

PolariSoft
CFR Part 11

V3.0.0.0

User Manual



Thank you for purchasing ATAGO's *PolariSoft* Software.

This manual provides guidance for installation, operation, data handling, and reporting functionalities of the software.

Please read this manual carefully before performing any operation on software.

Be sure to keep it handy for quick reference.

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Introduction

Polarioft (21-CFR) is designed to capture measurement data sent by Polarimeter, store it in non-editable form & generate the reports. The software explores possibility of displaying the measurement data and generating tabulated readings.

The software is developed according to guidelines given in 21 CFR Part 11, set by FDA for the use in pharmaceutical companies. The software uses three levels of access

- 1) Operator – Allowed taking the measurements.
 - 2) Reviewer – Allowed to review already recorded measurements, print tabulated reports, and view-&print audit trail information. Reviewer is also capable of accepting or rejecting specific data if it not fits to requirement.
 - 3) Administrator– Allowed handling user accounts, instrument setup, and backup-&-restore facility. Administrator/s can view-&-print audit trail information.
- The software allows electronic signature and password as a combination of alphabets, numbers, and special characters.
 - It also warns user to update/ change the password after set number of days.
 - According to company's policy, administrator can set minimum number of characters for password and duration of expiry in days for renewal of password.

The software has a login screen followed by selection menu. According to access granted to the user, menu options are enabled. Each menu item opens corresponding page if it is enabled for particular user. Details of the same are given in point-3.

1.1 System Requirements –

This software operates on computers having following configuration.

Operating System: Windows 10, Windows7 (32/64bit)

Hard Disk Space: > 200 GB free for this application

RAM: > 2 GB

Software: MS-office, PDF Reader (Ex.NitroPDF), Dotnet Framework

1.2 List of deliverables

- i. CD / Pend drive containing installable copy of **PolariSoft**
- ii. Soft copy of User manual
- iii. Drivers for Polarimeter

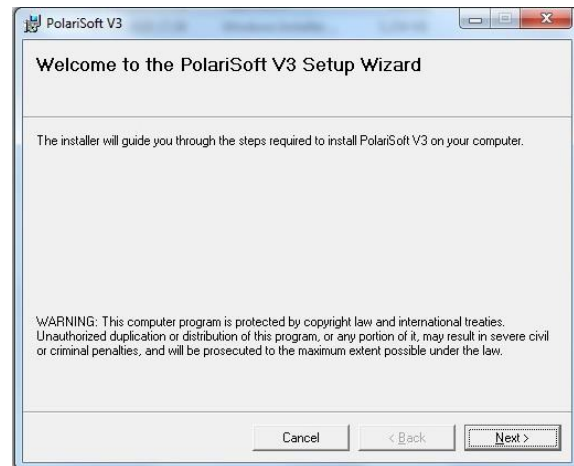
1. Installation procedure

2.1 Software Installation

Note: If previous version of the software is already installed. Uninstall the same from “Add and remove programs” from Control Panel.

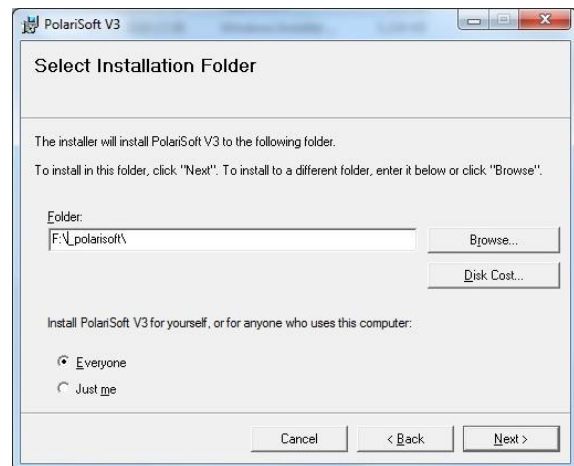
- i. Insert installation CD / Pen Drive. If setup does not start automatically. Run “setup.exe”. The setup will launch following screen -

Press *Next*,

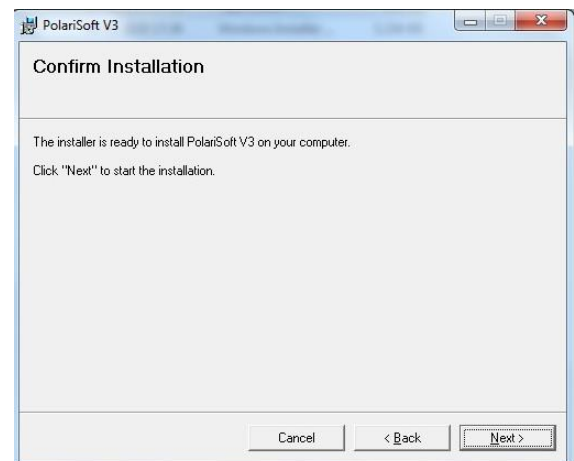


- ii. Change installation folder in “D” or any other drive than “C” drive by clicking “Browse” option. User can create their own folder viz. “PolariSoft”. One should install the software by selecting “everyone” option.

Press *Next*,

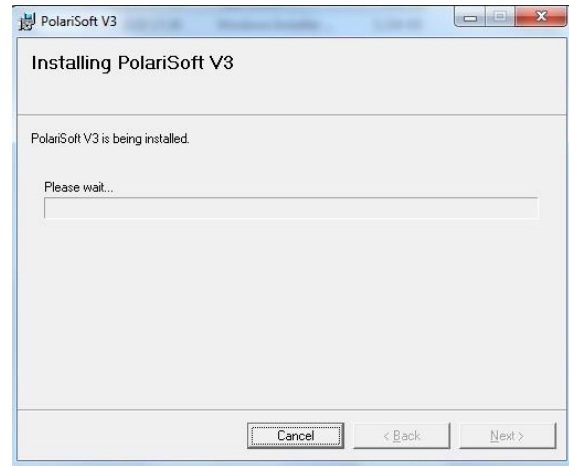


- iii. Confirm installation by clicking *Next*



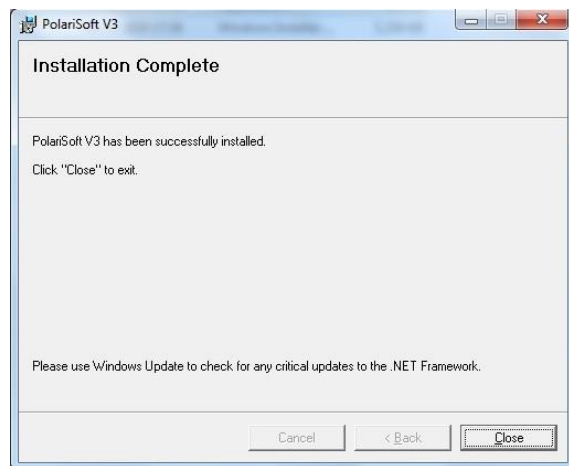
Click *Next*,

- iv. Displays progress of installation



Press *Cancel* to stop the installation

- v. Confirms completion of installation of *PolariSoft*.

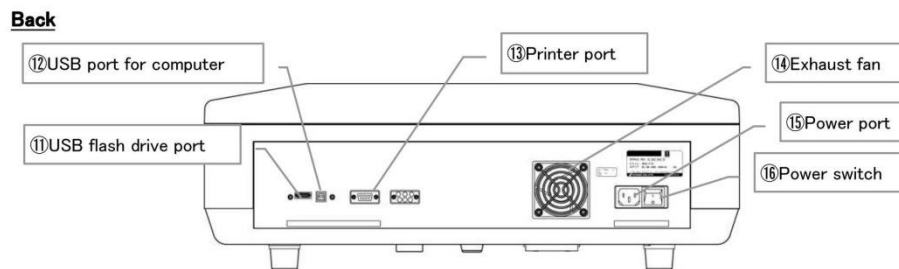


Press *Close*

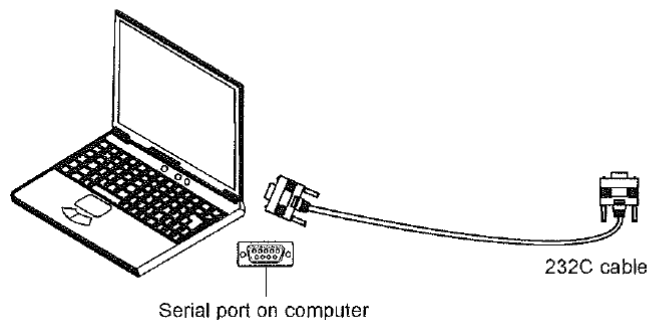
The installation creates shortcut on desktop. The program can be launched by double clicking the shortcut.

2.2 Hardware Installation

The Polarimeter has a RS232 port / USB port for connection with PC. If the PC or laptop does not have RS232 port then RS232-to-USB converter cable can be used. If using RS232 to converter cable, one must install appropriate driver from CD received with the converter cable. If Polarimeter has USB interface then user should install the FTDI drivers from the CD/ pen drive supplied along with polarisoft OR download the driver file (.exe) from the link <https://www.ftdichip.com/>. USB Port should be used for communication with New Computer Systems.



USB type A (left) and USB type B (right)



3. Users Manual -

3.1 Operational Information

The software is designed to comply “21 CFR Part 11” guidelines used in pharmaceutical industry (drafted by FDA). It uses three levels of authentication –

- 1) Operator – Allowed to carry out measurement and generate single page detailed report of measurements taken by him after log-in.
- 2) Reviewer – Allowed to inspect the measurements taken by operators, accept or reject selected measurement & generate report of the same. Reviewer is also allowed to inspect and print the “Audit Trail” information.
- 3) Administrator – Allowed to modify user details as well as instrument details. Administrator is also allowed to inspect & print the “Audit Trail”. Admin has access to create backup, Auto back up & restore the data from backup page.

The *PolariSoft* has its functionality spread over different pages. There are eight pages including login and selection menu, others accessible through selection menu –

- 1) Login page – Visible to all users
- 2) Selection page – Visible to all logged in users.
- 3) Measurement page – Visible to operator privileged users.
- 4) Review page – Visible to Reviewer privileged users.
- 5) Audit trail page – Audit trail visible to reviewer as well as Admin privileged users.
- 6) User accounts page – Visible to operator (limited access) & reviewer with limited functionality. It allows full functionality to administrator.
- 7) Instrument setup page – Visible to administrator privileged users.
- 8) Backup & restore page – Backup & restore visible to administrator only.

3.2 Description about various pages

3.2.1 Login Page –

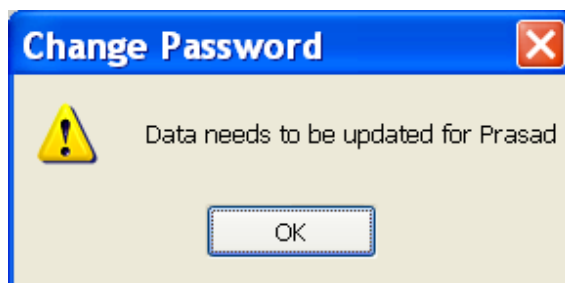
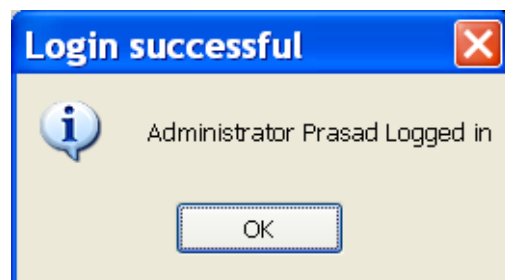


Default Administrator Login:

- Username: admin
- Password: 123456

One of the authorized user can login the software by putting above details.

On successful login operator gets confirmation message. E.g: *Admin Prasad*



If user logs for first time, he will be forced to update his personal details including password & hint question answer.

The software shows warning if your password is not updated before expiry period.

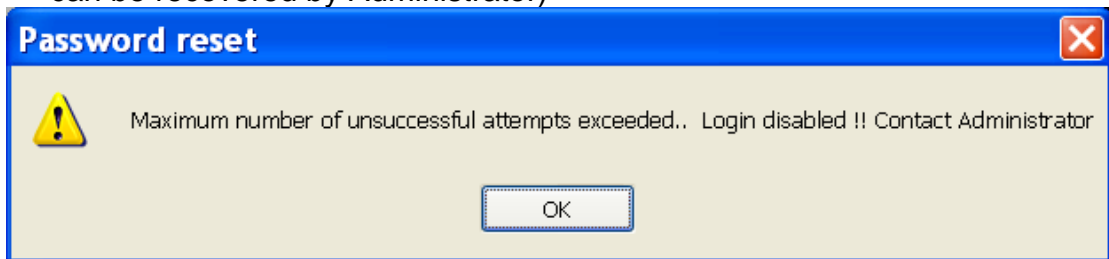


If the login details are not correct then user gets following message.



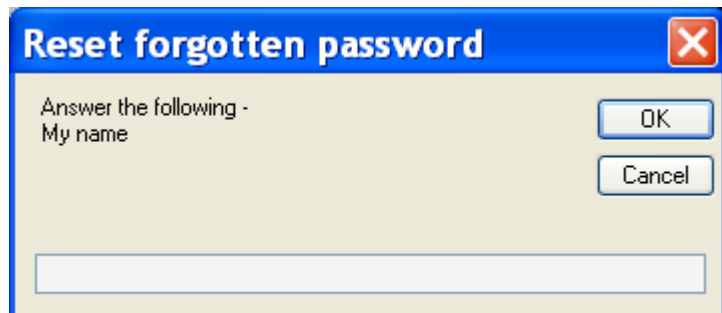
Note:

- 1 The software permits 6 retries for unsuccessful login. Each unsuccessful attempt will get logged into *Audit Trail*. Afterwards, data entry will be blocked for a minute. The software counts number of unsuccessful attempts for valid **Electronic Signature**, if it exceeds 6, the particular **Electronic Signature** will be disabled for the user (later can be recovered by Administrator)



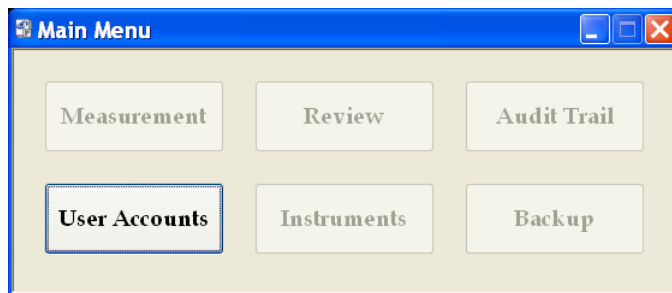
- 2 Password is expected and allowed to have combination of alphabets, numbers, and special printable characters.

- 3 If the user forgets the password, tick **Forgot password** with valid electronic signature. Software will display a question previously set by the user in user info page. The



answer should match exactly with answer given in user details section. Once the answer matches, the password will be reset to **123456**. User is expected to change the password in next login session.

3.2.2 Selection Page –



The options on selection page appears (enabled) according to privileges offered to the user. Rest of the pages will be disabled.

3.2.3 Measurement Page for AP-300

The screenshot shows the "Measurements" window for an AP-300 instrument. It is divided into several sections:

- Measurement Table:** A table with columns for Date, Time, and Measured parameter Selection. A callout points to the Date column: "Date & Time of PC".
- Test Setup Form:** A form with fields for Test Name, Instrument Tag / ID, Sample Name, Batch No, and Job Ref. A callout points to the Instrument Tag / ID field: "Select instrument".
- Buttons:** "Report" (with callout "Print the selected rows"), "Logout", and the ATAGO logo.
- Table of Measurements:** A table with columns: Test Name, Batch, Job Ref, Sample Name, Rotation, ISS(TC), Temp, Operator, Date, and Instru. Location. A callout points to the table: "Table of measurements conducted now".
- Callouts for Table Interaction:**
 - "Select rows by clicking row header" points to the first row of the table.
 - "Hide unwanted columns by double click (left), unhide all by double click (right), rearrange by dragging & sort by clicking" points to the column headers.
 - "Parsed measurement data arrived from refractometer 2" points to the first row of the table.
- Additional Callouts:**
 - "Input Test setup information. Input sample name, batch no & job ref.etc. User can logout by clicking on Logout button." points to the Test Setup form.
 - "Measured parameter Selection" points to the table's selection column.

Test setup will automatically be filled with data filled in previous login if the user doesn't close the application. Operator shall check and update latest test setup information¹.

3.2.3A Measurement Page for SAC-i

The screenshot shows the SAC-i Measurement Page interface. Callouts provide the following information:

- Parsed measurement data arrived from refractometer 2**: Points to the 'Angle of rotation' field.
- Date & Time of PC**: Points to the 'Date' and 'Time' input fields.
- Measured parameter Selection**: Points to the buttons for selecting parameters: α , ISS, ISS TC, SR, Conc, and Purity.
- Select instrument**: Points to the 'Instrument Tag / ID' dropdown menu.
- Print the selected rows**: Points to the 'Report' button.
- Table of measurements conducted now**: Points to the main data table.
- Select rows by clicking row header**: Points to the 'Sample Name' column header.
- Hide unwanted columns by double click (left), unhide all by double click (right), rearrange by dragging & sort by clicking**: Points to the table headers.

The 'Test Setup' panel includes fields for Test Name, Instrument Tag / ID (set to 'new sac-i'), Sample Name, Batch No, and Job Ref. A vertical toolbar on the right contains buttons for Report, Initialize, Sel Scale, Zero, Measure, Logout, and the ATAGO logo.

| Sample Name | Batch No | Job Ref | Test Name | Angle of Rotation | ISS | ISS TC | Specific Rotation | Concentratio | Purity | Pol | Temperature | Length |
|-----------------------------|----------|---------|-----------|-------------------|-----|--------|-------------------|--------------|--------|-----|-------------|--------|
| (Table content is obscured) | | | | | | | | | | | | |

Test setup will automatically be filled with data filled in previous login if the user doesn't close the application. Operator shall check and update latest test setup information¹.

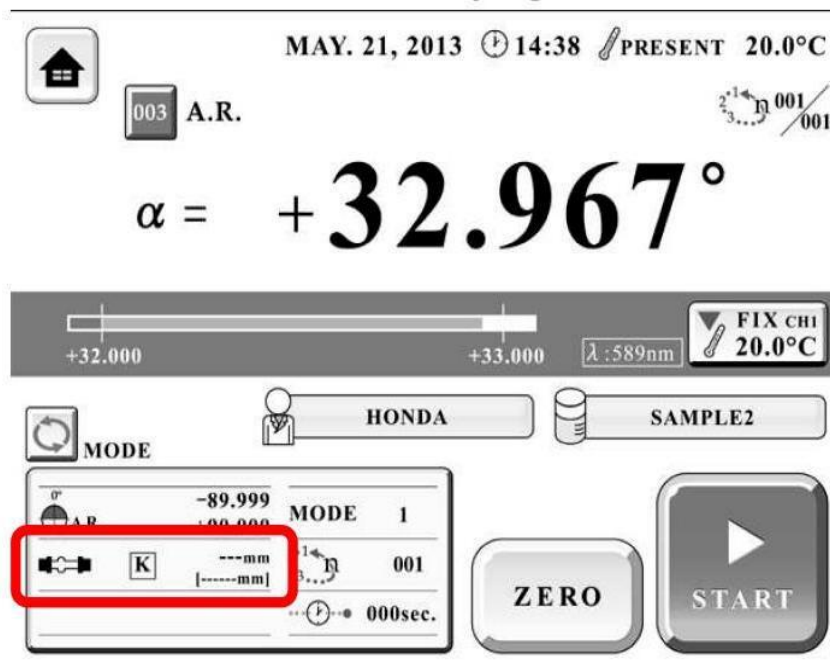
Using below keys, SAC-I polarimeter can be operated through computer.



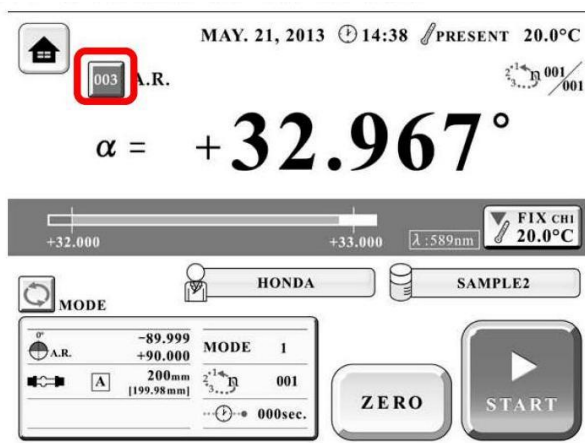
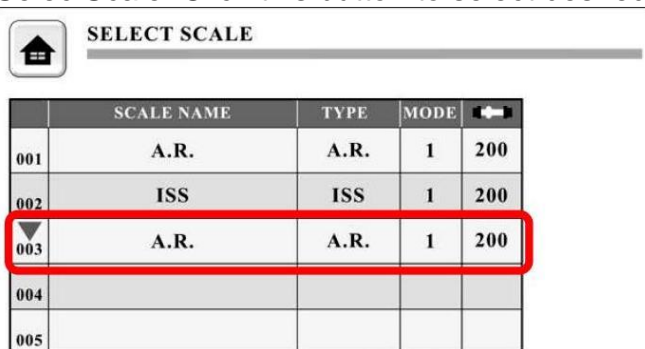
Description of these buttons is given below,

- 1) Initialize: Click this button to put the screen of SAC-I in measurement page. E.g.

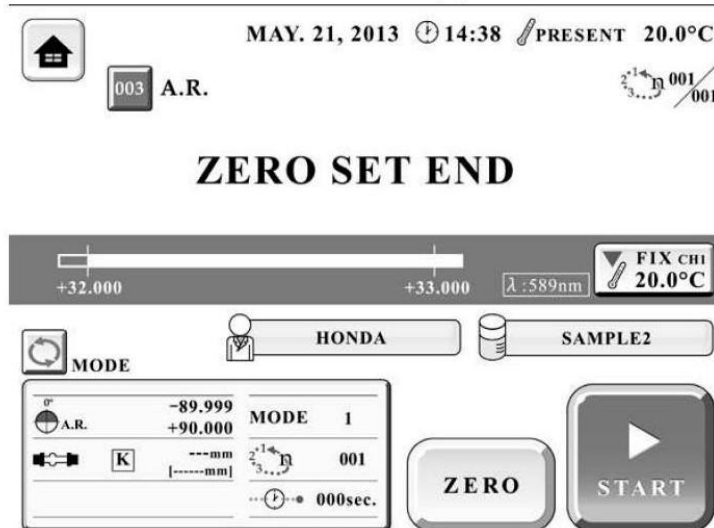
1. Set the observation tube type to "K" (no observation tube)(page 46).



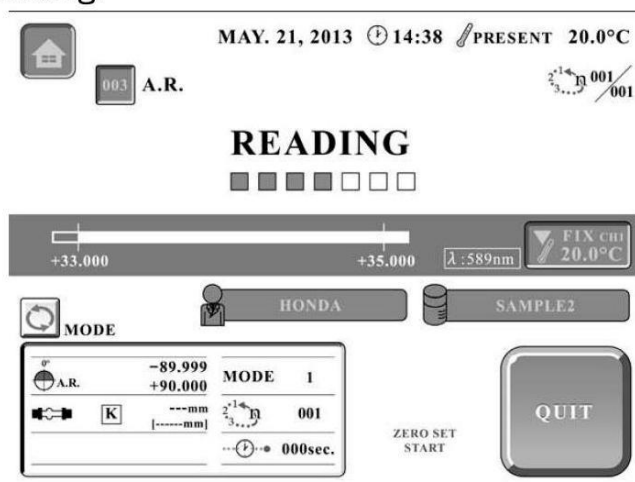
- 2) Select Scale: Click this button to select desired scale. E.g.



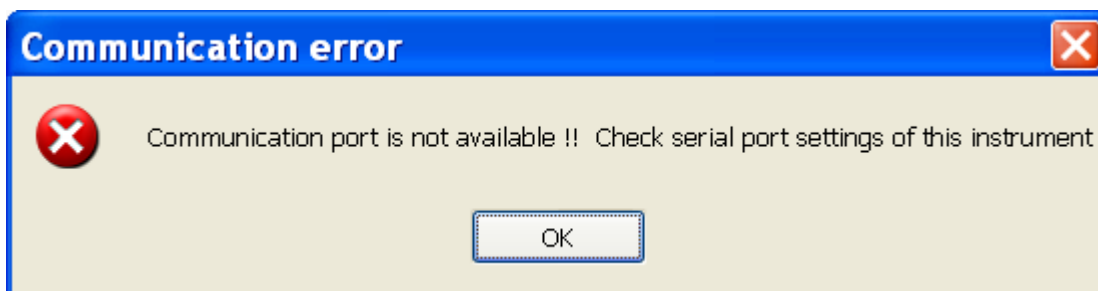
3) Zero: Click this button for zero setting (with water / Air / Solvents). E.g.



4) Measure: Click this button to start measurement. E.g.
 . "WAITING" and then "READING" will start blinking.



Operator must select a valid instrument. As the instrument is selected, its name and COM port will be displayed in status line. If COM port set for the selected instrument is not available, an error message will be displayed.



Once the proper instrument is selected by the operator, he has to press “Start” key on PolariMeter to take measurements (Polarimeter should have the same com port settings). Once the measurement is finished, the reading will be transferred to PC and will be displayed in **Measurement** section. The reading is also added to the table of measurements. Operator may check various parameters of the reading by selecting appropriate column.

Many cases, operator need to generate the report specifying test setup and measurement parameters. In order to print a single page report, operator has to select the row from table of measurements and click on *Report* button. The print facility then displays printer selection dialog box where operator has to select appropriate printer/PDF printer. User can change page settings from this menu. Once it is done, the print facility displays preview page of single page report. Operator may print the report or click cancel to try again with different page settings. Please find below the format of measurement page printout.

TIPS:

- 1) Left click on the measurement table displays field selection menu. User may select / deselect columns of the table from this menu.
- 2) Columns can be rearranged by dragging the header to desired place.
- 3) Data can be sorted by clicking on the header.
- 4) Admin can create their *Company Logo* by modifying “PrnCoLogo.JPG” file from



Measurement Details

20 Dec 2019 11:23:53

Test Name : Test-1

Sample Reference

Sample Name : Water
 Batch No. : 0101-AI
 Job Reference : 0202-AI

Measurement Data

Angle of Rotation : 0.000°
 ISS : °Z
 ISS (TC) : °Z
 Spec. Rotation : deg°
 Concentration : 24.9
 Purity :
 Pol :

Measurement Condition

Temperature : degC/1°C
 Tube Length :
 Wavelength : SUCROSE nm
 Date of measurement : 01 Jan 0001
 Time : 00:00:00
 Operator : admin

Instrument Details

Instrument Tag/ID : new sac-i
 Instrument Location : borivali

Report generated by : vivek
 Location : mumbai

Checked By : _____
 Approved by : _____

3.2.4 Review Page –

Select any one of the search options for displaying the filtered data in review table. User can also select the data by selecting start & end date.

Print the selected rows

Print single page report

Accept or Reject the readings.

| Sr No | Sample | Batch No | Job Ref | Angle of Rotation | Length | Date Time | Accept | Review status |
|-------|--------|----------|---------|-------------------|--------|------------------|-------------|---------------|
| 1 | air | 0101 | 0202 | 0.000° | 200 mm | 09-12-2019 13:55 | Accepted | admin |
| 2 | air | 0101 | 0202 | -0.002° | 200 mm | 09-12-2019 13:55 | Un-Accepted | admin |
| 3 | air | 0101 | 0202 | -0.002° | 200 mm | 09-12-2019 13:55 | Rejected | admin |
| 4 | air | 0101 | 0202 | -0.002° | 200 mm | 09-12-2019 13:55 | Accepted | admin |

Select rows by clicking row header

Review table. Data will appear here.

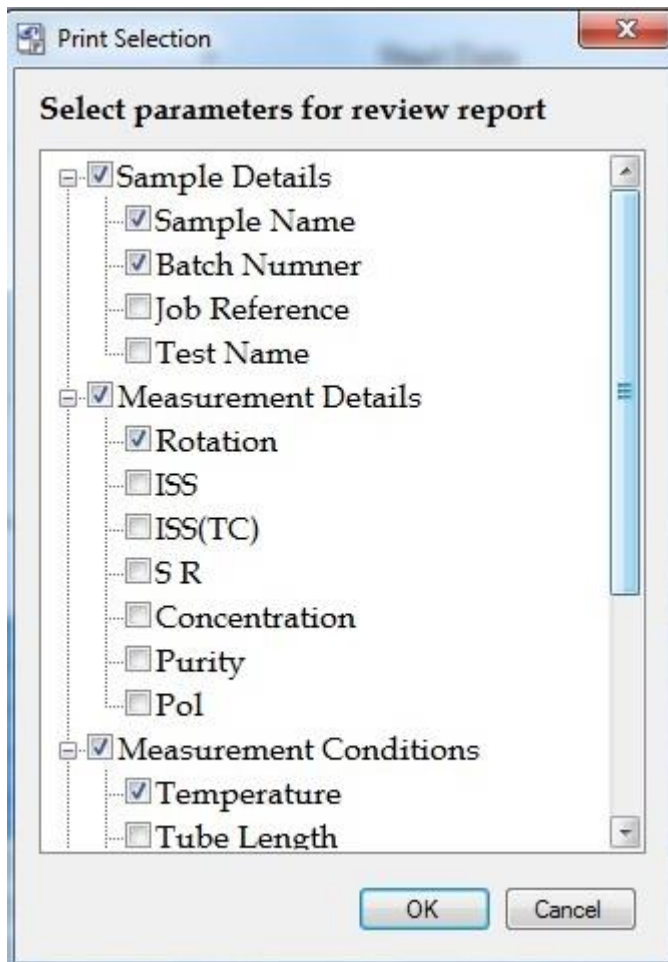
Hide unwanted columns by double clicking (left) & unhide all by double clicking (right) button of mouse. Rearrange the data by dragging & sort it by clicking on it.

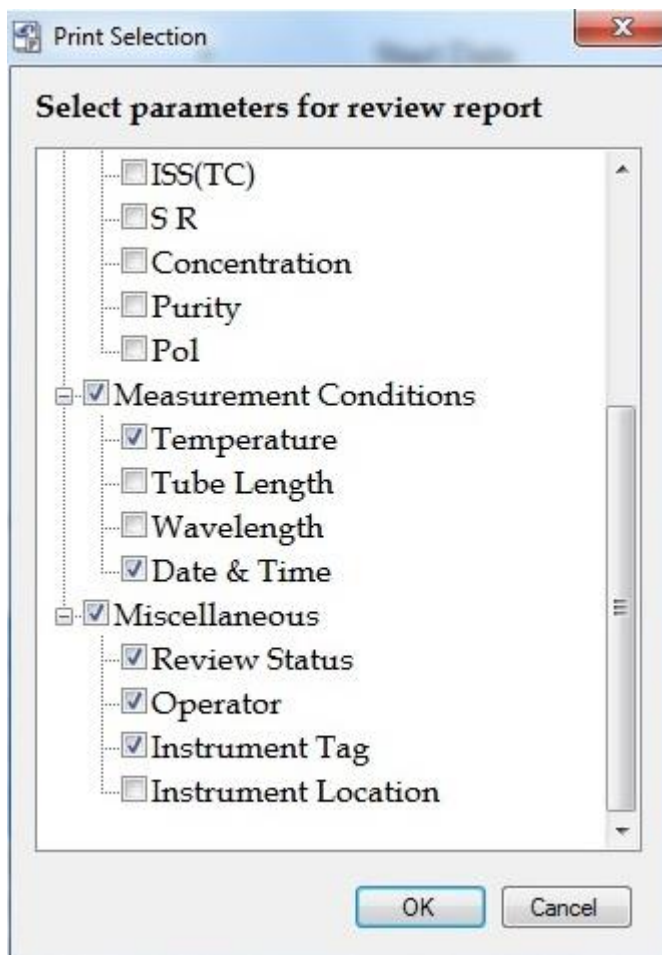
Reviewer page generates post measurement reports. Reviewer can search the data by selecting any of the above search option. Data is linked with each drop-down selection (for quick search). Once the selection is made, matching measurement data will be displayed in the reviewer's table. Reviewer may Accept/Reject the particular measurement, print review report by selecting required rows before clicking on **Print** button.

TIPS:

- 5) Left click on the measurement table displays field selection menu. User may select / deselect columns of this table.
- 6) Columns can be rearranged by dragging the header to desired place.
- 7) Data in table of measurements can be sorted by clicking on the header.
- 8) User can logout from this page by clicking on "Logout" button.
- 9) User can select the required data from print option as follows,







Data record for review

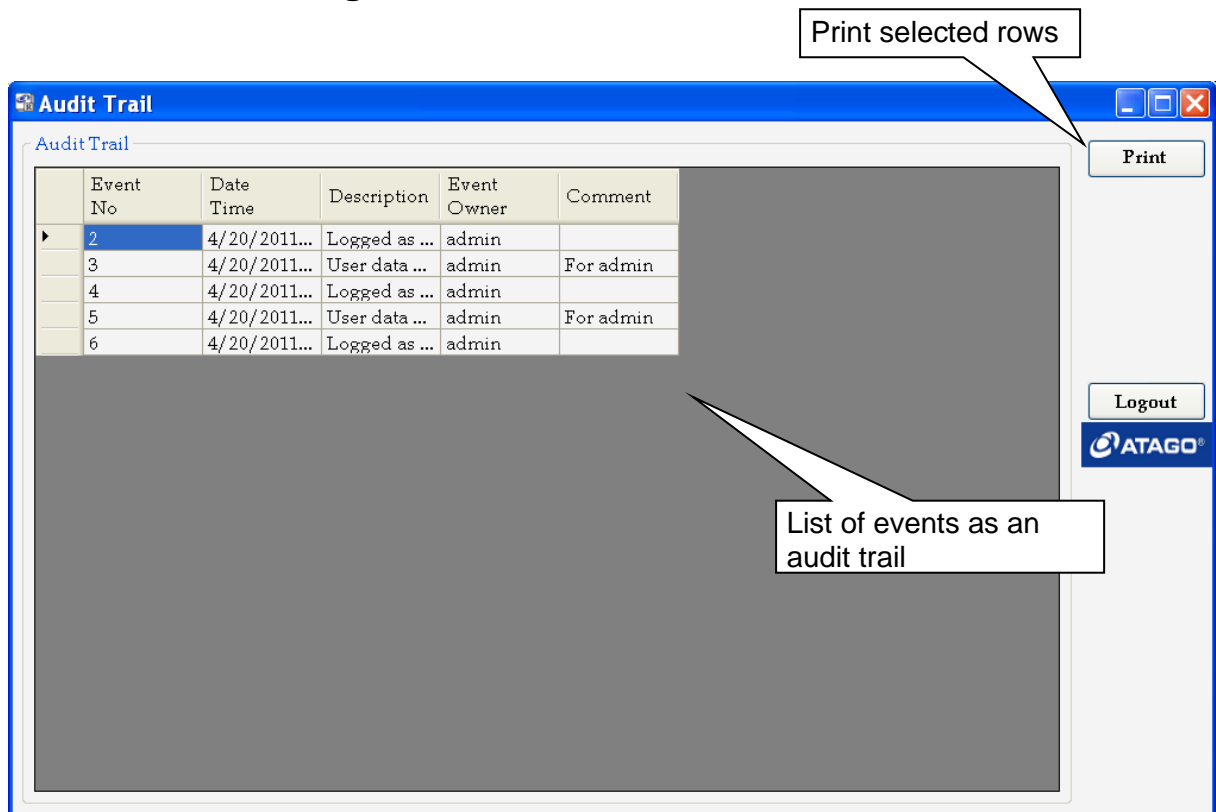
20 Dec 2019 11:37:36

| Sr No | Samp le | Batch No | Job Ref | Test Name | Angle of Rotati | ISS | ISS (TC) | S R | Conc. | Purity | Pol | Temp | Leengt h | Wavel ength | Date Time | Accep t | Opera tor | M/c Tag | M/c Locati on |
|-------|----------|----------|---------|-----------|-----------------|-----|----------|----------|-------|--------|-----|--------|----------|-------------|-------------------|-------------|-----------|-----------|----------------|
| 6 | Am03 | 0808 | ATC1 | Test-2 | 0.000° | | | | | | | 24.7°C | 200 mm | 589 nm | 10-12-19 11:41:10 | Un-Accepted | admin | new sac-i | boriva li ofc1 |
| 7 | Am03 | 0808 | ATC1 | Test-2 | 0.000° | | | 0.000° | | | | 24.7°C | 200 mm | 589 nm | 10-12-19 11:41:40 | Accepted | admin | new sac-i | boriva li ofc1 |
| 8 | Am03 sor | 0808 | ATC1 | Test-2 | - 0.002° | | | - 0.011° | | | | 24.7°C | 200 mm | 589 nm | 10-12-19 11:41:53 | Accepted | admin | new sac-i | boriva li ofc1 |
| 9 | Am03 sor | 0808 | ATC1 | Test-2 | - 0.002° | | | - 0.011° | | | | 24.7°C | 200 mm | 589 nm | 10-12-19 11:42:08 | Un-Accepted | admin | new sac-i | boriva li ofc1 |
| 10 | Am03 sor | 0808 | ATC1 | Test-2 | - 0.002° | | | | | | | 24.7°C | 200 mm | 589 nm | 10-12-19 11:42:31 | Un-Accepted | admin | new sac-i | boriva li ofc1 |

Report generated by : vivek
Location : mumbai

Checked By : _____
Approved by : _____

3.2.5 Audit Trail Page –



Audit trail is the black box of this software. Its information is displayed in read-only format. Each event will be recorded in Audit trail page. The audit trail report can be generated by selecting events and clicking on **Print** button. Sample print is shown below.

TIPS:

- 1) Columns can be rearranged by dragging the header to desired place.
- 2) Data in events table can be sorted by clicking on the header.
- 3) One can logout from this page by clicking on logout page.



Audit Trail Report

20 Dec 2019 12:25:30

| Sr No | User | Event Name | Date Time | Comment |
|-------|--------------|---------------------------------|---------------------|------------|
| 1 | (Autobackup) | Auto Backup created | 09-12-2019 12:44:29 | |
| 2 | admin | Logged as Administrator | 09-12-2019 12:46:22 | |
| 3 | admin | Password changed | 09-12-2019 12:48:44 | For admin. |
| 4 | admin | Full name changed | 09-12-2019 12:48:44 | For admin. |
| 5 | admin | Location detail changed | 09-12-2019 12:48:44 | For admin. |
| 6 | admin | Password reset question changed | 09-12-2019 12:48:44 | For admin. |
| 7 | admin | Password reset answer changed | 09-12-2019 12:48:44 | For admin. |
| 8 | admin | Minimum password char changed | 09-12-2019 12:48:44 | For admin. |
| 9 | admin | User data saved | 09-12-2019 12:48:47 | For admin. |
| 10 | admin | admin Logged out | 09-12-2019 12:48:48 | |
| 11 | admin | Logged as Administrator | 09-12-2019 12:48:57 | |

Report generated by : vivek

Location : mumbai

Checked By : _____

Approved by : _____

3.2.6 User Accounts Page –

The screenshot shows a web interface for managing user accounts. It includes a form for adding or editing a user, a table of existing users, and various control buttons. Callouts provide detailed explanations for key features:

- User account details. Fill each option. Its Compulsory.** Points to the form fields.
- Renewal time in days** points to the Password Renewal Time field.
- Password length: 8 min.** points to the Minimum Password Length field.
- Auto logout Time** points to the Auto Logout Time field.
- Add new or Save existing user data** points to the Add and Save buttons.
- Select Privilege of user** points to the Operator, Reviewer, and Administrator checkboxes.
- Question asked for resetting forgotten password** points to the Password Reset Question field.
- Answer needed for resetting forgotten password** points to the Password Reset Answer field.
- Details of all users** points to the user table.

| User Id | User Name | Is Operator | Is Reviewer | Is Administrator | Failed Attempts | Password Changed | Force Update | Expiry |
|---------|-----------|-------------------------------------|--------------------------|--------------------------|-----------------|---------------------|-------------------------------------|--------|
| 1 | admin | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 0 | 15-06-2017 16:41:31 | <input type="checkbox"/> | 120 |
| 2 | service | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 01-02-2011 | <input checked="" type="checkbox"/> | 120 |

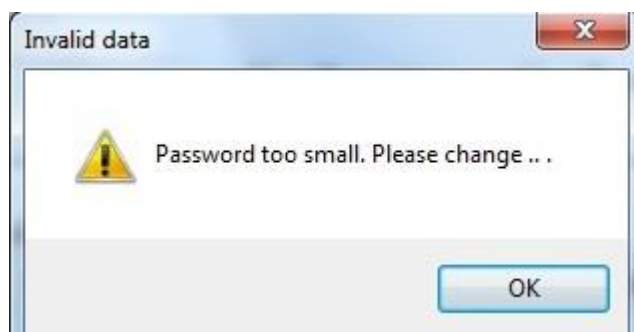
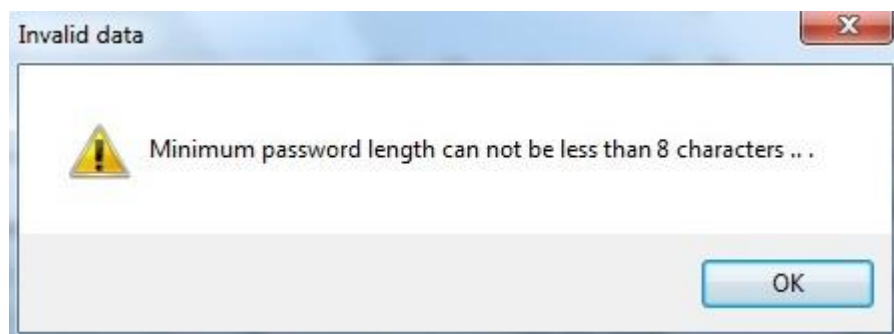
This page displays **user** details. Only Administrator is authorized to Add users, modify the existing user, modify user’s privilege, clear failed attempts (if wrong password is put), force user to change his/her password during next login. Other user can change their personal fields like password, full name, location, password reset question, password reset answer etc. User has to save the information after modification. Administrator has right to authorize other user as an operator, or a reviewer, or administrator with additional rights.

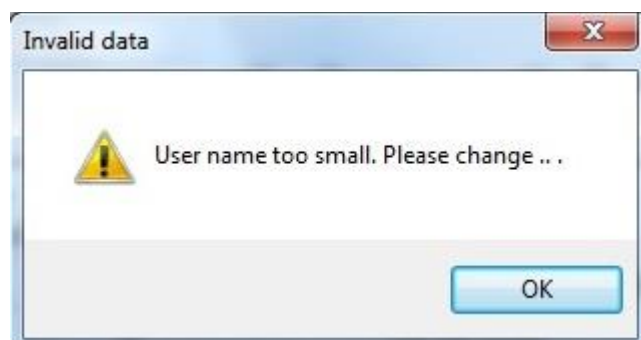
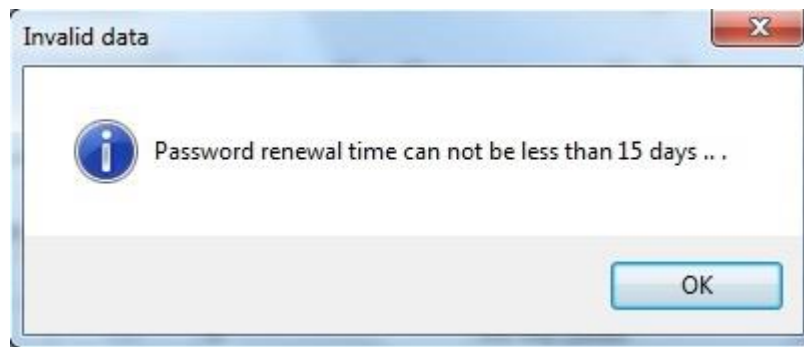
Note:

- 1 Renewal time – After specified number of days, software blocks regular access and force user to update password from user settings. Minimum password renewal time should be 15 days.
- 2 Password Length – Enter minimum characters (which can be set by the administrator) for password. Minimum characters can not be less than 8.
- 3 Auto logout – If the user leaves the software unattended, the software logs out after the set duration in Auto Log out time (in minutes, Max 120 mins).

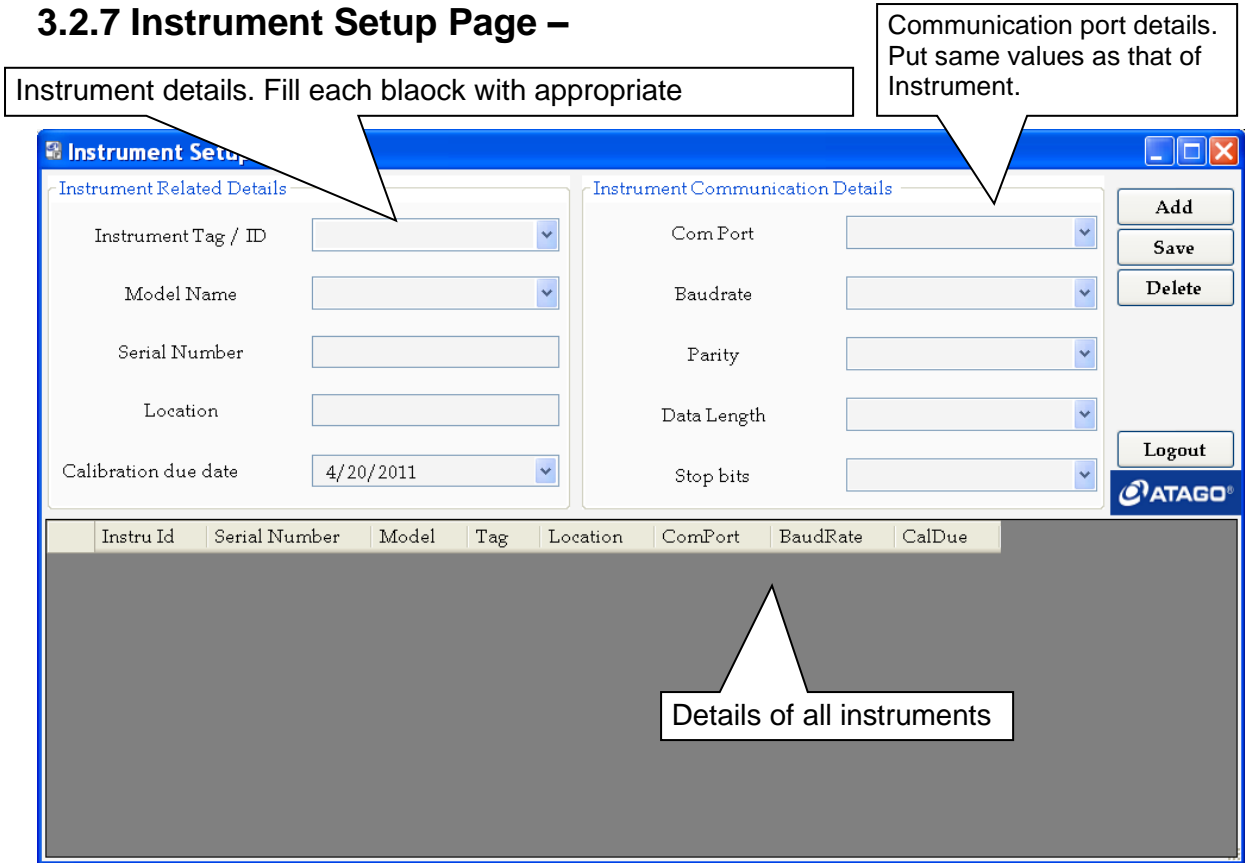
TIPS:

- 1) It is recommended to have 2 administrators. (Primary & secondary)
- 2) Length of the **Electronic Login** and the password should be minimum 8 characters.
- 3) The password shall contain combination of alphabets, numbers, and printable special characters.
- 4) Full name is used for printing the report generated by particular user while printing (Refer sample prints shown above).
- 5) Location information is printed below the full name while printing report (Refer sample prints shown above).
- 6) Password reset question & answer has to be set by each user. This question & answer will be known to user only. **IN THE EVENT USER FORGETS THE PASSWORD, HE/SHE HAS TO ENTER EXACT ANSWER (its case sensitive) AS TYPED IN PASSWORD RESET ANSWER.**
- 7) If invalid password is entered six times, user will get blocked under “maximum number of unsuccessful attempts”. Only administrator can unblock this user by ticking “Clear failed attempts” flag & saving the user account.
- 8) One can directly logout by clicking “Logout” button.
- 9) Error messages for password, renewal time, special character, invalid user name, small user name are as follows,





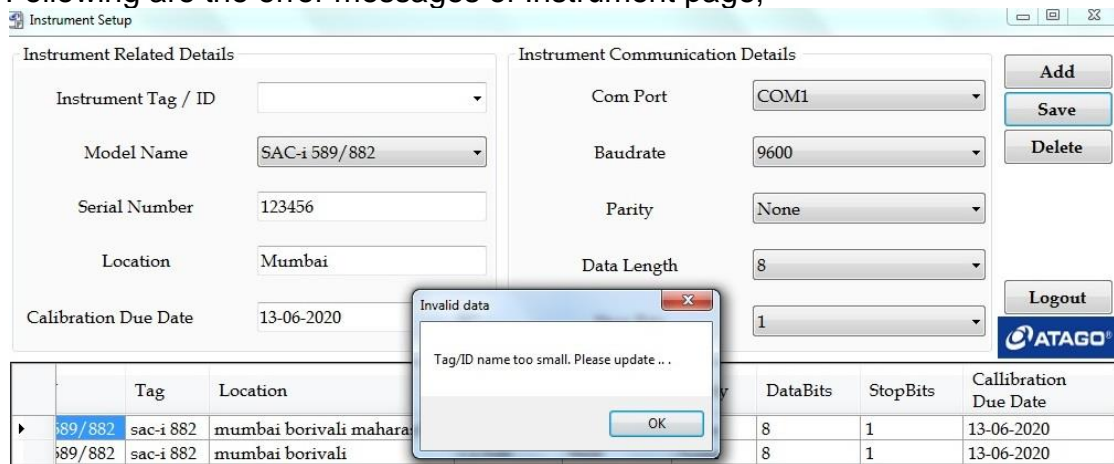
3.2.7 Instrument Setup Page –

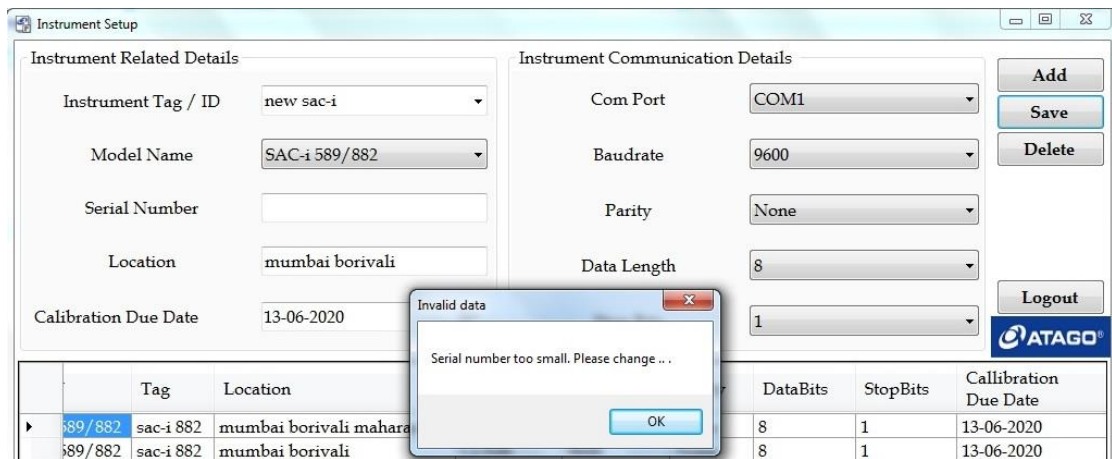
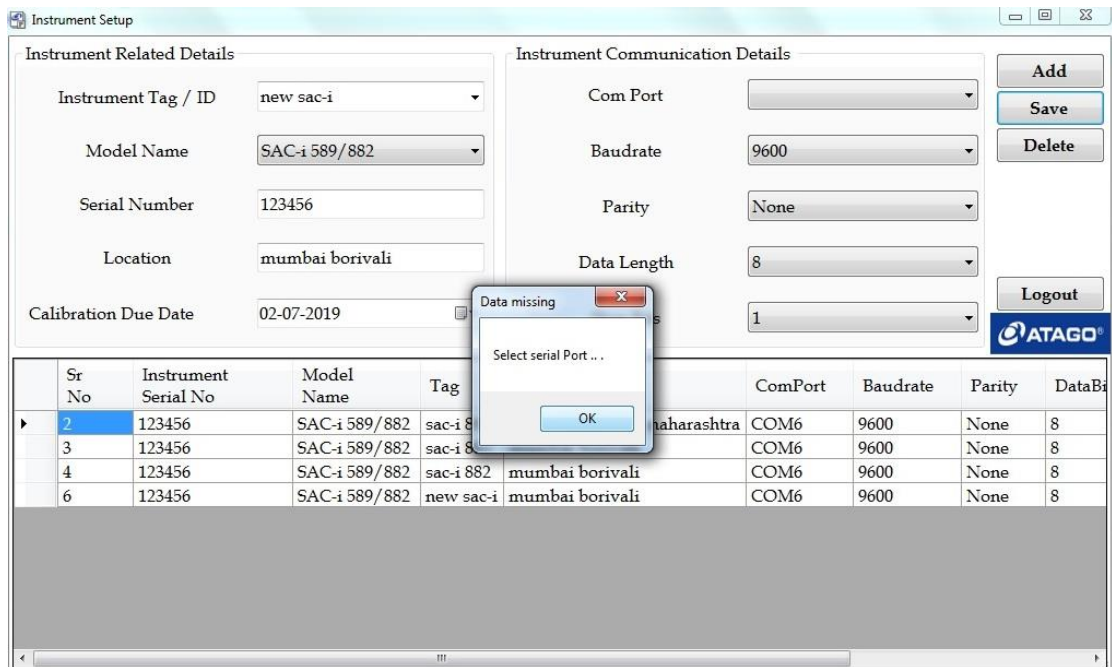


This page allows Administrator to create new instrument & to check instrument's details. Only administrator will have access to this page. Instrument ID/tag must be a unique identification code for each Polarimeter. Select appropriate model Name. Enter the serial number for reference. Enter location details for easy search while reviewing the data. One must enter correct communications settings (prefer Baud Rate=9600, Parity = None, Data Length = 8 & Stop bit = 1). Kindly refer Polarimeter's user manual for setting correct communication parameters of Polarimeter.

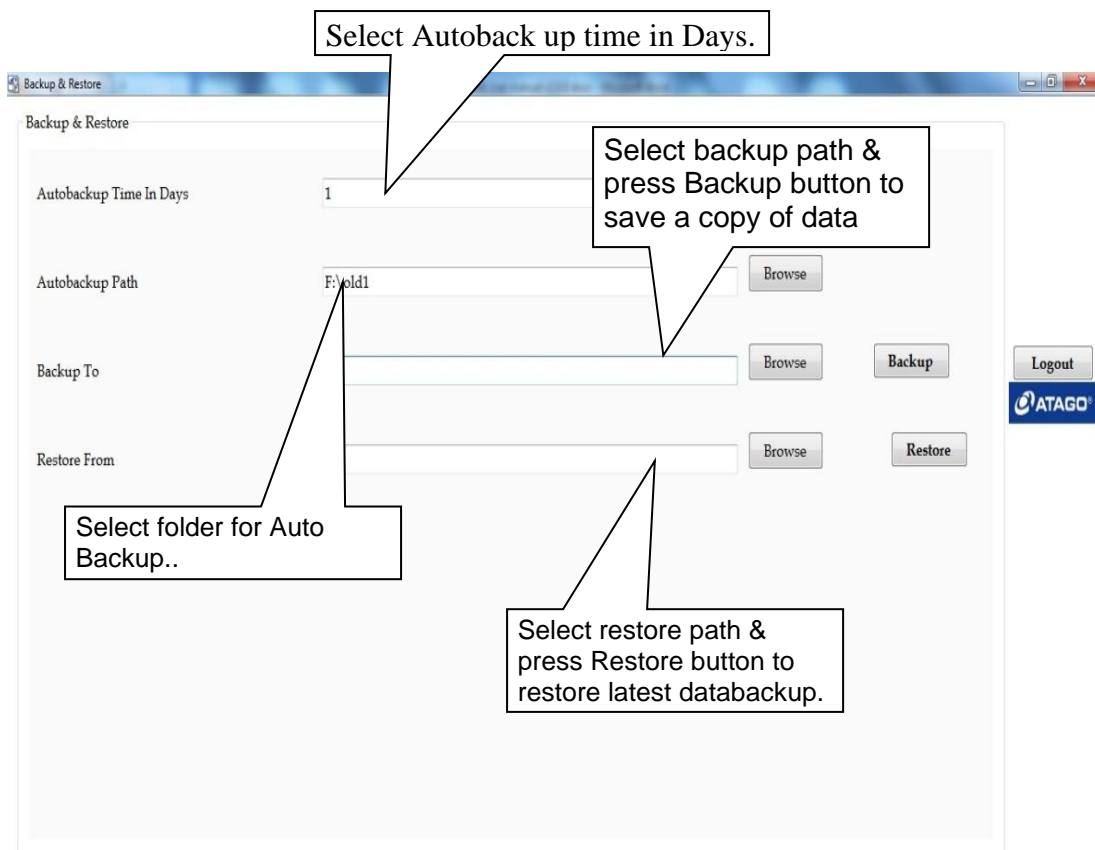
One can logout from this page by clicking on Logout button.

Following are the error messages of Instrument page,





3.2.8 Backup & Restore Page –



The administrator is expected to take periodic backup decided by organisation. By selecting the path for backup and then clicking on **Backup** button, administrator can create the backup file. It is his/her responsibility to preserve back up files properly. ATAGO will not be responsible for the loss of back up files OR restoration of wrong back up.

Similarly by selecting appropriate path, Administrator can restore the database by clicking **Restore** button.

Administrator can also keep a path for Auto backup by selecting no. of days for back up. Polarisoft will create auto back up as soon as the *Polarisoft* application is launched. E.g.: If Auto back up days are selected as 2 days then Polarisoft will create a back up file once the application is launched after 2 days. It will be saved as dataYYMMDD HHMMAM/PM format.

e.g. " Data 191212 0418PM.bak"



This message will appear if back up is created successfully.



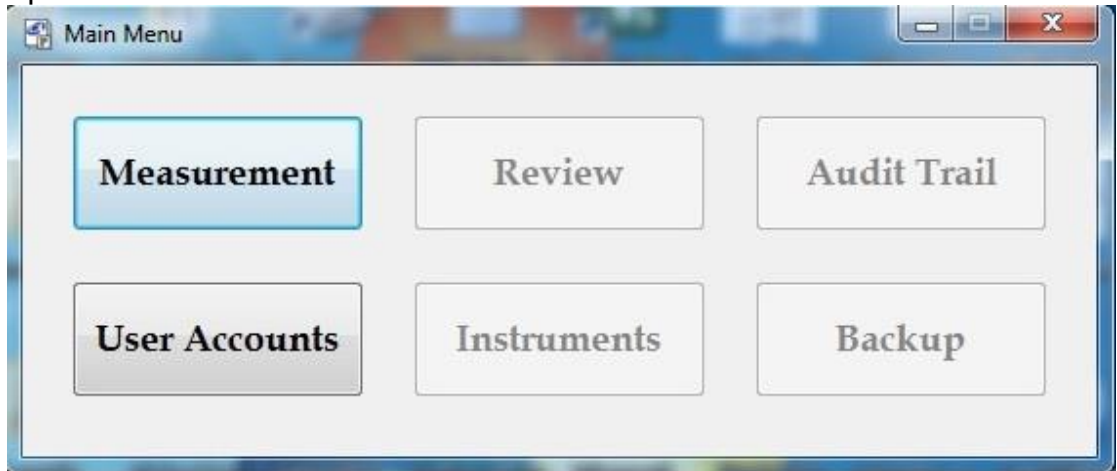
This message will appear if wrong path for restore is selected. If software couldn't find database file in the path then it will display this error message.



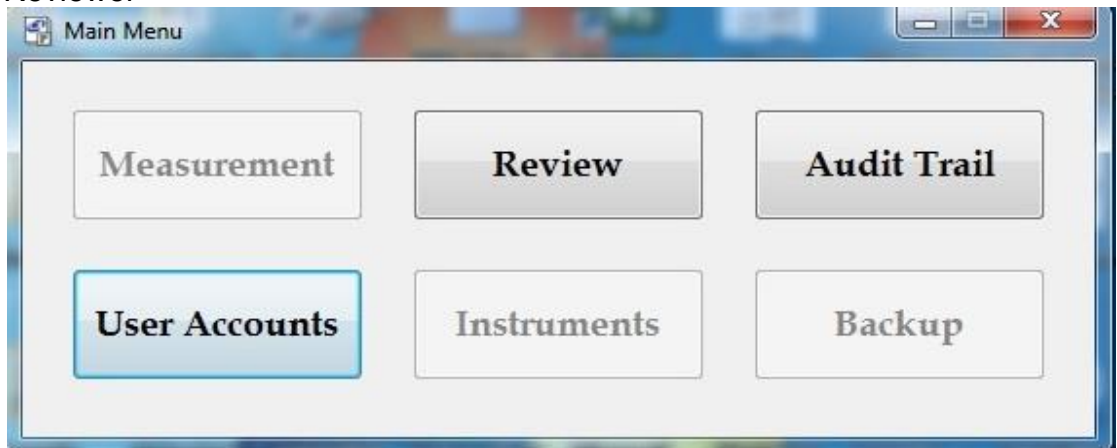
This message will appear if correct path is selected for data restore.

3.2.9 Main Menu Pages as per user Privilege –

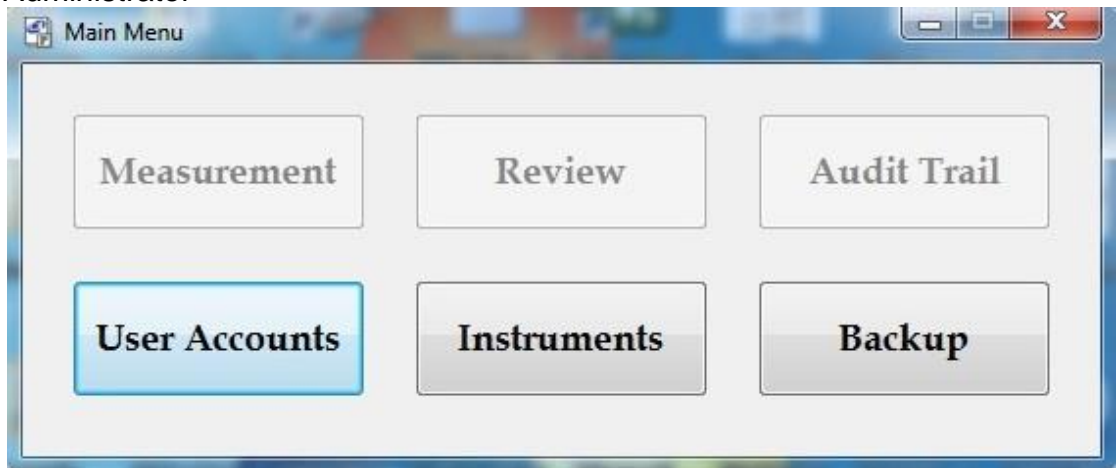
1) Operator



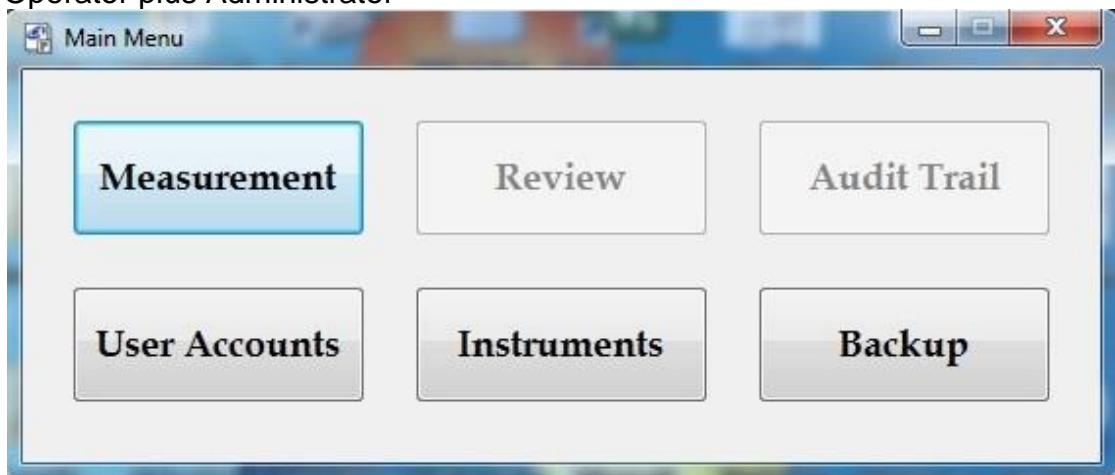
2) Reviewer



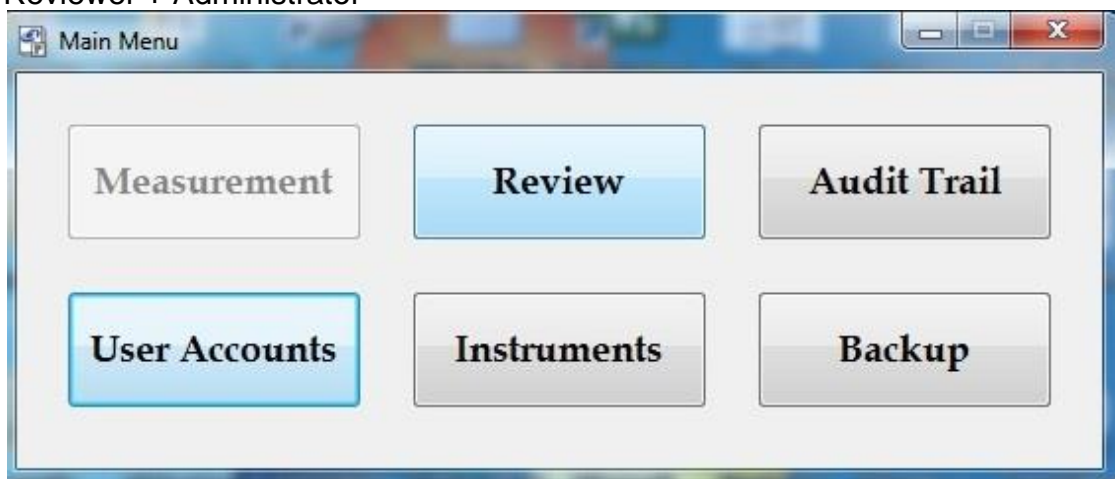
3) Administrator



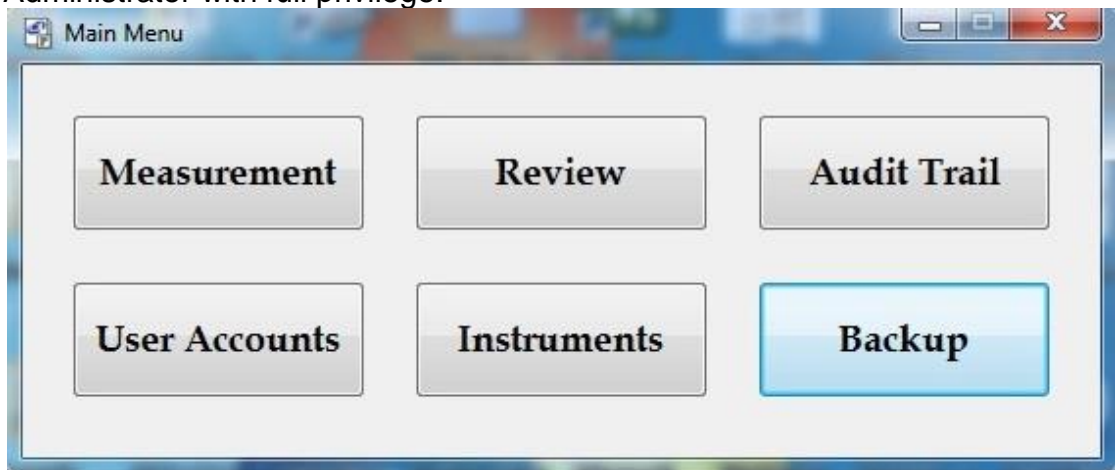
4) Operator plus Administrator



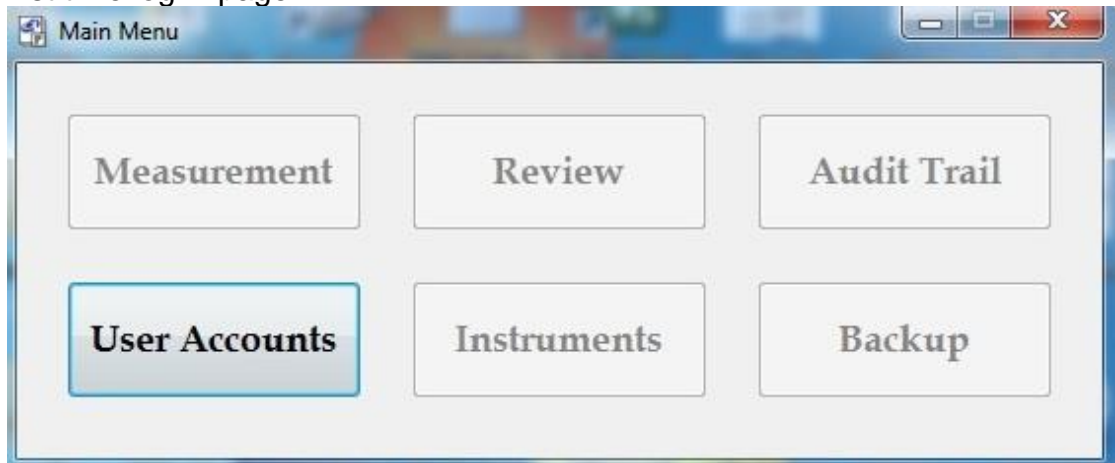
5) Reviewer + Administrator



6) Administrator with full privilege.



7) First time log in page.



8) Log out from Main Menu.

