

Atago RefractoSoft

V3.0.0.0

User's Manual



Thank you for purchasing ATAGO's *Refractosoft* 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 or any task of software.

Be sure to keep it handy for quick reference.

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Introduction

Refractosoft is designed to capture measurement data sent by Refractometer, store it in non-editable form & generate the reports. The software explores possibility of displaying the measurement data and generating tabulated readings.

This 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.
- i. The software allows electronic signature and password as a combination of alphabets, numbers, and special characters.
 - ii. It also warns user to update/ change the password after set number of days.
 - iii. 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. As per the user level assigned to the operator, menu options are enabled. 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 **Refractosoft**
- ii. Soft copy of User manual
- iii. Drivers for Polarimeter

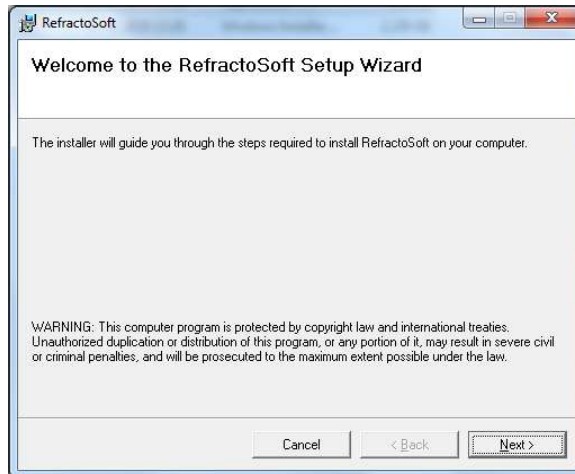
Installation procedure

2.1 Software Installation

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

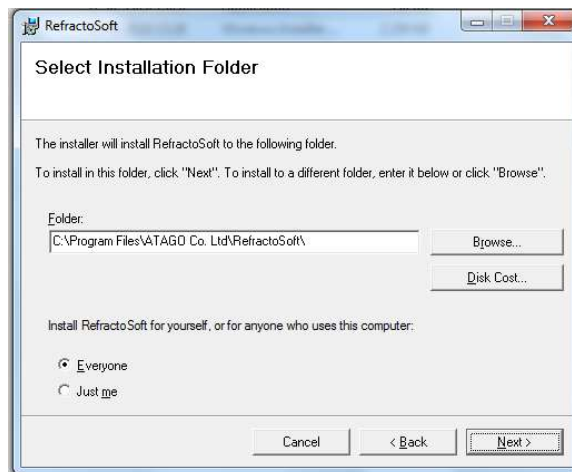
- i. Insert installation CD. If setup does not start automatically. Run “setup.exe”. The setup will launch following screen -

Press *Next*,



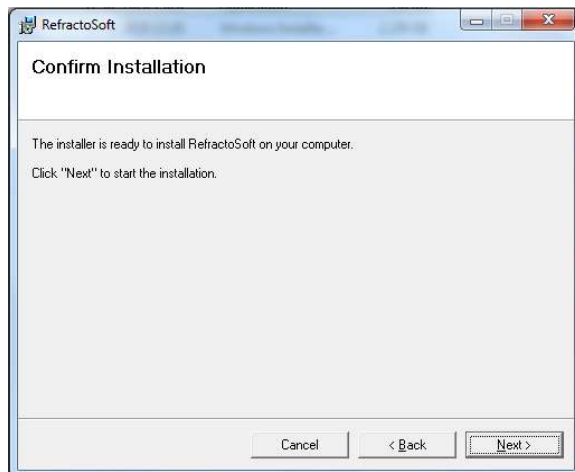
- ii. Change installation folder by clicking browse if needed. Generally one should install the software for everyone.

Press *Next*,

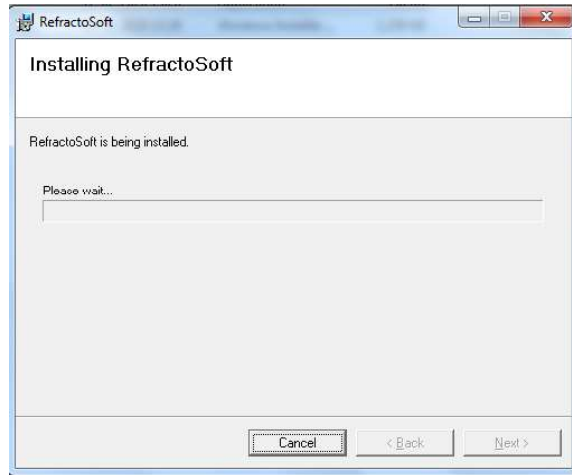


- iii. Confirm installation by clicking next

Click *Next*,

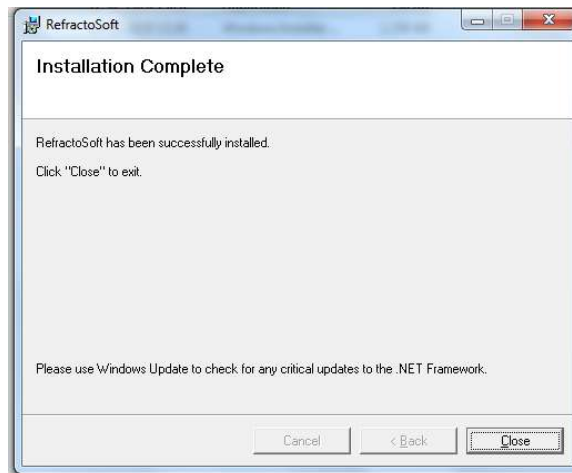


- iv. Displays progress of installation



Press *Cancel* to stop the installation

- v. Confirms completion of installation of RefractoSoft.

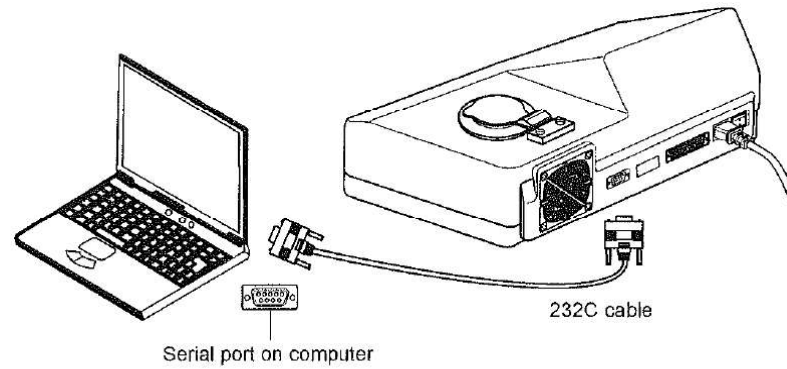


Press *Close*

By default the software is installed in **program files\ATAGO Co. Ltd\RefractoSoft** folder. The installation creates shortcut on desktop and program menu. The program can be launched by double clicking the shortcut.

2.2 Hardware Installation

The refractometer has a RS232 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. USB port should be used for communication with New Computer systems.



3. User's 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 –

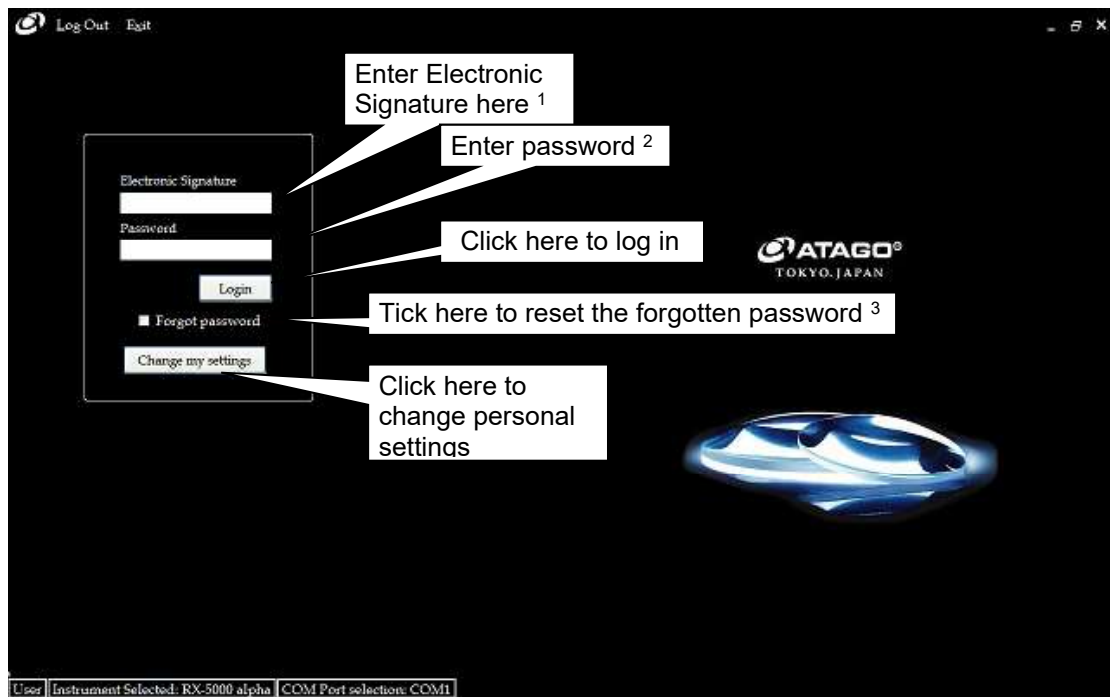
- 1) Operator – Allowed to carry out measurement and take single page detailed report of measurements currently taken.
- 2) Reviewer – Allowed to inspect the measurements collected so far and takes report of the same. Reviewer is also allowed to inspect and print the “Audit Trail” information.
- 3) Administrator – Allowed modifying **user's** details and instrument details. Administrator is also allowed to inspect & print the “Audit Trail” and can work with backup & restore utility.

The Refractosoft has its functionality spread over different pages. There are six pages –

- 1) Login page – Visible to every one as default page and the page before login after one logs out, Measurement page – Visible to operator privileged users.
- 2) User accounts page – Visible to operator & reviewer with limited functionality, and allows full functionality to administrator.
- 3) Review page – Visible to operator privileged users.
- 4) Instrument setup page – Visible to administrator privileged users.
- 5) Audit trail page – Audit trail visible to reviewer privileged users.
- 6) Backup & restore page – Backup & restore visible to administrator only.

3.2 Description about various pages

3.2.1 Login Page –

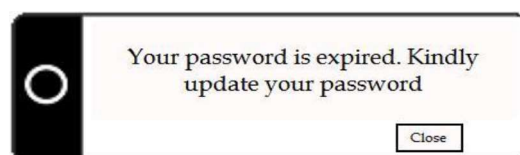
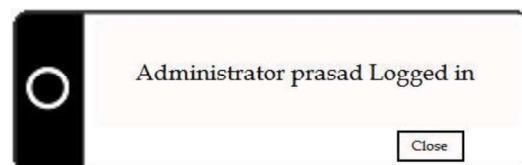


Default Administrator Login:

- Username: admin
- Password: 123456

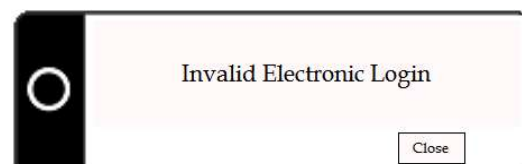
One of the authorized users can login the software.

On successful login operator gets confirmation message.



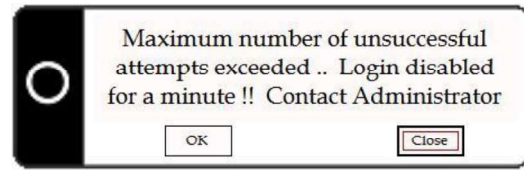
The software shows warning if your password is not updated for more than set duration.

If the login details could not be validated then user gets following message.



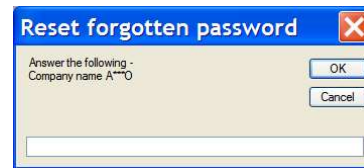
Note:

- The software permits 6 retries for unsuccessful login. 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)



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

- If the user forgets the password, tick **Forgot password** with valid electronic signature. Software will display a question previously set by him-self in user info section. The answer should match exactly with answer given in user details section. In case of matching answer the password will be reset to 123456. User is expected to change the password in next login session.

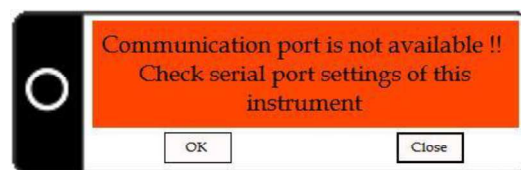


3.2.2 Measurement Page –

The screenshot shows the Measurement Page interface. At the top left, there are 'Log Out' and 'Exit' buttons. Below them are several icons representing different measurement units. The main area is divided into 'Measurement' and 'Test Setup' sections. The 'Measurement' section has fields for 'Date' and 'Temperature'. The 'Test Setup' section has fields for 'Test Name', 'Instrument Tag / ID', 'Sample Name', 'Batch No', and 'Job Ref', along with 'START', 'Measure', 'ZERO', and 'SCALE' buttons. A 'Unit Selection' section below the 'Measurement' section has radio buttons for 'nD', 'Brix', and another unit. A 'Print' button is located between the 'Unit Selection' and the table. The table below has columns: Sample, Batch No, Job Ref, Test, nD, F, Reading, User Scale, Temperature, Operator, Date Time, M/c Tag, and M/c Model. At the bottom, a status bar shows 'Administrator: admin | Instrument | Com port'. Callout boxes provide instructions: 'Parsed measurement data arrived from refractometer 2' points to the 'Temperature' field; 'Test setup information. Additional details related to set of measurements 1' points to the 'Test Setup' section; 'Print the selected rows' points to the 'Print' button; 'Select rows by clicking row header' points to the 'Sample' column header; 'Hide unwanted columns by double click (left), unhide all by double click (right), rearrange by dragging & sort by clicking' points to the column headers; and 'Table of measurements conducted now' points to the table.

Test setup will automatically be filled with test setup data recorded in previous record. Operator shall check and update latest test setup information¹.

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.



The operator then presses “Measurement” key on refractometer. The reading is transferred to PC and will be displayed in **measurement** section. The reading is also added to the table of measurements. Operator may check reading in nD, Brix, or other **user’s** scale by selecting the unit.

In many cases operator needs a report specifying test setup and measurements. In order to print a single page report operator selects row/rows from table of measurements and presses print button. The print facility then displays printer selection dialog where operator selects printer and may change page settings. Further the print facility displays preview of

single page report. Operator may print the report or press cancel to try again with different page settings.

TIPS:

- 1) Left double click on any unwanted column in the measurement table hides it.
- 2) Right double click on any column will show all unhide (show) all hidden columns.
- 3) Columns can be rearranged by dragging the header to desired place.
- 4) Data in table of measurements can be sorted by clicking on the header.

3.2.3 Review Page –

The screenshot shows the 'Review Page' interface. At the top, there are 'Log Out' and 'Exit' buttons. Below them are several icons. The main area contains search filters: 'Instrument Tag / ID', 'Location', 'Sample Name', 'Batch No', 'Start Date' (14 Feb 2020), 'End Date' (14 Feb 2020), and 'Operator'. There are buttons for 'Reject', 'Accept', 'Print Single Page', and 'Print Report'. Below the filters is a table with the following headers: Sr No, Sample, Batch No, Job Ref, Test, nD, Brix, Reading In User Scale, Temperature, Operator, Date Time, and M/c Tag. The table body is currently empty. At the bottom, there is a status bar showing 'Administrator - admin | Instrument | Com port'.

Callout boxes provide the following instructions:

- Select any one of the search options for displaying the filtered data in review table²
- Select rows by clicking row header
- Print Single page printout
- Print the selected rows
- Review table
- Hide unwanted columns by double click (left), unhide all by double click (right), rearrange by dragging & sort by clicking

Review page facilitates generating post measurement reports. Reviewer may search for data by selecting any of the search parameters. Most of the data variations are filled in a drop-down list of selection for quick search. As the selection is made matching measurements will be

displayed in the review table. Reviewer may print review report for the selected measurements by selecting particular row before pressing **Print** button. Similarly if **Export** button is pressed after selection of row/rows from the review table, a spreadsheet application MS-Excel is launched and data will be fed in cells of spreadsheet in tabulated fashion. Note: **Export button is removed in Version 1.0.0.0**

TIPS:

- 1) Left double click on any unwanted column in the measurement table hides it.
- 2) Right double click on any column will show all unhide (show) all hidden columns.
- 3) Columns can be rearranged by dragging the header to desired place.
- 4) Data in table of measurements can be sorted by clicking on the header.

3.2.4 Audit Trail Page –

The screenshot displays the 'Audit Trail' window. At the top, there are 'Log Out' and 'Exit' buttons. Below them is a toolbar with several icons. The main area contains a table with the following data:

| Event ID | Operator | Event | Date Time | Comment |
|----------|----------|--------------------------------|-------------------|-----------|
| 51 | | Application started | 6/11/2010 5:54 PM | |
| 52 | | Auto Backup created | 6/11/2010 5:54 PM | |
| 53 | | Application shutdown | 6/11/2010 5:55 PM | |
| 54 | | Application started | 6/11/2010 5:55 PM | |
| 55 | | Application shutdown | 6/11/2010 5:55 PM | |
| 56 | | Application started | 6/11/2010 5:55 PM | |
| 57 | | Application shutdown | 6/11/2010 5:55 PM | |
| 58 | | Application started | 6/11/2010 5:55 PM | |
| 59 | abcdefg | unsuccessful login attempt | 6/11/2010 5:55 PM | |
| 60 | abcdefg | unsuccessful login attempt | 6/11/2010 5:56 PM | |
| 61 | abcdefg | unsuccessful login attempt | 6/11/2010 5:56 PM | |
| 62 | abcdefg | unsuccessful login attempt | 6/11/2010 5:56 PM | |
| 63 | abcdefg | unsuccessful login attempt | 6/11/2010 5:56 PM | |
| 64 | abcdefg | unsuccessful login attempt | 6/11/2010 5:56 PM | |
| 65 | | Too many unsuccessful attempts | 6/11/2010 5:56 PM | |
| 66 | | Too many unsuccessful attempts | 6/11/2010 5:57 PM | |
| 67 | | Too many unsuccessful attempts | 6/11/2010 5:57 PM | |
| 68 | | Application shutdown | 6/11/2010 5:57 PM | |
| 69 | | Application started | 6/11/2010 5:57 PM | |
| 70 | admin | Logged as Administrator | 6/11/2010 5:57 PM | |
| 71 | admin | Password changed | 6/11/2010 5:58 PM | for admin |
| 72 | admin | Full name changed | 6/11/2010 5:58 PM | for admin |
| 73 | admin | Location detail changed | 6/11/2010 5:58 PM | for admin |
| 74 | admin | Device detail changed | 6/11/2010 5:58 PM | for admin |

The status bar at the bottom reads: Administrator : datta | Instrument Selected: RX-5000 alpha | COM Port selection: COM1

Audit trail information is displayed as read-only set of events, which records most of the important activities carried out by the operator. The audit trail report can be generated by selecting events to be printed, and then pressing **Print** button.

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.

3.2.5 User Accounts Page –

The screenshot shows the 'User Details' form and a table of users. Callouts point to specific fields and the table:

- User account details:** Points to the 'User name' dropdown menu.
- Renewal¹:** Points to the 'Password renewal time (days)' input field.
- Password length²:** Points to the 'Minimum password length (characters)' input field.
- Auto logout³:** Points to the 'Auto logout time (minutes)' input field.
- Select authority level:** Points to the 'Operator', 'Reviewer', and 'Admin'r' checkboxes.
- Question asked for resetting forgotten password:** Points to the 'Password reset question' input field.
- Answer needed for resetting forgotten password:** Points to the 'Password reset answer' input field.
- Details of all users:** Points to the table below the form.

| Sr No | Name | Is Operator | Is Reviewer | Is Admin | Failed Attempts | Password Updated On | Full Name | Location | Force Update | Expiry | Min Len |
|-------|---------|-------------------------------------|-------------------------------------|-------------------------------------|-----------------|---------------------|-------------------------|-------------|--------------------------|--------|---------|
| 2 | Service | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 0 | 6/11/2010 6:55 PM | ATAGO service personnel | rr | <input type="checkbox"/> | 120 | 4 |
| 3 | prasad | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 6/16/2010 11:09 AM | PRASAD | ATAGO INDIA | <input type="checkbox"/> | 120 | 4 |
| 5 | datta | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 6/16/2010 11:27 AM | DATTA | VASAI | <input type="checkbox"/> | 120 | 4 |

This page displays **user's** details. Only administrator can add, modify, and delete the users. Other user can change their personal fields like password, full name, location, password reset question, password reset answer, and save the information. Administrator has right to authorize other user as an operator, or a reviewer, or other administrator.

Note:

- 1 Renewal time – After specified number of days, software blocks regular access and force user to update user settings.
- 2 Password Length – Enter minimum characters (which can be set by the administrator) needed for password. **Note: Minimum 8 characters with one special character is necessary.**
- 3 Auto logout – If **the** user leaves the software unattended, the software logs out after specified minutes.

Note: Delete button is removed in V1.0.0.0

TIPS:

- 1) It is recommended to have 2 administrators. (Secondary)
- 2) Length of 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 “Report generated by: XYZ”, while printing the report.
- 5) Location information is printed below the full name while printing report.
- 6) Password reset question is to be set by the user, which is asking for some personal information unknown to other users. Password reset answer shall contain answer for password reset question. **IN THE EVENT OF FORGOTTEN PASSWORD, USER MUST ENTER EXACT PASSWORD AS TYPED IN PASSWORD RESET ANSWER.**
- 7) If person Y tries to log using electronic login of X. Y ends up entering invalid password for six times. Then user X will be blocked against “maximum number of unsuccessful attempts”. Only administrator can unblock the user by ticking “Clear failed attempts” flag.

3.2.6 Instrument Setup Page –

The screenshot shows the 'Instrument Setup Page' with the following components:

- Instrument Related Details:**
 - Instrument Tag / ID: [Dropdown]
 - Model Name: [Dropdown]
 - Serial Number: [Text Input]
 - Location: [Text Input]
 - Calibration due date: [Date Picker (8/ 8/2010)]
 - Buttons: Add, Save, Delete
- Communication details of the instrument:**
 - Com Port: [Dropdown]
 - Baudrate: [Dropdown]
 - Parity: [Dropdown]
 - Data Length: [Dropdown]
 - Stop bits: [Dropdown]
- Table of all instruments:**

| Model Name | Tag | Inst. Serial No | Location | ComPort | Baudrate | Parity | Data Bits | Stop Bits |
|---------------|--------|-----------------|--------------|---------|----------|--------|-----------|-----------|
| RX-5000 alpha | ATG/RX | 073232 | ATAGO MUMBAI | COM1 | 9600 | None | 8 | 1 |
- Status Bar:** Administrator : data | Instrument Selected: RX-5000 alpha | COM Port selection: COM1

This page displays instrument details. Only administrator can access this page. Instrument ID/tag must be a unique identification code for each refractometer you have. Select specific model number. Enter serial

number so that report can show serial number of the instrument. Enter location details for easy search while reviewing. One must enter correct communications settings. Kindly refer refractometer's user manual for setting correct communication parameters.

3.2.7 Backup & Restore Page –

Select backup path & press Backup button to save a copy of data

After specified number of days the software will create backup file automatically

Select restore path & press Restore button to retrieve latest copy of data

The administrator is expected to take periodic backup. By selecting the path for backup and then pressing **Backup** button will create backup copy of data. Similarly by selecting path for restore and then pressing **Restore** button / Key restores latest file in the software.

Software creates backup automatically if auto backup time is set. If the time is set to 3 days, the software creates backup (when the software is launched) after three days or later.