# ZEMLOG DATA ACQUISITION SYSTEM

# 21 CFR PART 11 COMPLIANCE

SOFTWARE SUPPLIER: GRAVITY TECHNO

**SOFTWARE MAKE** : RSWebTechSoft

SOFTWARE VERSION : RSWEBTECH\SW\ZEMLOG\1.01

#### SALIENT FEATURES OF ZEMLOG DATA ACQUISITION SYSTEM

#### **SOFTWARE**

#### VERSION RSWEBTECH\SW\ZEMLOG\1.01 HAVE THE FOLLOWING FEATURES.

- > PROVIDING DOWNLOADING OF ALL ACTIVE ZEMLOG.
- > PROVIDING DOWNLOADING OF ALL ACTIVE ZEMSCAN.
- > REPORTS FOR ZEMLOG, ZEMSCAN ARE PROPERLY FORMATTED.
- > GRAPH FOR ZEMLOG CAN BE PLOTTED AND PRINTOUTS CAN BE TAKEN.
- > CONTROLLER SETTING FOR SET VALUE OF ZEMLOG CONTROLLERS CAN BE DONE THROUGH SOFTWARE.
- > PRINT FREQUENCY AND PAGE LENGTH IS SETTABLE THROUGH THE SOFTWARE.
- > TIME CAN BE SYNCHRONIZED FOR THE ZEMLOG AND ZEMSCAN THROUGH SOFTWARE.
- USER FRIENDLY 'DATA BACKUP', 'BACKUP & DELETE DATA' AND 'RESTORE DATA' UTILITY
- DATABASE IS SECURED.

#### 21 CFR PARTS 11 COMPLIANCE FEATURES

- > USER SECURITY WHILE MODIFYING THE SETUP SETTINGS.
- > AUDIT TRAIL REPORT (IT KEEPS THE TRACK WHILE MODIFYING THE SETUP SETTINGS.
- > USER LEVEL SECURITY WHILE ENTERING INTO THE APPLICATION.
- > USER LEVEL PASSWORD POLICY IMPLEMENTED AS PER 21 CFR PART 11 COMPLIANCE FEATURES.
- > AUTO PASSWORD EXPIRY AFTER 1 MONTH FROM THE FIRST TIME LOGIN. AND DISPLAYING THE MESSAGE BEFORE 7 DAYS ASKING "YOUR PASSWORD WILL EXPIRE IN \*.\* DAYS DO YOU WANT TOCHANGE YOUR PASSWORD NOW. IF THE USER SAYS "YES" THEN HE IS ABLE TO CHANGE HIS PASSWORD.

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1	RAM	512 MB or Higher
2	PROCESSOR	Pentium dual core or above
3	HARD DISK	140 MB Installation Space +20 GB or Higher for Data Storage
4	OPERATING SYSTEM	Windows XP with Service Pack 2, Service Pack 3 And Window7 - 32-bit
5	CD-ROM\WRITER	CD -ROM for software installation and CD-Writer
6	COM PORT	9 Pin Comport for Communication
7	USB PORT	For Dongle (Hardware Lock)
8	PRINTER	For taking the printouts
9	MONITOR RESOLUTION	1024 * 768 Pixels

#### LOGIN:

This form is displayed as soon as the software is started either at system startup or by double clicking on the shortcut created on the desktop as soon as the software gets installed or by navigating Start Menu  $\square$  Programs  $\square$  RSWebTechSoft  $\square$  GDASZEMLog.EXE.

To Access the software user must Log in the software by supplying Proper User Name, Password and proper User Type.

### **Login Screen:**



#### MAIN SCREEN:

After successful Log in by supplying the proper User name, Password and User Type software's Main screen is displayed. The entire shortcut keys for specified functionality are displayed as F1, F1... etc. and the Navigational Menu to navigate for the functionalities. This Screen also

displays the Login User Name, Login Date and Login Time at the right bottom of the main screen.



If the dongle is not connected or removed in between while the software is running the following screen is displayed with the description of "**Dongle is missing**".

#### **CONFIGURATION SETTINGS:**

NAVIGATION PATH	UTILITIES -CONFIGURATION SETTINGS.
SHORTCUT KEY COMBINATION	ALT + F8

This form is displayed at the software startup for the first time when the software is started for very first time. This is the Software Configuration settings form where the user is selecting the Com Port which will be used for communication between the Printer/PC interface unit and the PC.

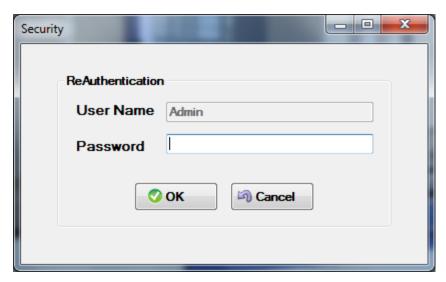
#### FIRST TIME LOG-IN CHANGE PASSWORD:

If the user is not 'an Administrator type' and he is Logging in the software for the first time then the user has to change the password and Re-Log-In in the software with new Password.

To check the Software Configuration Settings open the Software Configuration form by navigating menu Utilities Software Configuration or by accessing the shortcut Key, i.e. combination Alt + F8. It will ask to enter the password through the security form type the password and click Ok to enter Software Configuration. Select the Com Port through which the communication between Printer/Pc Interface Unit and PC will be done. Save settings by clicking on the 'Save' button of the Software Configuration form by providing reasoning for alteration of Software Configuration setting.

### **SECURITY:**

Each and every time if the user wants to open the form for any operation such as download data, Change settings except reports and graph he has to follow the security check by entering the password to verify that the reflections or changes are going to do by verified and valid user. If the password does not matches then the user is not able to access the form or he is not able to any changes or activities until and unless the proper Password is supplied.



### **MASTER MENU:**

#### **CONFIGURE USER TYPE:**

NAVIGATION PATH MASTER	CONFIGURE USER TYPE
SHORTCUT KEY COMBINATION	CTRL + T

This form is used for Addition, Alteration and Deletion of User Type i.e. Administrator, MANAGER, USER. which will be used for the user Login. Users are able to assign only specific writes for the particular User Type Except administrator User Type.



Add or Edit the User Type setting by providing reasoning for addition or alteration of User Type setting. Select the User type and check or uncheck the checkmarks of the functions available in the software as per the user type requirements.

#### Note:

- I. Administrator User Type will have all the functionalities available in the software.
- II. Administrator User Type is not Editable.
- III. Report functionality is compulsory for all other User Type.

#### **COMPANY MASTER:**

NAVIGATION PATH MASTER	COMPANY MASTER
SHORTCUT KEY COMBINATION	CTRL + O

This form is used for setting the Company Name and the Location of the company. These settings will be used in all the reports that are prepared through the ZEMLOG software.



To check the Company Master Settings open the Company Master form by navigating menu Master □ Company Master or by accessing the shortcut Key, i.e. combination Ctrl + O. It will ask to enter the password through the security form type the password and click 'Ok' to enter Company Master form. Add or Edit the company master by providing reasoning for addition or alteration of company master settings. Save settings by clicking on the 'Save' button of the company master form by providing reasoning for alteration of company master settings.

#### **CONFIGURE USER:**

NAVIGATION PATH MASTER	CONFIGURE USER TYPE
SHORTCUT KEY COMBINATION	CTRL + M

This form is used for Addition, Alteration and Deletion of User Type i.e. Administrator, Manager, User. which will be used for the user Login. Users are able to assign only specific rights for the particular User Type Except administrator User Type.



Add or Edit the User Type setting by providing reasoning for addition or alteration of User Type setting. Select the User type and check or uncheck the checkmarks of the functions available in the software as per the user type requirements.

#### NOTE:

- > Administrator User Type will have all the functionalities available in the software.
- > Administrator User Type is not Editable.
- > Report functionality is compulsory for all other User Type.

#### **ZEMLOG MENU:**

**ZEMLOG SETTINGS:** 

NAVIGATION PATH ZEMLOG	ZEMLOG SETTING
SHORTCUT KEY	FUNCTION KEY: F2

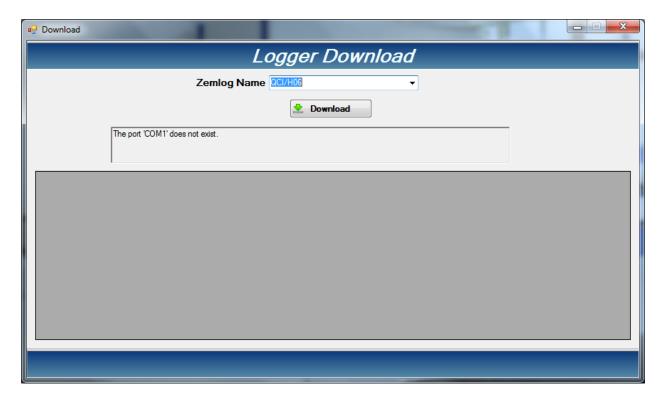
This form is used for Addition, Alteration of ZEMLOG settings. These Settings will be used for the reports and for downloading of corresponding Zemlog.



Select the corresponding ZEMLOG, Add or Edit the ZEMLOG setting by providing reasoning for addition or alteration of ZEMLOG settings. Select the ZEMLOG Type as 'Stability' or 'Temperature' as per the requirement. Check the checkmark of 'Active' since at the time of downloading the selected ZEMLOG's data will automatically gets downloaded. Uncheck the

checkmark of 'Active' if the ZEMLOG downloading is not required or the ZEMLOG is Not in Use.

# **ZemLog Download:**



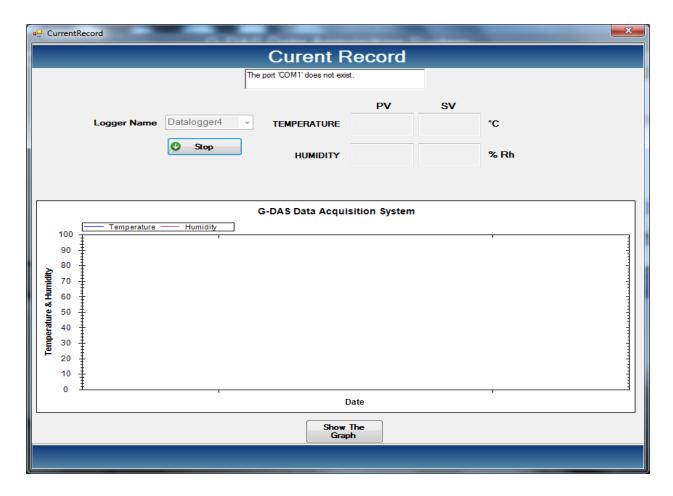
First of all we have to select the appropriate zemlog from the combobox. Then press the download button it will display the current downloading data with appropriate order. It will download until user not to press the stop button.

# **Zemlog current record:**

Similler to the zemlog download first of all user must select the logger name and press the get record button. Then it will show the current reading of the selected active logger.

- 1) If the active logger is stability then it will show temperature as well as humidity value.
- 2) If the active logger is temperature it will show only temperature value.

The graph button will be activated if it is stability logger. By pressing the button it will show the current zemlog graph.



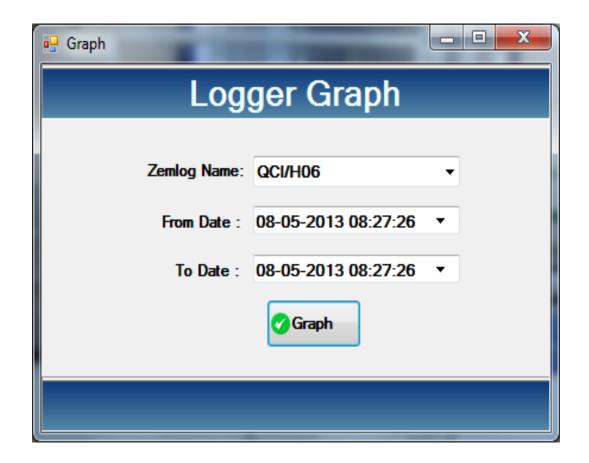
### **ZEMLOG GRAPH:**

This form is used to View ZEMLOG Graph for selected date and time range for the specified ZEMLOG. Select the ZEMLOG and select the date and time range for which the Graph has to be displayed and click on the Graph button of the ZEMLOG Graph form.

#### NOTE:

ZEMLOG Graph is Plotted as per the data which was downloaded for selected ZEMLOG and specified date and time for selected ZEMLOG in the ZEMLOG Settings Form.

NAVIGATION PATH REPORTS	ZEMLOG GRAPH
SHORTCUT KEY	FUNCTION KEY: F8

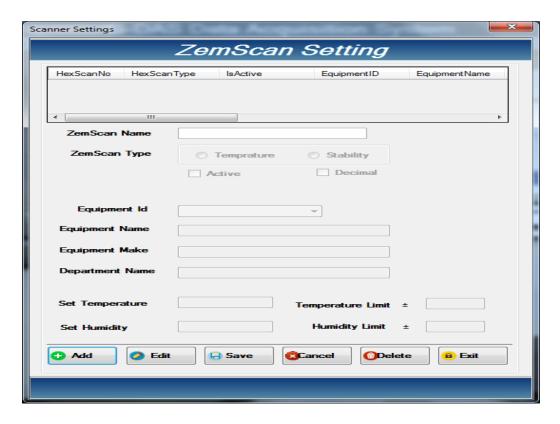


### **ZEMSCAN MENU:**

### **ZEMSCAN SETTINGS:**

NAVIGATION PATH	ZEMSCAN DETTING
SHORTCUT KEY	FUNCTION KEY: F4

This form is used for Addition, Alteration of ZemScan settings. These Settings will be used for the reports and for downloading of corresponding ZemScan.

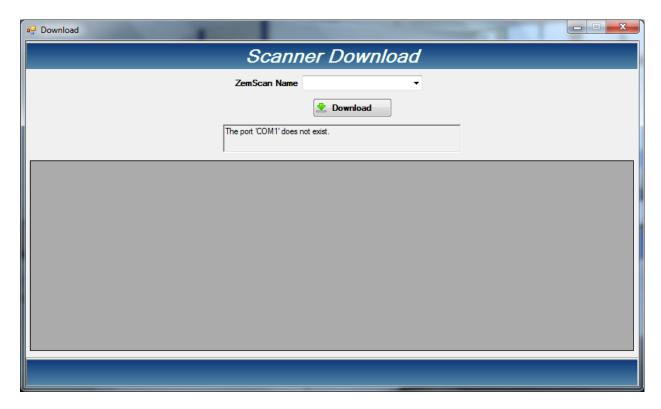


Select the corresponding ZemScan, Add or Edit the ZemScan setting by providing reasoning for addition or alteration of ZemScan settings. Check the checkmark of 'Active' since at the time of downloading the selected ZemScan's data will automatically gets downloaded. Un-Check the Checkmark of 'Active' if the ZemScan downloading is not required or the ZemScan is Not in Use. Select the ZemScan Type as 'Stability' or 'Temperature' as per the requirement.

#### **ZEMSCAN DOWNLOAD:**

NAVIGATION PATH ZEMSCAN	ZEMSCAN DOWNLOAD
SHORTCUT KEY	FUNCTION KEY: F6

This form is used for Downloading of ZemScan connected and which are set as 'Active' in ZemScan Settings Form. Downloading all the Active ZemScan will start after clicking the Button 'Start Download' on ZemScan Download Form.



Click on the 'Start Download' button on the ZemScan Download Form. Downloading of data from ZemScan to PC should start and the readings should be displayed in the grid of the ZemScan download Form.

#### **REPORTS MENU:**

#### **ZEMLOG REPORTS:**

NAVIGATION PATH REPORTS	ZEMLOG REPORTS
SHORTCUT KEY	FUNCTION KEY: F7

This form is used to View ZEMLOG Report and Alarm Report for selected date and time range for the specified ZEMLOG. Select the ZEMLOG Report option of the ZEMLOG Report Form. Select the ZEMLOG and select the date and time range for which the report has to be displayed and click on the Report button of the ZEMLOG report form. Select the Alarm Report option of the ZEMLOG Report Form. Select the ZEMLOG and select the date and time range for which alarm report has to be displayed and click on the Report button of the ZEMLOG report form.

#### NOTE:

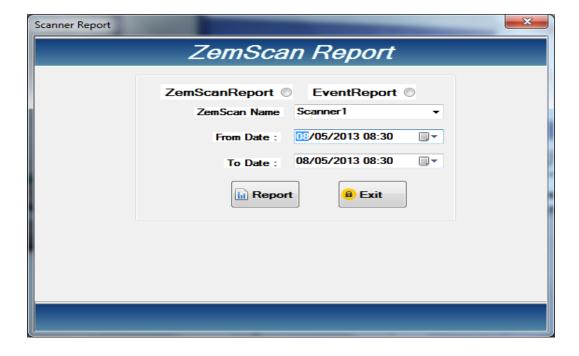
ZEMLOG Alarm Report Values are calculated as per the specified limits for selected ZEMLOG in the ZEMLOG Settings Form.



### **ZEMSCAN REPORT:**

NAVIGATION PATH REPORTS	ZEMSCAN REPORT
SHORTCUT KEY	FUNCTION KEY: F9

This form is used to View ZemScan Report for selected date and time range for the specified ZemScan. Select the ZemScan and select the date and time range for which the report has to be displayed and click on the Report button of the ZemScan report form.



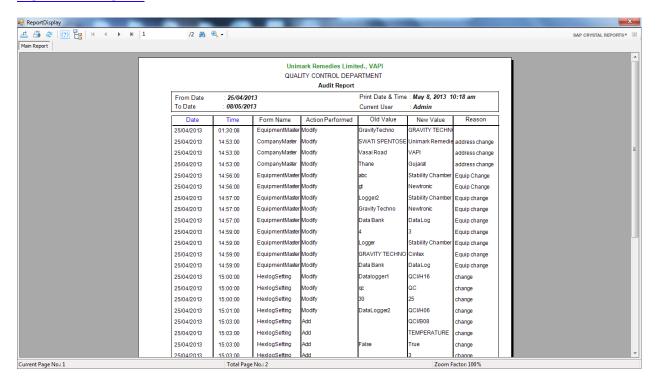
### **AUDIT REPORT:**

This form is used to View Audit Report for selected date range for the software.

NAVIGATION PATH REPORTS	AUDIT REPORT
SHORTCUT KEY	COMBINATION KEY: ALT + I



### **AUDIT REPORT**

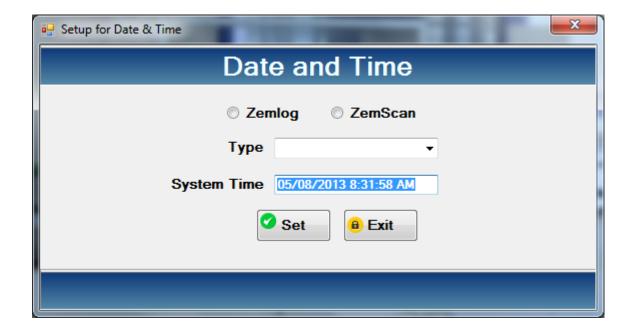


#### **UTILITIES MENU:**

#### TIME SYNCHRONIZATION:

This form is used to synchronize date and time of connected ZEMLOG and ZemScan time with reference to PC date and time

NAVIGATION PATH UTILITIES	☐ TIME SYNCHRONIZATION
SHORTCUT KEY	COMBINATION KEY: CTRL + H



Click the Set button in front of ZEMLOG Time Synchronization to Synchronize date and time with respect to the system date and time of connected ZEMLOG Units. Click the Set button in front of ZemScan Time Synchronization to Synchronize date and time with respect to the system date and time of connected ZemScan Units.

# **DELETE MEMORY:**

Select the appropriate zemlog or zemscan then press delete memory button to delete all the memory form the device.



#### **CONFIGURATION SETTINGS:**

NAVIGATION PATH UTILITIES	CONFIGURATION SETTINGS
SHORTCUT KEY	COMBINATION ALT + F8

This form is displayed at the software startup for the first time when the software is started for very first time. This is the Software Configuration settings form where the user is selecting the Screen Resolution of Monitor, Saves the Resolution and Select the Com Port which will be used for communication between the Printer/PC interface unit and the PC.

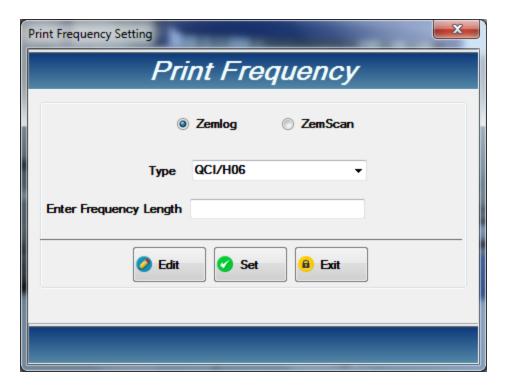


To check the Software Configuration Settings open the Software Configuration form by navigating menu Utilities  $\square$  Software Configuration or by accessing the shortcut Key, i.e. combination Alt + F8. It will ask to enter the password through the security form type the Password and click Ok to enter Software Configuration. Select the Com Port through which the communication between Printer/Pc Interface Unit and PC will be done. Save settings by clicking on the 'Save' button of the Software Configuration form.

### **PRINT FREQUENCY:**

NAVIGATION PATH UTILITIES	PRINT FREQUENCY
SHORTCUT KEY	COMBINATION KEY: CTRL + F

This form is used to Change Print Frequency of selected ZEMLOG or ZemScan from the PC.

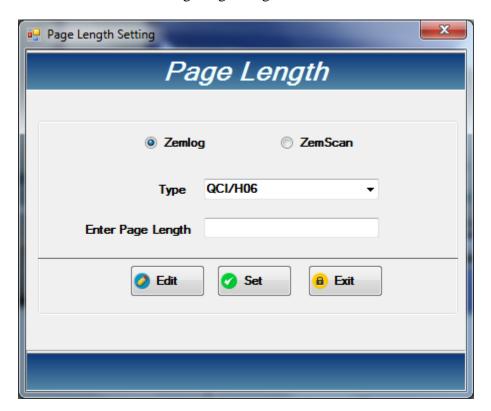


Select the ZEMLOG option and select the corresponding ZEMLOG, Edit the Print Frequency by providing reasoning for alteration. Click the Set button while the ZEMLOG option still selected to set the print frequency for selected ZEMLOG. Select the ZemScan option and select the corresponding ZemScan, Edit the Print Frequency by providing reasoning for alteration. Click the Set button while the ZemScan option still selected to set the print frequency for selected ZemScan.

#### **PAGE LENGTH:**

NAVIGATION PATH UTILITIES	□PAGE LENGTH
SHORTCUT KEY	COMBINATION KEY: CTRL + G

This form is used to Change Page Length of selected ZEMLOG or ZemScan from the PC.



Select the ZEMLOG option and select the corresponding ZEMLOG, Edit the Page Length by providing reasoning for alteration. Click the Set button while the ZEMLOG option still selected to set the Page Length for selected ZEMLOG. Select the ZemScan option and select the corresponding ZemScan, Edit the Page Length by providing reasoning for alteration. Click the Set button while the ZemScan option still selected to set the Page Length for selected ZemScan.

#### **DATA MAINTENANCE UTILITIES:**

#### **BACKUP DATA UTILITY:**

NAVIGATION PATH	DATA MAINTENANCE UTILITIES BACKUP DATA UTILITY
SHORTCUT KEY	FUNCTION KEY: F10

This form is used to take the software data backup for the security of data. All the backup of data will be taken whenever Backup Data Utility is used for taking the Backup.

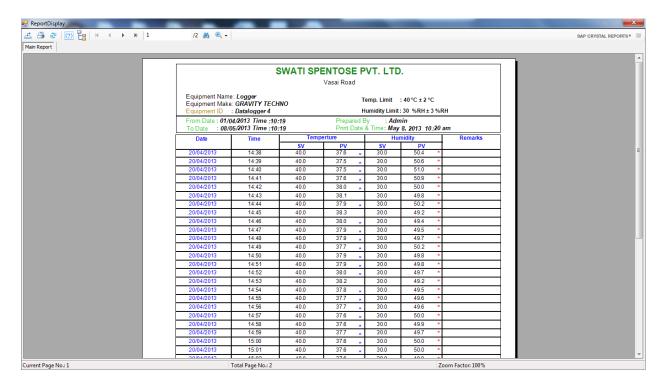


- Create a folder on your hard drive, before taking the backup. (It is required only when you are taking data backup for the first time.)
- Select the last created folder and press the OK Button.
- It will take some time to complete the backup process. After Backup process completion, one new folder will be created with Prefix.

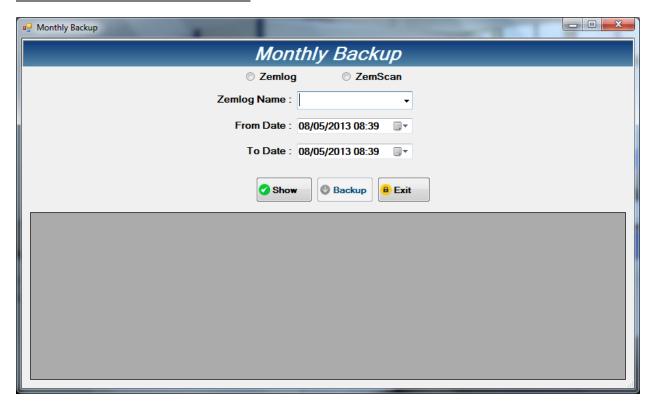
### RESTORE REPORT

#### **RESTORED DATA REPORTS:**

NAVIGATION PATHRESTORED DATA REPORTS	RESTORED ZEMLOG REPORTS
SHORTCUT KEY	FUNCTION KEY: F11



# **BACKUP AND DELETE:**



This form is designed for taking backup and delete record from the data base. First of all choose zemlog or zemscan and give corresponding from date and to date then press the show button. if it shows the record then backup button will be activated else it will be show a message that "there is no data in this filter".

#### **RESTORED ZEMLOG REPORTS:**

This form is used to view restored ZEMLOG reports and Alarm Reports of corresponding ZEMLOG.

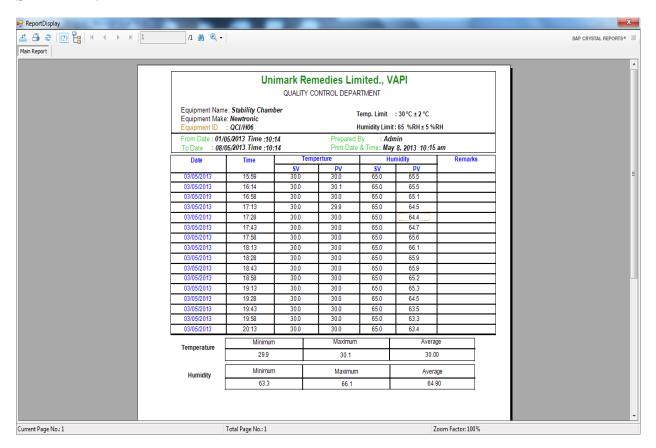


Select the ZEMLOG and select the date and time range for which the restored ZEMLOG Report has to be displayed and click on the Report button of the Restored ZEMLOG report form.

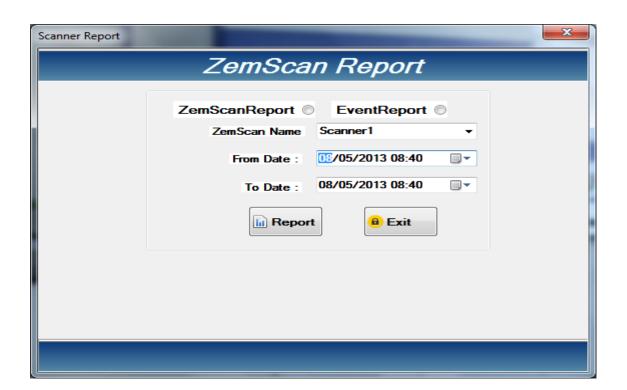
#### NOTE:

IN THE RESTORED ZEMLOG REPORT ONLY THE DATA WHICH HAS BEEN RESTORED WILL BE DISPLAYED.

#### **STABILITY:**



# **ZEMSCAN REPORT:**



# **ZEMSCAN CURRENT RECORD:**



#### **DISCRIPTION:**

First select the zemscan from the combo box then press get record button it will show all the channel readings.

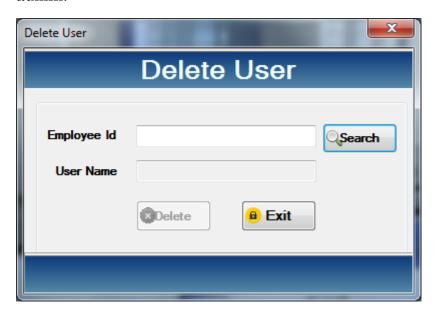
# **CHANGE PASSWORD**



This from is used for change password for the different user. User must give the appropriate user name,old password,new password and conform password then press save button.

# **DELETE USER:**

First enter employee id in thye text box and press serch button to find the user name.if it displayed the user name then delete button will be activated. If user delete the record then it will deleted from the data base. This operation is only for admin.



# **ADMIN MODULE FOR GENERATING REPORT:**