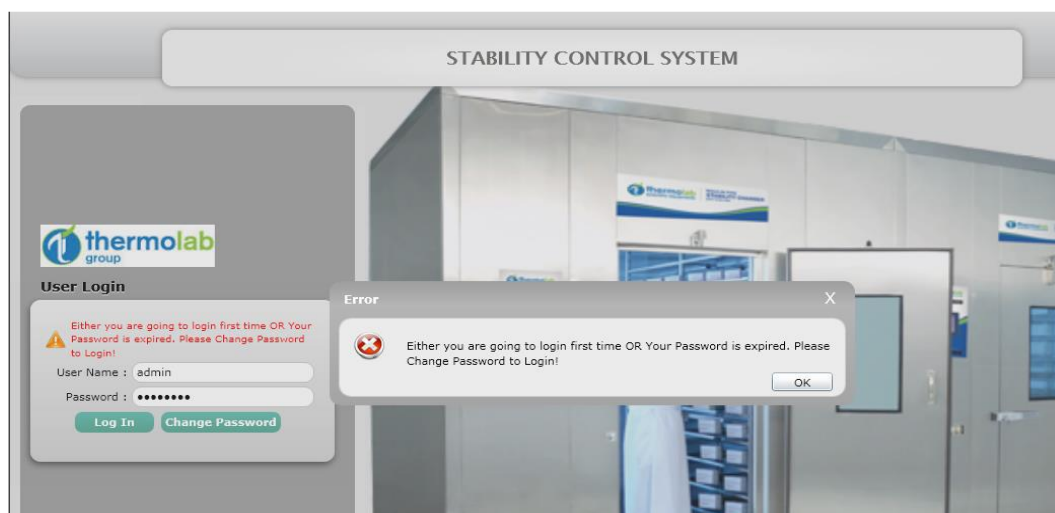
Supersedes: Nil

Review Date:

Issue Date:

Page No.:

6.9.14 After creating any new user, one can try to login software with "User Name" and default password as "Operator", an alert message stating "Either you are going to login first time User OR Your Password has expired. Please Change Password to Login!" as shown below:



6.9.15 User has to press OK button from popup and then press Change Password button on login screen. User can enter Min. 8 & Max. 12 Characters for New Password and Confirm Password.

6.9.16 If User has un-tick enable password complexity option in System Setting screen then User can enter default "Operator" password as an Old Password and enter any Min. 8 & Max. 12 Characters for New Password and Confirm Password.

6.9.17 If User has tick enable password complexity button in System Setting screen then User can enter default "Operator" password as an Old Password and enter Min. 8 & Max. 12 Characters using one capital letter, one small letter, one numeric letter and one special character for New Password and Confirm Password.

6.9.18 After entering all details, when User has to press on Submit button, an alert message will display "Your password has been changed successfully." as shown below:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

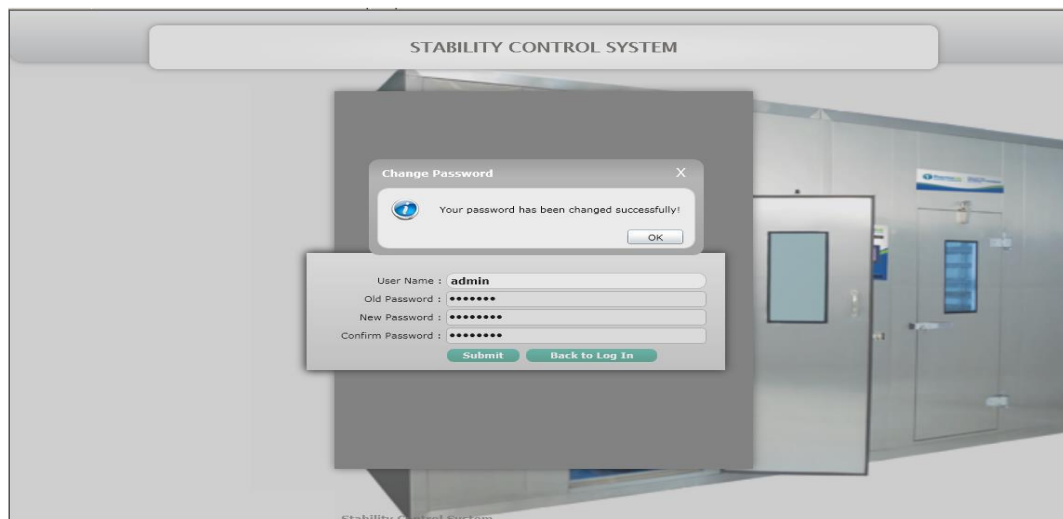
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.9.19 If user enters wrong User Name or Password while logging-in into the system, an alert will be shown "Invalid User Name or Password" as shown below:



6.9.20 If user does not enter the User Name(s) or Password(s) while logging-in into the system, an alert will be shown stating "Username or Password should not be blank." as shown below:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.9.21 If User tries 3 failed login attempts, the User account will be locked out and a message will be displayed "Account is locked. Please Contact Admin!" as shown below:



6.9.22 If user closes the software without clicking on 'Logout' button more than 2 times consecutively, then the user will be not be able to log-in into the software and an alert will be shown stating 'Maximum no. of Users are logged in! You need to restart the PC for new login' as shown below:

Note: User has to restart the system in order to re-login into the software.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

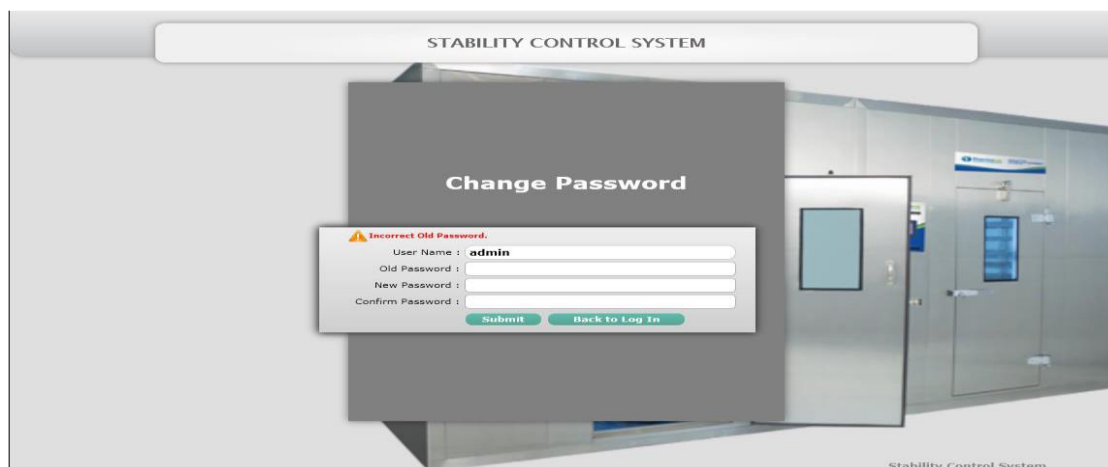
Review Date:

Issue Date:

Page No.:



6.9.23 In Change Password screen, if user types incorrect old password while changing the password, an alert will be shown stating "Incorrect Old Password." as shown below:



6.9.24 In Change Password screen, if user types less than 8 characters of Password in New Password or Confirm Password fields, then alert will be shown to stating "Password should be from 8 to 12 characters." as shown below:

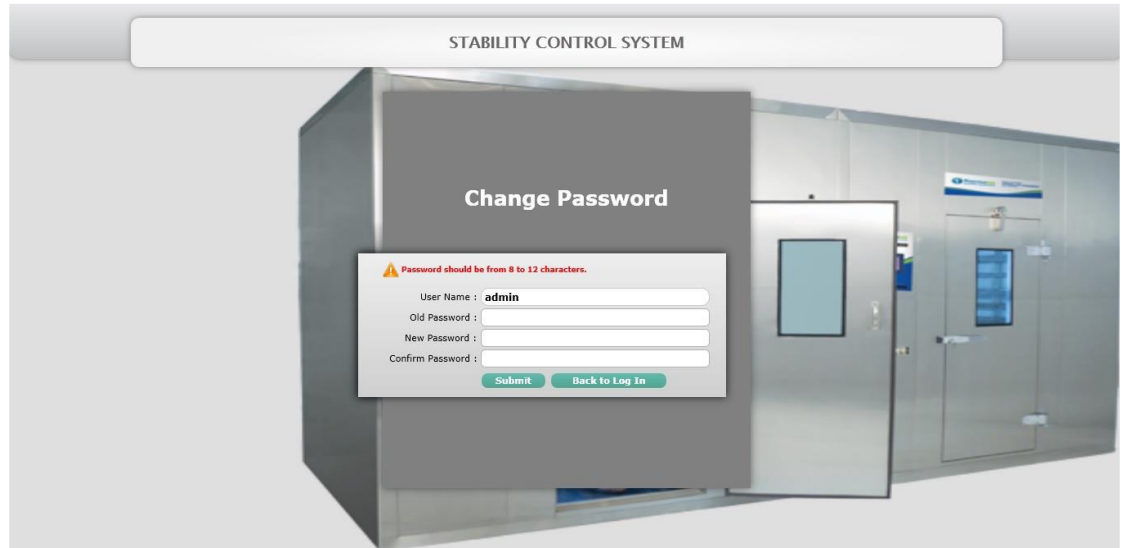


# DECODING PHARMA

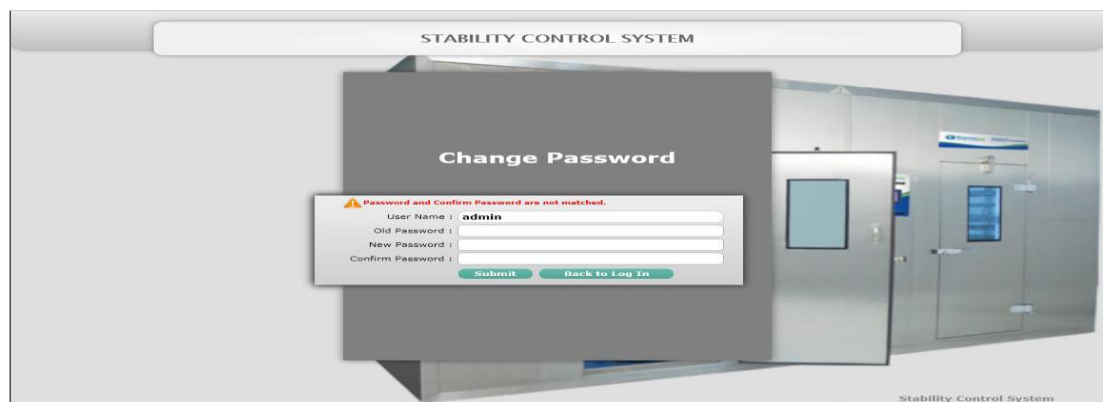
QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>



6.9.25 In Change Password screen, if New Password and Confirm Password does not match then an alert will be shown to user stating 'Password and Confirm Password are not matched.' as shown below:



6.9.26 During Change Password activity, if Password Complexity is kept enabled in the software and User enters New Password or Confirm Password without one capital letter, one small letter, one numeric and one special character during Change Password then an alert message 'Password must contain one capital letter, one small letter, one numeric and one special character' will appear as shown in below screenshot.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.9.27 During change password, if user try to use last five old passwords then software will not accept these passwords and an alert message will be displayed “You can’t use last 5 passwords” as shown in the below screenshot:



6.9.28 Administrator of the software can use Valid To date selection field for an account to expire from the day of creation of any new user. If User does not select Valid To date and keep the field empty, then this account will not expire. If User selects Valid To date as an any fixed date then software will notify the user 7 days before the fixed date expiry by displaying popup on every login. “Your Account is going to expire in X days. Please contact Admin.” as shown below screenshot:

Note: Valid To is not mandatory field, but can be set for individual users if required.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

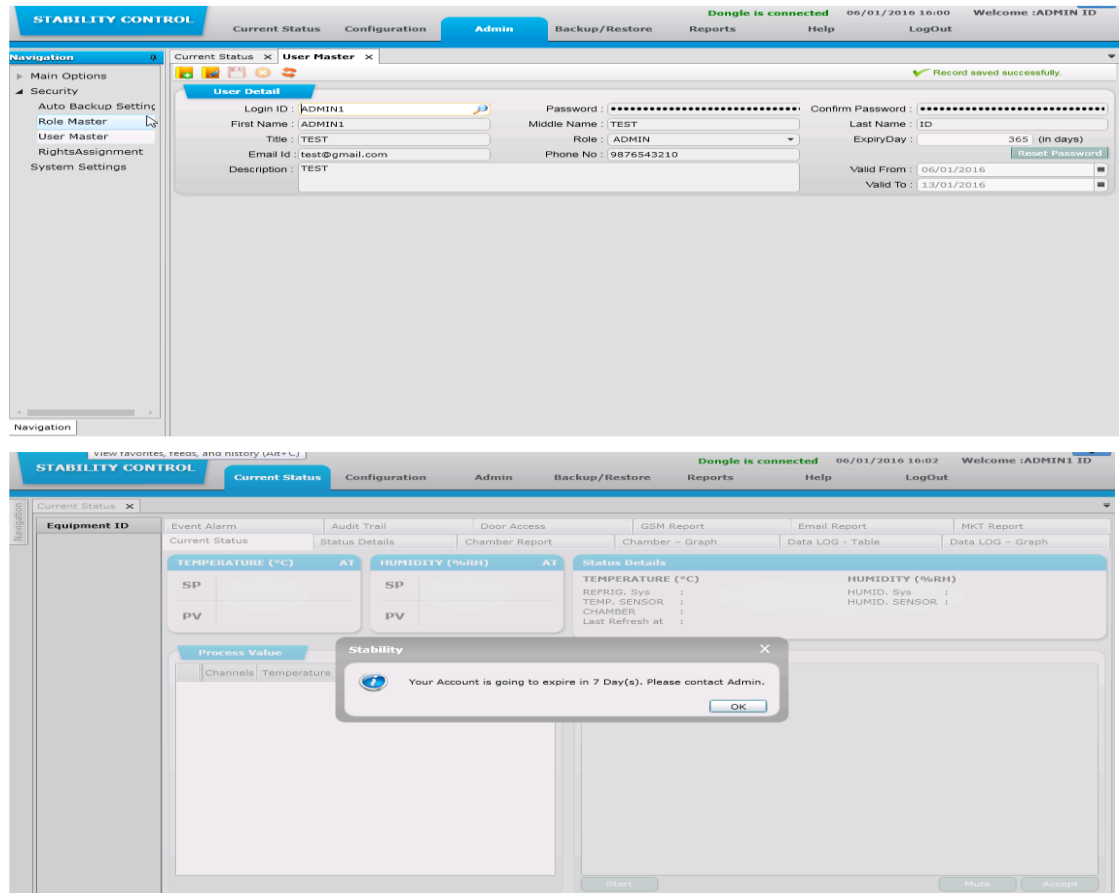
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.9.29 Administrator of the software can use Expiry Day field for setting password expiry period during creation of any new user. User can set expiry day minimum 1 and maximum 365. Software will notify the user 7 days before password gets expired in every login. It will display "Your Password will expire in X days. Please Change Password." as shown below screenshot:

Note: Expiry Day is mandatory field which has to be set for each users separately during user creation. If the user ignores password expiry popup and password gets expired then user can go to change password screen, fill the details and change the password to reactivate the password again.





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

The image displays two screenshots of the STABILITY CONTROL software interface. The top screenshot shows the 'User Master' configuration page under the 'Admin' tab. It includes fields for Login ID (ADMIN1), Password, Confirm Password, First Name (ADMIN1), Middle Name (TEST), Title (TEST), Role (ADMIN), Email Id (test@gmail.com), Phone No (9876543210), and Description (TEST). It also shows ExpiryDay (7 in days) and Valid From/To dates (06/01/2016 to 31/12/2020). A 'Record saved successfully' message is visible at the top right. The bottom screenshot shows the 'Current Status' page with a 'Stability' dialog box overlaying the interface. The dialog box contains the message: 'Your Password will expire in 7 Day(s). Please Change Password.' with an 'OK' button. The background interface shows various monitoring options like Event Alarm, Audit Trail, Door Access, GSM Report, Email Report, and MKT Report, along with real-time data for Temperature and Humidity.

### 6.10 Current Status

6.10.1 The Current Status navigation contains 12 sub-navigation options:

6.10.2 Current Status

6.10.3 Status Details

6.10.4 Chamber Report

6.10.5 Chamber – Graph

6.10.6 Data LOG – Table

6.10.7 Data LOG – Graph



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

6.10.8 Event Alarm

6.10.9 Audit Trail

6.10.10 Door Access

6.10.11 GSM Report

6.10.12 Email Report

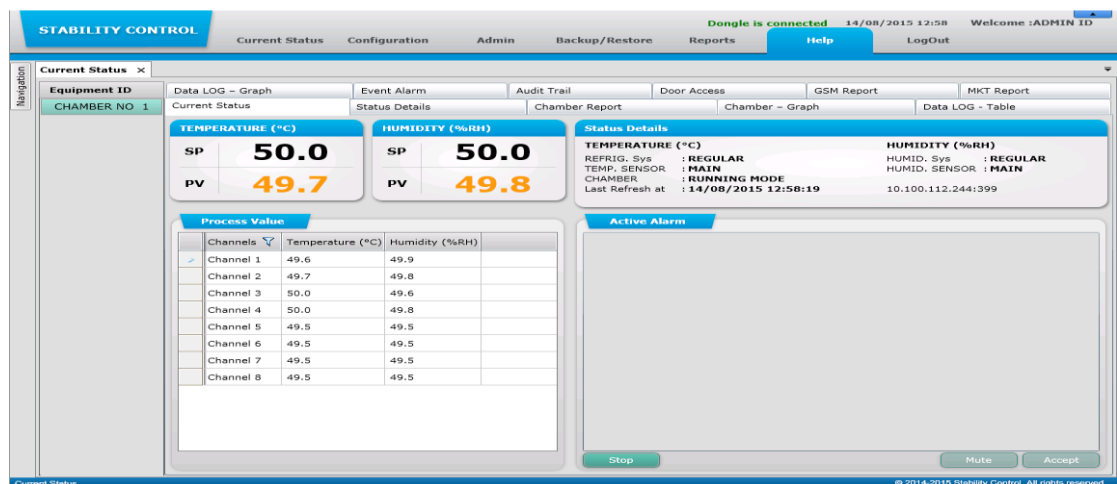
6.10.13 MKT Report

### 6.11 Current Status :

6.11.1 To know the Current Status of the chamber, the User has to select the chamber from Equipment ID section on the left hand side of the screen. The current Temperature & Relative Humidity of the chamber will be listed in the box.

SP: - Set point | PV: - Process Value

6.11.2 When the user will select the chamber type like Stability then the details of Temperature and Relative Humidity will be shown on the screen as shown in the following screen shot:



6.11.3 When the user will select the chamber types like Cooling, Deepfreeze, BOD & Incubator then only the details of Temperature will be shown on the screen. The details of Relative Humidity will not be available as shown in the below screen shot:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

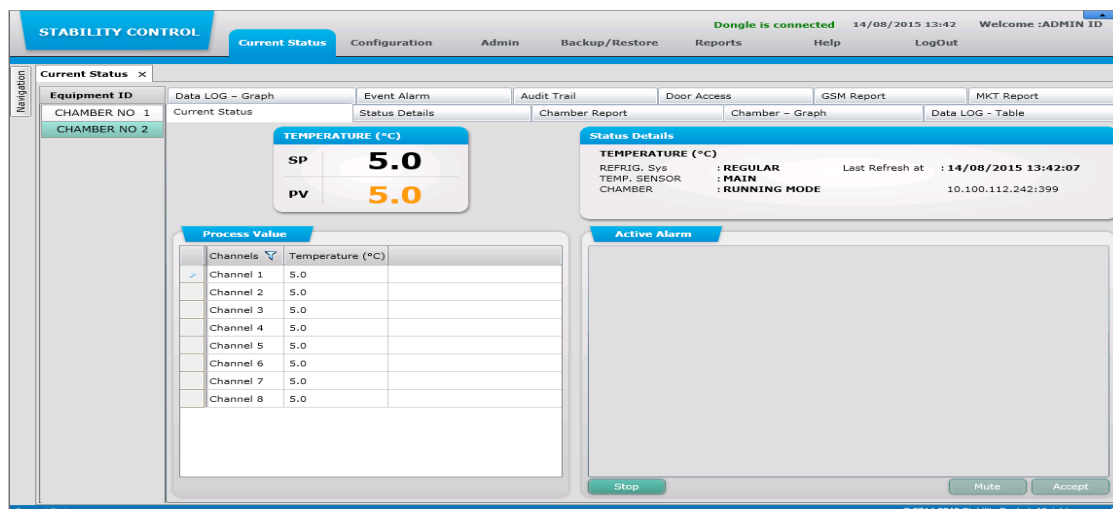
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



- 6.11.4 **Temperature:** The Temperature will be displayed in Degree Celsius. The Temperature field will display the temperature conditions inside the chamber. The current temperature data is updated periodically.
- 6.11.5 **Relative Humidity:** The Relative Humidity will be displayed in percentage. The Relative Humidity field will display the percentage of the Relative Humidity conditions inside the chamber. The current Relative Humidity data is updated periodically.
- 6.11.6 **Status Details:** Status details section contains the details regarding different aspects of Temperature & Relative Humidity. The user can view the details of all the inputs and outputs connected to chamber.
- 6.11.7 **Process Value:** The process value will list all the channels available in the chamber. The Temperature and Relative Humidity of each channel will be displayed in the process value section.
- 6.11.8 **Active Alarm:** Active alarm will display all the alarms that are active. Under Alarm condition, an Audio alarm is triggered and a notification of the alarm will be displayed. The user can take action on the alarm from here. The user can mute the alarm by clicking on the Mute button & once the user clicks on the Accept button the alarm will be stopped.
- 6.11.9 The user can Turn On and Turn Off the chamber by clicking on the **Start & Stop** button. When the chamber is in running mode then **Stop** button will be visible and if the chamber is in off mode then **Start** button will be visible.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

### 6.12 Status Details

#### Input Status/Output Status

6.12.1 Status Details is the screen which contains the details regarding the current status of the elements like refrigeration, sensor, system, blower, etc. The user can view whether the system is healthy or faulty. The user can also view the Input & Output status.

6.12.2 When the user will select the chamber types like **Stability** then the details of **Temperature** and **Relative Humidity** will be shown in below screen:

The screenshot shows the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The main content area is titled 'Current Status' and shows 'Equipment ID' as 'CHAMBER NO 1'. Below this, there are several sections: 'Reset System' with a list of components (Refrigeration System Regular, Refrigeration System Standby, Humidity System Regular, Humidity System Standby, Temperature Sensor Main, Temperature Sensor Standby, Humidity Sensor Main, Humidity Sensor Standby) and their status (Healthy); 'Input Status' with a list of components (Main Power Supply, Door, Regular Water Level, Standby Water Level, Thermostat Regular Humidity, Thermostat Standby Humidity, Thermostat - Temperature) and their status (ON, CLOSE); and 'Output Status' with a list of components (Main Contactor, Regular Humidity System, Standby Humidity System, Regular Refrigeration System, Standby Refrigeration System, Buzzer, Scanner Alarm, Door Magnet) and their status (ON, OFF).

6.12.3 When the user will select the **Cooling & Deepfreeze** type of chamber then only the details of **Temperature** will be shown on the screen. The details of **Relative Humidity** will not be available; the blower status will not be available on the below screen:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

STABILITY CONTROL

Current Status Configuration Admin Backup/Restore Reports Help LogOut

Dongle is connected 14/08/2015 14:32 Welcome :ADMIN ID

Navigation

Current Status x

Equipment ID

CHAMBER NO 1

CHAMBER NO 2

CHAMBER NO 3

Data LOG - Graph Event Alarm Audit Trail Door Access GSM Report MKT Report

Current Status Status Details Chamber Report Chamber - Graph Data LOG - Table

Reset System

Refrigeration System Regular : Healthy Healthy

Refrigeration System Standby : Healthy Healthy

Temperature Sensor Main : Healthy Healthy

Temperature Sensor Standby : Healthy Healthy

Input Status

Main Power Supply : ON

Door : CLOSE

Thermostat - Temperature : ON

Output Status

Main Contactor : ON

Regular Refrigeration System : ON

Standby Refrigeration System : OFF

Buzzer : ON

Scanner Alarm : ON

Door Magnet : OFF

Current Status © 2014-2015 Stability Control. All rights reserved.

6.12.4 1 When the user will select the chamber types like **BOD & Incubator** then only the details of **Temperature** will be shown on the screen. The details of **Relative Humidity** will not be available as shown in the following screen shot:

STABILITY CONTROL

Current Status Configuration Admin Backup/Restore Reports Help LogOut

Dongle is connected 14/08/2015 14:03 Welcome :ADMIN ID

Navigation

Current Status x

Equipment ID

CHAMBER NO 1

CHAMBER NO 2

Data LOG - Graph Event Alarm Audit Trail Door Access GSM Report MKT Report

Current Status Status Details Chamber Report Chamber - Graph Data LOG - Table

Reset System

Refrigeration System Regular : Healthy Healthy

Refrigeration System Standby : Healthy Healthy

Temperature Sensor Main : Healthy Healthy

Temperature Sensor Standby : Healthy Healthy

Input Status

Blower Status : ON

Main Power Supply : ON

Door : CLOSE

Thermostat - Temperature : ON

Output Status

Main Contactor : ON

Regular Refrigeration System : ON

Standby Refrigeration System : OFF

Buzzer : OFF

Scanner Alarm : OFF

Door Magnet : OFF

Current Status © 2014-2015 Stability Control. All rights reserved.

**Reset System :**

6.12.5 In status details, the user can see the status of Refrigeration system, Humidity system, Temperature sensor and Humidity sensor. The status will show as **Healthy / Faulty**. The user can



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

know what the current status is and if the status is shown as **Faulty** then after rectifying it the user can click on **Healthy** button and the status will be changed to **Healthy**.

### 6.13 Chamber Report :

6.13.1 Chamber report screen will help the user to view the report of the chamber. The Report will include the Temperature & Humidity (SP/PV) details of a particular time.

6.13.2 When the user will select the chamber types like **Stability** then the details of **Temperature** and **Relative Humidity** will be shown on the screen as shown in the following screen shot:

Date Time	SP(°C)	PV(°C)	Remarks(°C)	SP(%RH.)	PV(%RH.)	Remarks(%RH.)
14/08/2015 00:00	50.0	49.6	ABCDERFGHIJKLMNOPQR	50.0	49.9	1234567890123456789
14/08/2015 00:01	50.0	49.6		50.0	49.9	
14/08/2015 00:02	50.0	49.6		50.0	49.9	
14/08/2015 00:03	50.0	49.6		50.0	49.9	
14/08/2015 00:04	50.0	49.6		50.0	49.9	
14/08/2015 00:05	50.0	49.6		50.0	49.9	
14/08/2015 00:06	50.0	49.6		50.0	49.9	
14/08/2015 00:07	50.0	49.6		50.0	49.9	
14/08/2015 00:08	50.0	49.6		50.0	49.9	
14/08/2015 00:09	50.0	49.6		50.0	49.9	
14/08/2015 00:10	50.0	49.6		50.0	49.9	
14/08/2015 00:11	50.0	49.6		50.0	49.9	
14/08/2015 00:12	50.0	49.6		50.0	49.9	
Avg Value.	50.00	49.60		50.00	49.90	
Min Value.	50.00	49.60		50.00	49.90	
Max Value.	50.00	49.60		50.00	49.90	

6.13.3 When the user will select the chamber types like **Cooling, Deepfreeze, BOD & Incubator** then only the details of Temperature will be shown on the screen. The details of Humidity will not be available as shown in the following screen shot:



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

The screenshot displays the 'STABILITY CONTROL' software interface. The main window shows a 'Current Status' tab with a navigation pane on the left listing 'CHAMBER NO 1', 'CHAMBER NO 2', and 'CHAMBER NO 3'. The central area features a 'Search Record' section with 'From Date' and 'To Date' set to 14/08/2015, and a 'Print Interval' dropdown. Below this is a 'View Only Alarms' checkbox and a 'Click on (+) to add the remarks.' instruction. A table displays the following data:

Date Time	SP(°C)	PV(°C)	Remarks(°C)
14/08/2015 00:00	44.0	44.2	ABCDEFGHIJKLMNQRS (+)
14/08/2015 00:01	44.0	44.3	(+)
14/08/2015 00:02	44.0	44.2	(+)
14/08/2015 00:03	44.0	44.2	(+)
14/08/2015 00:04	44.0	44.2	(+)
14/08/2015 00:05	44.0	44.2	(+)
14/08/2015 00:06	44.0	44.2	(+)
14/08/2015 00:07	44.0	44.2	(+)
14/08/2015 00:08	44.0	44.2	(+)
14/08/2015 00:09	44.0	44.3	(+)
14/08/2015 00:10	44.0	44.3	(+)
14/08/2015 00:11	44.0	44.3	(+)
14/08/2015 00:12	44.0	44.3	(+)
Avg Value.	44.00	44.15	
Min Value.	44.00	43.80	
Max Value.	44.00	44.30	

6.13.4 The report generated, will help the user to know what was the exact Temperature or Relative Humidity at a specific time. User can also view all data using **1, 5, 10, 15, 20, 30, 60 and 120** minute's different time print interval.

### View Only Alarms check box:

6.13.5 If the user will tick the **View Only Alarms** check box and then generate the report, the report will be generated only of the records that are out of specified limit.

6.13.6 If the user wants to add remark to any chamber report data, then it can be done by clicking on the (+) button. When the user will click on the (+) button, a pop up window will open where the user can enter **Min. 1 & Max. 20 Characters** remarks for each record of temperature and humidity and click on the ADD button.

6.13.7 To search the record, the user will have to specify a range of date & time and then click on **Show Records** button.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

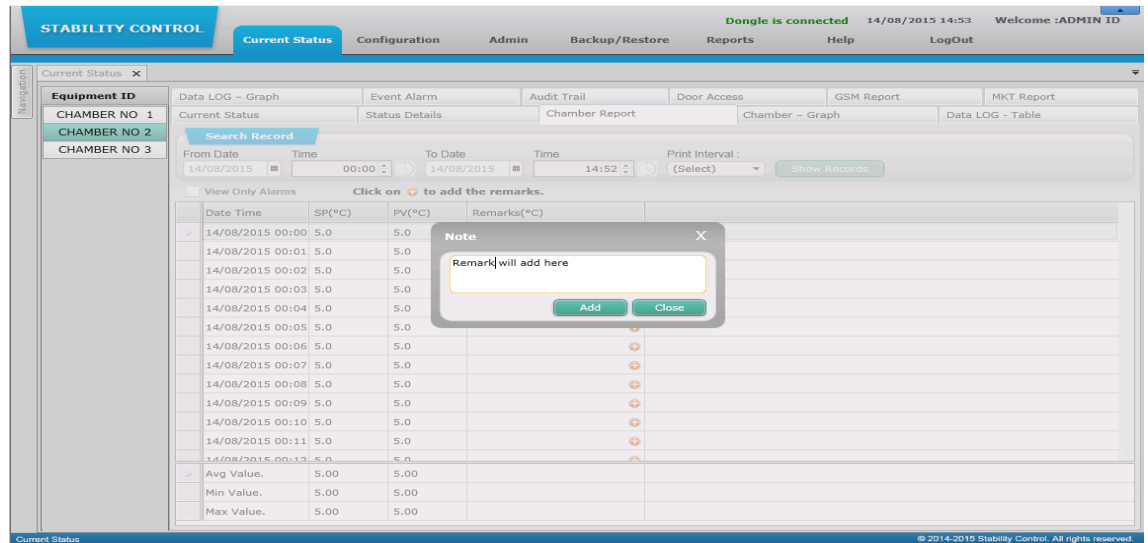
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



### 6.14 Chamber - Graph

6.14.1 Chamber Graph section shows the **Temperature & Relative Humidity** line graph for **Main/Standby** (whichever is controlling) sensor.

6.14.2 When the user will select the chamber types like **Stability** then the details of **Temperature** and **Relative Humidity** will be shown on the screen. As shown in the following screenshot the user can view the Graphs of **Temperature** as well as **Relative Humidity** (Temp & RH).

6.14.3 User can view better **Chamber Graph** if **22" inch** monitor screen is used.





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

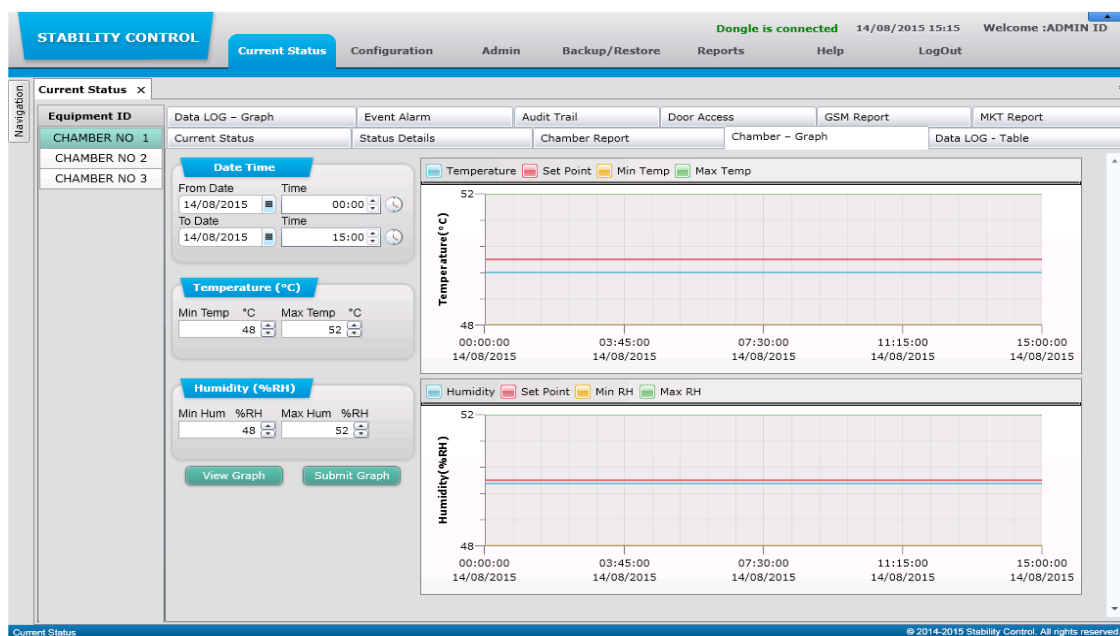
Effective Date:

Supersedes: Nil

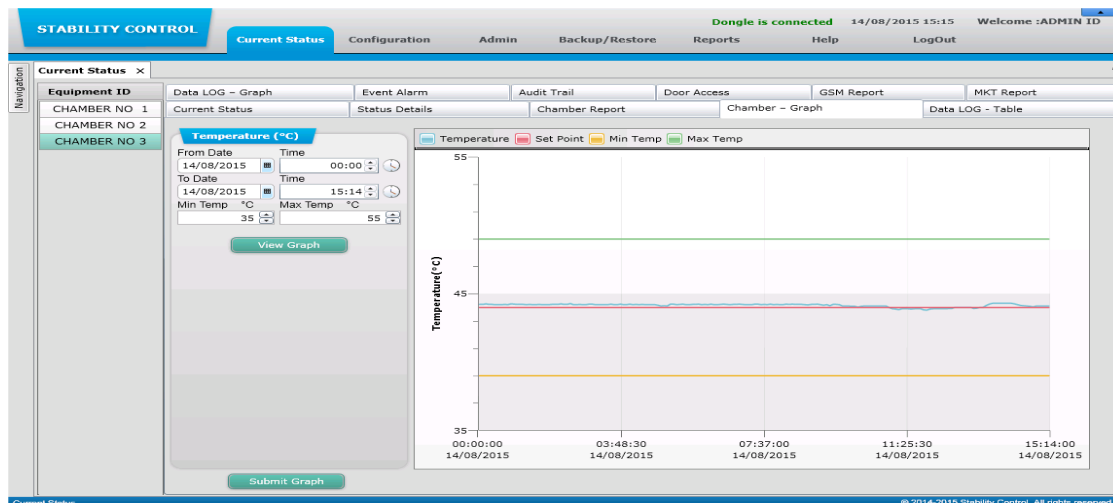
Review Date:

Issue Date:

Page No.:



6.14.4 When the user will select the chamber types like **Cooling, Deepfreeze, BOD & Incubator** then only the details of **Temperature** will be shown on the screen. The details of Relative Humidity will not be available. As shown in the following screen shot the user can only view the Graphs of Temperature (T).



6.14.5 **Temperature** : If the user wants to view the graphical report of the Temperature then the User will have to give the date & time range and then click on **View Graph** button. If the User wants to filter the result than the User can mention the Minimum Temp & Maximum Temp.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

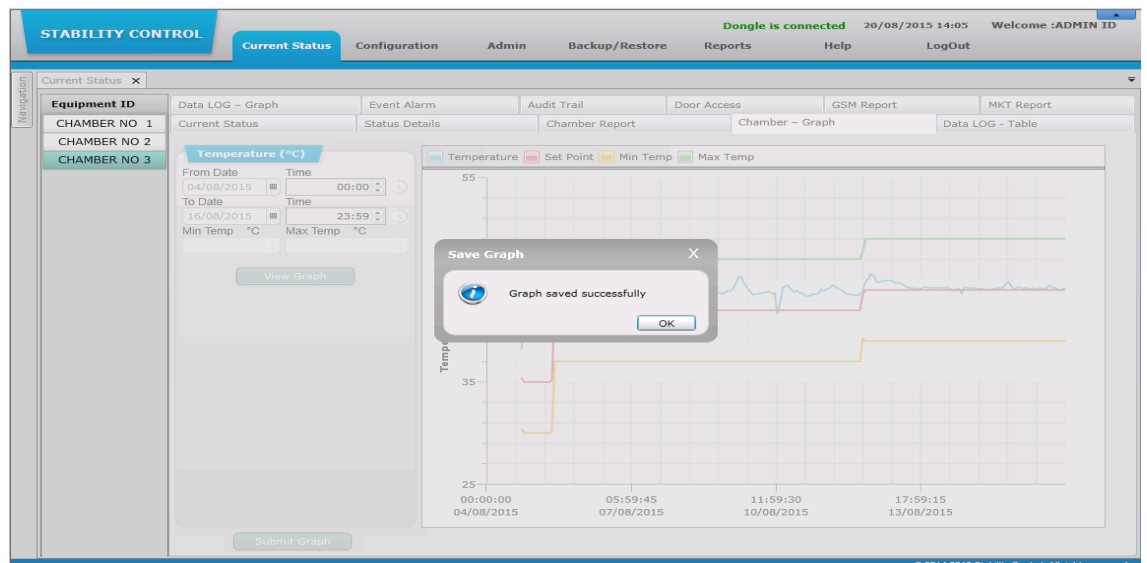
Review Date:

Issue Date:

Page No.:

6.14.6 **Relative Humidity:** If the User wants to view the graphical report of the relative humidity then the User will have to give the date & time range and then click on **View Graph** button. If the User wants to filter the result then the User can mention the Minimum Relative Humidity & Maximum Relative Humidity.

### 6.14.7 Submit Graph:



6.14.8 As soon as the User will click on the **Submit Graph** button, Chamber Graph report is send to **Submit Report** screen as shown in the below screen shot:

The screenshot shows the 'STABILITY CONTROL' software interface with the 'Submit Report' screen. The screen displays a list of reports with columns for Report Name, From Date, To Date, Equipment Id, Print, Us, Submitted By, Submitted Date, Re, and Action. The reports listed include 'Audit Trail Common Report', 'Chamber Graph', 'Data Log Graph', 'Chamber Report', 'Data Logger Report', 'Audit Trail Report(Chamberwise)', 'Audit Trail Report(Userwise)', 'Audit Trail Common Report', 'MKT Report', 'Email Report', and 'Door Access Report'.

Report Name	From Date	To Date	Equipment Id	Print	Us	Submitted By	Submitted Date	Re	Action
Audit Trail Common Report	07/11/2015	07/11/2015		0		admin	07/11/2015		Send To Review Reject
Chamber Graph	07/11/2015	07/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject
Data Log Graph	07/11/2015	07/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject
Chamber Report	07/11/2015	07/11/2015	SAMYAK\BOD\VER1.3	120		admin	08/11/2015		Send To Review Reject
Data Logger Report	07/11/2015	07/11/2015	SAMYAK\BOD\VER1.3	30		admin	08/11/2015		Send To Review Reject
Audit Trail Report(Chamberwise)	08/11/2015	08/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject
Audit Trail Report(Userwise)	08/11/2015	08/11/2015		0	ac	admin	08/11/2015		Send To Review Reject
Audit Trail Common Report	08/11/2015	08/11/2015		0		admin	08/11/2015		Send To Review Reject
MKT Report	01/11/2015	14/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject
Email Report	07/11/2015	08/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject
Door Access Report	07/11/2015	08/11/2015	SAMYAK\BOD\VER1.3	0		admin	08/11/2015		Send To Review Reject



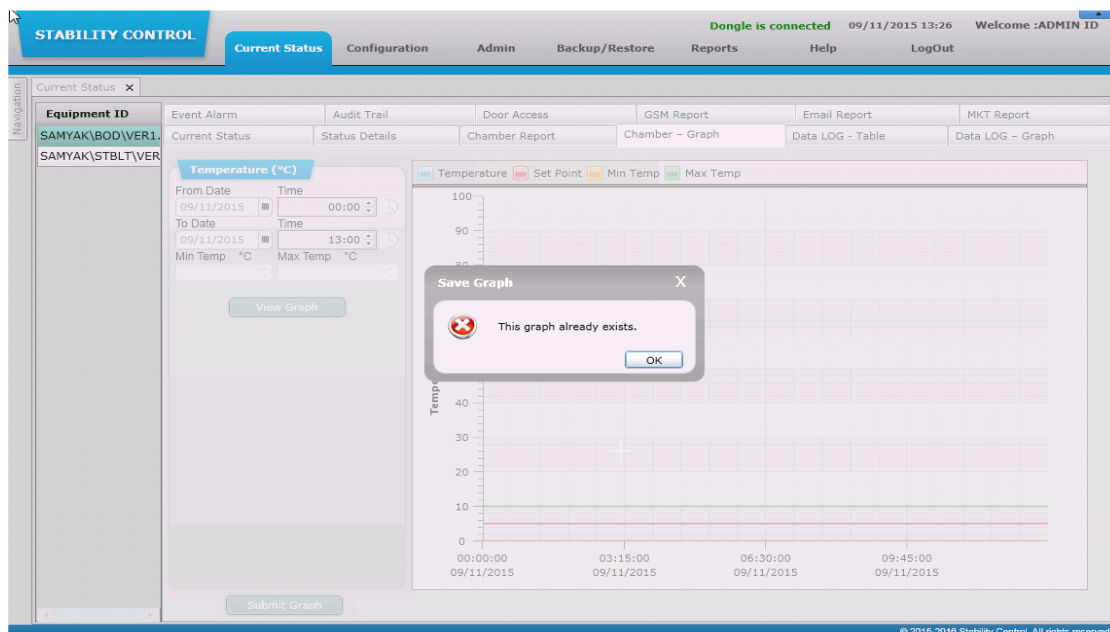
# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

6.14.9 When User has made a Chamber Graph Report with same date, same time and same chamber ID, then alert message will be shown "**This graph already exists.**" as shown in the following screenshot:



### 6.15 Data LOG – Table :

6.15.1 Through Data LOG - Table screen the user can search the record of Temperature and Relative Humidity of the channel in a particular chamber. The temperature and humidity details should be retrieved from the hardware. In the tables and graphs T denotes Temperature & RH denotes Relative Humidity.

6.15.2 User can view Temperature and Relative Humidity details for each channels of selected chamber. The information that the user can view in the reports are:

- Date Time
- Channel No.
- Temperature value for that channel
- Humidity value for that channel
- User can view Avg. Value, Min Value and Max. Value of all data of displayed date.
- User can also view all data using 1, 5, 10, 15,20,30,60 and 120 minute's different time Print Interval.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- To view the records the user has to specify the date and time range and then click on the Show Records button.

### View Only Alarms check box:

6.15.3 The user will tick the View Only Alarms check box and then generate the report. The report will be generated only for the alarm records and not for the general records.

6.15.4 When the user will select the chamber types like Stability then the details of Temperature and Relative Humidity will be shown with Minimum, Maximum & Average on the screen as shown in the following screen shot:

Date/Time	T1	RH1	T2	RH2	T3	RH3	T4	RH4	T5	RH5	T6	RH6	T7	RH7	T8
14/08/2015 00:00	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:01	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:02	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:03	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:04	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:05	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:06	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:07	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:08	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:09	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:10	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
14/08/2015 00:11	49.6	49.9	49.7	49.8	50.0	49.6	50.0	49.8	49.5	49.5	49.5	49.5	49.5	49.5	49.5
Avg Value.	49.60	49.90	49.70	49.80	50.00	49.60	50.00	49.80	49.50	49.50	49.50	49.50	49.50	49.50	49.50
Min Value.	49.60	49.90	49.70	49.80	49.90	49.60	50.00	49.80	49.50	49.50	49.50	49.50	49.50	49.50	49.50
Max Value.	49.60	49.90	49.70	49.80	50.00	49.60	50.00	49.80	49.50	49.50	49.50	49.50	49.50	49.50	49.50

6.15.5 When the user will select the chamber types like Cooling, Deepfreeze, BOD & Incubator then only the details of Temperature will be shown on the screen. The details of Relative Humidity will not be available. As shown in the following screen shot the user can only view the tables of temperature (T).

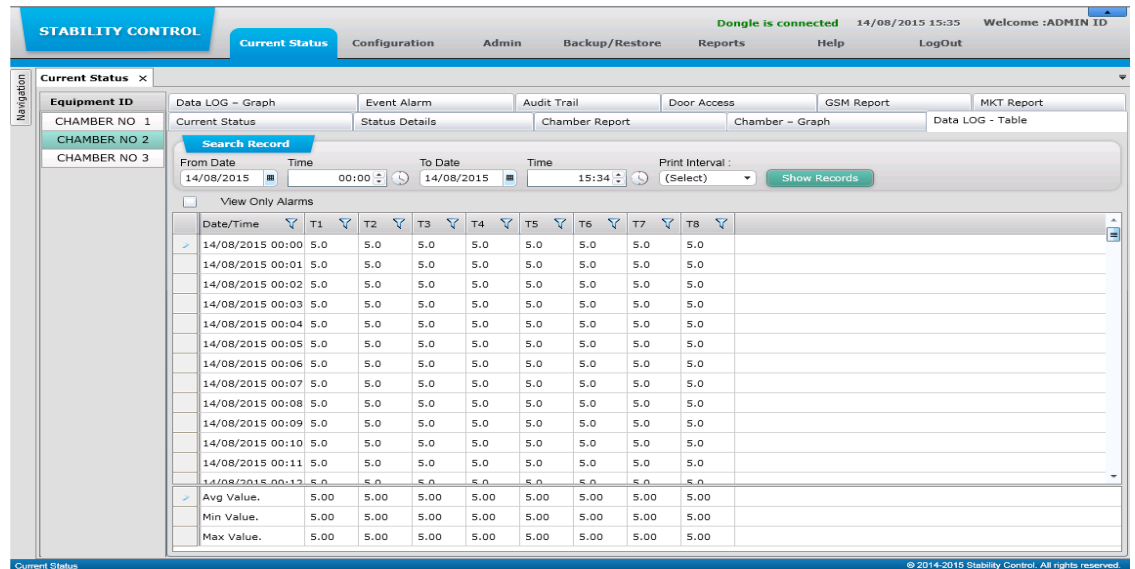


# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>



### 6.16 Data LOG – Graph

- 6.16.1 Data LOG Graph is a scanner graph and it shows the Temperature & Relative Humidity trends for all channels.
- 6.16.2 When the user will select the chamber type like Stability then the details of Temperature and Relative Humidity will be shown on the screen. As shown in the following screen shot the user can view the Graphs of Temperature as well as Relative Humidity (Temp & RH).
- 6.16.3 User can view better Data Log Graph if 22" inch monitor screen is used.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

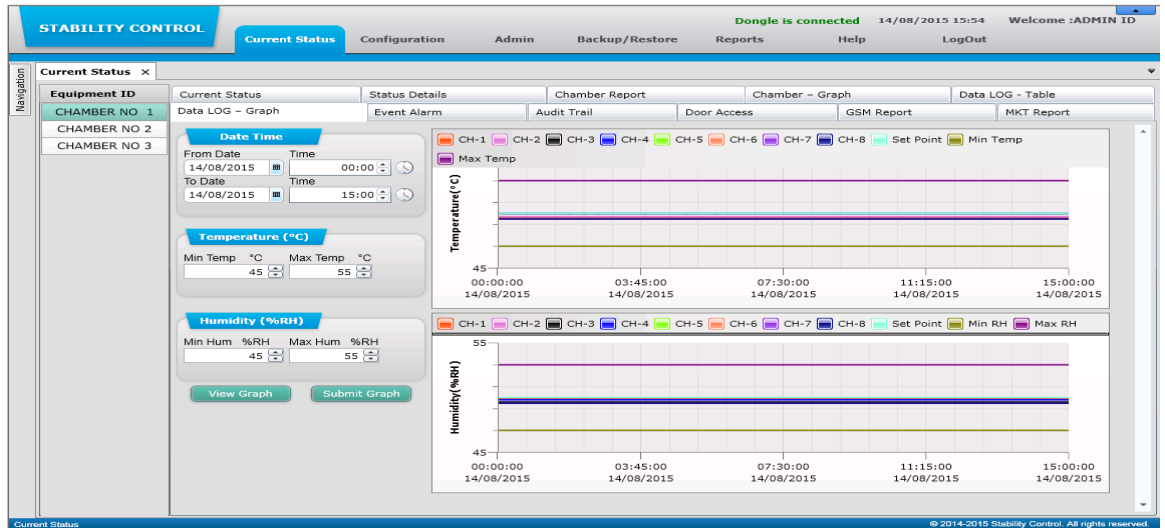
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.16.4 When the user will select the chamber types like Cooling, Deepfreeze, BOD & Incubator then only the details of Temperature will be shown on the screen. The details of Relative Humidity will not be available. As shown in the following screen shot the user can only view the Graphs of temperature (T).





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

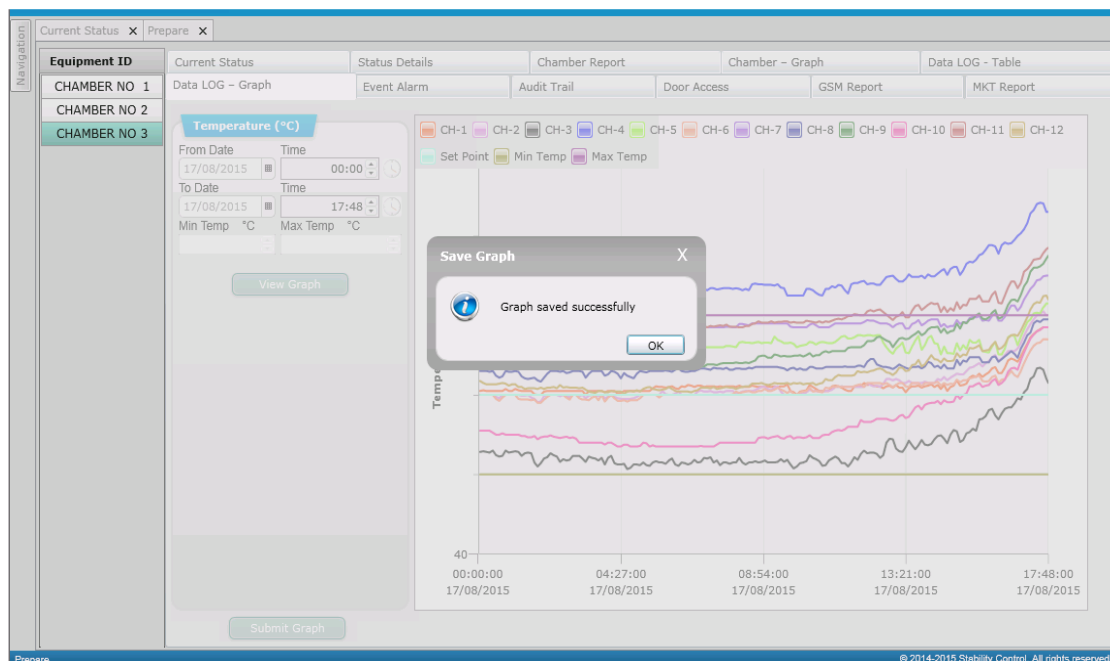
## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

6.16.5 **Temperature:** View graphical report of the temperature, the user has to provide the date & time range and then click on View Graph button. To filter the result the user can enter the Minimum Temp & Maximum Temp.

6.16.6 **Relative Humidity:** View the graphical report of Relative Humidity, the user has to provide the date & time range and then click on View Graph button. To filter the result the user can enter the Minimum Hum & Maximum Hum.

6.16.7 **Submit Graph:** If the user wants to save the graph details with electronic signature then the user have to click on the Submit Graph button. An Alert message will be show “Graph saved successfully” as shown in the following screenshot:



6.16.8 As soon as the user will click on the Submit Graph button, Data Log Graph report is send to Submit Report Screen as shown in the below screen shot:

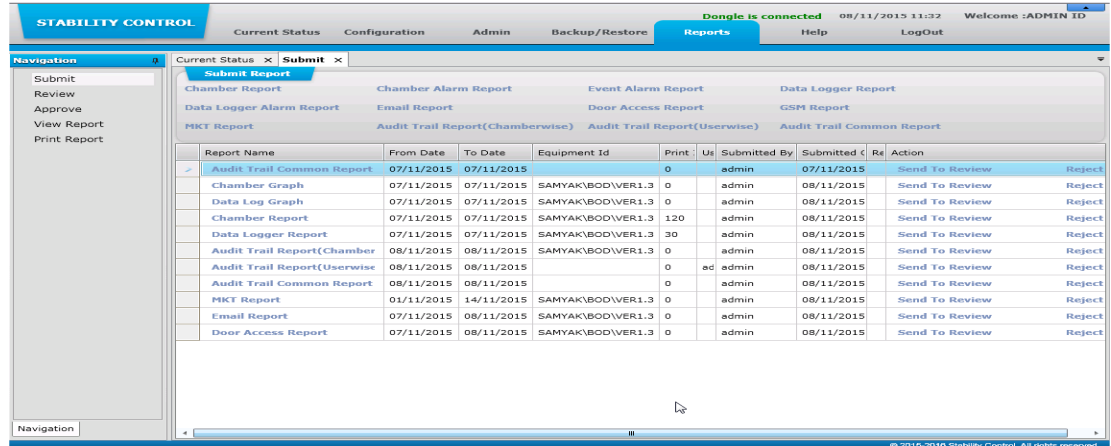


# DECODING PHARMA

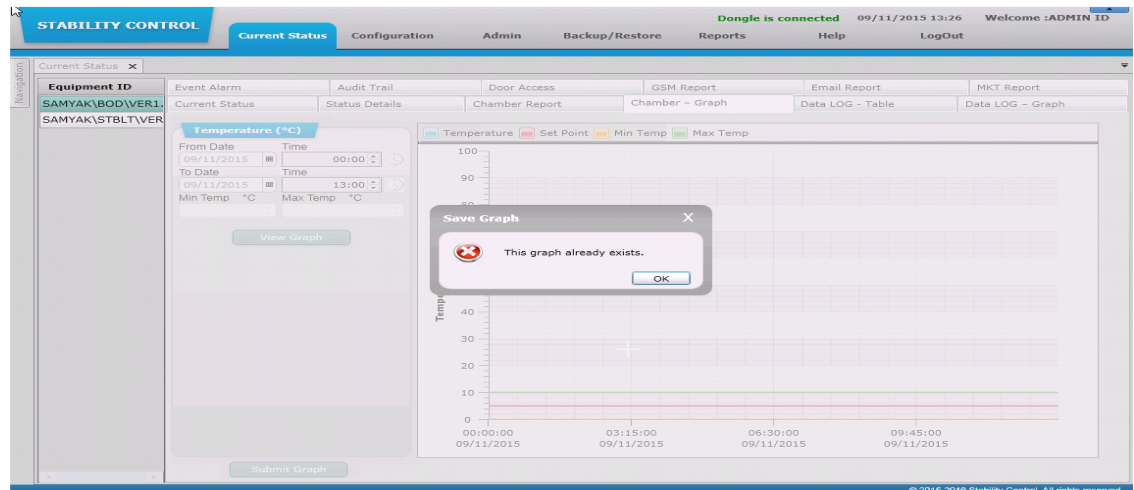
QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>



6.16.9 When User has made this Data Log Graph report with same date, same time and same chamber ID an alert message will be shown "This graph already exists" as shown in the following screenshot:



### 6.17 Event Alarm

6.17.1 Event Alarm screen will help the user to get a report of any event of changes done in the chamber.

6.17.2 Whenever any event such as any error or fault occurs in the system. The system will log these events and the user can view the list of the events from Event Alarm Screen. The Event Alarm report will be available to user with the Event Date and string of the event that had happened.





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

6.17.3 If the user wants to add remark to any chamber report data, then it can be done by clicking on the button. When the user will click on the button, a pop up window will open where the user can enter Min. 1 & Max.60 Characters remarks for each event alarm record and click on the ADD button.

6.17.4 To search the record, the user have to specify a range of date & time and then click on Show Records button.

The screenshot shows the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The 'Current Status' section is active, displaying a list of event logs. The 'Search Record' section allows filtering by 'From Date' (11/08/2015) and 'To Date' (14/08/2015). The event log table has columns for 'Event Date Time', 'Event String', and 'Remarks'. The first event is '11/08/2015 11:56:41 ALARM ON : SCADA COMMUNICATION FAIL' with a remark '12345678901234567890'. A 'Show Records' button is visible below the search filters.

The screenshot shows the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The 'Current Status' section is active, displaying a list of event logs. The 'Search Record' section allows filtering by 'From Date' (05/01/2016) and 'To Date' (05/01/2016). The event log table has columns for 'Event Date Time', 'Event String', and 'Remarks'. A 'Note' pop-up window is open over the table, with the text 'Remarks will be add here' and buttons for 'Add' and 'Close'. The first event is '05/01/2016 00:25:04 ALARM OFF : SCA'.

### 6.18 Audit Trail :

6.18.1 Audit Trail will help the user to know the complete details of the events that have occurred in the system, for example if the user Logs in to the application then this action will get listed under the



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

audit trail and the software Administrator/the user having rights to view Audit Trail can know at which time the user has accessed the system.

- 6.18.2 In Chamber Configuration, whenever the user modifies any value in Settings tab page, the system logs these changes and the user can view the changes that have been done.
- 6.18.3 Now every software audit activity is captured with IP Address of software operating pc and also some important activity has come with remarks (reason for change).
- 6.18.4 To search the record, the user has to specify a range of date & time and then click on Show Records button.

The screenshot displays the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The 'Current Status' tab is active, showing a navigation pane on the left with 'Equipment ID' options: CHAMBER NO 1, CHAMBER NO 2, and CHAMBER NO 3. The main area features a 'Search Record' section with 'From Date' (13/08/2015) and 'To Date' (14/08/2015) fields, along with 'Time' dropdowns (00:00 and 15:06) and a 'Show Records' button. Below this is a table of audit records with columns for Audit Date Time, Audit String, User Name, User Type, Remark, and IP Address.

Audit Date Time	Audit String	User Name	User Type	Remark	IP Address
13/08/2015 16:08:28	ROLE ADMIN ASSIGNED TO USER admin	thermolab	SOFTWARE	create user	10.100.112.53
13/08/2015 17:43:09	ROLE ADMIN ASSIGNED TO USER admin1	admin	SOFTWARE	test	10.100.112.53
14/08/2015 12:31:53	GET CONFIGURATION BUTTON PRESSED	admin	SOFTWARE		10.100.112.53
14/08/2015 12:32:36	EQUIPMENT ID CHANGED FROM CHAMBER NO. 1 to CHAMBER NO 1	admin	SOFTWARE	test	10.100.112.53
14/08/2015 12:32:36	IP ADDRESS CHANGED FROM 10.100.112.92 to 10.100.112.244	admin	SOFTWARE	test	10.100.112.53
14/08/2015 12:32:36	EQUIPMENT NAME CHANGED FROM COOLING to WALK IN STABILITY	admin	SOFTWARE	test	10.100.112.53
14/08/2015 12:33:13	CHAMBER NO 1 ASSIGNED TO USER admin	admin	SOFTWARE	test	10.100.112.53
14/08/2015 12:58:14	ACCEPT BUTTON PRESSED	admin	SOFTWARE	aaa	10.100.112.53
14/08/2015 12:58:15	ACK ALARM :REGULAR REFG. SYSTEM ON AS PER CALENDAR FUNCTION	admin	SOFTWARE		
14/08/2015 13:07:38	GET CONFIGURATION BUTTON PRESSED	admin	SOFTWARE		10.100.112.53
14/08/2015 13:09:42	CHAMBER NO 1,CHAMBER NO 2 ASSIGNED TO USER admin	admin	SOFTWARE	aaa	10.100.112.53
14/08/2015 14:06:39	GET CONFIGURATION BUTTON PRESSED	admin	SOFTWARE		10.100.112.53
14/08/2015 14:07:27	GET CONFIGURATION BUTTON PRESSED	admin	SOFTWARE		10.100.112.53
14/08/2015 14:31:14	GET CONFIGURATION BUTTON PRESSED	admin	SOFTWARE		10.100.112.53
14/08/2015 14:31:45	CHAMBER NO 1,CHAMBER NO 2,CHAMBER NO 3 ASSIGNED TO USER admin	admin	SOFTWARE	aaaa	10.100.112.53
14/08/2015 15:05:20	SYSTEM HAS TAKEN AUTO BACKUP	SYSTEM	SOFTWARE		
14/08/2015 15:05:20	Stability140815150520.bak BACKUP GENERATED	SYSTEM	SOFTWARE		

### 6.19 Door Access

- 6.19.1 Through Door Access screen the user can view the Door Access details like User Name, Door Open Time, Door Date Time etc. This details will be retrieved from the hardware. This will help the user to know that at which time the door was accessed.
- 6.19.2 If the user wants to add remark to any chamber report data, then it can be done by clicking on the (+) button. When the user will click on (+) the button, a pop up window will open where the user can enter Min. 1 & Max.30 Characters remarks for each door access record and click on the ADD button.
- 6.19.3 To search the record, the user has to specify a range of date & time and then click on Show Records button.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

The top screenshot shows the 'STABILITY CONTROL' software interface. The 'Current Status' page is active, displaying a table of door events. The table has columns for Door Date Time, Alarm String, Door Open Time(sec.), Remarks, and User Name. The events listed are:

Door Date Time	Alarm String	Door Open Time(sec.)	Remarks	User Name
11/08/2015 13:42:17	DOOR OPEN FORCEFULLY		ABCDEFGHIJKLMNOQRT	
11/08/2015 13:42:22	DOOR CLOSE FORCEFULLY	5		
11/08/2015 13:42:31	DOOR OPEN FORCEFULLY			
11/08/2015 13:42:38	DOOR CLOSE FORCEFULLY	7		
11/08/2015 13:42:40	DOOR OPEN FORCEFULLY			
11/08/2015 13:42:42	DOOR CLOSE FORCEFULLY	2		
11/08/2015 13:42:45	DOOR OPEN FORCEFULLY			
11/08/2015 13:42:49	DOOR CLOSE FORCEFULLY	4		
11/08/2015 13:42:51	DOOR OPEN FORCEFULLY			
11/08/2015 13:43:05	DOOR CLOSE FORCEFULLY	14		

The bottom screenshot shows the 'Backup/Restore' page. A 'Note' dialog box is open, with the text 'Remarks will be add here' and buttons for 'Add' and 'Close'.

### 6.20 GSM Report :

- 6.20.1 The GSM Report screen will help the user to generate the report of the alert messages send on the mobile phone.
- 6.20.2 If any changes are made in the chamber then an alert message will be send to the mobile number associated with that alert message. The track of the messages send on the mobile will be visible in the report.
- 6.20.3 To View the records of the message the user has to first enter the specific date & time range and then click on Show Records button.
- 6.20.4 Once the user click on the Show Records button, the record list will be generated and the user will be able to view the Date & Time of the message, user name, mobile number & the message which was send to the user.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

The screenshot shows the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The 'Current Status' section is active, showing 'Equipment ID: SAMYAK|TEST|VER1.3'. Below this, there are tabs for 'Event Alarm', 'Audit Trail', 'Door Access', 'GSM Report', 'Email Report', and 'MKT Report'. The 'Search Record' section is visible, with filters for 'From Date' (05/01/2016) and 'To Date' (05/01/2016), and a 'Show Records' button. The table below displays the search results:

Date Time	User Name	Mobile No	Message
05/01/2016 15:11:17	admin	8511106804	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user1	123456	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user2	789456	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user3	1234567890123456	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user4	1234567	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user5	123457890	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER, DOOR IS OPENED FORCEFULLY 05/01/2016 15:11:17
05/01/2016 15:11:17	user6	011234567890	SAMYAK TEST VER1.3, WALK IN TYPE BOD CHAMBER,

### 6.21 Email Report

- 6.21.1 The Email Report screen will help the user to generate the report of email alerts send on the selected email ids.
- 6.21.2 If any changes are made in the chamber then an email alert will be send to the associated email id. The track of the emails send on the email ids will be visible in the report.
- 6.21.3 To View the records of the emails the user has to first enter the specific date & time range and then click on Show Records button.
- 6.21.4 Once the user clicks on the Show Records button, the record list will be generated and the user will be able to view the Date & Time of the email, Alarm Name, Equipment Name & Email ID which was send to the user.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

Date Time	Alarm Name	Equipment Name	Email Id
04/01/2016 12:55:43	START FAILED	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,aa@aa.com,test4@samyak.com
04/01/2016 13:00:40	MAINS POWER FAILURE	SAMYAK\TEST\VER1.3	kkhamar@samyak.com
04/01/2016 13:00:41	CHAMBER SHUTDOWN	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test4@samyak.com,test5@samyak.com
04/01/2016 13:04:17	START FAILED	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test6@samyak.com,test7@samyak.com,test8@samyak.com
04/01/2016 13:05:57	START FAILED	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test6@samyak.com,test7@samyak.com,test8@samyak.com
04/01/2016 13:07:36	START FAILED	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test6@samyak.com,test7@samyak.com,test8@samyak.com
04/01/2016 13:12:32	MAINS POWER FAILURE	SAMYAK\TEST\VER1.3	kkhamar@samyak.com
04/01/2016 13:12:32	DOOR IS OPENED FORCEFULLY	SAMYAK\TEST\VER1.3	test6@samyak.com,test8@samyak.com,test10@samyak.com,test12@samyak.com
04/01/2016 13:12:34	CHAMBER SHUTDOWN	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test4@samyak.com,test5@samyak.com
04/01/2016 13:20:21	DOOR IS OPENED FORCEFULLY	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,test6@samyak.com
04/01/2016 13:23:46	MAINS POWER FAILURE	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,aa@aa.com,test4@samyak.com
04/01/2016 13:23:46	CHAMBER SHUTDOWN	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,aa@aa.com,test4@samyak.com
04/01/2016 13:40:57	MAINS POWER FAILURE	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,aa@aa.com,test4@samyak.com
04/01/2016 13:40:57	DOOR IS OPENED FORCEFULLY	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,test6@samyak.com
04/01/2016 13:42:08	CHAMBER SHUTDOWN	SAMYAK\TEST\VER1.3	kkhamar@samyak.com,test@samyak.com,test@samyak.com,aa@aa.com,test4@samyak.com
04/01/2016 13:49:36	START FAILED	SAMYAK\TEST\VER1.3	test@samyak.com,aa@aa.com,test5@samyak.com,test7@samyak.com,test9@samyak.com

### 6.22 MKT Report :

#### MKT Report (Mean Kinetic Temperature Report)

6.22.1 MKT Report can be generated by the user. The report will be generated on a weekly basis. MKT

Report screen can be used to generate the report which will include the following details:

6.22.2 The MKT report will include the following details:

1. Lowest Temperature of the week
2. Highest Temperature of the week
3. Average Temperature of the week
4. Mean Kinetic Temperature

6.22.3 Refer to the following example for better understanding: Suppose, the user has set start date as 01/08/2015 (Which is a Saturday & it comes in the 31th week) and end date as 15/08/2015 (Which is a Saturday & it comes in the 32th week). The system will provide the MKT Report of 31th week to 32th week and the start date will be taken as 26/07/2015 since it is the 1st day of the 31th week and last day will be taken as 15/08/2015 since it is the last day of the 32th week.

6.22.4 To generate the report, the user has to specify the start date & end date. The system will automatically generate the start week & end week. Then click on Show button.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

The screenshot displays the 'STABILITY CONTROL' software interface. The top navigation bar includes 'Current Status', 'Configuration', 'Admin', 'Backup/Restore', 'Reports', 'Help', and 'LogOut'. The 'Current Status' section is active, showing a 'MKT Report' for 'CHAMBER NO 1'. The report includes a table with columns for Weeks, Start Date Time, End Date Time, Min.(°C), Max.(°C), Avg(°C), and Avg(°K). The data shows two weeks of operation with consistent temperature readings.

Weeks	Start Date Time	End Date Time	Min.(°C)	Max.(°C)	Avg(°C)	Avg(°K)
31	02/08/2015	08/08/2015	49.60000	49.60000	49.60000	322.75000
32	09/08/2015	15/08/2015	49.60000	49.60000	49.60000	322.75000
Average Temp. :						49.60000 Deg.C
Mean Kinetic Temp. :						322.75000 Deg.K
						49.60000 Deg.C

### 6.23 Rights Assignment

6.23.1 On the "**Rights Assignment**" screen, the user can assign the rights to the role. The Role is then assigned to the user. The word Rights refers to Enable or Disable function for any screen.

6.23.2 Rights Assignment screen helps the user to assign proper rights to a particular role.

6.23.3 With the help of rights assignment different roles can be given different rights to access the module.

#### **How to Assign Rights to the Role (Rights Assignment)**

6.23.4 To Assign the rights, Select the Role from drop down menu and Press Edit Button then select the Module as per below screenshot (whose rights is to be changed).

6.23.5 After selecting the module, the user can see a list of screens available in that module (On the right hand side).

6.23.6 The user can tick Enable check boxes for display screen rights and un-tick Disable check boxes for hide screen rights.



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Module	Code/DisplayName	Screen Name	Enable/Disable
<input checked="" type="checkbox"/>	Admin	Reports	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Backup/Restore	Admin	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Configuration	Backup/Restore	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Current Status	Configuration	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Help	Help	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Reports	Current Status	<input checked="" type="checkbox"/>

### 6.24 Generate Chamber Monitoring Report :

6.24.1 Then Go to **Submit** screen from **Reports** module. Tick the **Use Restore Database** check box, enter search criteria and click on **Sign** button for **save** this report as shown in the screenshot.

Click on the report name to open this report

Using Restore Database of 17/08/2015 14:27:39

Report Search

From Date: 11/08/2015 To Date: 17/08/2015 Equipment Id: CHAMBER NO 1  
From Time: To Time: Print Interval: 120

View Report Reset



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**THERMOLAB SCIENTIFIC PVT. LTD.**  
**DESIGN DEPARTMENT**  
**Chamber Report**

Equipment Name : WALK IN STABILITY  
Equipment Make : THERMOLAB SCIENTIFIC EQUIPMENTS PRIVATE LIMITED  
Equipment ID : CHAMBER NO 1  
Duration : 11/08/2015 00:00 To 17/08/2015 23:59

Date Time	SP(°C)	Temperature(°C) PV(°C)	Remarks	SP(%RH)	Rel. Humidity(%RH) PV(%RH)	Remarks
Temperature Controller	Set Point : 50.0	Min Limit : 48.0	Max Limit : 52.0	Sensor : Main		
Humidity Controller	Set Point : 50.0	Min Limit : 48.0	Max Limit : 52.0	Sensor : Main		
11/08/2015 00:00	50.0	49.6		50.0	49.9	
11/08/2015 02:00	50.0	49.6		50.0	49.9	
11/08/2015 04:00	50.0	49.6		50.0	49.9	
11/08/2015 06:00	50.0	49.6		50.0	49.9	
11/08/2015 08:00	50.0	49.6		50.0	49.9	
11/08/2015 10:00	50.0	49.6		50.0	49.9	
11/08/2015 12:00	50.0	49.6		50.0	49.9	
11/08/2015 14:00	50.0	49.6		50.0	49.9	
11/08/2015 16:00	50.0	49.6		50.0	49.9	
11/08/2015 18:00	50.0	49.6		50.0	49.9	

### 6.25 Backup / Restore

6.25.1 If User has set Backup folder Path (which is the local drive of the PC ,D drive) and Backup Move Path (which is company's server or network drive) for transferring auto-backup and if access to Backup Move Path is denied then pop-up window will display on pressing "View button" as shown below:

Note: In case of connectivity failure to Backup Move Path, the backup will generate in Backup Folder Path.





# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

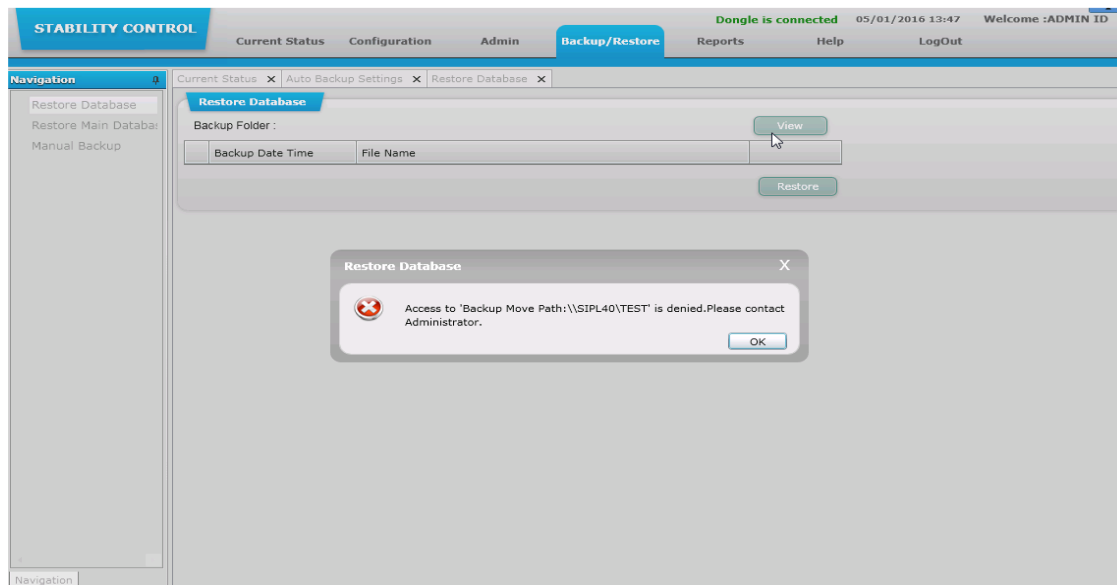
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



6.25.2 Open the data after restore the file.

### 6.26 Cleaning Procedure :

6.26.1 Clean the outer part of the system and surrounding by lint free cloth before and after the use.

6.26.2 The chamber shall be de-dusted externally with a clean dry cloth, once in a day. Wet mopping using detergent solution, shall be used to remove adhered dust. wipe the surface with a clean dry cloth to remove the traces of detergent

6.26.3 Remove the spots or stains on the outer side of the instrument with the help of Collin cleaner or 70 % Isopropyl alcohol.

6.26.4 Do not use acid/ alkali solutions or solvents for the cleaning of the instrument.

6.26.5 Cleaning of Stability chamber also shall be recorded as per SOP Stability Management (SOP No.-.....) Annexure-5

### 6.27 Generals :

6.27.1 Stability chamber temperature & RH shall be recorded twice in a shift as per Chamber Software (Stability Control System Software Version 1.3).



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department: Quality Assurance</b>	<b>SOP No.:</b>
<b>Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)</b>	<b>Effective Date:</b>
<b>Supersedes: Nil</b>	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 6.27.2 Do not block the air passage area with samples.
- 6.27.3 Do not place anything on the top of equipment or do not stand on the top of the equipment.
- 6.27.4 A continuous supply of purified water is required for the Humidity systems.
- 6.27.5 ACCEPTANCE CRITERIA : The temperature recorded should be within the range of  $\pm 2^{\circ}\text{C}$  and humidity should be  $\pm 5\%$  RH of the set value for all stability chambers.
- 6.27.6 QA personnel carry out temperature mapping of the Walk in type Stability Chamber once in every year. Temperature controller / indicator calibration is done by outside party once in every year.
- 6.27.7 Check the incoming electric supply of 230 V AC with neutral and proper earthing.
- 6.27.8 The environment should be with proper exhaust fan or air conditioner.
- 6.27.9 Clean the condenser by blowing air through it after every 2 months.
- 6.27.10 Connect proper earthing to the Walk in Type Stability Chamber.
- 6.27.11 Connect drainpipe connection.
- 6.27.12 Close the chamber door properly.

### 7.0 ABBREVIATION:

Pvt.	Private
SOP	Standard Operating Procedure
No.	Number
QC	Quality Control
QA	Quality Assurance
HMI	Human Machine Interface
PLC	Programmable Logic Controller



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: OPERATION AND CALIBRATION FOR WALK IN TYPE STABILITY CHAMBER (MAKE: THERMOLAB SCIENTIFIC)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Temp.	Temperature
RH	Relative Humidity
Mains	Equipment's mains supply switch

### 8.0 ANNEXURES :

NA

### 9.0 DISTRIBUTION:

- Controlled Copy No. 01 Stability Dept.
- Master Copy Quality Assurance Department

### 10.0 REFERENCES:

- Equipment Manual

### 11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		