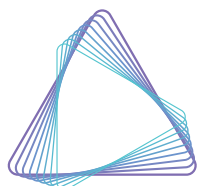# Tube Auditor™ Operator Manual

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LIFE SCIENCES

Azenta US, Inc.

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Original manual printed in English.

These are the original instructions for the Tube Auditor.

Corporate Headquarters

2910 Fortune Circle West
Indianapolis, IN 46241 U.S.A.

European Union Representative

Im Leuschnerpark 1B
64347 Griesheim, Germany

For Technical Support:

Location	Contact Number	Website
North America	+1.888.2.AZENTA (+1.888.229.3682)	www.azenta.com
Europe	+44.0.161.777.2000	
Japan	+81.45.4477.5570 (ext. 24)	

Revision History

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Tube Auditor Operator Manual

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Revision A	16 APR 2020
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Table of Contents

1. Overview

The Tube Auditor™ is an instrument that uses a high-resolution vision system to quickly and accurately audit sample microtubes. It can be used to calculate the volume of liquid in a tube and optionally detect precipitates (usually arising if the sample has partially or completely come out of solution). The following table illustrates the features of the instrument:

Feature	Included/Optional
Volume measurement	Included
Cap detection	Included
Empty tube detection	Included
Image capture and recall	Included
User interface software	Included
Manual operation	Included
Integrated operation	Optional
1D rack barcode reader	Included
Precipitate detection	Optional
2D tube barcode reader	Optional

This manual is intended to provide the user with an easy explanation of how to operate the instrument.

NOTE: This issue of the operator manual is consistent with Tube Auditor software released for Windows 10.

2. Safety

When operating or carrying out any maintenance procedures, various safety hazards may exist; this chapter sets out to highlight any such hazards.

The procedures or instructions provided in this manual must be considered as additional to normal safe working practice and a safety icon together with an appropriate safety warning is inserted into the text where a risk is known.

All appropriate safety precautions must be taken to protect the user and instrument. Safe and reliable operation is conditional on all installation, operation and maintenance being carried out in accordance with this manual, by personnel having appropriate qualifications, experience, and training.

If the requirements of this manual are not followed, the user will be fully responsible for the consequences and any such action may invalidate any warranty. Azenta Life Sciences accepts no liability for unauthorized modifications to supplied equipment.

Safety Symbols

The following symbols appear on the system and in the documentation to alert the operator to potential hazards. Read the warnings, be aware of the potential hazards, and act accordingly.

Meaning of Hazard Alert Symbols

The following hazard alert symbols may be installed on your equipment.

Description	Symbol	Part Number
Signal Word: "Warning"	⚠ **WARNING**	237967
Laser		85-017
Hand Crush		85-024
Electrical shock		85-021

Electrical and Mechanical Hazards

The instrument operates at low voltage: testing and repairs should only be carried out by authorized technicians. Any unauthorized interference with any electrical controls may result in major damage to the instrument. Any mechanical damage to interconnecting cables or electrical equipment must be reported to the relevant personnel. No unauthorized person should touch or otherwise interfere with a suspected electrical fault.

NOTICE
Untrained or Improperly Equipped Personnel
Untrained or improperly equipped personnel performing this procedure may cause damage to the equipment. • Only Azenta Life Sciences trained personnel should perform this procedure. • Personnel performing this procedure must read and understand this procedure and have the proper tools and supplies ready before starting. • Personnel performing this procedure must know the applicable safety codes, facility safety procedures, safety equipment, and emergency contact information.

Chemical and Biological Hazards

The Tube Auditor is designed for use with labware that contains solvents, chemicals, and biological samples. Be aware of the substances that are in use. Always take care, use common sense, and follow good laboratory practice when handling such substances.

⚠️ WARNING	
Chemical Hazard	
The robot may be used in equipment that exposes users to chemical hazards which, if not properly handled, may result in death or serious injury. • Read and understand the safety information for the equipment where the robot is used. • Know the location of the Safety Data Sheets (SDS) or Material Safety Data Sheets (MSDS) in your facility. • Become familiar with the proper handling of material in the environment of the robot.	⚠️

Displayed Machine Marking

A number of additional safety warning labels are positioned within the instrument. The operator must always comply with the instructions given on safety warning labels while operating the instrument; these signs are used to indicate either specific hazards within the instrument or dangers associated with operating the instrument.

Enclosure

The Tube Auditor enclosure forms a physical barrier between the operator and the moving equipment and other potentially hazardous elements of the instrument. The enclosure can only be removed by using a standard hex key (not provided).

Only fully trained and authorized personnel should remove the enclosure as it provides access to all the electrical and mechanical components within.

All warnings and guidance in this manual should be followed at all times. All national and company regulations regarding the operation of the instrument must be followed.

Residual Risks

Equipment Motion

The system uses stepper motors and moving parts which under normal operation are enclosed within fixed guarding. Should these guards be removed for maintenance purpose and the equipment operated in this state, there is a risk of harm from these parts as well as potential electrical hazards. In addition, interference with these parts could cause major damage to the instrument.

A 'garage door' opening allows for the introduction and ejection of parts under test and prevents access to the internal moving parts and electrical components while the system is running.

Under no circumstances should an operator reach inside the instrument through the garage door as there are moving parts and electrical items which could cause harm; a minor 'finger trap' residual risk is present when the 'garage door' closes.

Warnings

Training

Planning or implementing the installation, start-up and subsequent maintenance of the instrument must only be undertaken by personnel who are familiar with the Tube Auditor. Failure to comply with this requirement can result in equipment damage.

NOTICE
Untrained or Improperly Equipped Personnel
Untrained or improperly equipped personnel performing this procedure may cause damage to the equipment. • Only Azenta Life Sciences trained personnel should perform this procedure. • Personnel performing this procedure must read and understand this procedure and have the proper tools and supplies ready before starting. • Personnel performing this procedure must know the applicable safety codes, facility safety procedures, safety equipment, and emergency contact information.

Electrostatic Discharge

Components used within the instrument contain electrostatic discharge sensitive devices. To avoid any potential component damage, always employ static control precautions when installing, testing, servicing, or repairing such components.

⚠ CAUTION	
Electrostatic Discharge	
Failure to follow proper grounding techniques can cause electrostatic discharge which may damage electronic components. • Always follow appropriate grounding techniques when working with electronic components and PC boards.	

3. Operation

Powering On

For the correct functioning of the Tube Auditor, follow the sequence below:

Step	Action
1.	Ensure that the front panel **Stop** button is released (turn clockwise). *NOTE: This button is a quick stop button, not an emergency stop.*
2.	Switch on the Tube Auditor.
3.	Switch on the Tube Auditor PC.
4.	Start the Tube Auditor application software at the PC.

Software User Interface

The Tube Auditor software was designed to provide an easy to use user interface. This section explains how to operate the software and how to access all aspects of the software.
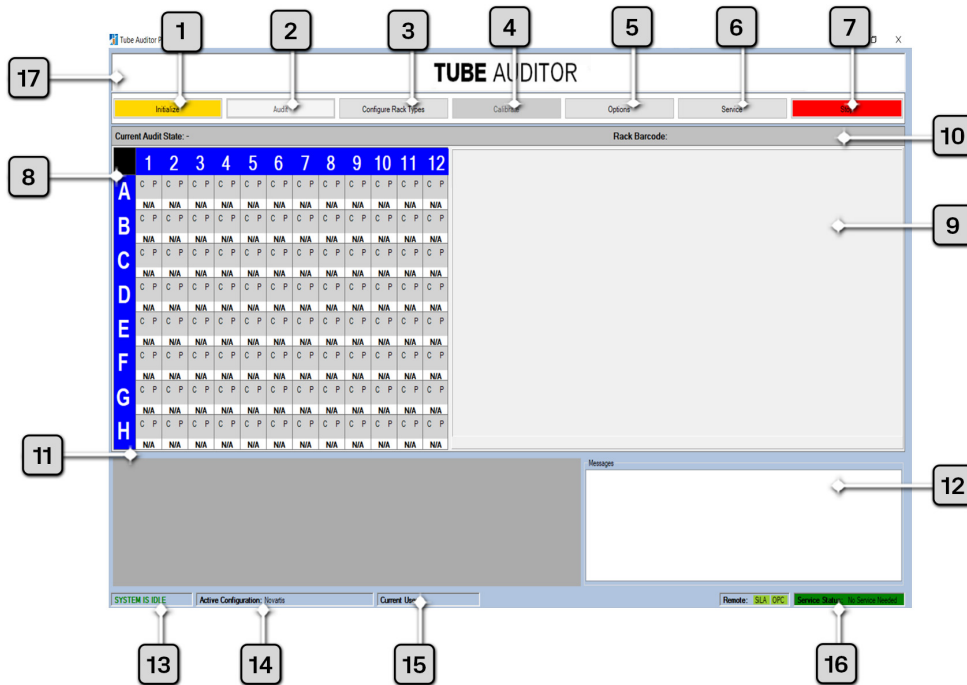
Number	Description
1	Initialize button
2	Audit button
3	Configure Rack Types button
4	Calibrate button
5	Options button
6	Service button
7	Stop button
8	Graphical Rack Display
9	Audited Tubes Image
10	Current Rack Barcode
11	Detailed Audit Information
12	System Message Log

Number	Description
13	System Status
14	Active Configuration
15	Current User
16	Service Status

Initialize Button

The **Initialize** button performs three tasks: it loads the default system parameters into the internal control boards, performs a calibration of the vision system, and then homes the system axes. This button must be clicked before most other tasks can be performed.

> *NOTE:* When the software first starts, the user only has the ability to click on the following buttons; **Initialize, Configure Rack Types, Options, Service**, and **Stop**.

This button is also used when the system encounters a stop or a power failure; in such a scenario, it must be clicked before performing any other operations.

Audit Button

The **Audit** button provides the main functionality of the system. When auditing a rack of tubes, this button must first be clicked before any audit data can be gathered. Two modes of operation are supported:

- **Configure On Audit**: This mode is followed if the user only specifies the rack/tube configuration after clicking the **Audit** button.
- **Pre-configured**: This mode enables faster use of the instrument when auditing multiple racks with the same rack/tube configuration.

Configure Rack Types Button

The **Configure Rack Types** button allows the user to define rack/tube configurations for future use. Users may fully configure racks/tubes to be audited by specifying the rack type, tube type, cap type, liquid type, label type and various other tube/sample characteristics.

By using this feature it is possible to create custom rack/tube configurations based on any of the default or existing configurations.

Calibrate Button

The **Calibrate** button is used when the operator wishes to generate a new tube/liquid calibration; the frequency of calibration should be determined as required by the user's quality control processes.

This button allows the user to calibrate the system for a specific tube/rack/liquid configuration using a rack of tubes containing known sample volumes.

Options Button

The **Options** button displays a menu that allows the operator to specify system parameters and enable options for the Tube Auditor. These options range from defining a default folder location, to specifying the COM port for the 1D barcode reader inside the instrument.

This dialog defines critical information for the operation and performance of the instrument and should therefore only be edited by a system administrator or trained technician. For this reason, the operator is prompted for a password before gaining access to this dialog.

Service Button

Clicking the **Service** button displays a dialog showing basic manual operations for the average operator, or for advanced operation, for the trained technician.

Because this dialog allows direct control of the motion control system within the instrument, and could possibly cause system failure or damage if used inappropriately, the operator is prompted for a password before being allowed access.

Stop Button

The **Stop** button performs an immediate halt of any currently running processes. This button should be clicked if the system is malfunctioning.

> *NOTE:* Although the system is stopped following the clicking of this button, motor power is not removed from the driven axes.

The external **Stop** button or rear Power Switch should always be used if there is a risk of injury to the user.

Graphical Rack Display

The *Graphical Rack Display* provides the user with a graphical representation of the rack currently being audited and shows the data the instrument has determined. This information is displayed until a new audit is performed.

During an audit, all pertinent information is displayed, including the calculated volume of liquid in the tube, whether a cap was detected, and whether any precipitate was detected.

Audited Tubes Image

The *Audited Tubes Image* shows the column of tubes currently being audited. The image of the tubes is displayed together with a graphical representation of the Regions Of Interest (ROI) used by the vision system to analyze the tubes (e.g. detection of liquid meniscus, presence of tube, cap, and precipitate).

If liquid, precipitate, or a cap is detected, a different color is used to represent this.

Current Rack Barcode

This shows the barcode of the rack currently being audited (or the barcode of the rack that was last audited if the system is idle).

Detailed Audit Information

This section of the user display (lower left-hand corner) shows detailed information about the rack being audited (or about the rack last audited when the system is idle).

This information includes some additional details that are not shown in the *Graphical Rack Display*, such as the measured liquid height, the sequence number of the tube (1-96), and optionally the 2D tube barcode (if the instrument is fitted with this option).

This information is for advanced users and offers a little more insight to the collected data; all the data displayed in this grid is also included in the output file at the completion of every audit.

System Message Log

The *System Message Log* displays all primary actions the system has performed and/or is in the process of performing.

System Status

The *System Status* located at the lower left-hand corner of the screen, displays whether the system is in use (busy) or idle. If in use, the label is shown in red, and if idle, in green.

Active Configuration

The *Active Configuration* is located at the base of the main screen, to the right hand side of the *System Status* section. This label is either blank (meaning no active configuration has been set) or the label will have a configuration name associated with it, indicating that an active tube/rack configuration has been set.

To cancel the current active configuration and return to the *Configure On Audit* mode, right-click on the display and select accordingly.

Current User

Located in the mid base part of the screen, this label displays the name of the current user. The current user can enter their name through the *Options* menu.

Right-clicking on the *Current User* field allows the user to be changed or canceled. When a user name has been specified, this is saved in the output file, indicating who performed the audit.

Service Status

Located in the lower right corner of the screen, this label shows whether the instrument is due a service visit.

If the number of racks audited is below the predefined service level, **No service is needed** is displayed (in green). If the number of racks audited exceeds the predefined service level then **Service visit due** appears (in red and blinking).

Current Audit State

The *Current Audit State* displays the current audit process being executed. The current process in execution is shown as "-" until an audit has been started.
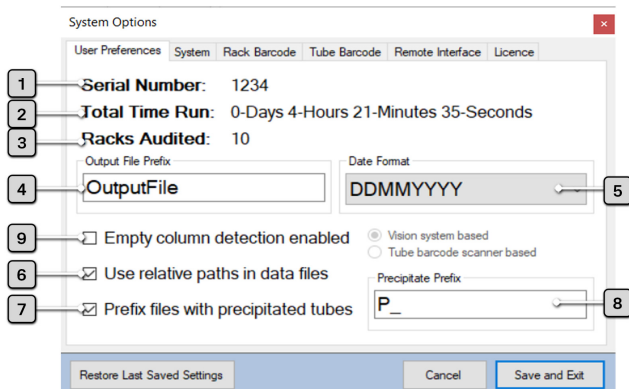
Setting System Preferences

By clicking the **Options** button, a dialog to allow the setting of system options is displayed. Six tabs are presented to the user, as detailed in the following sections, however a supervisory password is required to access any tab other than the *User Preferences* tab; this password can be changed on the *System* tab.

Note that the factory default password is set to **admin123**.

Once any changes have been made, click **Save** and **Exit** to ensure the changes are saved, or **Cancel** to exit from the dialog. Clicking the **Restore Last Saved Settings** button will undo all changes made since the last save operation was performed.

User Preferences

General user preferences, including file prefixes, date formats, and modes of operation.

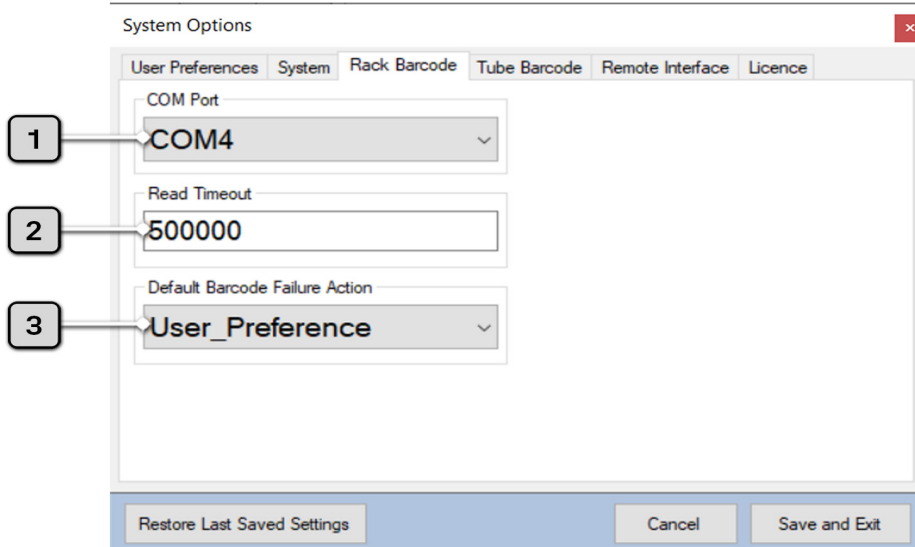| Number	Function	Description
1	Serial Number	The serial number of the instrument.
2	Total Time Run	The elapsed time the instrument has been in use.
3	Racks Audited	The total number of tube racks audited.
4	Output File Prefix	Allows the user to customize the output file name by adding a prefix e.g. OutputFile.
5	Date Format	Allows the user to select the date format from either Year-Month-Day or Day-Month-Year (shown).
6	Use Relative Paths in Data Files	If selected, the image file paths in the output file will be relative, otherwise they are absolute.
7	Prefix Files with Pre-cipitated Tubes	If selected, those output files containing any samples that have been determined to contain precipitate will have their image filenames prefixed with a user defined string.
8	Precipitate Prefix	Allows the user to specify the string used to prefix the image filenames of containing tubes with precipitated samples.
9	Empty Column Detec-tion Enabled	If selected, the Tube Auditor will use either 2D bar code or vision information to determine, and take action on identification of empty column(s); the audit data is still written to the output file If the "Empty column detection enabled" box is unchecked no detection of empty columns occurs. However, if it is checked, empty columns are detected according to the selection of the related radio button options, as follows: • Vision system based – if the vision system detects no tubes in a column, the rack audit is ended at that point and no further columns will be audited. • Tube barcode scanner based – if the scanner detects "no tube" for all tubes in a particular column, auditing of that column will be skipped; all columns containing tubes will be audited.

System

Password, system file paths, file names and extensions.
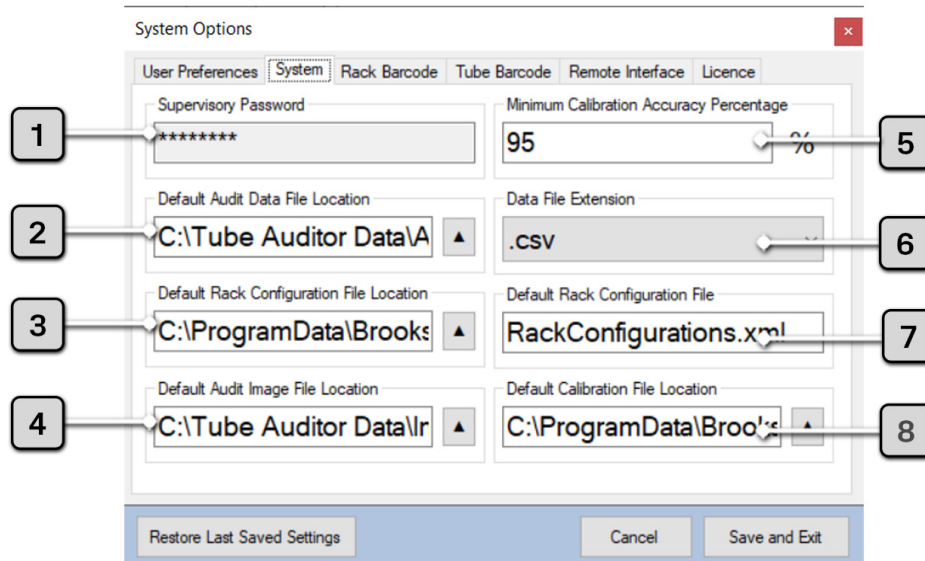
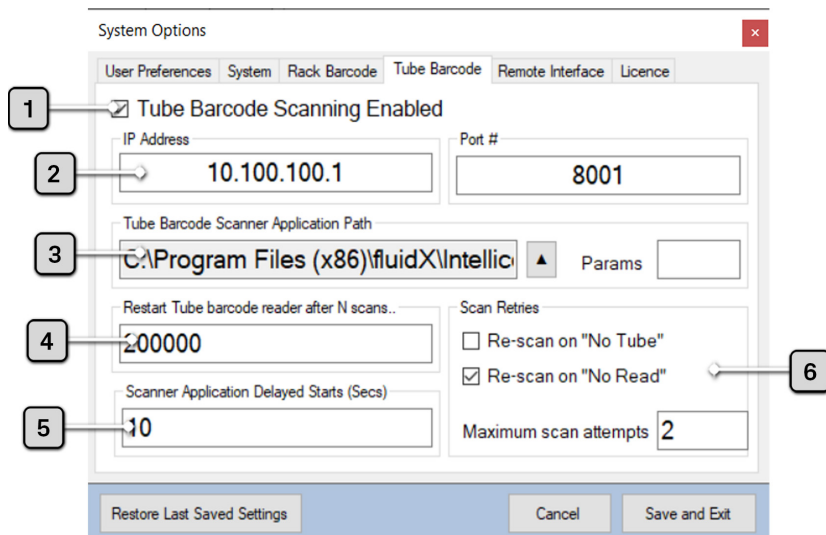| Number	Function	Description
1	Supervisory Password	Allows the supervisor to define the password (factory default is 'admin123').
2	Default Audit Data File Location	Pathname where output files will be placed after an audit.
3	Default Rack Configuration File Location	Pathname where the rack configuration file is located.
4	Default Audit Image File Location	Pathname where tube image files will be placed after an audit.
5	Minimum Calibration Accuracy Percentage	Defines the minimum 'accuracy level' (%) for the acceptance of a calibration (This figure represents the accuracy of the calibration curve fit to the acquired calibration data points; it should normally be set to 95%).
6	Data File Extension	Allows the user to select between .xml or .csv output file formats.
7	Default Rack Configuration File	Name of the rack/tube configuration file.
8	Default Calibration File Location	Pathname where the calibration file(s) are located.

Rack Barcode

1D rack barcode operation.

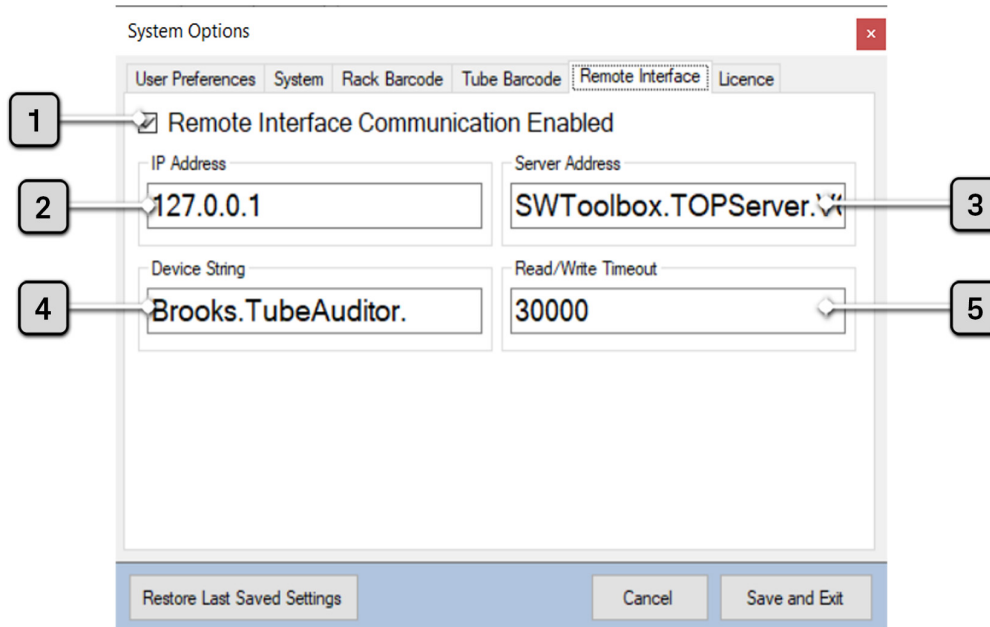| Number	Function	Description
1	COM Port	The COM port used to communicate with the 1D rack barcode scanner.
2	Read Timeout	The amount of time (in milliseconds) the 1D rack barcode scanner will stay in a reading state before timing out Both of these settings are system parameters that should only be changed by a suitably trained technician.
3	Default Bar-code Failure Action	Allows the user to specify how the instrument should react when it fails to read the rack barcode Four options are available: • Proceed_Without_Barcode • Auto_Eject_Rack • Manual_Barcode_Entry • User_Preference If the latter option is selected, the user is prompted at the time of audit with a dialog which allows any of the three preceding options to be selected.

Tube Barcode

2D tube barcode scanner operation. Note all of the settings on this tab are system parameters that should only be changed by a trained technician; they are password protected.

| Number	Function	Description
1	Tube Barcode Scanning Enabled	Select if the instrument is fitted with the 2D tube barcode scanner option and tube barcode reading is to be enabled.
2	IP Address & Port #	The IP address and port used to connect to the 2D tube barcode scanner; this value should match the corresponding value defined in the Azenta Decoding Software (formerly Intellicode Software) configuration.
3	Tube Barcode Scanner Application Path	Installation path of the Decoding Software (formerly Intellicode Software).
4	Restart Tube Barcode Reader After N Scans	Number of tube rack scans after which the Decoding Software (formerly Intellicode Software) is to be restarted (This parameter has been included to overcome an intermittent issue which has sometimes been seen after extended periods of operation with the Decoding Software).
5	Scanner Application Delayed Starts	The number of seconds the Tube Auditor should wait after starting the Decoding Software (formerly Intellicode Software) before establishing connection. This allows the software to fully start up before the Tube Auditor software attempts to establish a connection to it. If this parameter is too short, refused connections may occur. The default value of 10s should be adequate for most installations.
6	Scan Retries	The group box at the bottom right contains the functionality for retries. The two checkboxes decide when to retry and the maximum scan attempts. If this value is set to 3, then a maximum of 3 scans will occur, but once all tubes have been read scanning will end, so 3 would be the maximum number of scans.

Remote Interface

Remote software interface operation. Note all of the settings on this tab are system parameters that should only be changed by a trained technician; they are password protected.

| Number	Function	Description
1	Remote Interface Communication Enabled	Select if the remote interface is to be enabled i.e. the instrument is integrated into an automated system.
2	IP Address	The IP address used to connect to the remote interface OPC client (127.0.0.1 for local host). Refer to the Tube Auditor Remote Interface Specification document (PN: 382723) for further details.
3	Server Address	The address of the server for the remote OPC interface; this value should match the corresponding value in the server software configuration.
4	Device String	The name of the Tube Auditor on the remote OPC interface; this value should match the corresponding value in the server software configuration.
5	Read/Write Timeout	The amount of time (in milliseconds) the Tube Auditor will stay in a reading/writing state before timing out.

Licence

Licence upgrade option:
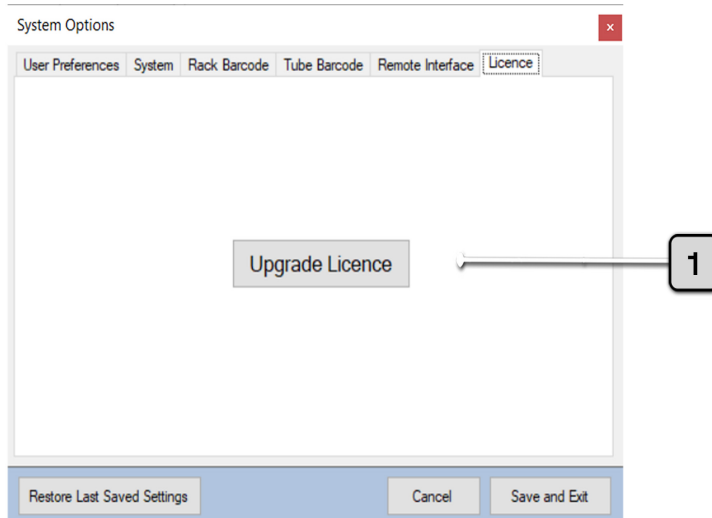
Number	Function
1	Upgrade Licence

Upgrade Licence

If you purchased the standard Tube Auditor (i.e. volume measurement only), this button allows you to upgrade to Tube Auditor Pro (with precipitate detection functionality) on payment of the appropriate licence fee.
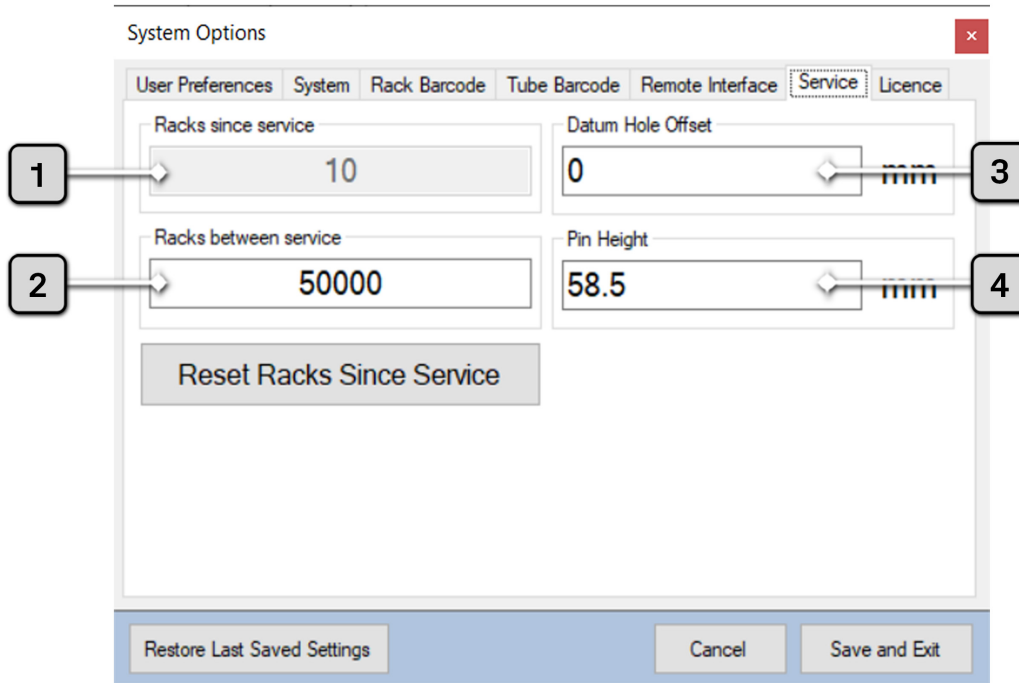
Pressing it displays the dialog shown below, contact Azenta Life Sciences for further assistance.
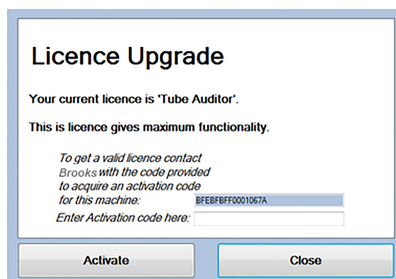
Once you have received your activation code, return to this dialog to enter it. Then press **Activate** to complete the licence upgrade process.
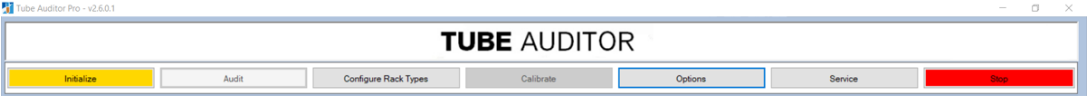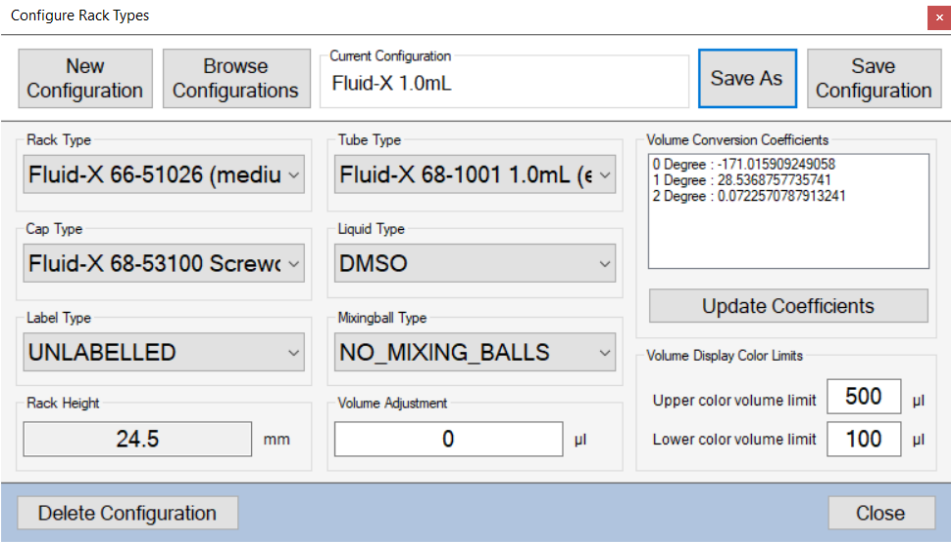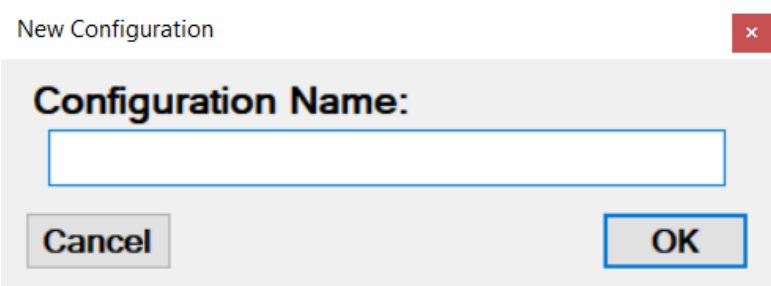
Service

The following dialog is only available when the application is run in *Technician Mode*; all of the settings on this tab are system parameters that should only be changed by a trained technician.
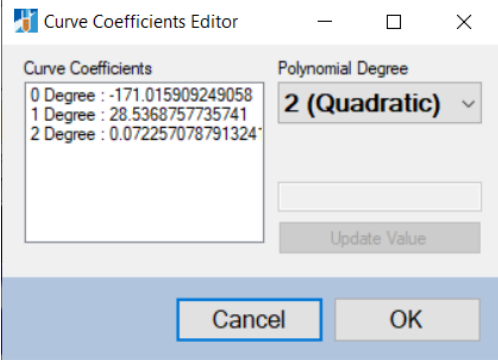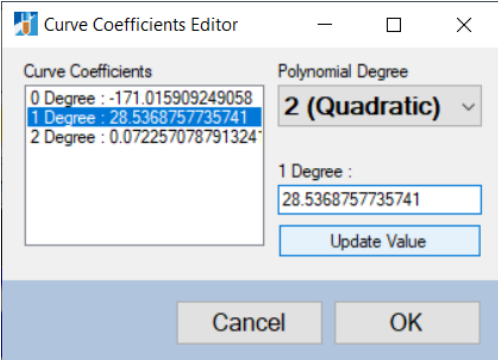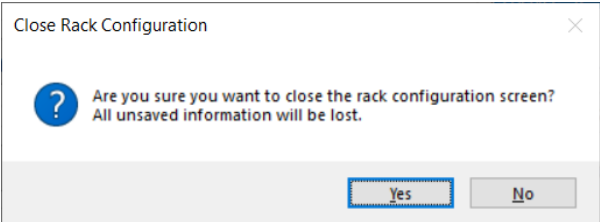

Number	Function	Description
1	Racks Since Service	The number of tube racks audited since the service indicator was last reset.
2	Racks Between Service	The number of tube racks that may be audited before the service indicator is illuminated (up to 50000 racks). Refer to "Maintenance Schedule" for an overview of the Tube Auditor maintenance schedule.
3	Datum Hole Offset	This offset can be used to adjust the relationship between the lifter datum hole and the top of the tube lifter to account for differences in instrument hardware. The default value for this offset is 0mm and it should only be adjusted by a trained technician. *NOTE: A full system recalibration must be performed if this value is changed.*
4	Pin Height	The distance between the base of the rack and the bottom of the upper guide pins when the guide pins are in the park position. This value is set for the instrument hardware and should only be changed by a trained technician.

Creating a Rack Configuration

Step	Action
1.	Click the **Configure Rack Types** button.
2.	Click the **New Configuration** button.
3.	Enter the desired name of the new configuration into the dialog box and click **OK**.

Step	Action
4.	Use the drop down selection boxes in the *Configuration* dialog to select and enter the parameters of the desired tube/rack configuration. • **Rack Height:** This parameter corresponds to the physical height of the tube rack specified in the *Rack Type* field. It should not generally be edited by a user, as damage could be caused to the instrument. • **Volume Adjustment:** Normally set to zero. *NOTE: For easy identification of depleted samples, color limits can be set. The volumes in the graphical rack display are color coded in a traffic light system, where volumes greater than the upper color volume limit are displayed in green, those volumes between the upper and lower color volume limits are displayed in amber, and volumes below the lower volume limit are displayed in red.*
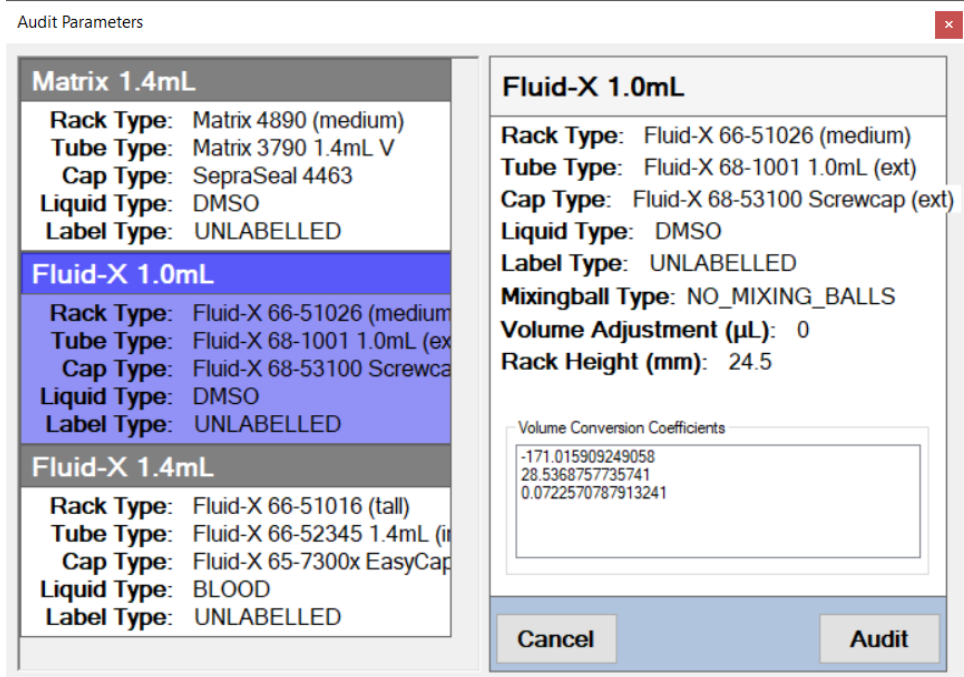
Step	Action
5.	Liquid height is converted to volume using a polynomial curve fitting algorithm. The number of coefficients depends on the polynomial order of the curve fit that was chosen. These coefficients are listed in the box and can be edited by pressing the **Update Coefficients** button. When updating coefficients, a dialog box is displayed that allows you to select and update individual coefficients and change the polynomial order. Manual editing of coefficients allows you to copy a calibration from one configuration to another. This can be useful if the same tubes, but different caps, are used in multiple configurations, allowing a single volume calibration to be copied and used for all.
6.	On completion, click **Save Configuration** and then close the dialog.
7.	Select **Yes** on the *Close Rack Configuration* dialog box. *NOTE: Clicking No will return the user back to the Configure Rack Types dialog.*

Performing an Audit
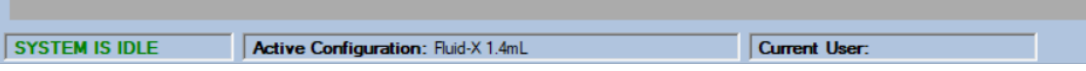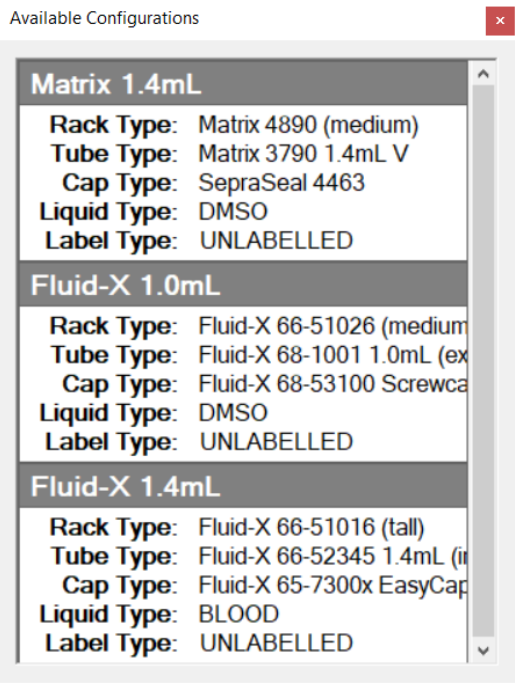
There are two methods by which a user can perform an audit.

The first method uses the *Configure On Audit* mode, the second uses the *Preconfigured* mode. This latter mode is the best way to perform repeated audits of the same rack/tube configuration.

Configure on Audit Mode

Step	Action
1.	Place the rack to be audited on the infeed tray of the instrument. Ensure the rack is correctly oriented (i.e. position A1 closest to the front panel, opposite side to the **Audit** and **Stop** buttons).
2.	Click the **Audit** button.
3.	The following dialog will be displayed listing all current rack configurations.
4.	Select the required rack configuration (the corresponding parameters are displayed on the right hand side of the dialog and click **Audit**.
5.	The audit will commence and can be monitored via the main screen.
6.	When the audit is complete, the status above the progress bar will display *Complete* and the rack will be returned to the user.
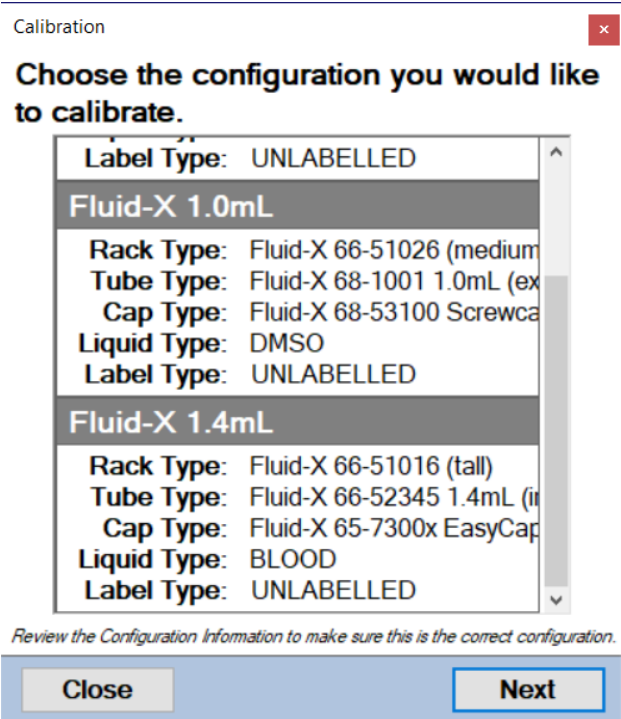
Pre-Configured Mode
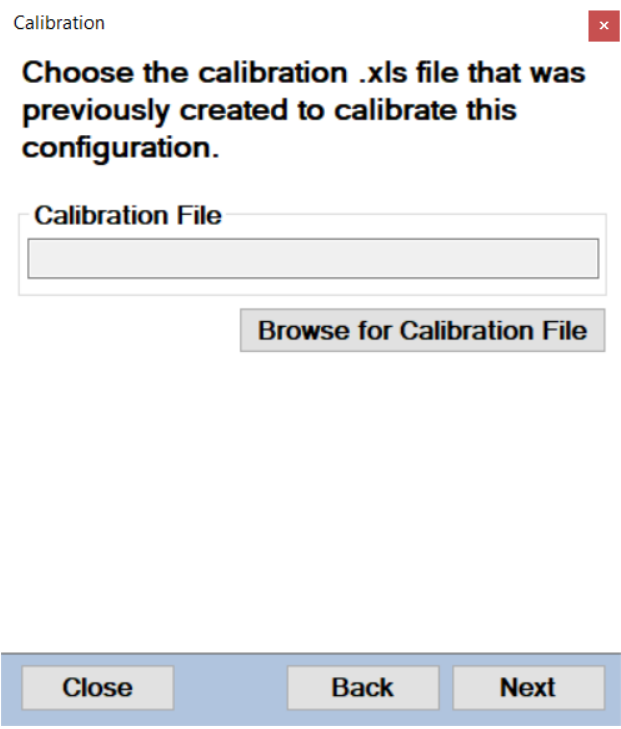
Step	Action
1.	Double-click on **Active Configuration** at the bottom-left of the screen. SYSTEM IS IDLE Active Configuration: Fluid-X 1.4mL Current User:
2.	A list of available configurations (i.e. those which have been defined) pop up in a separate dialog. **Available Configurations** **Matrix 1.4mL** Rack Type: Matrix 4890 (medium) Tube Type: Matrix 3790 1.4mL V Cap Type: SepraSeal 4463 Liquid Type: DMSO Label Type: UNLABELLED **Fluid-X 1.0mL** Rack Type: Fluid-X 66-51026 (medium Tube Type: Fluid-X 68-1001 1.0mL (ex Cap Type: Fluid-X 68-53100 Screwca Liquid Type: DMSO Label Type: UNLABELLED **Fluid-X 1.4mL** Rack Type: Fluid-X 66-51016 (tall) Tube Type: Fluid-X 66-52345 1.4mL (i Cap Type: Fluid-X 65-7300x EasyCap Liquid Type: BLOOD Label Type: UNLABELLED
3.	Select the desired configuration.
4.	The **Active Configuration** section at the bottom-left of the screen will display the selected configuration.
5.	Once the **Audit** button is clicked, the instrument begins auditing using the information from the active configuration.
6.	Subsequent audits may also be started by pressing and holding the green **Audit** switch on the front panel of the instrument for two seconds. *NOTE: Audits will utilize the active configuration.*
7.	To deactivate the selected *Active Configuration*, right-click on **Active Configuration** at the bottom-left of the screen.
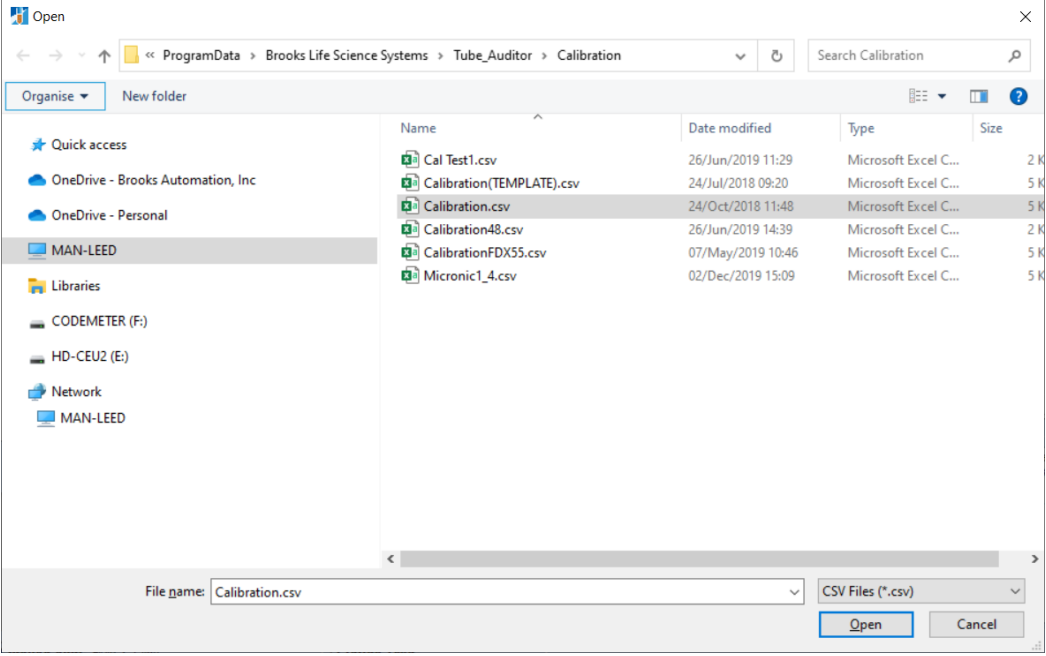
Performing a Calibration
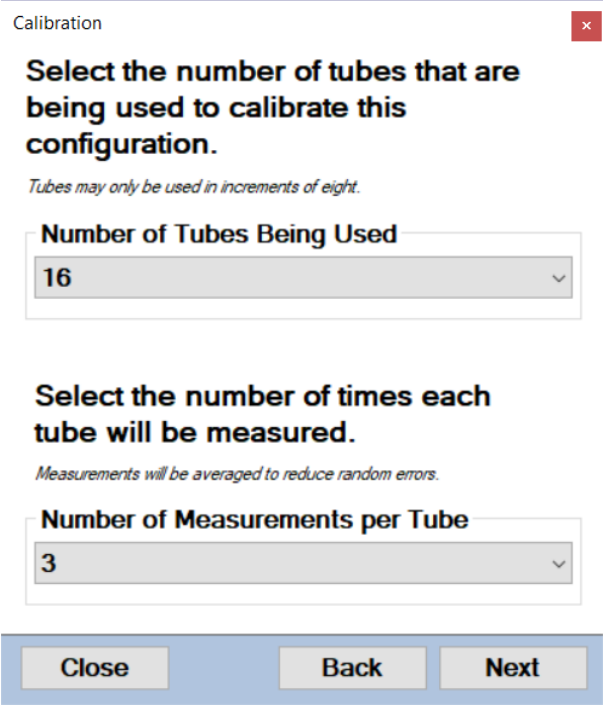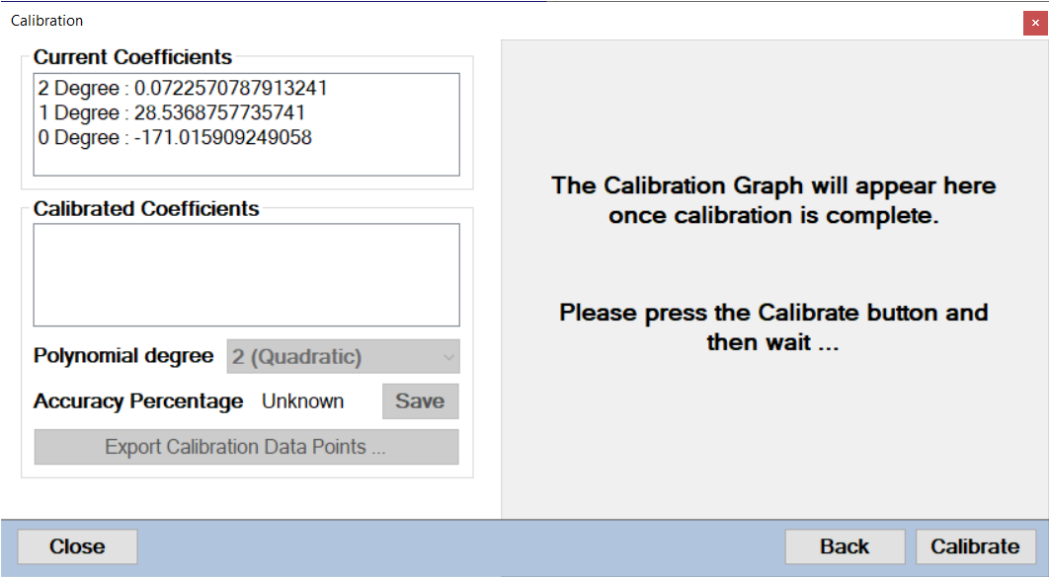
To perform a calibration, use the calibration wizard in conjunction with the following steps:

Step	Action
1.	First ensure that a configuration has been defined for the tubes you want to calibrate.
2.	Create a calibration set of tubes. The number of tubes can range from a minimum of 8 (one column) to a maximum of one full rack, in increments of one complete row. It is recommended that the tubes be prepared using the gravimetric method, so that each tube has an accurate known volume. Each tube in the calibration set should have a unique volume. The first tube in the set should typically have a volume no less than 50µl, and the last tube should have a volume such that the meniscus is close to the underside of the cap but without touching it (i.e. the meniscus should be at a distance of approximately 1 to 2mm from the cap). The incremental volume difference between tubes in the calibration set should be 25µl, 50µl or 100µl (depending on how many tubes are to be used in the process, and the size of the tube). So, for example, the following volumes might be used to calibrate a 1.4ml tube: 50, 75, 100, 125, 150, 200, 250, 300 350, 400, 500, 600, 700, 800, 900, 1000 *NOTE: There is no need to use round numbers; values such as 47, 102, 155, etc. can also be used as long as they are entered into the .CSV file used for system calibration.* Azenta Life Sciences typically recommends a calibration set of 16 tubes, as this gives a good compromise between the accuracy of the calibration and the time required to prepare the calibration set.
3.	Position the calibration tubes in the appropriate rack(s) starting from column 1 and then subsequent columns. Place the lowest volume tube in position A1 and work 'upwards' from there. Do not leave any gaps between columns of tubes. Do not leave any gaps between tubes in the same column.
4.	Create a calibration file (.CSV file) for the specific set of tubes used in the process. To do so the template file located in the calibration folder (depicted overleaf left) should be used.

Step	Action
5.	Return to the main user screen and click **Calibrate**. The following dialog box is displayed:

Step	Action
6.	Choose the rack configuration you want to calibrate and then click **Next**. The following dialog box is displayed: **Calibration** [×] **Choose the calibration .xls file that was previously created to calibrate this configuration.** **Calibration File** [ ] **Browse for Calibration File** **Close** **Back** **Next**

Step	Action
7.	Browse to the calibration file that was previously created. Select that calibration file. *NOTE: In earlier releases of the Tube Auditor software, the dialog defaults to displaying .xls files only (as shown below) as calibration was performed directly using MS Excel 2003, a copy of which needed to be installed on the Tube Auditor PC.* In more recent releases of the Tube Auditor software, the dialog defaults to displaying .csv files, although .xls calibration files may still be selected if available. In either case, starting from software release 2.2.0.3036, it is no longer necessary to install a copy of MS Excel 2003 on the Tube Auditor PC; it is however recommended that MS Excel (2003 or later) is available, as this simplifies the generation of calibration files in either format (.csv files may be generated by a **Save As** from Excel). Once the desired calibration file has been selected, click **Next**.

Step	Action

8.	Specify the number of tubes used for the calibration. This number must be equal to the number of tubes gravimetrically prepared for the calibration process. Click **Next**.
	
	 Calibration
	 Select the number of tubes that are being used to calibrate this configuration.
	 Tubes may only be used in increments of eight.
	 Number of Tubes Being Used
	 `16`
	
	 Select the number of times each tube will be measured.
	 Measurements will be averaged to reduce random errors.
	 Number of Measurements per Tube
	 `3`
	
	 [Close] [Back] [Next]
	
	 The *Number of Measurements per Tube* option sets how many times each calibration tube is measured. This is used to calculate an average measurement taking into account any variation in tube presentation. The tubes are raised and lowered for each measurement. Any menisci that are not detected are ignored and omitted from this averaging.

9.	Click **Calibrate** to begin. A progress bar is displayed until the calibration is complete. **Calibration** **Current Coefficients** 2 Degree : 0.0722570787913241 1 Degree : 28.5368757735741 0 Degree : -171.015909249058 **Calibrated Coefficients** **Polynomial degree** 2 (Quadratic) **Accuracy Percentage** Unknown [Save] Export Calibration Data Points … The Calibration Graph will appear here once calibration is complete. Please press the Calibrate button and then wait … [Close] [Back] [Calibrate]

Step	Action
10.	Once complete, a calibration curve will be shown as illustrated below. The *Polynomial degree* drop-down menu should be used to select the degree that gives the best visual curve fit to the data points. The number of coefficients changes to reflect the degree selected. The accuracy percentage must be greater than 99%. The calibration curve, shown in close-up above, describes the relationship between liquid meniscus height and volume (generated from the calibration sample set); the calibration coefficients (zero, first and second degree) are determined from the curve, and then used during subsequent sample audits.

Calibration Recommendations, Hints, and Tips

a. Always calibrate with unlabeled tubes.

b. During the calibration, make sure that the meniscus is correctly detected in every single tube. If not, repeat the process.

c. After the tubes have been gravimetrically prepared, it is recommended that they be spun in a centrifuge before using them for the calibration.

Performing Service Operations

NOTE: Access to this dialog screen is password protected.
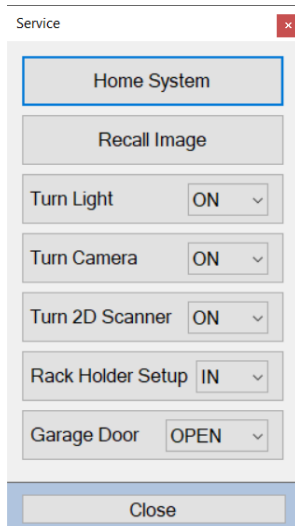
Function	Description
Home System	The **Home System** button re-homes the system from any state it is currently in. *NOTE: This function does not reinitialize the system.*
Recall Image	The **Recall Image** button opens a separate dialog that allows the user to recall a previously saved image and then re-audit it.
Turn Light On/Off	The **Turn Light On/Off** button allows the user to manually turn the vision system backlight on or off.
Turn Camera On/Off	The **Turn Camera On/Off** button allows the user to manually turn the camera on or off; this operation should only be performed by a trained technician. *NOTE: The underlying functionality for this button has been removed from later instruments.*
Turn 2D Scanner On/Off	The **Turn 2D Scanner On/Off** button allows the user to manually turn the 2D Scanner on or off; note this operation should only be performed by a trained technician. *NOTE: The underlying functionality for this button has been removed from later instruments.*
Rack Holder Setup In/Out	The **Rack Holder Setup In/Out** button is reserved for commissioning and setup only.
Open/Close Garage Door	The **Open/Close Garage Door** button can be used to manually open and close the garage door.

Recalling Images

The image recall function allows the user to re-audit tubes which have previously been audited, by recalling the captured images (that were stored in the image folder after they were audited).

This function can be used to re-analyze the sample characteristics (meniscus height, volume, presence of precipitate and cap etc.) and also to visually check the samples themselves.

After clicking **Recall Image** in the *Service* dialog, the user is prompted to select the required tube/rack configuration from the list of available configurations, as illustrated below.
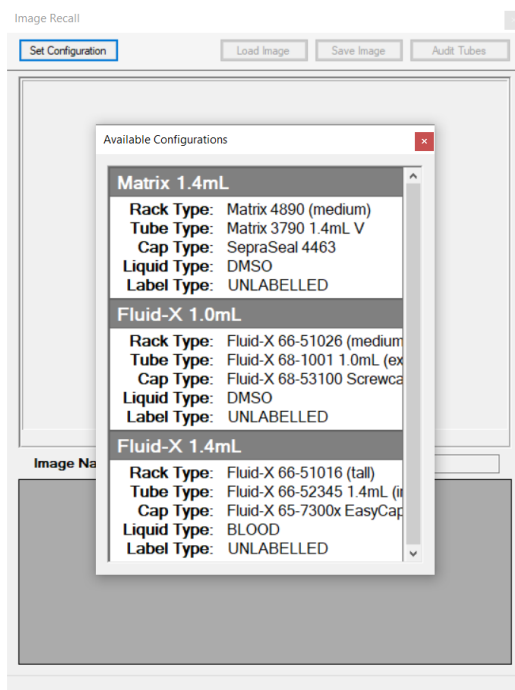
 Figure 3-1: Image Recall

The **Set Configuration** button enables the user to select the configuration corresponding to the tubes in the image.

Clicking **Load Image** then allows the required image to be selected from the image folder and subsequently audited by clicking the **Audit Tubes** button.

The results of the audited tubes are shown in the bottom pane of the dialog, as illustrated overleaf.
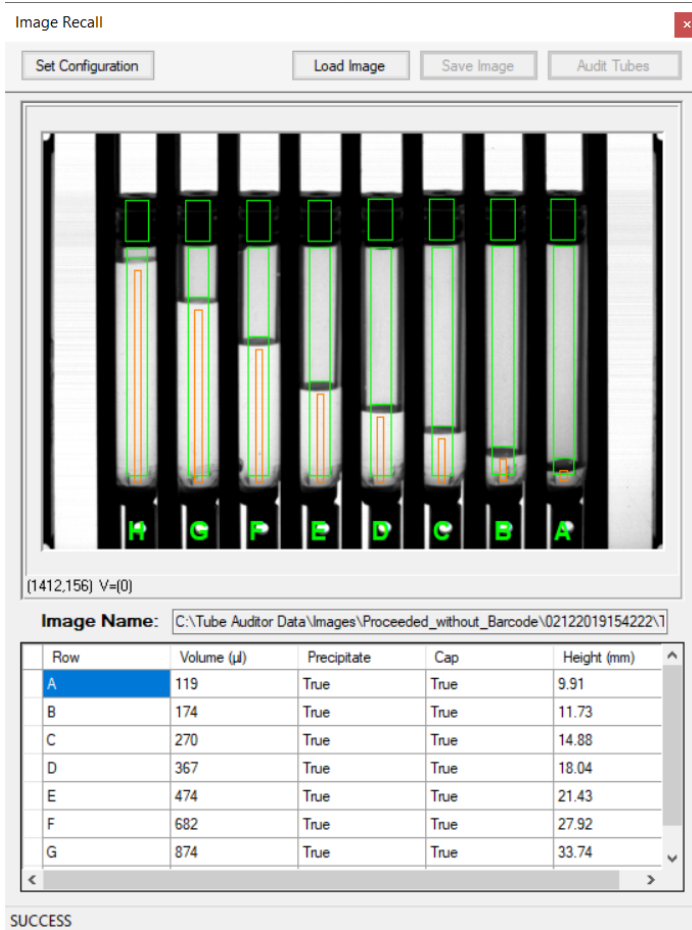
Figure 3-2: Image Recall

4. Output Files

An output file is automatically created and saved in the *Audit Data* folder each time a tube rack is audited. This file can be generated in either of two formats i.e. .xml or .csv. The file naming convention incorporates a user defined prefix, the time and date of the audit, and the rack barcode (or whatever text was manually input if no barcode was detected).

NOTE: The date can be in Year-Month-Day or Day-Month-Year format, depending on user selection. Time is always indicated using 24hour format.

In the examples shown, the filename is OutputFile_1034401290_26072011101537 i.e.

- User Prefix: OutputFile
- Rack barcode: 1034401290
- Date/time: 26072011101537 i.e. 26-07-2011 10:15:37

.csv Output File

The file is structured as follows:

Cell	Content
1	Rack configuration used to perform the audit
2 to 6	Details of the rack configuration
7	Date and time of the audit
8	Rack barcode number
9	Username
10	Number of tube locations (96)
11	Number of tubes actually present in the rack
12	Calibration coefficients
13	Results header
14 to 109	Audit results

An example output file in .csv format is depicted below:

.xml Output File

An example (older format) .xml file is shown below. As for the .csv file, the calibration coefficients are listed in the following order:

- Constant
- 1st degree coefficient
- 2nd degree coefficient - Etc.

NOTE: The number of coefficients is dependent on the curve fitting algorithm selected.

```xml
<?xml version="1.0" standalone="yes" ?>
<NewDataSet>
  <xs:schema id="NewDataSet" xmlns="" xmlns:xs="http://www.w3.org/2001/XMLSchema" xmlns:msdat
    <xs:element name="NewDataSet" msdata:IsDataSet="true" msdata:UseCurrentLocale="true">
      <xs:complexType>
        <xs:choice minOccurs="0" maxOccurs="unbounded">
          <xs:element name="Rack_Header">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="DATE_TIME" type="xs:string" minOccurs="0" />
                <xs:element name="RACK_BARCODE" type="xs:string" minOccurs="0" />
                <xs:element name="USERNAME" type="xs:string" minOccurs="0" />
                <xs:element name="NUM_TUBES_TO_AUDIT" type="xs:string" minOccurs="0" />
                <xs:element name="NUM_TUBES_AUDITED" type="xs:string" minOccurs="0" />
                <xs:element name="CAL_COEFFICIENTS" type="xs:string" minOccurs="0" />
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <xs:element name="TUBE">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="ID" type="xs:int" minOccurs="0" />
                <xs:element name="Row" type="xs:string" minOccurs="0" />
                <xs:element name="Column" type="xs:string" minOccurs="0" />
                <xs:element name="Height" type="xs:double" minOccurs="0" />
                <xs:element name="Volume" type="xs:double" minOccurs="0" />
                <xs:element name="Precipitate" type="xs:boolean" minOccurs="0" />
                <xs:element name="Cap" type="xs:boolean" minOccurs="0" />
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:choice>
      </xs:complexType>
    </xs:element>
  </xs:schema>
  <Rack_Header>
    <DATE_TIME>20100406035354</DATE_TIME>
    <RACK_BARCODE>1034401290</RACK_BARCODE>
    <USERNAME />
    <NUM_TUBES_TO_AUDIT>96</NUM_TUBES_TO_AUDIT>
    <NUM_TUBES_AUDITED>92</NUM_TUBES_AUDITED>
    <CAL_COEFFICIENTS>0,1,0</CAL_COEFFICIENTS>
  </Rack_Header>
  <TUBE>
    <ID>1</ID>
    <Row>A</Row>
    <Column>1</Column>
    <Height>0</Height>
    <Volume>0</Volume>
    <Precipitate>false</Precipitate>
    <Cap>true</Cap>
  </TUBE>
  <TUBE>
    <ID>2</ID>
    <Row>B</Row>
    <Column>1</Column>
    <Height>0</Height>
```

5. Cleaning and Maintenance

Cleaning Instructions

To clean the exterior of the Tube Auditor, use a mild non-abrasive cleaning agent and a clean cloth.

Operator Checks

In order to ensure that the Tube Auditor continues to operate safely, reliably, and efficiently, record any unusual or unexpected instrument symptoms or noises, and report these to the appropriate support personnel.

Maintenance and Repair

The message *Service Visit Due* located in the lower-right corner of the main user interface alerts the user to the fact that the Tube Auditor is due a service visit.

Only trained personnel must carry out any servicing, routine maintenance, and repairs on the instrument. Failure to comply with this may invalidate any warranty and may adversely affect the performance of the instrument.

Azenta Customer Support can provide fully trained engineers who have access to the technical information which is constantly updated. Only Azenta engineers can maintain the instrument to the original standards and design intent, ensuring safe operation and optimum performance.

Appendix A: Output File Format Changes

This appendix tracks changes to the format of the Tube Auditor output data file. Software releases are listed in reverse chronological order, so that the most recent version (associated with a change in file format) is at the top.

Changes from previous version are listed for each release, along with an updated file structure and an example output.

NOTE: Only the first 3 lines of audit results are shown at the end of each example for simplicity. Please contact Azenta for sample data files should you require them.

Release 2.1.4.2935

Changes

- 'Precipitate' and 'Cap' values in the audit data are now populated with 'FALSE' if no tube is present, instead of being left undefined.

File Structure

Cell	Content
A1:A109	Data value descriptions
B1:B6	Rack configuration information
B7	Date & Time
B8	Rack Barcode
B9	Username

Cell	Content
B10	Total number of possible tubes in given rack
B11	Number of tubes present in rack
B12:D12	Calibration coefficients (constant, 1st order, 2nd order)
B13:I13	Column Headings
B14:I109	Audit Data

Example

	A	B	C	D	E	F	G	H	I
1	CONFIGURATION_NAME	Micronic 1.4ml - Flat Bottom							
2	RACK_TYPE	MICRONIC							
3	TUBE_TYPE	MICRON_PST_1_4							
4	CAP_TYPE	MICRON_EVA							
5	LIQUID_TYPE	DMSO							
6	LABEL_TYPE	UNLABELLED							
7	DATE_TIME	25072011150428							
8	RACK_BARCODE	6206001636							
9	USERNAME								
10	NUM_TUBES_TO_AUDIT	96							
11	NUM_TUBES_AUDITED	2							
12	CAL_COEFFICIENTS	0	1	0					
13	TUBE_DATA_HEADER	ID	Row	Column	Height (mm)	Volume (ul)	Precipitate	Cap	Image_Filename
14	TUBE	56266536	A	1	29.41	875	TRUE	TRUE	..\Imag...
15	TUBE	56267245	B	1	29.15	865	TRUE	TRUE	..\Imag...
16	TUBE	No_Tube	C	1			FALSE	FALSE	..\Imag...

Release 2.1.2.2880

Changes

- Image filename added to the end of audit data in column I.

File Structure

Cell	Content
A1:A109	Data value descriptions
B1:B6	Rack configuration information
B7	Date & Time
B8	Rack Barcode
B9	Username
B10	Total number of possible tubes in given rack
B11	Number of tubes present in rack
B12:D12	Calibration coefficients (constant, 1st order, 2nd order)
B13:I13	Column Headings
B14:I109	Audit Data

Example

	A	B	C	D	E	F	G	H	I
1	CONFIGURATION_NAME	Micronic 1.4ml - Flat Bottom							
2	RACK_TYPE	MICRONIC							
3	TUBE_TYPE	MICRON_PST_1_4							
4	CAP_TYPE	MICRON_EVA							
5	LIQUID_TYPE	DMSO							
6	LABEL_TYPE	UNLABELLED							
7	DATE_TIME	20110519082820							
8	RACK_BARCODE	6206001636							
9	USERNAME								
10	NUM_TUBES_TO_AUDIT	96							
11	NUM_TUBES_AUDITED	2							
12	CAL_COEFFICIENTS	0	1	0					
13	TUBE_DATA_HEADER	ID	Row	Column	Height (mm)	Volume (ul)	Precipitate	Cap	Image_Filename
14	TUBE	56266536	A	1	29.41	875	TRUE	TRUE	..\Imag…
15	TUBE	56267245	B	1	29.15	865	TRUE	TRUE	..\Imag…
16	TUBE	No_Tube	C	1					..\Imag…

Release 2.1.1.2840

Changes

- Rack configuration settings added in rows 1-6, existing data values shifted down.

File Structure

Cell	Content
A1:A109	Data value descriptions
B1:B6	Rack configuration information
B7	Date & Time
B8	Rack Barcode
B9	Username
B10	Total number of possible tubes in given rack
B11	Number of tubes present in rack
B12:D12	Calibration coefficients (constant, 1st order, 2nd order)
B13:H13	Column Headings
B14:H109	Audit Data

Example

	A	B	C	D	E	F	G	H
1	CONFIGURATION_NAME	Marks Test						
2	RACK_TYPE	MATRIX_LATCH						
3	TUBE_TYPE	MATRIX_0_75						
4	CAP_TYPE	SEPRASEAL						
5	LIQUID_TYPE	WATER						
6	LABEL_TYPE	UNLABELLED						
7	DATE_TIME	4052011162833						
8	RACK_BARCODE	40002998						
9	USERNAME							
10	NUM_TUBES_TO_AUDIT	96						
11	NUM_TUBES_AUDITED	2						
12	CAL_COEFFICIENTS	0	1	0				
13	TUBE_DATA_HEADER	ID	Row	Column	Height (mm)	Volume (ul)	Precipitate	Cap
14	TUBE	56266536	A	1	7.06	7	FALSE	FALSE
15	TUBE	56267245	B	1	0	0	FALSE	FALSE
16	TUBE	No_Tube	C	1				

Release 1.0.0.2

Changes

- Username data value added in row 3, existing values shifted down.
- Calibration coefficient data values added in row 6, existing values shifted down.
- Descriptions of data values added to first column, existing values shifted right.

File Structure

Cell	Content
A1:A103	Data value descriptions
B1	Date & Time
B2	Rack Barcode
B3	Username
B4	Total number of possible tubes in given rack
B5	Number of tubes present in rack
B6:D6	Calibration coefficients (constant, 1st order, 2nd order)
B7:H7	Column Headings
B8:H103	Audit Data

Example

	A	B	C	D	E	F	G	H
1	DATE_TIME	20100406032308						
2	RACK_BARCODE	1034401290						
3	USERNAME							
4	NUM_TUBES_TO_AUDIT	96						
5	NUM_TUBES_AUDITED	2						
6	CAL_COEFFICIENTS	0	1	0				
7	TUBE_DATA_HEADER	ID	Row	Column	Height	Volume	Precipitate	Cap
8	TUBE	1	A	1	0	0	FALSE	TRUE
9	TUBE	2	B	1	0	0	FALSE	TRUE
10	TUBE	3	C	1				

Release 1.0.0.1

Changes

- Initial Release

File Structure

Cell	Content
A1	Date & Time
A2	Rack Barcode
A3	Total number of possible tubes in given rack
A4	Number of tubes present in rack
A5:G5	Column Headings
A6:G101	Audit Data

Example

|	A	B	C	D	E	F	G
1	1/20/2010 2:48:29 PM						
2	R90023225						
3	96						
4	2						
5	ID	Row	Column	Height	Volume	Precipitate	Cap
6	1	A	1	19.73	402.56	FALSE	TRUE
7	2	B	1	20.34	419.7	FALSE	TRUE
8	3	C	1				

Appendix B: Maintenance Schedule

Document ref. 24408\0206 details the current maintenance schedule for the Tube Auditor and should be referred to prior to undertaking any maintenance activities; the following table is included for information only.

Who	Sub-System/ Action	Category	Weekly	Monthly	6 monthly or After 2000 Audits	Annual or After 4000 Audits	Every 2 Years	Notes
User	Perform a test audit using samples with known volumes	Suggested	Y					
	Perform a liquid calibration for required tube/rack configurations	Recommended		Y				More or less frequent liquid calibration can be performed at the discretion of the end user.
	Archive audit data and images	Recommended			Y			
Service Engineer	Lead screw assembly - guide pins	Compulsory				Inspect and grease		Check security of drive coupling and condition of threaded carrier, replace carrier if worn.

Who	Sub-System/ Action	Category	Weekly	Monthly	6 monthly or After 2000 Audits	Annual or After 4000 Audits	Every 2 Years	Notes
Service Engineer	Lead screw assembly - push pins	Compulsory				Inspect and grease		Check security of drive coupling and condition of threaded carrier, replace carrier if worn.
	Tray wear strips	Compulsory				Inspect (replace)	Replace	Check condition of tray wear strips at service interval - replace if necessary, only replace as a pair.
	Drive belts - rack transfer	Compulsory				Inspect (replace)	Replace	Check tension and condition of drive belts at service interval - replace if necessary, only replace as a pair.
	Drive belts - garage door	Compulsory				Inspect (replace)	Replace	Check tension and condition of drive belts at service interval - replace if necessary.
	2D tube scanner (if fitted)	Compulsory				Inspect and clean		Clean any dust from scanner glass surface.
	Lightsource	Compulsory				Inspect (replace)		Check illumination level at service interval - replace if necessary.

Who	Sub-System/ Action	Category	Weekly	Monthly	6 monthly or After 2000 Audits	Annual or After 4000 Audits	Every 2 Years	Notes
Service Engineer	Electrical subsystems	Compulsory				Inspect		Check all cables, sensors, and other items.
	Perform system calibration	Compulsory				Y		Check optical setup and (if necessary) perform pin calibration.
	Perform liquid calibrations for all tube/rack configurations	Compulsory				Y		Liquid calibrations for all tube/rack configurations are only required if a pin calibration has been performed.
	Perform test audit cycles for all tube/rack configurations	Compulsory				Y		Check for correct mechanical and optical alignment and system operation.

Appendix C: Compliance
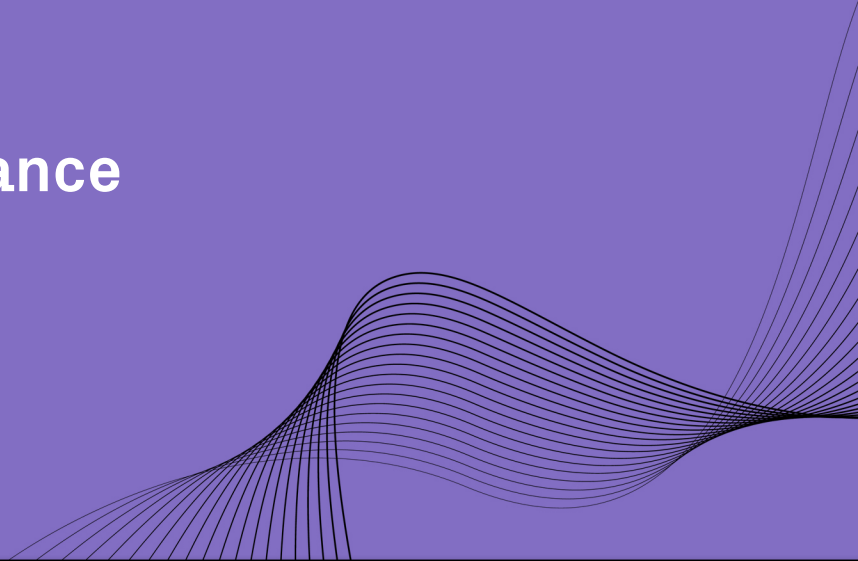
The following appendix contains the compliance information for the system.

Declaration of Conformity

DOCUMENT NUMBER:	TITLE:	
252438	**Declaration of Conformity, Machinery Directive**	**AZENTA** LIFE SCIENCES
REVISION: C	DOCUMENT CLASSIFICATION:	
ECO# EC132455	04-Form, Template or Other	

DECLARATION OF CONFORMITY

Description: Tube Auditor™

Function: The Tube Auditor™ is an instrument that use a high-resolution vision system to quickly and accurately audit sample microtubes. It can be used to calculate the volume of liquid in a tube and optionally detect precipitates.

Product code: 96-000x and 98-000x

Business name and full address of the manufacturer of the machinery:
Azenta Life Sciences, 15 Elizabeth Drive, Chelmsford, MA, USA 01824

Name and address of the person, established in the Community, authorized to compile the relevant technical documentation:
Azenta Life Sciences (Germany) GmbH, Im Leuschnerpark 1B, 64347 Griesheim, Germany

The manufacturer declares:
- That this machinery fulfills all the relevant provisions of Directive 2006/42/EC (Machinery Directive)
  - EN 12100:2010 Safety of machinery. General principles for design. Risk assessment and risk reduction
  - ISO/TR 14121-2:2012 ED2 Safety of machinery. Risk assessment. Practical guidance and examples of methods
  - EN 61010-1:2010+A1:2019. Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements

- That this machinery fulfils all the relevant provisions of Directive 2014/30/EU (EMC Directive)
  - EN 61326-1:2021 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements

- That this machinery is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and amendment 2015/863/EU.
  - BS EN IEC 63000:2018. Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

Year CE Marking Affixed to Product: 2020

Signed for and on the behalf of Azenta Life Sciences:

Rob Woodward

Rob Woodward (Oct 25, 2021 05:58 GMT+1)

Print name: Rob Woodward
Position: Senior Vice President, Global Quality Executive Management
Place: Irlam, Manchester

Confidential: The information is confidential and is to be used only in connection with matters authorized by Azenta and no part of it is to be disclosed to others without prior written permission from Azenta.		
Date Printed: Saturday, October 23, 2021	**This is uncontrolled when printed**	PAGE **1** OF **1**

WEEE Statement (European Union)

The symbol above indicates that Waste Electrical and Electronic Equipment (WEEE) is not to be disposed of as unsorted municipal waste. Equipment marked with this symbol is to be collected separately.

The objectives of this program are to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally. Specific treatment of WEEE is indispensable in order to avoid the dispersion of pollutants into the recycled material or waste stream. Such treatment is the most effective means of protecting the customer's environment.

The waste collection, reuse, recycling, and recovery programs available to Azenta Life Sciences customers vary by customer location. Please contact the responsible body (e.g., your laboratory manager) for information about local requirements.