Bionova® Cloud Traceability Software

Automatic System for Quality Control &
Traceability of Infection Control Processes

Terragene®

Index

# ■ Onboarding

About Bionova® Cloud

Bionova® Cloud Environment is a Cloud based solution that integrates the information generated by Terragene® electronic devices with an easy-to-use Web App for the traceability of sterilization and disinfection control applications.

The Bionova® Cloud Environment is composed by two main components: the Bionova® Cloud Traceability Software which is a Web Based application, and the Bionova® Cloud Agent which is a Microsoft™ Windows App that acts as an interface between the Terragene® compatible devices and the web based application.
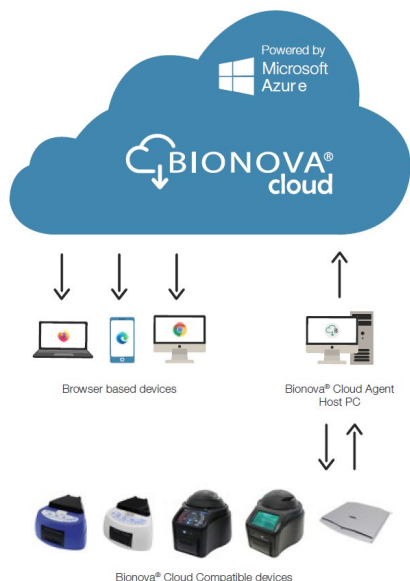
Browser based devices

Bionova® Cloud Agent Host PC

Bionova® Cloud Compatible devices

The Bionova® Cloud Agent handles all communications with Terragene® compatible electronic devices and the Host PC where the Agent App runs.

Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Traceability Software and sends the information generated from the devices to the Microsoft™ Azure powered Cloud server where the Traceability Software Web App runs and stores the information.

The user can then access to the Cloud saved information through any device with a compatible web browser.

First Access

1|Create your Company and the Administrator Account accessing to https://bionovacloud.com

2|Fill your company details and complete the registration process. Keep in mind that the e-mail provided during the registration process will be considered by the system as the administrator user account email address.

3|Verify the Administrator user account through the verification email sent to the provided email address.

4|Log-in to Bionova® Cloud Web interface accessing to https://bionovacloud.com/login. During the first time access, the system will ask for the administrator to set a new password.

5|Go to the *Company > Sector* tab on the Bionova® Cloud Web Interface left side menu and create new Sectors for your Company. After a sector has been created, the administrator user can assign users to each sector and set at the same time each user role as a Sector Supervisor or a Sector Operator accessing the *Company > Users* tab on the Web Interface left side menu.

6|Download and Install the Bionova® Cloud Agent APP to your Computer.

7|Run and log in into the APP using the credentials of one of the previously created users (Administrator, Supervisor, Operator).

8|Connect a compatible Terragene® electronic device to the host PC where the Agent is running and use the device as described in its user manual to obtain a readout result of a compatible indicator.

Important: Bionova® Cloud Agent APP will upload readout result data to the Bionova® Cloud web interface using the credentials of the user logged-in to the Agent at the moment where the upload process takes place. Each time a readout result is uploaded, the data will be linked to the sector to which the user belongs. Please refer to the *User Account Types And Access Permissions* section for more information.

9|Access to the readout results through the Bionova® Cloud Web Interface. Depending on the indicator used, the results will be available on the *Biological Indicators* tab, the *Hygiene Monitoring* tab, or the *Trazanto Results* tab on the Web Interface left side menu.

Important: Make sure to log-in to the web interface with the same user credentials used on the Bionova® Cloud Agent APP to make sure you have the access rights to access to the uploaded data. Please refer to the *User Account Types And Access Permissions* section for more.

You can also access to a Step-by-step quick start video to learn how to use Bionova® Cloud environment following this LINK

◼ Bionova® Cloud Web Interface Screen layout

Main Screen layout

Bionova® Cloud Traceability Software's web interface screen is divided in 4 sections:

1|Header: Contains the current user's session information and a button to show or hide the left side menu.
2|Download Panel: A panel with links to download useful resources such as User Manual, Bionova® Cloud Agent, and more.
3|Key process indicators: A customizable panel with KPI graphics and statistics of the company overall performance.
4|Left Side menu: Contains links to all key sections of Bionova® Cloud Traceability software.

General Screen layout

Bionova® Cloud features a standardized way of representing information on all Tables and Reports screens.

1|Table/Report name
2|Search engine: Allows to filter the table records by keyword.
3|Header: Contains the name of each column, and allows you to sort the rows contents by clicking on it.
4|Body: The table body contains in its rows all the readout results information.
5|Action buttons: Buttons that allow you to perform actions as Editing, See details of a result, deleting a result, and more.
6|Table footer: Allows to browse readout results by page.

◼ User account types and access permissions

User account types

Bionova® Cloud features 3 different types of user accounts with different level of access to Bionova® Cloud Features and stored data.

1|Administrator account
The Administrator user (Admin account) has full access rights to all Bionova® Cloud Features. The Admin account is created at the moment of creating the company on Bionova® Cloud Web interface and has the following permissions.
◼ Add or remove Sectors (see *Managing company sectors and equipment* section).
◼ Add or remove users accounts associated to any Sector of the company. Reset the password of an account (see *User Account Management* section).
◼ Modify Bionova® Cloud global company settings (see *Company settings* section).
◼ Manage Licenses for extended functionality modules such as Bionova® Exchange (see *Licenses* section).
◼ Access to the Company User Activity Event log (see *Company event log* section).
◼ View readout result information of all the Sectors of the company.

2|Supervisor account
The Supervisor user has access rights to sector management settings. The account has the following permissions.

◼ Add or remove users accounts associated to the Sector. Reset the password of an account (see *User Account Management*).
◼ Manage equipment associated to the Sector as Sterilizers, Washers, and Disinfectors (see *Managing company sectors and equipment* section).
◼ View all Auto-readers associated to the Sector (see *Connected Auto-readers* section).
◼ View readout result information of the sector.

3|Operator account
The operator account does no have access to any company or sector management settings, and its intended to be used by the sector technicians. The account has the following permissions.
◼ Add new readout results.
◼ View readout result information of the sector.

User account management

Adding and removing accounts

The Administrator user of can add or remove any user

↵ User account types and access permissions

accounts of the Company regardless of the sector to which the user belongs. In the other hand, supervisor users can add or remove users as well but only of their own sector. To add or remove users access to *Company > Users* section tab on the Bionova® Cloud Web Interface left side menu.

Once a company is created, no user can register to the company by its own. All new accounts can only be created by Administrator or Supervisor users.

Password management

The Admin user can reset the password of any account of the company, and supervisor users can reset the password of accounts linked to the sector to which they belong. This can be useful to make sure the passwords of all users are changed regularly to comply with each institution IT policies.

Nevertheless, if a user forgets their own password and can not log in to the Bionova® Cloud Environment, the user can carry out an automated password recovery process through the login screen of Bionova® Cloud Web Interface. An email will be sent to the user email address to start the process.

Also, if a user wish to change their password, that can be accomplished accessing to the *Configuration > Change Password* section tab on the Bionova® Cloud Web Interface left side menu.

Readout result data access rights

Bionova® Cloud Environment philosophy for readout results information data access is that users of the same sector (Supervisors and Operators) should be able to access to the sector's readout result data at any moment. This approach allows each user to know the status of the readout results of the sector to which they belong in real time, avoiding re-works and communication problems that could arise because of poor situational awareness.

As an exemption to this rule, the Admin user can access to the readout result data of all sectors of the Company. This allows the Admin user to be able to be aware of the global performance of the company.

■ Managing Company sectors and equipment

Managing sectors
The Administrator user can add or remove sectors from the

company accessing the *Company > Sectors* section tab on the Bionova® Cloud Web Interface left side menu. A good practice is to create a sector for each sterilization and cleaning department of your company.

Managing equipment

The Administrator and Supervisor users can add or remove Sterilizers, Washers, or Disinfectors of the Company Sectors accessing the *Equipment* section tab on the Bionova® Cloud Web Interface left side menu. Adding details of the sterilization and infection control equipment used physically on your processes is a good practice, as this will allow to link the equipment information each time a readout result is saved. This allows you to analyze equipment performance trends based on the readout results history.

■ Connected Auto-readers

All the Auto-readers on your Company or Sector will be listed on the *Auto-Readers* section tab on the Bionova® Cloud Web Interface left side menu.
Color codes: *Green* means the Auto-readers is connected, *Red* means the Auto-reader is disconnected, *Yellow* means the Auto-reader is not assigned to a Sector.
To assign an Auto-reader to a sector, click on the *Assign sector action* button. To Free an incubator from a sector, click on the *Free incubator* button.

■ Biological Indicators

The *Biological Indicators* tab of the left side menu its the main place for accessing to information related to the incubation and readout results of Self-Contained Biological Indicators (SCBIs). Readout results in this section can be in either 2 stages:
■ **Incubation is still running:** All ongoing readings will be listed on the *Running* section.
■ **Incubation is finished:** All finished incubations will be listed on the *Finished* section.

Running Screen

This screen allows real-time monitoring of the incubation and readout process. It shows elapsed incubation time and status of SCBIs ongoing readings.
The user will find the list of fields *(columns)* below:
■ **Readout number:** *(Automatic information)* Number assigned to index each SCBI readout results.
■ **Position number:** *(Automatic information)* Shows the Incubation position number where the SCBI is being incubated

↵ **Biological Indicators**

on the Auto-reader.
■ **Program:** *(Automatic information)* Shows the Incubation Program selected on the Auto-reader.
■ **Start time:** *(Automatic information)* Shows the exact date and time when the incubation process started.
■ **Time elapsed:** *(Automatic information)* Shows the minutes that have passed since the beginning of the incubation process.
■ **Incubator:** *(Automatic information)* Shows Model, Batch, and serial number, of the Auto-reader in which the incubation process is carried out.

Finished Screen

Once an incubation process has been completed, and a readout result informed by the Auto-reader, the result will be moved from the *Running Screen* to the *Finished Screen* automatically.
The *Finished Screen* allows the user to access all finished incubations, and use the *Action* buttons on each readout result row to add detailed information to provide context to the result. Such information include: Bach number of the SCBI, Visual result status, equipment used to expose the SCBI, etc.

Saving results

Once the details of a readout result have been edited and the required fields completed, click on the *Confirm* button to link changes to the finished result.
Linking the changes using the *Confirm* button will update the details of a readout result. The result will be kept on the *Finished Screen* allowing further editions to the details.
Once all the details of a readout results are completed and the result is ready to be saved, click on the *Confirm And Move To Saved* button on the result editing screen to save the result to Bionova® Cloud database. Saved results will be available on the *Dashboard > Saved* tab on the left side menu.

Multiple results can also be saved at the same time by selecting the completed readout results, and clicking on the *Multiple To Saved* button on the *Finished Screen*.

Finished Screen references

The colored icon at the beginning of each record represents the result of the readout.
Status colors:

Red: POSITIVE

Green: NEGATIVE

Grey: ANY OTHER STATUS

The user will find the list of fields *(columns)* below:
■ **Readout number:** *(Automatic information)* Number assigned to index each SCBI readout result.
■ **Position number:** *(Automatic information)* Position on the incubator where the SCBI is being incubated and read.
■ **Start time:** *(Automatic information)* Shows the exact date and time of the incubation start.
■ **End time:** *(Automatic information)* Shows the exact date and time of the incubation end.
■ **Program:** *(Automatic information)* Selected program in the incubator.
■ **Result:** *(Automatic information)* Readout result informed by the incubator (Positive, Negative, or Canceled).
■ **Average Temperature:** *(Automatic information)* Average temperature during the SCBI incubation period.
■ **Ticket number:** *(Automatic information)* Shows the ticket number assigned by the Auto-reader.
■ **Incubator:** *(Automatic information)* Shows Model, Batch, and serial number, of the Auto-reader in which the incubation process is carried out.

Edit window references: Sterilization SCBIs

Note: When editing each readout result details, some of the fields of the editing screen are automatically completed by the Auto-reader, and some of the fields must be completed manually by the user. The amount of required fields to be manually completed by the user can be configured by modifying the *Mandatory fields level* setting on the Company Settings. (see *Company Settings* section).

■ **Product:** SCBI being incubated.
■ **Lot:** SCBI lot number.
■ **Process:** Conditions for the calculation of the D-value. The

↵ Biological indicators

user can find this information on the SCBI *Instructions for Use* (which includes the SCBI lot quality certificate).

■ **D-value:** Provides information about the resistance of that SCBI batch. The user can find this information in the SCBI accompanying documentation (which includes the SCBI instructions for use and quality certificate). Be careful to choose the correct D-value considering the *Process* selected in the previous field.

■ **SCBI condition:** You have to choose between 2 options: *Positive* (positive control, not exposed) or *Exposed* (to the sterilization cycle).

■ **Book number:** Complete with the number of the record book corresponding to the sterilization process.

■ **Page number:** Complete with the page number of the record book corresponding to the sterilization process.

■ **Program number:** The sterilizer program used for that cycle.

■ **Cycle:** Cycle number, provided on the sterilizer display and/ or the ticket.

■ **Sterilizer:** The sterilizer used for the process.

■ **Conditions:** You can fill in this box with details about the cycle (not mandatory information).

■ **Comments:** You can fill in this box with any relevant information not considered in the other fields (not mandatory information).

■ **Load Number:** Day's load number.

Edit window references: Disinfection SCBIs

Note: When editing each readout result details, some of the fields of the editing screen are automatically completed by the Auto-reader, and some of the fields must be completed manually by the user.

The amount of required fields to be manually completed by the user can be configured by modifying the *Mandatory fields level* setting on the Company Settings (see *Company Settings* section).

■ **Product:** SCBI being incubated.

■ **Lot:** SCBI batch number.

■ **SCBI condition:** You have to choose between 2 options: *Positive* (positive control, not exposed) or *Exposed* (to the sterilization cycle).

■ **Book number:** Complete with the number of the record book corresponding to the sterilization process.

■ **Page number:** Complete with the page number of the record book corresponding to the sterilization process.

■ **Cycle:** Cycle number, provided on the sterilizer display and/ or the ticket.

■ **Disinfection machine:** The disinfection machine used for the process.

■ **Conditions:** You can fill in this box with details about the cycle (not mandatory information).

■ **Peroxide level**: Peroxide level used during the disinfection.

■ **Comments:** You can fill in this box with any relevant information not considered in the other fields (not mandatory information).

■ Hygiene Monitoring

The *Hygiene Monitoring* tab of the left side menu its the main place for accessing to information related to the incubation and readout of PRO1 indicators.

Readout results in this section can be in either 2 stages:

■ **Incubation is still running:** All ongoing readings will be listed on the *Running* section.

■ **Incubation is finished:** All finished incubations will be listed on the *Finished* section.

Running Screen

This screen allows real-time monitoring of the incubation and readout process. It shows elapsed incubation time and status of PRO1 indicators ongoing readings.

The user will find the list of fields *(columns)* below:

■ **Reading number:** *(Automatic information)* Number assigned to index each PRO1 indicator readout result.

■ **Position number:** *(Automatic information)* Shows the Incubation position number where the PRO1 indicator is being incubated.

■ **Start time:** *(Automatic information)* Shows the exact date and time when the incubation process started.

■ **Elapsed time:** *(Automatic information)* Shows the minutes that have passed since the beginning of the incubation process.

■ **Program:** *(Automatic information)* Program selected in the incubator.

■ **Visual result:** *(Manual information)* Visual confirmation of protein quantity through color change interpretation.

■ **Incubator:** *(Automatic information)* Shows model, batch, and serial number, of the Auto-reader in which the incubation process is carried out.

Finished Screen

Once an incubation process has been completed, and a readout result informed by the Auto-reader, the result will be moved from the *Running Screen* to the *Finished Screen* automatically.

The *Finished Screen* allows the user to access all finished incubations, and use the *Action* buttons on each readout result row to add detailed information to provide context to the result. Such information include: bach number of the PRO1 indicator, visual result status, equipment used to expose the PRO1 indicator, etc.

Saving results

Once the details of a readout result have been edited and the required fields completed, click on the *Confirm* button to link changes to the finished result.

Linking the changes using the *Confirm* button will update the details of a readout result. The result will be kept on the *Finished Screen* allowing further editions to the details.

Once all the details of a readout results are completed and the result is ready to be saved, click on the *Confirm And Move To Saved* button on the result editing screen to save the result to Bionova® Cloud database. Saved result will be available on the *Dashboard > Saved* tab on the left side menu.

Multiple results can also be saved at the same time by selecting the completed readout results, and clicking on the *Multiple To Saved* button on the *Finished Screen*.

Important: If the working mode for your Auto-reader is set as ISO 15883-5, the *Confirm* button will be replaced by the *Assign Area* button. This allows to link swabbing surface information obtained through the Surface Eye APP to your readout result. To know more about how to configure Bionova® Cloud Working Mode please refer to the *Company Settings* section.

Finished screen references

The colored icon at the beginning of each record represents the result of the readout.
Status colors:

Red: POSITIVE

Green: NEGATIVE

Grey: ANY OTHER STATUS

The user will find the list of fields *(columns)* below:
■ **Readout number:** *(Automatic information)* Number assigned to index each PRO1 indicator readout result.
■ **Position number:** *(Automatic information)* Position on the

incubator where the PRO1 indicator is being incubated and read.
■ **Start time:** *(Automatic information)* Shows the exact date and time of the incubation start.
■ **End time:** *(Automatic information)* Shows the exact date and time of the incubation end.
■ **Result:** *(Automatic information)* Readout result informed by the incubator.
■ **Visual result:** *(Manual information)* Visual confirmation through color change interpretation.
■ **Protein level (µg):** *(Automatic information)* Shows the protein quantity found on the sample. This result inform the equivalent µg of protein quantity found on the sample using a BSA (Bovine Seric Albumin) calibration curve.
■ **Ticket number:** *(Automatic information)* Shows the ticket number assigned by the Auto-reader.
■ **Incubator:** *(Automatic information)* Shows model, batch, and serial number, of the Auto-reader in which the incubation process is carried out.

Edit window references: PRO1 Indicators

Note: When editing each readout result details, some of the fields of the editing screen are automatically completed by the Auto-reader, and some of the fields must be completed manually by the user. The amount of required fields to be manually completed by the user can be configured by modifying the *Mandatory fields level* setting on the Company Settings (see *Company Settings* section).

■ **Product:** PRO1 indicator being incubated.
■ **Lot:** PRO1 indicator lot number.
■ **Book number:** Complete with the number of the record book corresponding to the cleaning process.
■ **Page number:** Complete with the page number of the

record book corresponding to the cleaning process.
■ **Cycle:** Cycle number, provided on the Washer display and/or the ticket.
■ **Surface:** Provides information about the item that has been sampled.
■ **Washing machine:** The machine used for the process.
■ **Visual result:** Visual confirmation of proteins through color change interpretation.
■ **Comments:** You can fill in this box with any relevant information not considered in the other fields (not mandatory information).

■ Chemical Indicators

The *Trazanto Results* tab of the left side menu its the main place for accessing to information related to readout information of Chemical Indicators for washing and sterilization process read by the Trazanto Reader. Readout results in this section can be in either 2 sections depending on the chemical indicator used:

■ **Sterilization chemical indicators:** All Trazanto readout results of compatible indicators will be listed on the *Sterilization* tab.
■ **Cleaning chemical indicators:** All Trazanto readout results of compatible indicators will be listed on the *Cleaning* tab.

Sterilization And Cleaning Screens

The *Sterilization* and *Cleaning Screens* allows the user to carry out an image acquisition process of a chemical indicator using the Trazanto reader and to edit the readout details.

To carry out a new chemical indicator scan press the 📷 *Analyze* button and wait for a readout result to be informed. Once the readout process is completed on the Trazanto reader, the readout result will be displayed as a new row on the screen on the correct tab for the indicator type.

After the readout process is completed, use the *Action* buttons on each readout result row to add detailed information to provide context to the result. Such information include: batch number of the indicator, visual result status, equipment used to expose the indicator, etc.

Important: Before scanning an indicator make sure that indicator is compatible with the Trazanto reader by clicking on the *Chemical Indicators With Trazanto* drop-down menu. Readout results will only be informed for compatible indicators.

Saving results

Once the details of a readout result have been edited and the required fields completed, click on the *Confirm* button to link changes to the finished result.
Linking the changes using the *Confirm* button will update the details of a readout result. The result will be kept on the *Sterilization* or *Cleaning Screen* allowing further editions to the details.
Once all the details of a readout results are completed and the result is ready to be saved, click on the *Confirm And Move To Saved* button on the result editing screen to save the result to Bionova® Cloud database. Saved result will be available on the *Dashboard > Saved* tab on the left side menu.

Multiple results can also be saved at the same time by selecting the completed readout results, and clicking on the *Multiple To Saved* button on the *Finished Screen*.

Sterilization and Cleaning Screen references

The colored icon at the beginning of each record represents the readout result.
Status colors:

Red: POSITIVE

Green: NEGATIVE

Grey: ANY OTHER STATUS

The user will find the list of fields *(columns)* below:
■ **Readout number:** *(Automatic information)* Number assigned to index each chemical indicator readout result.
■ **Test date time:** *(Automatic information)* Shows the exact date and time of the readout.
■ **Automatic Readout:** *(Automatic information)* Shows the readout result detected by the Trazanto Reader.
■ **User evaluation:** *(Manual information)* States if the visual analysis carried out by the user agrees or not agrees with the readout result detected by Trazanto reader.
■ **Manufacture date:** *(Automatic information)* Manufacturing date of the chemical indicator.
■ **Product:** *(Automatic information)* Shows the Product code of the chemical indicator.

Edit window references

■ **Cycle number:** Cycle number of the sterilization or cleaning process.

■ **Temperature:** Temperature of the sterilization or cleaning process cycle.

■ **Machine [Sterilizer or Washer]:** Descriptive name of the sterilizer or washer used in the process.

■ **Machine serial number:** Serial number of the sterilizer or washing machine. This field is completed by the machine search tool [🔍].

■ **Exposure time:** Time during which the indicator was exposed to the process.

■ **Package number:** *(Exclusive for Sterilization processes)* The number of the package in which the chemical indicator is found at the time of sterilization.

■ **Location:** *(Exclusive for washing processes)* Location of the chemical indicator inside the washing machine.

■ **Relative dampness:** *(Exclusive for Sterilization processes)* Relative humidity condition, given in percentage, in which the sterilization process was performed.

■ **Concentration:** Percentage of concentration of the detergent (for washing) or the sterilizing agent (for sterilization processes).

■ **Type of detergent:** *(Exclusive for washing processes)* You can select between enzymatic, alkaline, non-ionic, or you can complete with the value you want.

■ **Program:** Program number of the equipment used for that cycle.

■ **Visual result:** Visual confirmation of the process result.

■ **Book Number:** Number of the record book corresponding to the process.

■ **Page number:** Number of record page corresponding to the process.

■ **Observations:** You can fill in this box with any relevant

information that has not been considered in the other fields. This field can be filled in or modified after the result has been saved.

■ **Water hardness:** *(Exclusive for Washing processes)* Parameter that defines the quality of the water. This data can be obtained from the quality parameters of the water treatment system used in the establishment.

■ **Water pressure:** *(Exclusive for Washing processes)* Pressure of the water used in the cycle. You can obtain this data from the washing equipment.

■ Licenses

Bionova® Cloud Environment features advanced functionality modules that expand Bionova® Cloud core behavior. Such modules are: Exporter module, and Exchange & Exchange+ modules.

Licenses for the advanced functionality modules can be requested by the Company Administrator User accessing to the *License > My Licenses* tab on the Bionova® Cloud Web Interface left side menu.

Licensing fees may apply to some modules. Nevertheless, all modules allow for a free trial period. Contact us to: info@terragene.com for more information.

Exporter module

The exporter module allows the user to export readout results stored on Bionova® Cloud database to different file formats (Excel, CSV, XML).

Using the Exporter module

1| Access the *Dashboard > Saved* tab of the left side menu, to export readout results stored on Bionova® Cloud database.

2| Select an indicator type to show the saved readout results for that indicator.

3| Click the *Export* button.

4| Select your exporting preferences such as: readout result type, export format, and which columns should the exported file should include. You can also filter the results by User, Incubator Auto-reader, and period of time on which the readout were carried out.

5| Click the *Export* button and download the resulting file.

Bionova® Exchange and Exchange+ modules

The Bionova® Exchange and Exchange+ licenses allows the interconnection of Bionova® Cloud Traceability Software with other third party traceability softwares.

■ **Bionova® Exchange:** Allows third party software to connect to Bionova® Cloud endpoints to request readout information through HL7 standard.

■ **Bionova® Exchange+ (Plus):** Allows third party software to subscribe to Bionova® Cloud to receive a notification each time a readout result is uploaded to Bionova® Cloud Servers, the notifications allows the IT specialist to develop an automated request of readout information through HL7 standard.

To know more about the Exchange and Exchange+ module technical features, please contact us to info@terragene.com to obtain the Exchange module's developers Manual.

■ Dashboard

Accessing previously saved results

The *Dashboard > Saved* tab of the left side menu its the main place for accessing to all the information of readout results previously saved to Bionova® Cloud database.
Readout results are sorted by Indicator Type as follows:

| Biological Indicator ▾ | Protein Indicator | Chemical Indicators ▾ |

    i | Biological Indicators
        (a) Sterilization
        (b) Disinfection
    ii | Protein indicators
    iii | Chemical Indicators
        (a) Cleaning
        (b) Sterilization

The Company Administrator has access to all the company readout results, while Supervisors and Operators can only access to the readout results from the Sector to which they belong. Please refer to the *User account types and access permissions* section for more information.
Readout result can be filtered by pressing the ▤ button.

Creating Reports

A report of readout results can be created by pressing the [GENERATE REPORT] button. By default, the reports will include all the readout results showed in the screen. Filtering the results allows to print reports with a smaller sets of results. Once ready, the report will be exported on PDF format.

KPI for sterilization process risk (SPR)

Bionova® Cloud allows the user to obtain Key Process Indicators (KPI) related to the sterilization process risk (SPR) of a set of readout results. You can access this functionality through the *Dashboard > SPR* tab on the left side menu.
This tool helps to make the most of SCBIs readout results, to control not only the sterility of a single sterilization cycle but also to analyze trends and the overall performance of a specific sterilizer (called historical performance). SPR calculation is based on a sophisticated algorithm that takes into account parameters of the sterilization process such as: cycle number, sterilizer (brand and serial number), number of SCBIs processed (in case you use more than one SCBI in a given cycle), the resistance of the SCBI lot (through the reported D-value), the SCBIs result (positive or negative) and the time in which a positive result is found (in case positive results), among others.
Depending on such parameters values the SPR calculation result can reveal None or negligible risk, Low, Medium, or High risk, following applicable international regulations. However, the user should consider that a low risk result does not mean the process is safe; every time a positive readout result is obtained for a particular sterilization cycle it implies that cycle cannot guarantee the load's sterility, so the load needs to be reprocessed, without exception. For this reason, the SPR value is not supposed to be examined cycle by cycle, but, considering the trend of a group of cycles over a period of time.

The user can perform a thorough inspection of each sterilizer historical performance at the CSSD by implementing this innovative tool, saving valuable time for the sterilizer audit examination. In this way, the SPR provides useful data that can be used to reduce production costs, anticipate sterilizer repairs, or review sterilization procedures.

SPR Trends graph

To generate the SPR trends graph for a sterilizer:
1| Select the sterilizer from the drop down menu.
2| Set a period of time for the software to take into account only the cycles carried out on the sterilizer between the defined dates (by default the current months is selected).
**3|** Press the *Generate* button.

↵ Dashboard
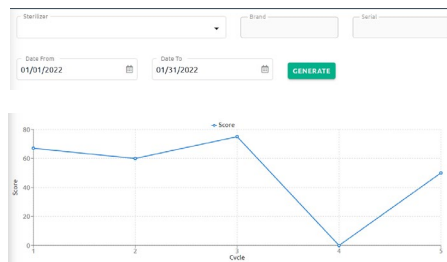
The *X-axis* on the graph represents sterilization cycles carried out on the sterilizer, while the *Y-axis* draws the SPR score for each cycle. Hover the mouse pointer over each point on the graph to see more details about the SPR assessment of a single sterilization cycle.

The SPR graph allows the user to quickly detect good and bad trends on the Sterilizer historical performance. In the following sections the most typical trends are analyzed for convenience.

Example 1|Correction of Sterilizer performance
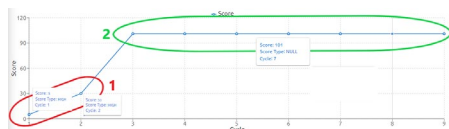
This case shows the situation in which a technician detects a trend of sub optimal consecutive cycles (on cycles 1 and 2 - Region 1) on the sterilizer, and takes the corrective actions to solve the problem (Sterilizer service, smaller loads, etc). The CSSD can show that the corrective actions implemented were correct based on the evidence that the SPR graph shows a trend of consecutive optimal cycles (on cycle 3 to Cycle 9 - Region 2) over a period of time.

### Example 2|Random sterilizer failure
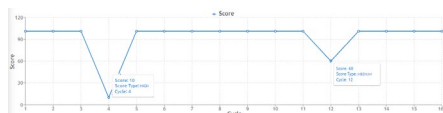
This case shows the situation in which a technician detects the sporadic occurrence of positive SPR values. This behavior is an indicator of random sterilization failure, which could be due to premature cycle interruption, operator error, incorrect positioning of the SCBI within a test package or sterilization chamber, sterilizer chamber overload, among others. The detection of this type of failure can help improve the general protocol of the sterilization process through the analysis of the reasons for these failures each time they occur.

If the user places the mouse pointer at any point, both the cycle number and the score received will be displayed, helping to identify the exact cycle. With this information and the results filtering tool, the user can track the rest of the data to evaluate the possible causes and reverse the situation.

Example 3|Trend of sub optimal consecutive cycles
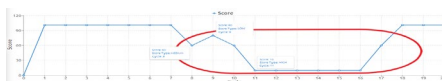
This case shows the situation in which a technician detects a trend of sub optimal consecutive cycles, showing that the occurrence can not be related to a random mishap but to a consistent failure in some of the sterilization parameters. This case shows the need to urgently check the sterilizer status and carry out the necessary corrective actions to reverse the situation. Once the corrective actions are implemented, the sterilizer should show a trend as shown in Example 1.

KPI for HTM 01-01 based IQAS

Implementing an Internal Quality Assurance System (IQAS) allows each CSSD to show objectively that the effectiveness of their washing processes can be achieved consistently. Analyzing and monitoring trends on cleaning process allows the CSSD to show that such process are stable and within accepted quality ranges of residual protein levels after instrument reprocessing.

Important: Refer to the HTM 01-01 guidelines for detailed information on how to implement the standard to your processes.

Defining a Baseline level

The first step to establish an IQAS involves the sampling of reprocessed surgical instruments that represent the full range of your workload to provide the a baseline over which the monitoring system can be developed (benchmark).
There are two main approaches to instrument sampling:
■ *SINGLE* instrument sampling that takes place at any given time.
■ *GROUPS* instrument sampling, established by the user (for example, five instruments per week).
In the case of the *SINGLE* approach, a total of 20 measurements should initially be sufficient to estimate the baseline. In the

case of *GROUPS*, it will take more than 30 measurements.

Procedure

1|Process the instrument in your washing machine as usual, following the recommendations of both the instrument and the washing machine manufacturers.

2|Pick from the load a representative instrument to test for residual protein.

3|Test the selected instrument with a Chemdye® PRO1 Indicator compatible device, strictly following the to the indicator instructions for use.

4|Incubate the PRO1 Indicator, according to the compatible Auto-reader Instructions for use.

5|Before or during incubation, connect the incubator to your PC following the instructions detailed in the incubator user manual. Make sure you Bionova Cloud® Agent is installed on your PC.

6|The ongoing reading will be shown on *Hygiene Protein System > Running* screen. Once the readout is completed, the reading will be moved to the *Hygiene Protein System > Finished* screen to inform the readout result.

7|Click on the *Edit* action button of the result to provide details to the readout result, and save the result. Please refer to the *Hygiene monitoring* section for more information about automatically filled, manually filled information, and saving results.

IQAS Control analysis

Continuous monitoring (Recommendation HTM 01-01)

You should create a graph for each Chamber/Washer-Disinfector. The number and type of instruments should be tested as follows:

50 instruments per Chamber/Washer-Disinfector, at least every three months, chosen among those that are difficult to clean (for example, box joints, serrated edges, hinges, graters, and complex surfaces) when used. Other difficult to clean instruments should also be identified and included in this test.

Procedure

1|After the first 20 protein readout results have been saved into Bionova Cloud database, the control analysis can be started by going to the screen *Dashboard > Iqas*.

2|Select your washing machine by clicking on the drop-down menu. By default, the date range for the analysis corresponds to the current month.

3|Modify the measurement grouping option if *GROUPS* instrument sampling is implemented. According to HTM 01-01, more than 30 measurements should be considered for the basis, and 10 as the maximum number per group.

4|If you wish to proceed your IQAS implementation with *SINGLE* instrument sampling (measurement grouping = 1), two options will be displayed in the *Graphics* menu:

■ **"Graph I":** *(Individual Graph)* log10 protein residues vs. measurement number.

■ **"MR Graph":** *(Moving Range Graph)* Absolute differences between log10 protein residues vs. the number of differences.

5|If you wish to proceed your IQAS implementation with *GROUPS* instrument sampling (measurement grouping > 1) two options will be displayed in the *Graphics* menu:

■ **"XBAR Graph":** Group average vs. group number.

■ **"R-Graph":** *(Range graph)* Group range vs. group range number.

IQAS Results interpretation

The monitoring of each process should vary randomly between the average and the control limits (Upper Control Limit and Lower Control Limit). The process variation should also be random and within the region defined by the control limits. If a measurement exceeds the Upper Control Limit, the load from which the sample was taken must be washed again and the instruments sampled again. The maximum upper limit allowed by the HTM 01-01 standard is 5 µg for each side of the instrument.

Nevertheless, if samples consistently fall outside the defined control limits it is an indication that the process is no longer under control. On such case, the CSSD should carry out a root cause analysis to detect and eliminate any underlying causes. Keep in mind that before interpreting *Graph I* (individual approach) or *XBAR Graph* (group approach), the *MR Graph* or *R Graph* (respectively) should be examined to determine if the process variations are under control. If the *MR-chart* or the *R-chart* are not controlled, then the control limits of *Graph I* or *XBAR* cannot be considered accurate. Even when the measurements of the *Graph I* or *XBAR* are within the control limits, it does not necessarily mean that the system is under control.

It is important to analyze trends and the systematic behavior in sequential measurements. For example, if the graph reveals that 10 sequential samples fall on the centerline, this may indicate that a systematic change in the process has occurred, because the expected behavior is that samples distribute randomly at both sides of the centerline (baseline average). To assist in the interpretation of statistical control process graphs,

several case studies have been suggested (HTM 01-01) that may indicate an *out of control* process. Bionova® Cloud assists the user to monitor the *out of control* programs, detecting these situations indicated 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: Alternating. In this case, there are 14 measurements where there is an alternating pattern.
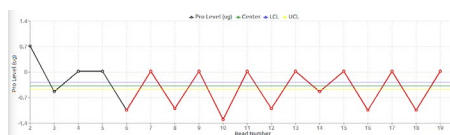
Example 3|Out of control type 3: Monotonous. In this case, 6 consecutive measurements show a monotonous trend (all rising or falling).
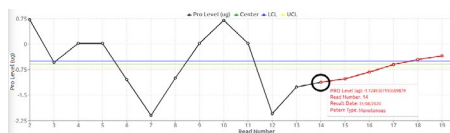
■ Company settings

The Admin user can modify the Company global settings accessing to the *Configuration > Parameters* section tab on the Bionova® Cloud Web Interface left side menu.

■ **Mandatory fields level:** Sets the amount of required fields

to completed by the user when saving a finished readout result. A low mandatory field level implies the least amount of required fields for the user to complete.

■ **Days for notification of license Expiration:** Set the number of days before the system notifies the expiration of a Exchange or Exchange+ license.

■ **Company Logo:** Set the company logo to be shown on Reports.

■ **Working Mode:** This option sets the Protein Quantification Threshold mode for Auto-readers compatible with Terragene® Chemdye® PRO1 indicators. Once the working mode is set, the preference will be applied on all Auto-readers of the company. To know more about how to configure this setting and how to use it along compatible Auto-readers please refer to your Auto-reader's user manual.

Company language

Sets the Bionova® Cloud Web Interface language for all company users.

Advanced localization: Regional format

Based on your selected language, you can apply additional regional configurations such as Date format & Time format automatically by selecting your country or region on the *Regional Format* drop down menu.

Once selected, the correct date format (DD/MM/YY or MM/DD/YY or YY/MM/DD) and time format (24hs or AM/PM) for your country or region will be selected.

For selecting your Regional format configuration please select your preferred language, and afterwards your country or region.

Please make sure to save the settings once selected.

Regional format default values
By default, the *Regional format* field will be set-up to your default company language and to your default company

↵ **Company settings**

country. The language and country selected when the company was first created.

Regional format advanced selection

Different countries and regions have different date and time formats. If you prefer to set a different date and time format that the one your country uses, just select your preferred language on the *Company language* field, and then select the country or region that uses the date and time format of your preference.

Advanced localization: Temperature units

Select your preferred temperature units: (Celsius or Fahrenheit).

Advanced localization: Connected Auto-readers

Once the regional format and temperature units have been selected for your Bionova® Cloud Web Interface. The same preferences will be synchronized to all connected Bionova® Auto-readers through Bionova® Cloud Agent.

This includes the selected time and time format, date and date format, and temperature units. Please keep in mind though, that the Auto-reader's printed ticket language selection should be carried out manually on the Auto-reader as described on the Auto-reader's user manual.

Important: To be able to synchronize Bionova® Cloud preferences with the connected Auto-readers. The Auto-reader's firmware needs to be updated to the latest version available. Please refer to the Auto-reader's User manual for more information about firmware update.

Important: To be able to synchronize Bionova® Cloud preferences with the connected Auto-readers. Bionova® Cloud Agent should be manually updated to the latest version available. For this you can download and install the Agent installer from Bionova® Cloud Home page. Additionally, if you already have the Agent installed on your PC, just run the Bionova® Cloud Agent, and click on the *Update Available* button for the update to be automatically downloaded.

Once the Bionova® Cloud preferences are synchronized with the connected Auto-readers. Such preferences will be included on printed tickets.

Automatic Local time and UTC timezone

Bionova® Cloud Web interface automatically shows the correct

local time and UTC timezone for you, based on your PC's local time and timezone. This feature allows Bionova Cloud to show all information regarding readout results displayed on the web interface, printed reports, and exported files   on the same timezone as the one configured on your PC.

Additionally, the time and timezone of your company Auto-readers will be automatically updated at all times by Bionova® Cloud through Bionova® Cloud Agent. This feature is particularly useful for countries that have summer or winter time corrections as all connected devices will be updated automatically.

Important: Please make sure that your PC time & timezone are set-up correctly. As both, Bionova® Cloud, and all connected Auto-readers will be automatically synchronized to your PC's time and timezone. For Microsoft® Windows PCs, just right click on the *clock* shown on the lower right corner of your screen and select *Adjust date and time*. Check that your PC sets up the time automatically, and that the correct Timezone is selected for your country.

Advanced information: All readout results are stored on a timezone independent format on Bionova® Cloud database to keep your results safe and unmodified at all times. What the automatic time and UTC feature does, is actually *translating* each stored result's timezone information for the web interface to show each result on your local time frame.

Company event log

The Admin user can access to the Company Events Log to monitor all the activity that takes place within the company by accessing to the *Configuration > Change Password* section tab on the Bionova® Cloud Web Interface left side menu.

■ Bionova® Cloud Agent

The Bionova® Cloud Agent handles all communications with Terragene® compatible electronic devices and the Host PC where the Agent App runs.

Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Traceability software and sends the information generated from the devices to the Microsoft™ Azure powered Cloud server where the Traceability Software Web App runs and stores the information.

①

Important: Make sure that Bionova® Cloud Agent is installed,

↵ **Bionova® Cloud Agent**

running, and logged-in with the correct User credentials on your PC. If not, none of Terragene electronic devices will be able to synchronize data with Bionova® Cloud Web Interface.

Besides the synchronization functionality, Bionova® Cloud Agent also features the following options:

Clock synchronization

Synchronize the internal clock of an Auto-reader to your PC's Clock running Bionova® Cloud Agent, by selecting the device, and pressing the ⏱ button.

■ Bionova® Cloud Environment system requirements

Bionova® Cloud Web-interface requirements

- PC with an active Internet connection.
- Updated Web-browser such as Mozilla Firefox, Google Chrome, Microsoft Edge, etc.

Bionova® Cloud Agent requirements

Software requirements

- Microsoft® Windows 7 SP1 (Updated to January 24th, 2020)
- Microsoft® Windows 8, 8.1
- Microsoft® Windows 10

Important: Microsoft Net Framework 4.6.1 is required for the Agent to run currently. If your Microsoft® Windows version does not have Net framework 4.6.1 installed. The Agent will ask the user permission to download and install the package during installation.

Hardware requirements

- 1Ghz or faster processor.
- 200 MB of free disk space.
- 100 MB of free RAM.

Cloud resources exemptions

Please check with your IT department if any PROXY, Firewalls, or in place on your network infrastructure that could filter or block the following Cloud Internet sites:

- https://BionovaCloud.com/
- https://BionovaCloudapi.azurewebsites.net/

Bandwidth requirements

Bionova® Cloud Agent Internet Bandwidth minimum requirements.
For active engagement of the user with the Bionova® Cloud Environment: 0,15 Mbps of Internet bandwidth per user.
Environment in stand-by mode (user not engaging actively): 0,01 Mbps of Internet bandwidth per user.

Note: For a given user, predicted use is that the Environment will be on stand-by mode 98 % of the time.

■ What's new on Bionova® Cloud?

Current version implements the following improvements over the previous version:

- Automatic local time and UTC timezone for Web interface, Reports, and Exported results. For more information please visit section: *Company Settings > Local UTC timezone*.
- Advanced localization options for Bionova® Cloud Web Interface and connected Auto-readers. For more information please visit section: *Company Settings > Advanced Localization*.
- Improved Web interface on *Saved results* screen. Now filtering and exporting results is more intuitive. New Date filters and single result filters.
- Improved Trazanto user interface. Edit windows will dynamically show only the fields applicable to your indicator. Additionally, now auto screen refresh is enabled for Trazanto finished results so there is no need to manually update the screen to check out your new results.
- Ten selectable languages for Web interface. Added Romanian language.