

# Traceability Software

Automatic System for Quality Control  
& Traceability of Infection Control Processes



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## Introduction

### Starting the application

The following actions take place every time the user starts up the application:

**1. Presentation screen:** this screen is the first message displayed when the application is launched. The presentation screen disappears automatically in 10 seconds, but the user has the possibility to skip it by clicking on the "Close" button, which appears in the upper right corner.

**2. Access control:** the last step in the sequence of start up is the request of access credentials to operate the program. Here the user must enter the username and password, whereupon can start using the application.



### Access rights and users commutation

The Administrator user (Admin) has full access rights to operate the application. By using this user account, the Administrator will be able to:

- Add or eliminate other user accounts (see User account management).
- Reset passwords for existing accounts (see Password reset and modification).
- Modify the application settings.
- Display the history of results in full.

Additional user accounts (corresponding to the operators) can only see the results of the analysis that they have done, but not those that have been made by other users. In case that different user accounts have been enabled, it is possible to switch from one user to another by using the option [Home >> Sign out](#).

When logging out, the program presents a screen asking for a user name and password, and from there you can re-enter the program with a different account.

**NOTE:** In case the Admin user forgets the password, please contact us to perform a password clearance.

### User account management

- With the option [Home >> Create a new user account](#) the Admin user can add a new user account to the program.
- Through the option [Home >> User management](#) the Admin user can deactivate existing accounts and reset passwords.

### Password reset and modification

The Admin user can reset the password of other users; this feature can be useful in case a user has forgotten their password. Once the administrator has reset the password of a user, the user may enter the program using as password their user name followed by a hyphen and the numbers 321. For example, if the user account is called Technician and the administrator resets their password, the new password will be Technician-321. Moreover, all users have the possibility to change their own password, using the option: [Home >> Change password](#)

# Language configuration

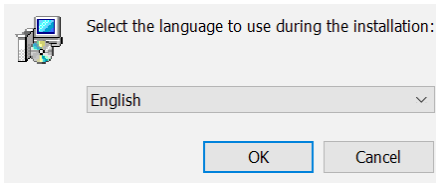
## Language selection

The application is available in the following languages:

- **English**
- **Spanish**
- **Portuguese**
- **Turkish**
- **Simplified Chinese**
- **Traditional Chinese**
- **Italian**
- **Korean**
- **Japanese**

When installing the program, it is possible to select the language you want to use during the installation procedure.

Select Setup Language



There are three important points to consider:

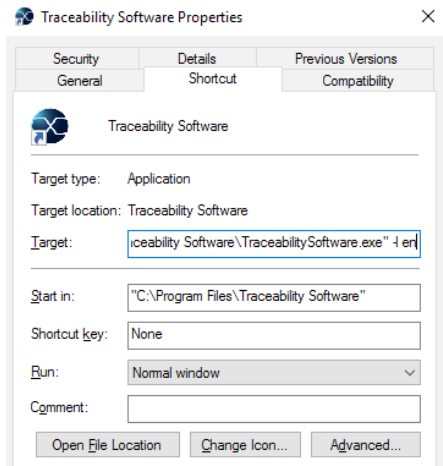
1. The language you choose when installing the program refers exclusively to the language to be used during the installation procedure.
2. The actual implementation is always installed in all available languages (regardless of the language you have chosen when installing).
3. When the program starts up, the application will automatically be presented in the appropriate language according to the default language of the Operating System:
  - If running on an Operating System in Spanish, the program will be displayed in Spanish.
  - If running on an Operating System in Portuguese, the program will be displayed in Portuguese.
  - If running on an Operating System in English (or in any other language other than those supported), the application will be displayed in English.

## How to force the language selection

As mentioned above, the application is always automatically shown in the corresponding language according to the language of the operating system.

However, it is also possible to force the use of a specific language, different from the one of the Operating System. In that case, these steps should be followed:

1. Locate the shortcut icon to the Traceability software. This icon can be on the desktop, or in the Applications menu, depending on which options are selected during the installation procedure
2. Click the right mouse button on the program's icon and select the option Properties.
3. When selecting the option Properties, a window like the one shown below, containing the configuration of the shortcut will be displayed:



In this window, in the Target box, you must add:

-I es (space hyphen followed by the letter I in small letter, a space and the word es).

**NOTE:** the word **es** refers to the language Spanish and tells the program you want to work in that language. To force the use of other language: English: **en**, Portuguese: **pt**, Simplified Chinese: **zh\_cn**, Traditional Chinese: **zh\_tw**, Turkish: **tr**, Italian: **it**, Korean: **ko** and Japanese: **jp**.

4. Finally, press the Apply button.

Once you have modified the configuration of the shortcut, next time you run the application, it will be displayed in the selected language (regardless of the Operating System language).

## Main screen

The main screen of the application is organized into four tabs:

**1. SCBIs Tab:** This Tab shows the data of the ongoing analysis for the biological indicator, using automatic information provided by the incubator. Moreover, from this section the operator can complete all the data that should be uploaded manually.

**2. SCBIs Results Tab:** This Tab shows the stored results, corresponding to prior analysis. In this section the complete history of results can be consulted, allowing organizing and filtering the results in different ways.

**3. HMS Tab:** This Tab shows the data of the ongoing analysis for the Hygiene Monitoring System, using automatic information provided by the incubator. Moreover, from this section the operator can complete all the data that should be uploaded manually.

**4. HMS Result Tab:** This Tab shows all the saved results of protein analysis, allowing to order and filter the results.

In addition to these tabs, the main screen contains the following elements for the interaction with the program:

- **Title bar:** Displays the application name and the name of the user who is running the program (in brackets).

- **Main menu:** Allows accessing the various functions provided by the application. Main functions are available within *Home* menu.

- **Toolbar:** The toolbar is located under the main menu and is composed of a set of buttons that allow a quick access to certain functions in the program such as results record, print, etc.

**NOTE:** Some buttons are available only when the user is working on the SCBIs Tab, while others only work when using the SCBIs Results Tab. The same is true for the HMS and HMS Results Tab.

- **Status bar:** Is the bar that appears at the bottom of the screen, containing information on the operation of the program (in *Status bar* section you will find more details about the information displayed).

### Status bar

At the bottom of the main screen there is a status bar divided into three sections:

- **Connection to the incubator:** it shows the connection status with the incubator, which can be "Connected" (highlighted in green) or "Disconnected" (highlighted in magenta). When the connection with the incubator is established, it shall also indicate the incubator model, lot and serial number.

- **Selected program:** it shows which of the programs have been selected in the incubator, followed by the current temperature (separated with a slash). When no program is selected in the incubator, it will show "Stand-by".

- **Last reading data:** it shows the date and time of the last reading data. It also indicates the actual temperature detected by the system. Another data is shown as "S", and the value looks like a fraction or ratio. This value helps to confirm if the selected temperature has been correctly reached. The numerator can take the values 1 or 2, where 1 means "unstable" and 2 means "stable". The denominator corresponds to the selected temperature (37 or 60 °C). The item "Readings", displays the number of times that the software has been communicated with the incubator.

### Incubator selection

At the toolbar there is a drop-down list that shows all the incubators connected to the computer or the local network. In order to see analysis in progress, archive data or perform temperature calibration, an incubator must be selected from the list.

While no incubator is selected, the analysis are tracked on the background but no data will be archived.

If an analysis is done on the background, a notification will appear informing in which incubator the event occurred.



## SCBIs Tab (Self-contained Biological Indicators Tab)

Traceability Software [admin]

Home View Help

Incubators available: 2

Traceability Software® v4.4 User: admin

#	Start time	Final time	Ticket number	Brand	Product code	Batch	Process	D-Value [min.]	SCBI Status	Result	Avg. T	Book #	Sheet #	Cycle	Identification	Steriliz
1	21/5/2020 08:36:06	Running (0:04)	---	Generic	GN220	G0445	STEAM (121)	2,000	Positive	---	0,0	4	3	2		
2	21/5/2020 08:35:42	21/5/2020 08:36:00	10	Generic	GN220	G0445	STEAM (121)	2,000	Positive	Cancelled	60,0	4	3	2		
3	21/5/2020 08:36:08	Running (0:04)	---	Generic	GN220	G0445	STEAM (121)	2,000	Positive	---	0,0	4	3	2		
4	21/5/2020 08:36:11	Running (0:04)	---	Generic	GN220	G0445	STEAM (121)	2,000	Positive	---	0,0	4	3	2		
5	21/5/2020 08:35:49	21/5/2020 08:36:00	9	Generic	GN220	G0445	STEAM (121)	2,000	Positive	Cancelled	60,0	4	3	2		
6	21/5/2020 08:36:16	Running (0:04)	---	Generic	GN220	G0445	STEAM (121)	2,000	Positive	---	0,0	4	3	2		

Incubation Data

Position: 1 Start time: 21/5/2020 08:36:06 Final time: Running (0:04) Ticket number: --- Avg. Temp.: 0,0

Biological Indicator Information (\*)Required Fields

Brand\*: Generic Product code\*: GN220 Batch\*: G0445 Process\*: STEAM (121) D-Value [min.]\*: 2,000 SCBI Status\*: Positive Result\*: ---

Printed Ticket Destination

Sterilization Process Information

Book #: 4 Sheet #: 3 Sterilizer ID\*: Serial num.\*: Load number: 3 Program Number\*: 3

Cycle\*: 2 Cycle Parameters: Observations:

Selected incubator: B1x12 9999 028 Incubation Prog. 1: 1h / 60°C Incubation Prog. 2: 1/2h / 60°C Last readout: 21/5/2020 08:40 T: 60,0°C S: 2/60 Readings: 40/40

The SCBIs Tab contains a grid similar to a spreadsheet, where the user can view the data for all the ongoing Biological Indicator readings. The grid comprises 12 rows, each of which corresponds to a position in the incubator. In addition, the grid displays a series of columns that will guide the user to complete all the relevant information about a specific SCBI result before saving it. Some of these fields will be automatically filled with information provided by the incubator, while other fields should be manually completed (details given below for each column). Next, the user will find the list of fields (columns) with a short guide for filling with the correct information.

- **#:** (Automatic information) Position of the incubator where the SCBI is being incubated and read.
- **Start time:** (Automatic information) gives the exact date and time of beginning of the incubation.
- **Final time:** (Automatic information) gives the exact date and time of finalization of readout. During incubation, this field will display the elapsed incubation time.
- **Ticket ID** (Automatic Information) Displays the ticket number from the incubator. During Incubation, this field will display empty
- **Purple fields:** Information about SCBI
  - **Brand:** (Manual information) Brand of the SCBI.
  - **Product code:** (Manual information) Product code of the SCBI.
  - **Batch:** (Manual information) Batch number of the SCBI.
  - **Process:** (Manual information) Conditions for calculation of

the D-Value. The user can find this information in the product Directions for use (which includes the Quality Certificate of that SCBI batch).

- **D-Value:** (Manual information) Provides information about the resistance of that SCBI batch. The user can find this information in the product Directions for use (which includes the Quality Certificate of that SCBI batch). Be careful to choose the correct D-Value considering the "Process" selected in the previous field.

**Note:** The time in minutes is equal to the time in seconds divided by 60. Then, the time conversion of 26 seconds to minutes is carried out as  $26 \text{ sec} / 60 = 0.43 \text{ minutes}$ .

- **SCBI Status:** (Manual information) Dropdown menu. You have to choose between 2 options: "Positive" (positive control, non-exposed) or "Exposed" (to the sterilization cycle).

• **Yellow fields:** Result: (Automatic information) Actual result given by the incubator (Positive, Negative or Cancelled).

• **Green fields:** Avg. T: (Automatic information) Average temperature during the incubation period of that SCBI.

• **Blue fields:** Logbook information (book where you keep your records, including the incubator's printed ticket).

- **Book #:** (Manual information) Complete with the logbook number corresponding to sterilization process.

- **Sheet #:** (Manual information) Complete with the logbook page number corresponding to sterilization process.

• **Orange fields:** Sterilizer and cycle information

## SCBIs Tab (Self-contained Biological Indicators Tab)

**-Cycle:** (Manual information) Cycle number, provided in the sterilizer screen and/or ticket.

**-Sterilizer ID:** (Manual information) Descriptive name of the sterilizer used for the process. This field must be completed using the Search Sterilizer tool .

**-Sterilizer brand:** (Manual information) Brand of the sterilizer. This field must be completed using the Search Sterilizer tool .

**-Serial num.:** (Manual information) Serial number of the sterilizer, in case you have 2 or more of the same brand. This field must be completed using the Search Sterilizer tool .

**-Load #:** (Manual information) Load number of the day.

**-Prog. #:** (Manual information) Program of the sterilizer used for that cycle.

• **Conditions:** (Manual information) you can fill this box with details about the cycle (not mandatory information).

• **Observations:** (Manual information) you can fill this box with any information you consider relevant and it is not already considered in the other fields (not mandatory information). This is the only field that can be filled or modified after the result has been saved in the SCBIs Result Tab.

To modify the data of a field, click the corresponding box and start typing.

The first time you enter a new input, you have to type it down. Then, next time you choose a box under the same title (or column), it will display a dropdown menu so that you only have to choose the desired option (no typing needed).

**NOTE:** This is true only for alphanumeric inputs; for numerical inputs you have to type down the value every time.

### Color codes

The first column in the SCBI grid (#) presents the numbers corresponding to each position of the incubator. The numbers of that column may adopt different colors:

- **Blue:** This color is used to indicate the positions in which there are tubes in process of incubation.

- **Purple:** This color indicates tubes whose analysis are completed.

- **Green:** Indicates that the analysis of the tube in that position has finalized, but the incubator already possesses data of a new analysis initiated in the same position. In these cases, the program cannot import the new data until the user releases the position, archiving the results permanently. The highlight in green of those cases is intended to alert the user that they must archive those results to release the position on the Biological Indicator grid. Once the position is released, the program will import the data that matches the new analysis.

### Expedited data upload

In order to simplify and expedite the data uploading, the program provides a records copy mechanism.

This mechanism works as follows. Suppose we are analyzing 10 samples whose general data are coincident (brand, product code, lot, sterilizing machine, sterilizing cycle, etc.). What we do in that case is to load the data for the first sample. Then we have to right-click on the incubation position and select the "Copy data from" option. This allows uploading repetitive data rapidly and with minimal effort.

The screenshot shows the 'Traceability Software' interface. At the top, there's a menu bar with 'Home', 'View', and 'Help'. Below it, a toolbar with various icons. The main area is divided into several sections. The top section is a table with columns: '#', 'Start time', 'Final time', 'Ticket number', 'Brand', 'Product code', and 'Incubator'. The table has 12 rows. The first row is highlighted in blue. A context menu is open over the table, showing options: 'Copy data from', 'Clear record', and 'Clear ALL records'. Below the table, there's a section titled 'Incubation Data' with fields for 'Position', 'Start time', 'Final time', and 'Running (h)'. Below that, 'Biological Indicator Information' with fields for 'Brand', 'Product code', 'Batch', and 'D-Value (min)'. Then 'Printed Ticket Destination' with fields for 'Book #', 'Sheet #', 'Sterilizer ID', 'Sterilizer Brand', 'Serial num.', and 'Load number'. Finally, 'Sterilization Process Information' with fields for 'Cycle', 'Cycle Parameters', and 'Observations'. At the bottom, there's a status bar showing 'Selected incubator: Bix12 9999 028' and 'Incubation Prog. 1: 1h / 60°C Incubation Prog. 2: 1/2h / 60°C Last readout: 2'.

**NOTE:** the contextual menu is accessed by pressing the right mouse button on the grid.

### Form view

In addition to the grid described above, the SCBIs Tab also offers a view that shows the same data as in the grid but presented as a form.


The form is divided into several sections (Incubation Data, Machine Performance Data, etc.), grouped with the same Color code as in the grid.

It is worth mentioning that working with the grid or the form is indistinct, since both allow you to query and modify the data corresponding to the ongoing analysis. If you use the grid, the information will be automatically loaded in the form and vice versa.

## SCBIs Tab (Self-contained Biological Indicators Tab)

This rule applies to all fields except those related to the sterilizer, which must be completed using the sterilizer search tool

**NOTE:** Users can hide the form view using the option:

View  Show or hide form view or by pressing the corresponding button on the toolbar.

Traceability Software [ admin ]

Home View Help

Incubators available: 2

Traceability Software® v4.4

User: admin

SCBIs	SCBIs Results	HMS	HMS Results																
#	Start time	Final time	Ticket number	Brand	Product code	Batch	Process	D-Value [min.]	SCBI Status	Result	Avg. T	Book #	Sheet #	Cycle	Identification	Sterilizer			
1			---						---		80								
2			---						---	0.0									
3			---						---	0.0									
4			---						---	0.0									
5			---						---	0.0									
6			---						---	0.0									
7			---						---	0.0									
8			---						---	0.0									
9			---						---	0.0									
10			---						---	0.0									
11			---						---	0.0									
12			---						---	0.0									

Selected Incubator: Bix12 9999 028 Incubation Prog: 1: 1h / 60°C Incubation Prog: 2: 1/2h / 60°C Last readout: 21/5/2020 08:29 T: 56,6°C S: 2/60 Readings: 17/17

### SCBI's results storage

When storing a set of results, these will be transferred from the SCBIs Tab to the SCBIs Results Tab, remaining stored and available for future reference.

Before performing permanent storage of data, the program performs a number of verifications aimed at ensuring the completeness thereof. This guarantees that the user won't miss any important information about that test when saving the SCBI result.

The data that are mandatory for the result archiving depend on the "Required fields Level" setting. If it's set on "High" (by default) the following fields are mandatory, which means that the operator needs to complete them before archiving a new registry.

- **All purple fields:** Brand, Product Code, Batch, Process, D-Value, SCBI Status
- **Both blue fields:** Book # and Sheet #
- **Orange fields:** Cycle, Machine brand, Serial num., Prog. # (all but Load #)

A configuration set on "Medium" or "Low", has fewer mandatory fields, making them optional.

### Automatic storage

After SCBI's incubations end, the results are automatically

transferred to the grid of the SCBIs Results Tab. It is worth mentioning that the storage of the results will be automatically performed only when the mandatory data of the SCBI test is complete at the time of finishing the analysis.

If the user has a Traceability Exchange+ license, the completed results will be stored automatically, regardless of the fields completed

If the analysis of a SCBI finalizes and its information is not complete, the user must complete the missing information (on the SCBIs Tab) and then save the results manually. This is explained in the following section.

### Manual storage

- **Storing an individual result**

To permanently store the information corresponding to a particular SCBI, we have to right-click on the incubation position and select "Archive Record".

- **Storing a set of results**

To permanently store two or more results in a single step, the user can use the button "Save results", available in the toolbar:



## SCBIs Results Tab

The SCBIs Results Tab contains a table displaying all the loaded information that has been completed during incubation of the SCBIs and correspondingly saved after incubation has finished. This grid is quite similar to the one in the SCBIs Tab, but contains some additional data:

- **Lot:** (Automatic information) Lot number of the incubator, information provided by the incubator itself.
- **Serial #:** (Automatic information) Serial number of the incubator, information provided by the incubator itself.
- **Operator:** (Automatic information) Name of user that was logged in during incubation of this SCBI. Given by the software.
- **Visual result:** (Manual information) Dropdown menu where you can choose between "Positive" or "Negative". You need to complete this field only if you have performed the optional

incubation for 48 hours (visual confirmation through culture medium color change). Please, read the SCBI Directions for use before performing this optional incubation.

- **SPR (Sterilization Process Risk):** (Optional information) This value corresponds to an optional calculation. For further information, please refer to the **Calculation of the Sterilization Process Risk (SPR)** section.

The data displayed in the results grid cannot be modified, with the exception of the fields "Visual Result" and "Observations", which do allow making changes. The SPR value can only be registered and calculated by using the corresponding tool (refer to the **Calculation of the Sterilization Process Risk (SPR)** section).

Traceability Software [ admin ]

Home View Help

----- Incubators available: 2 ----- Traceability Software ® v4.4 User: admin

SCBIs SCBIs Results HMS HMS Results

Sort by: Start time From 14/05/2020 Until 21/05/2020 Operator Brand Result Positive

Showing all results

#	Lot	Serial #	Operator	Start time	Final time	Ticket number	Incubation Prog.	Brand	Product code	Batch	Process	D-Value [min.]	SCBI Status	Result	Visual res.
5	Blx129999	28	admin	20/5/2020 14:44:56	20/5/2020 14:45:00	5	1h / 60°C	Generic	GN220	GX445	STEAM (121)	4,000	Exposed	Negative	---
6	Blx129999	28	admin	20/5/2020 14:44:56	20/5/2020 14:45:00	6	1h / 60°C	Generic	GN220	GX445	STEAM (121)	4,000	Positive	Negative	---
10	Blx129999	28	admin	20/5/2020 14:43:57	20/5/2020 14:44:00	1	1/2h / 60°C	Generic	GN220	GX445	STEAM (121)	4,000	Positive	Positive	---
11	Blx129999	28	admin	20/5/2020 14:43:59	20/5/2020 14:44:00	2	1/2h / 60°C	Generic	GN220	GX445	STEAM (121)	4,000	Positive	Positive	---
2	Blx129999	28	admin	21/5/2020 08:33:42	21/5/2020 08:36:00	10	1h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---
3	Blx129999	28	admin	21/5/2020 08:35:23	21/5/2020 08:45:00	17	1h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Cancelled	---
4	Blx129999	28	admin	21/5/2020 08:35:25	21/5/2020 08:45:00	18	1h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Exposed	Negative	---
5	Blx129999	28	admin	21/5/2020 08:35:49	21/5/2020 08:36:00	9	1h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Exposed	Negative	---
6	Blx129999	28	admin	21/5/2020 08:35:28	21/5/2020 08:45:00	19	1h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---
7	Blx129999	28	admin	21/5/2020 08:43:58	21/5/2020 08:44:00	15	3h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---
8	Blx129999	28	admin	21/5/2020 08:43:56	21/5/2020 08:44:00	16	3h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---
9	Blx129999	28	admin	21/5/2020 08:43:55	21/5/2020 08:44:00	14	2h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Cancelled	---
10	Blx129999	28	admin	21/5/2020 08:42:58	21/5/2020 08:43:00	11	1/2h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---
11	Blx129999	28	admin	21/5/2020 08:43:58	21/5/2020 08:44:00	13	2h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Exposed	Negative	---
12	Blx129999	28	admin	21/5/2020 08:43:57	21/5/2020 08:44:00	12	1/2h / 60°C	Generic	GN220	GX445	STEAM (121)	2,000	Positive	Positive	---

Selected incubator: Blx12 9999 028 Incubation Prog. 1: 1h / 60°C. Incubation Prog. 2: 3h / 60°C. Last readout: 21/5/2020 09:20 T: 60.0°C S: 2/60 Readings: 123/123

### Sorting and filtering of results

At the top of the SCBIs Results Tab there is a panel that offers different options to filter or sort the results shown.

To sort the results use the selector "Sort by", which appears in the upper left corner, and then choose the desired criteria.

Otherwise, you can directly click in the field's title and automatically sort by that criteria.

The rest of the boxes allow specifying different criteria for filtering. Once the criteria is defined, the filter can be applied by pressing the button located at the right end of the panel ( button allows access to more options for filtering data).

# SCBIs Results Tab

Traceability Software® v4.4

User: admin

HomeViewHelp

SCBIsSCBIs ResultsHMSHMS Results

Sort by: Start time

From: 14/05/2020

Until: 21/05/2020

Operator:

Brand:

Result: Positive

Book #

Sheet #

Sterilizer Brand

Serial num.

Load number

Program Number

Cycle


Showing all results

#	Lot	Serial #	Operator	Start time	Final time	Ticket number	Incubation Prog.	Brand	Product code	Batch	Process	D-Value [min.]	SCBI Status	Result	Visual res.
1	Blx129999	28	admin	20/5/2020 14:44:56	20/5/2020 14:45:00	5	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	4,000	Exposed	Negative	---
6	Blx129999	28	admin	20/5/2020 14:44:56	20/5/2020 14:45:00	6	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	4,000	Positive	Negative	---
10	Blx129999	28	admin	20/5/2020 14:43:57	20/5/2020 14:44:00	1	1/2h / 60°C	Generic	GN220	GX445	STEAM (12:1)	4,000	Positive	Positive	---
11	Blx129999	28	admin	20/5/2020 14:43:59	20/5/2020 14:44:00	2	1/2h / 60°C	Generic	GN220	GX445	STEAM (12:1)	4,000	Positive	Positive	---
2	Blx129999	28	admin	21/5/2020 08:35:42	21/5/2020 08:36:00	10	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Positive	---
3	Blx129999	28	admin	21/5/2020 08:35:23	21/5/2020 08:45:00	17	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Cancelled	---
4	Blx129999	28	admin	21/5/2020 08:35:25	21/5/2020 08:45:00	18	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Exposed	Negative	---
5	Blx129999	28	admin	21/5/2020 08:35:49	21/5/2020 08:36:00	9	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Exposed	Negative	---
6	Blx129999	28	admin	21/5/2020 08:35:28	21/5/2020 08:45:00	19	1h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Positive	---
7	Blx129999	28	admin	21/5/2020 08:43:58	21/5/2020 08:44:00	15	3h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Positive	---
8	Blx129999	28	admin	21/5/2020 08:43:56	21/5/2020 08:44:00	16	3h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Positive	---
9	Blx129999	28	admin	21/5/2020 08:43:55	21/5/2020 08:44:00	14	2h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Positive	---
10	Blx129999	28	admin	21/5/2020 08:42:48	21/5/2020 08:43:00	11	1/2h / 60°C	Generic	GN220	GX445	STEAM (12:1)	2,000	Positive	Cancelled	---

Selected Incubator: Blx12 9999 028

Incubation Prog. 1: 1h / 60°C Incubation Prog. 2: 3h / 60°C Last readout: 21/5/2020 09:26 T: 60,0°C S: 2/60 Readings: 134/134

## Sterilization Process Risk (SPR) calculation

The application allows calculating the Sterilization Process Risk (SPR) of a set of results. This function can be accessed by the button  in the toolbar. This button only works when the user is viewing the SCBIs Results Tab.

The idea of this tool is to take advantage of the SCBI results to monitor not only the sterility of a certain cycle but also the performance of a specific sterilizer in time (historical performance). This calculation relies in a very sophisticated and exclusive algorithm that takes into consideration the next information: cycle number, sterilizer (brand and serial number), number of processed SCBIs (in case you use more than one SCBI in a given cycle), resistance of the SCBI batch (through the informed D-Value), results of SCBIs (positive or negative) and the time to give positive result (in case of having a positive result), among others.


The SPR calculation will be informed as None, Low, Medium or High, according to applicable international regulations. Nevertheless, the user must consider that a Low risk doesn't mean that the cycle is not risky; a positive result implies that the cycle being monitored cannot guarantee sterility of the load, so the load needs to be reprocessed, without exception. For this reason, the SPR value is not intended to be examined cycle by cycle but, on the contrary, considering a group of cycles during a considerable period of time.

For this reason, these SPR calculations are used to represent the sterilizer performance by using the Historical Sterilizer Performance tool (see next section).

By implementing this innovative tool, the user will be able to perform a thorough inspection of every sterilizer in the CSSD by saving a lot of time for the audit sterilizer's examination. In this way the SPR provides useful data that can be used to reduce productive costs, foresee the sterilizer repairs, or revise the sterilization procedures.

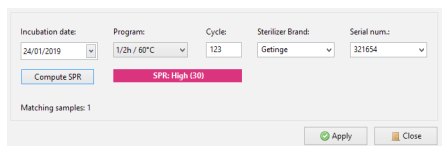
Incubators available: 2

## SCBIs Results Tab

When pressing the button  , the program will display a form where the user must indicate the grouping criteria for the calculation (date of incubation, sterilization cycle, sterilizing machine and number thereof). Once the criteria are defined, the user must press the button "Compute SPR" for the program to perform the calculation.

After completing the calculation, the program will show the result. Pressing the "Apply" button, the SPR will be transferred to the results grid (where it will remain available for reference in the "SPR" column).

**NOTE:** This tool should be validated by each institution according to the specific requirements for each application.




**NOTE:** To simplify the specification of the criteria for grouping, when entering the form for the calculation of the SPR, the program completes the boxes with the values corresponding to the result that has been selected at the time of entry.

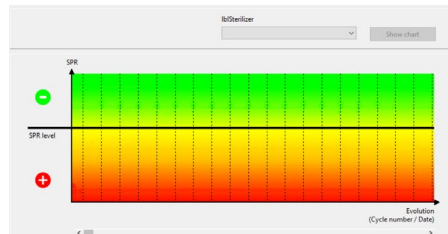
### Historical Sterilizer Performance

By implementing this innovative tool, the user will be able to perform a thorough inspection and audit of every sterilizer in the CSSD. In this way the SPR provides useful data that can be used to reduce productive costs, foresee the sterilizer repairs, or revise the sterilization procedures.

This tool will only be active when working on the SCBIs Results Tab (graph button next to the SPR button).



The Historical Sterilizer Performance consists of a chart that represents all the SPR values for every cycle. When pressing the button  , a window will appear as below.

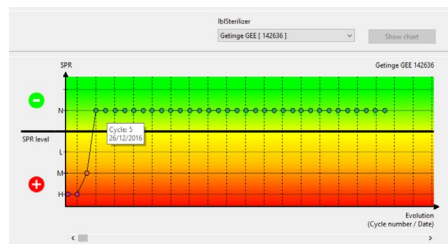


In the X axis the performance Evolution is represented, through the Cycle number/Date, while in the Y axis the SPR level is drawn. You choose the sterilizer you want to analyze through the dropdown menu and press the "Show chart" button. This way, every sterilizer will have its own historical performance.

The chart is divided into 2 halves; the top one corresponding to Negative SPR values (green zone of the chart) while the lower half (orange and red zones) correspond to Positive SPR values (including Low, Medium and High). Every cycle will have a SPR value represented by a dot.

Next, a few examples of sterilizer performance evolution and their interpretation to illustrate the versatility and usefulness of this tool.

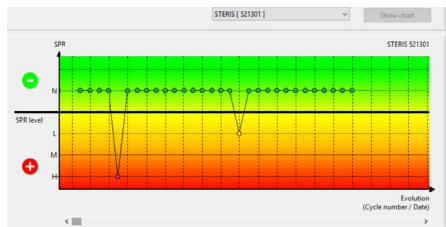
**Example 1.** Correct sterilizer performance.



In this case, the user can see that the sterilizer was showing some failure, as shown by the first three SPR values with High and Medium levels. In this case, thanks to the use of this tool it was possible to detect this sterilizer malfunction and arrange for a proper maintenance. The user can corroborate through the chart that after this maintenance the sterilizer performance was acceptable since the SPR values return to Negative levels (Cycle 5 on the 26th of December 2016), corroborating the correct sterilizer performance from that moment on.

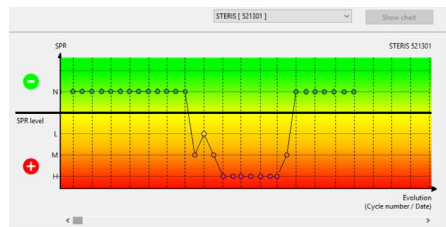
## SCBIs Results Tab

### Example 2. Random sterilizer failure.



The sporadic occurrence of positive SPR values is an indication of random failure, which could be due to premature cycle abortion, operator mistake, wrong SCBI positioning inside a test pack or sterilizer chamber, overloading of the sterilizer chamber, among others. Detecting this type of failures could definitely help improve the general protocol of the sterilization process by analyzing the reasons of these failures whenever they are identified. If the user positions the mouse pointer in any dot, both cycle number and date will be shown, helping to identify the exact cycle. With this information and the Results grid filtering tool, the user can trace the rest of information in order to evaluate the possible causes and revert the situation.

### Example 3. Sterilizer malfunction.



This is an example of sterilizer failure chart, where you can observe that the sterilizer consecutively shows positive SPR levels, which demonstrates that there are no random situations but a consistent failure in some of the sterilizer's parameters. Here, the sterilizer was showing normal Negative SPR values and started to develop positive values, until the sterilizer was repaired and SPR values return to negative levels. If you obtain a chart like this, you need to urgently stop using that sterilizer, program its maintenance/repair and re-evaluate its performance after repair (where you need to obtain consecutive negative SPR values).

## HMS Tab (Hygiene Monitoring System Tab)

The HMS Tab contains a form in which all relevant information about protein pen test analysis is displayed, along with the incubation remaining time.

This form shows a number of editable fields, very similar to those found in the SCBIs Tab, such as:

- **Incubation Data:** Information about the incubation process.
- **Position** (automatic information): Shows the position in which the protein incubation process is being performed.
- **Date:** (Automatic information) Displays date and time of Protein pen incubation.

- **Remaining time status bar:** (Automatic information) Displays the incubation remaining time.

### • Operating Data of the Incubator.

- **Avg. Temp.:** (Automatic information) Average temperature during the incubation period of that Protein test.

• **Hygiene Indicator Data:** Information about the Protein test used.

- **Product code:** (Manual information) Product code of the protein test.

- **Brand:** (Manual information) Brand of the protein test.

- **Batch:** (Manual information) Batch number of the protein test.

- **Result:** (Automatic information) Protein test result according to the incubator's information. This result can be "Positive" or "Negative", "Cancelled", "Invalid pen" or "Pen not detected".

- **Visual result:** (Manual information) Protein test visual confirmation through color change interpretation.

- **Protein level (µg):** (Automatic information) Quantitative Protein test result according to the incubator's information. This result is given in micrograms (µg) of protein. This information is provided through a BSA calibration curve.

- **Threshold:** Defines the protein level (µg) from which the hygiene indicator result will be considered as positive. For configuration enter [Home >>> Options](#)

Reference default value: 1 µg.

• **Printed Ticket Destination:** Book where you keep your washing records

- **Book #:** (Optional information) Complete with the logbook number corresponding to the washing process.

- **Sheet #:** (Optional information) Complete with the logbook page number corresponding to the washing process.

• **Process Information:** Information about the washing cycle and washer machine.

- **Cycle:** (Manual information) Cycle number, provided in the washer ticket or display.

- **Prog. Number:** (Manual information) Program used for that specific washing cycle.

- **Surface:** (Manual information) Gives information about the item that has been sampled.

- **Identification:** (Manual information) Descriptive name of the washer machine used for the process. This field must be filled utilizing the Search Washer tool [🔍](#).

- **Washer brand:** (Manual information) Washer's brand. This field must be filled utilizing the Search Washer tool [🔍](#).

- **Machine serial:** (Manual information) Serial number of the washer. This field must be filled utilizing the Search Washer tool [🔍](#).

- **Observations** (optional information): You can fill in this box with any relevant information that has not been considered in other fields.

The screenshot displays the HMS Tab software interface. At the top, there's a menu bar with 'Home', 'View', and 'Help'. Below it is a toolbar with icons for file operations and a status bar indicating 'Incubation available 2'. The main area is divided into several sections:

- SCBIs Results:** A table with columns: #, Date, Ticket number, Brand, Product code, Batch, Result, and Visual result. It shows three rows of data.
- Incubation Data:** Fields for Position, Date, Remaining time (00:00), Ticket number, and Avg. Temp. (0).
- Protein pen data:** Fields for Product code, Brand, Batch, Result, Visual result, Protein level (µg), and Threshold.
- Printed Ticket Destination:** Fields for Book #, Sheet #, Cycle Number, Program Number, and Surface.
- Washing Process Information:** Fields for Washer ID, Washer brand, and Washer serial.
- Observations:** A text area for additional notes.

At the bottom, a status bar shows: 'Selected incubator: BSL12 9999 0208', 'Incubation Prog. 1: 1h / 60°C', 'Incubation Prog. 2: 3h / 60°C', and 'Last readout: 21/11/2020 09:20 T: 60.2°C S: 2.60 Kg'.



## HMS Tab (Hygiene Monitoring System Tab)

### Storing HMS Results

Once the Protein test incubation has finished, the amount of protein will be shown in the "Protein Level" field, and two buttons will be automatically enabled in the lower right corner of the form, except for those incubations with "Pen not detected" or "Invalid pen" as result, which cannot be archived. The left "bin" button will allow the user to eliminate that reading and the right one will let the user save the Protein test result. If you want to save the results you have to complete all the mandatory information, otherwise, you won't be able to permanently archive the protein tests results. Similarly to the Biological Indicators, the amount of mandatory fields depends on the "Required fields Level" setting.

If the user has a Traceability Exchange+ license, the completed results will be stored automatically, regardless of the fields completed.

The list of required fields for "High" (default configuration) includes: product brand and batch, visual result, Cycle, Surface, Washer identification, brand and serial number

The screenshot displays the HMS Tab software interface. At the top, there is a navigation bar with 'Home', 'View', and 'Help' options. Below this is a toolbar with various icons. The main window is divided into two sections: a table of incubation results and a detailed form for a specific incubation.

**Incubation Results Table:**

#	Date	Ticket number	Brand	Product code	Batch	Result	Visual result	Protein level (ug)	Avg. Temp.	Book #	Sheet #
1	21/5/2020 09:33:00	20		Protein Test		Cancelled	---	0	59,9		
2		---		Protein Test			---	0	0		
3		---		Protein Test			---	0	0		

**Incubation Data Form:**

**Incubation Data:** Position: 1, Date: 21/5/2020 09:33:00, Remaining time: 00:00, Ticket number: 20, Avg. Temp.: 59,9

**Protein pen data:** Product code: Protein Test, Brand: [dropdown], Batch: [dropdown], Result: Cancelled, Visual result: ---, Protein level (ug): 0, Threshold: 1

**Printed Ticket Destination:** Book #: [input], Sheet #: [input]

**Washing Process Information:** Cycle Number: [input], Program Number: [input], Surface: [dropdown]

**Washer Information:** Washer ID: [dropdown], Washer brand: [dropdown], Washer serial: [dropdown]

**Observations:** [text area]

**Buttons:** Save result (blue button), [bin icon] (blue button), [refresh icon] (blue button)

**Status Bar:** Selected incubator: Bix12 9999 028, Incubation Prog. 1: 1h / 60°C, Incubation Prog. 2: 3h / 60°C, Last readout: 21/5/2020 09:33 T: 60,0°C S: 2/60 Readings: 150/150

## HMS Tab (Hygiene Monitoring System Tab)

### Overlapping results

In case you start a new Protein test analysis without having saved the previous results, the system will immediately inform this overlap through an emerging pop-up alert and a notification in red letters below the form. In this situation you must eliminate or save the actual (finished) readout so as to allow the system to update the program with the new reading given by the incubator. Once you have performed either elimination or saving of the previous result, your HMS Tab will automatically be updated with the new reading and display the regular options.

Home View Help

Incubators available: 2 Traceability Software ® v4.4 User: admin

#	Date	Ticket number	Brand	Product code	Batch	Result	Visual result	Protein level (ug)	Avg. Temp.	Book #	Sheet #
1	21/5/2020 09:33:00	20		Protein Test		Cancelled	---	0	59.9		
2	---	---		Protein Test		---	---	0	0		
3	---	---		Protein Test		---	---	0	0		

**Incubation Data** **Incubator Performance Data**

Position: 1 Date: 21/5/2020 09:33:00 Remaining time: 14:17 Ticket number: 20 Avg. Temp.: 59.9

**Protein pen data** (\*)Required Fields

Product code\*: Protein Test Brand\*: Batch\*: Result: Cancelled Visual result\*: --- Protein level (ug): 0 Threshold: 1

**Printed Ticket Destination** **Washing Process Information**

Book #: Sheet #: Cycle Number\*: Program Number\*: Surface\*: Washer ID\*: Washer brand\*: Washer serial\*: Save result

Observations:

**There is a PRO test in progress but the fields on this screen will not be updated until you save or discard the results from the previous test**

Selected Incubator: Bix12 9999 028 Incubation Prog. 1: 1h / 60°C Incubation Prog. 2: 3h / 60°C Last readout: 21/5/2020 09:35 T: 60,0°C S: 2/60 Readings: 153/153

# HMS Tab (Hygiene Monitoring System Tab)

## IQAS

Monitoring reprocessing of instruments by the use of statistical control charts provides assurance that the process is working as anticipated, and the residual protein on instruments is within the expected range.

An Internal Quality Assurance Scheme (IQAS) can be established with the aim of monitoring, over time, the efficiency of the cleaning process.

## Baseline development

The first step for an SSD is to measure reprocessed surgical instruments representing the full range of their workload to provide the basis upon which a monitoring system can be developed (Baseline).

There are two main approaches to instrument sampling:

- If a single measurement is to be made at each time point.
- For measurements that fall naturally into groups established by the user (for example, five instruments per week).

In case of the single approach, a total of 20 measurements should suffice initially from which parameters of the process can be estimated. In case of group more than 30 measurements will be required.

### • Procedure

- 1.1. Process your instrument as usual in your washer machine following the recommendations of the instrument manufacturer and the washer manufacturer.
- 1.2. Select a representative instrument for testing residual protein.
- 1.3. Test the instrument selected with a suitable Protein Pen test device following strictly the instructions for use of the device.
- 1.4. Incubate the Protein used according to the device Instructions for use or the Auto-reader User manual.
- 1.5. Before or during the incubation connect the auto-reader incubator to your PC and run the Traceability Software following the auto-reader User Manual.
- 1.6. Once within the Traceability Software, select the corresponding auto-reader in the drop-down menu:
- 1.7. Select the incubation position where the Protein Pen test is being incubated.
- 1.8. The first information displayed in the table refers to the Incubation Data and it will be filled automatically when the incubation finishes: Date and Average Temperature during the incubation.

HomeViewHelp

Traceability Software v4.4

User: admin

SCBIsSCBIs ResultsHMSHMS Results

PRO:3 COM4 4444 001

Bin 12 COM6 9999 003

#	Start time	Final time	Ticket number	Brand	Product Code	Batch	Process	D-Value [min.]	SCBI Status	Result	Avg. T	Book #	Sheet #
1			---						---		0,0		
2			---						---		0,0		
3			---						---		0,0		
4			---						---		0,0		
5			---						---		0,0		
6			---						---		0,0		

Incubation Data

Incubator Performance Data

Position: 1Start time:Final time:Ticket number:Avg. Temp.: 0,0

Biological Indicator Information

(\*)Required Fields

Brand:Product code:Batch:Process:D-Value [min.]:SCBI Status:Result:

Printed Ticket Destination

Sterilization Process Information

Book #:Sheet #:Sterilizer ID: Sterilizer Brand: Serial num.: Load number: Program Number:

Cycle:Cycle Parameters:Observations:

Selected Incubator:

## HMS Tab (Hygiene Monitoring System Tab)

During incubation:

#	Date	Ticket number	Brand	Product code	Batch
1	Running	---		Protein Test	
2	---	---		Protein Test	
3	---	---		Protein Test	

**Incubation Data**

Position: 1 Date: 21/5/2020 09:33:00 Remaining time: 14:39 Ticket number: --- Avg. Temp.: 0

After incubation:

#	Date	Ticket number	Brand	Product code	Batch
1	21/5/2020 09:33:00	20	Generic	Protein Test GX455	
2	---	---		Protein Test	
3	---	---		Protein Test	

**Incubation Data**

Position: 1 Date: 21/5/2020 09:33:00 Remaining time: 00:00 Ticket number: 20 Avg. Temp.: 59.9

1.9. The second information displayed in the table refers to the Protein Pen Test Data. Complete all required fields, including product code, product brand, and batch. The information can be found in the Protein Pen Test label. Or in the Protein Pen Validation Test label, either in the Positive Test (PPVTP) or in the Negative Test (PPVTN). Monitoring type and results are filled automatically as well as Protein level and Threshold. Visual Result instead should be filled according to the color of the reactive solution after incubation.

#	Date	Ticket number	Brand	Product code	Batch
1	21/5/2020 09:33:00	20	Generic	Protein Test GX455	
2	---	---		Protein Test	
3	---	---		Protein Test	

**Incubation Data**

Position: 1 Date: 21/5/2020 09:33:00 Remaining time: 00:00 Ticket number: 20 Avg. Temp.: 59.9

**CAUTION:** In order to record the visual result, remove the Protein Pen Test and verify the solution color at the moment the quantitative readout finishes.

1.10. The third information displayed in the table refers to the Printer Ticket Destination. Fill these fields with logbook number and page where the ticket will be saved. This is not mandatory

information to fill.

1.11. The fourth information displayed in the table refers to the Washing Process Information. Add the main information of your washer machine to the program pressing:

#	Identification	Brand	Machine serial
1	Washer1	Steelco	2233
2	Washer2	Belimed	123456
3	Washer3	Matachana	789
4	Washer11	Miele	5427

The washer database will open. You can add a new washer, edit the information about a specific washer or select the washer used for reprocessing the instrument tested.

#	Date	Ticket number	Brand	Product code	Batch
1	21/5/2020 09:33:00	20	Generic	Protein Test GX455	
2	---	---		Protein Test	
3	---	---		Protein Test	

**Incubation Data**

Position: 1 Date: 21/5/2020 09:33:00 Remaining time: 00:00 Ticket number: 20 Avg. Temp.: 59.9

**Protein pen data**

Product code: Protein Test Brand: Generic Batch: GX455 Result: Cancelled Visual result: Negative Protein level: ---

**Printed Ticket Destination**

Book #: 4 Sheet #: 3

**Washing Process Information**

Cycle Number: 4 Program Number: 3 Surface: 3

Washer ID: Washer brand: Washer serial:

Observations:

1.12. Once selected the washer machine, you must complete the information about the cycle number, program number and identify the surface/instrument tested.

1.13. Save the result pressing the button:

1.14. You can delete all the information pressing the button: All results saved will be available in HMS Results Tab. Repeat 1.1 - 1.13 steps anytime you want to record a test result of a washing instrument.

### Control Analysis


Ongoing Monitoring (HTM 01 - 01 Recommendation):

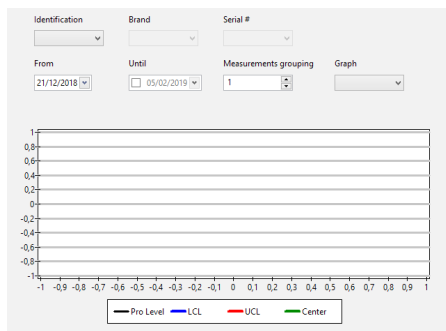
A chart for each wash chamber/WD should be set up. The

## HMS Tab (Hygiene Monitoring System Tab)

number and types of instruments should be tested as follows:  
50 instruments per wash chamber/WD, at least every three months, chosen from difficult-to-clean instruments (for example, box joints, serrations, hinges, graters and reamers and complex retractors) where used. Other difficult-to-clean instruments should be identified and included in this testing.

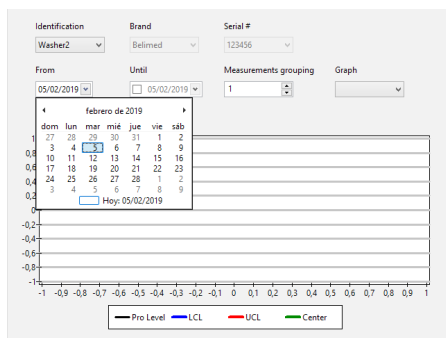
### Procedure

2.1. Once the first 20 measurements have been obtained, you can start the control analysis by pressing the button:   
The graph Tab will be displayed:



2.2. Select your washer by pressing the Identification drop-down menu. The Brand and Serial number of the washer will be filled automatically.

2.3. Select your washer by pressing the Identification drop-down menu. The Brand and Serial number of the washer will be filled automatically.

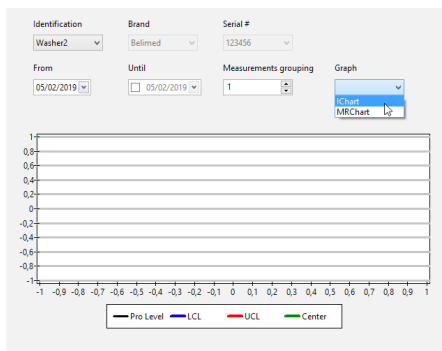


2.4. By default, the final date corresponds with the actual date. You can modify this information by pressing the corresponding drop-down menu.

2.5. Modify the measurement grouping option if you want to execute a group approach. You must consider more than 30 measurements for the baseline and 10 as a maximum number of measurements per group, in accordance with HTM 01-01.

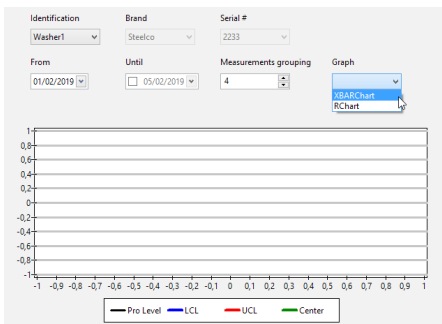
2.6. If you want to continue with the single approach (measurement grouping = 1) two options will be displayed in the Graph Menu:

- I-Chart (Individual Chart): log<sub>10</sub> residual protein vs. measurement number.
- MR-Chart (Moving Range Chart): absolute difference between log<sub>10</sub> residual proteins vs. difference number.



2.7. If you want to execute a group approach (measurement grouping >01) two options will be displayed in the Graph Menu:

- XBAR-Chart: group average vs. group number.
- R-Chart (Range Chart): group range vs. group range number.



## Results interpretation

The monitoring of each process must vary randomly among the average and within the control limits (Upper control Limit and Lower Control Limit), and the process variation must be random and within below the control limit also. If a measure goes above the Upper Control Limit, the sample must be rewashed and the instruments must be sampled again. The maximum upper limit that is permitted in the standard is 5 µg per instrument side (according to HTM 01-01).

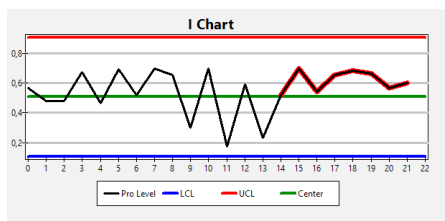
Anyway, measurements that fall outside of the control limits are an indication that the process is no longer in control. This may warrant an investigation to detect and eliminate any underlying causes.

Before interpreting the I-Chart (single approach) or XBAR-Chart (group approach), the MR-Chart or R-Chart (respectively) should be examined to determine if process variations are in control. If the MRChart / R-Chart are not in control, then the control limits in the I-Chart / XBAR-Chart cannot be considered approximate. Even when the measurements in the I-Chart / XBAR-Chart are within the control limits, it does not necessarily mean that the system is under control.

What is important is whether there appears to be any systematic behavior in sequential measurements. For example, if there were ten successive measurements all above the center line, then this might indicate that a systematic change to the process has occurred, since we would expect half of these measurements to fall either side of the center line. To aid interpretation of statistical process control charts, a series of situations that may indicate an "out of control" process have been suggested (HTM01-01). Our software is prepared to monitor "Out of control" Schemes detecting this situations shown below.

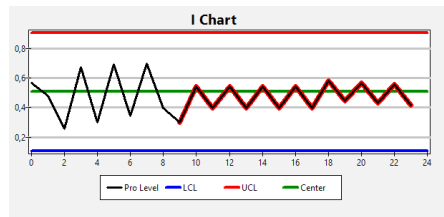
### Example 1. Out of control type 1: Instability.

In this case 8 or more consecutive measurements are on the same side of the average.



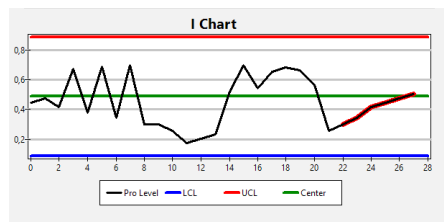
### Example 2. Out of control type 2: Alternated.

In this case, there are 14 measurements where there is an alternating pattern.



### Example 3. Out of control type 3: Monotonic.

In this case 6 consecutive measurements present a monotonic trend (all increasing or decreasing).



# HMS Results Tab

This Tab shows all saved results for Hygiene Monitoring tests performed with the incubator. As in the SCBIs Results Tab, this Tab displays the same functionality and allows filtering and sorting of the HMS tests results. For more details, please read the *Sorting and Filtering of results* section.

Additionally, this Tab possesses a column with a checkable field for every record. If it is checked, that measurement will be taken into account for the HTM01-01 calculations, otherwise it will be omitted.

HomeViewHelp

Incubators available: 2

Traceability Software® v4.4

User: admin

SCBIsSCBIs ResultsHMSHMS Results

Sort by:Start timeFrom14/05/2020Until21/05/2020OperatorBrandResultNegative

Showing all results

#	Lot	Serial #	Operator	Finish Date	Ticket number	Brand	Product code	Batch	Monitoring Type	Result	Visual result	Protein level
1	PROx34444	1	admin	21/5/2020 09:45:00	105	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
3	PROx34444	1	admin	21/5/2020 09:46:00	108	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
1	PROx34444	1	admin	21/5/2020 09:46:00	106	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
1	PROx34444	1	admin	21/5/2020 09:47:00	109	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
3	PROx34444	1	admin	21/5/2020 09:49:00	112	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
2	PROx34444	1	admin	21/5/2020 09:48:00	111	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
1	PROx34444	1	admin	21/5/2020 09:50:00	113	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
2	PROx34444	1	admin	21/5/2020 09:50:00	114	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
3	PROx34444	1	admin	21/5/2020 09:50:00	115	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
2	PROx34444	1	admin	21/5/2020 09:51:00	117	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
1	PROx34444	1	admin	21/5/2020 09:52:00	118	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
1	PROx34444	1	admin	21/5/2020 09:54:00	120	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
2	PROx34444	1	admin	21/5/2020 09:54:00	121	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0
2	PROx34444	1	admin	21/5/2020 09:55:00	122	Generic	Protein Test	GX455	HTM01-01	Positive	Positive	0
1	PROx34444	1	admin	21/5/2020 09:56:00	123	Generic	Protein Test	GX455	HTM01-01	Negative	Negative	0

Selected incubator: PROx3 4444 001Last readout: 21/5/2020 09:57 T: 59,9°C S: 2/60 Readings: 111/111

## Reports generation

### Printed reports

The results stored in the history can be printed by pressing the corresponding button on the toolbar (this is shown highlighted in the following image):

Print icon

Incubators available: 2

By default, the printing comprises the totality of the results stored by the application. However, if any filter was previously applied, the printing will be delimited to the records that match the criteria for filtering. On the other hand, there is also the possibility to print a single result. For this, the user should display the printing options (by

clicking on the arrow to the right of the printing button) and select the option *Print selected record*. Once the printing order is given, the program presents a preview screen as shown in the following image:


## Reports generation



<b>Company Name</b> Departament Name Sector Name Traceability Software				
<b>Start time</b> 20/5/2020 14:44 <b>Machine lot:</b> Blix129999 <b>Product brand</b> mn <b>Sterilizer Brand</b> Gener001 <b>Book #</b> 54 <b>Cycle Parameters</b>	<b>Final time</b> 20/5/2020 14:45 <b>Machine serial</b> 28 <b>Product code</b> mn <b>Serial num.</b> 1245 <b>Sheet #</b> 54	<b>Biological Indicator label</b> Incubation Prog.: 1h / 60°C <b>Product batch</b> 534 <b>Cycle Number</b> 5435 <b>SCBI Status</b> Positive <b>Observations</b>	<b>Ticket number</b> 3 <b>Sample #</b> 2 <b>Process:</b> STEAM (121) <b>Load number</b>  <b>Result</b> Cancelled	<b>Operator</b> admin <b>Avg. Temp.</b> 60.0 <b>D-Value</b> 4,000 <b>Program Number</b> 5435 <b>SPR</b> N/A

From that preview the user can perform the printing itself, by clicking on the first button on the toolbar.

### Virtual Ticket Generation



From version 4.3, the software includes the possibility to generate a virtual report of the last incubations made, similar to the ticket printed by the device. You can access this tool

through the button  on the toolbar. The following window will be displayed

Ticket number	Start Time	Final Time	Program	Sample Tube	Result	Temp
<input checked="" type="checkbox"/> 90	22/04/2020 10:20:19	22/04/2020 10:21:00	Ultra / 60°C	1	Cancelled	59.9
<input checked="" type="checkbox"/> 89	22/04/2020 10:18:48	22/04/2020 10:21:00	Ultra / 60°C	2	Cancelled	59.9
<input checked="" type="checkbox"/> 88	22/04/2020 09:49:00	22/04/2020 10:09:00	Ultra / 60°C	1	Negative	60.0
<input checked="" type="checkbox"/> 87	22/04/2020 09:49:59	22/04/2020 09:50:00	Ultra / 60°C	2	Cancelled	60.0
<input checked="" type="checkbox"/> 86	22/04/2020 09:43:54	22/04/2020 09:46:00	Ultra / 60°C	2	Cancelled	59.9
<input checked="" type="checkbox"/> 85	22/04/2020 09:43:54	22/04/2020 09:46:00	Ultra / 60°C	1	Cancelled	59.9
<input checked="" type="checkbox"/> 84	22/04/2020 09:43:15	22/04/2020 09:44:00	Ultra / 60°C	2	Cancelled	59.9
<input checked="" type="checkbox"/> 83	22/04/2020 09:43:13	22/04/2020 09:44:00	Ultra / 60°C	1	Cancelled	59.9
<input checked="" type="checkbox"/> 82	22/04/2020 09:24:09	22/04/2020 09:27:00	Ultra / 60°C	1	Cancelled	59.9
<input checked="" type="checkbox"/> 81	22/04/2020 09:24:11	22/04/2020 09:27:00	Ultra / 60°C	2	Cancelled	59.9

☒ Select All

Page 1 of 5
 


It is possible to select up to a maximum of 10 records in order to generate a printed report.



## Equipment calibration



Before starting the calibration process, make sure that you won't need the incubator for the next 2-3 hours, because that's approximately what this process takes.

The temperature calibration tool available in the Traceability Software allows adjustment of the auto-reader incubator's temperature. It is an easy-to-use tool that facilitates regular temperature calibration according to a procedure determined by the program. As a consequence of equipment's aging, some changes in the heating system may happen. In order to compensate those small changes, the function allows a precise adjustment of the incubation temperature.

This tool allows to generate a calibration certificate for the equipment. Some of the info registered in this certificate is the institution to which the equipment belongs, staff who performed the procedure, equipment information, the reference device ID, environmental conditions and data on calibration.



The calibration process failure or operating errors could cause equipment malfunction.

Make sure you have the knowledge and the proper equipment to perform this procedure properly. Any loss or damage that may result from the unsuitable use of the equipment or failures of the calibration tool will not be covered by the warranty. Please refer to the warranty certificate included with your auto-reader incubator for more information.

### Calibration process

To perform this procedure, make sure you have at hand the stock external thermometer included with your auto-reader incubator. If the thermometer is not available, please contact us for a replacement.

To start calibration process, press button  and follow the program's instructions.



Only start calibration process when the equipment temperature is stable.

After calibration has finished, a certificate of calibration will automatically appear on your screen. You will be able to print or save it.


### Traceability Exchange

From version 4.4, a new module named Traceability Exchange is added, which acts as interface between the compatible incubators and the third parties software, creating files available for the user to implement the data interchange between both systems.

Each result is exported at the time it is saved within the software.

A file that once generated, represents a unique incubation process. In order to know in greater detail the structure and the internal format of these files for a correct implementation, the **Developer's manual** is available.

This module is the only component that requires a license in order to operate. It has a one-year trial period, and once finished, it automatically deactivates in case it does not have a valid license.

When installing the new software version, the functionality is deactivated by default. You have to access the menu  in order to activate it and start the trial period. If the trial period was never initiated, the license status will appear as "Not activated" and an option to start this functionality will also show up.

**NOTE:** It is necessary to have access to Internet in order to start the trial period or to renew the license

### Traceability Exchange+ (Plus)


From version 4.4, the software incorporates a new mode to achieve the export of incubation data to XML. The trial period is 3 months, and it has priority over the module's classic mode.

Unlike the one mentioned in the previous section, this license allows the results of Biological and Hygiene Indicators incubations to be automatically stored as soon as they are finished, without the need for user intervention, and archiving only the minimum and indispensable data. This new module promotes the interconnection with other third party systems, however, the records archived with mode are not compatible with the calculation tools of RPE and HTM01-01.

The structure and internal format are maintained between the modes but due to their nature, those generated by the PLUS version will have a greater amount of uncompleted data.

## Other functionalities

### Clock synchronization


By pressing the icon  you can synchronize the incubator's clock (date and time) with that of your computer's system.

### Full screen mode

The program offers a "Full Screen Mode". This mode can be activated by pressing the F11 key or through corresponding option in the menu.

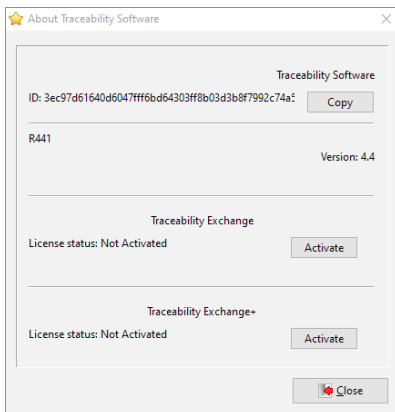
View >> Full Screen Mode

### Screen captures

The application provides a function that allows taking a screenshot and saving it in a folder at the user's choice. This function can be accessed through the  button on the toolbar. This feature serves the user to easily take a snapshot in the event that the program is defective, so that it can then be sent for analysis.

### Software and incubator information

The application includes a screen through which various data can be consulted, such as the serial number of the incubator and the program version.



This screen is accessed through the option:

Help >> About ...

### Software requirements

The application is compatible with Windows 7, 8 and 10 (32/64 bits versions). In terms of software, the application does not raise any additional requirement, for the installer already contains all the necessary elements for its operation.

### Hardware requirements

The program is extremely light in relation to the use of the system resources, so it should work without problems in any computer model that has come to market in the last four years. As a general guideline, these are the minimum recommended hardware requirements:

- Microprocessor: Intel Atom 330
- RAM: 2 GB
- Display: 1360 x 768 resolutions
- Other:
  - Free USB ports to allow the connection to incubators.
  - Network connection to access Ethernet incubators (no internet required).



