BIONOVA®

Bionova® MiniPro Auto-reader

for Hygiene Monitoring Systems

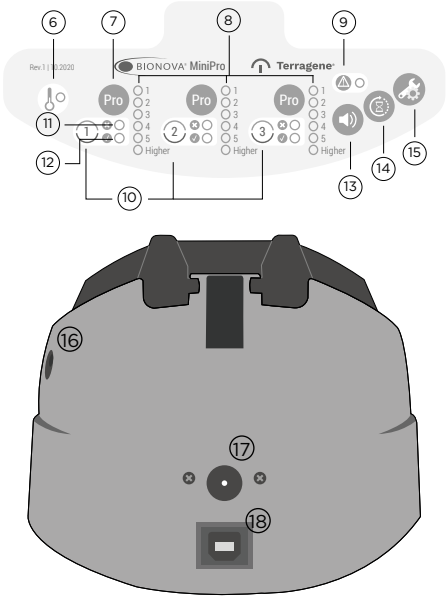
R14 | 05.2026

WARNING: This product contains dry natural rubber.

Terragene®

Index

■ Composition



Product description

The Bionova® MiniPro Auto-reader was designed for the automatic readout of Terragene® Chemdye® Hygiene Monitoring System PRO1 Indicators (PRO1 Protein Pen Indicators) appropriate for the detection and quantification of surface proteins.

The Bionova® MiniPro Auto-reader incubates at 60 °C and performs a quantitative analysis over the Chemdye® PRO1 Protein Pen Indicators, adjusted by a BSA (Bovine Serum Albumin) reference curve. The Bionova® MiniPro allows the incubation and readout of three independent Chemdye® PRO1 Indicators simultaneously.

The Bionova® MiniPro Auto-reader quantitative analysis has a detection limit of 0.5 µg and a quantification range from 1 to 50 µg of equivalent BSA Protein. The results are indicated with a resolution of 0.1 µg, with an accuracy greater than 90 % in the whole quantification range (CI95 %).

The Bionova® MiniPro Auto-reader also provides a printed ticket each time an automatic readout is completed for recording the results. This allows for easy result management, for documentation compliance and record keeping.

Note: Do not place a new Protein Pen until the temperature is stable and the temperature stability indicator stops blinking.

Indications for use

The Bionova® MiniPro Auto-reader incubates at 60 °C and reads the Terragene® Chemdye® Hygiene Monitoring System Indicators at the time prescribed in this User Manual.

Features

1. Protective cover
2. Incubation area
3. Control panel
4. Cavity for paper
5. Thermal printer
6. Temperature stability indicator
7. Start incubation program buttons / Time left
8. Quantitative protein concentration indicators
9. Attention indicator light
10. Incubation position

⑪ Red light / Protein concentration above the selected threshold

⑫ Green light / Protein concentration below the selected threshold

⑬ Alarm cancellation button

⑭ Reprint of results button

⑮ Configuration / Paper traction button

⑯ Hole for external temperature control

⑰ Socket for power supply plug (12 Volts DC)

⑱ USB port

■ Safety information

Symbols

You may see one or more of these symbols on the packaging or labeling of this product:

Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed.

Temperature limit. Indicates the temperature limits to which the medical device can be safely exposed.

Caution. Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Caution, hot surface. To indicate product can be hot and should not be touched without taking care.

CE mark. Indicates the product conforms to all legal requirements to be sold within the European Union/European Economic Area (EU/EEA).

Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully.

Direct current. To indicate on the rating plate that the equipment is suitable for direct current only to identify relevant terminals.

For indoor use only. Indicates medical device be used indoors.

Keep away from sunlight. Indicates a medical device that needs protection from light sources.

Batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.

Manufacturer. Indicates the medical device manufacturer.

Date of manufacture. Indicates the date when the medical device was manufactured.

Recycle electronic equipment. DO NOT throw this unit into a municipal trash bin when this unit has reached the end of its lifetime. Please recycle.

Keep dry. Indicates a medical device that needs to be protected from moisture.

This way up. To indicate correct upright position of the transport package.

Do not stack. Indicates product should not be stacked or top loaded.

Recyclable. Indicates that the marked item or its material is part of a recovery or recycling process.

Class II equipment. To identify equipment meeting the safety requirements for Class II equipment according to IEC 61140.

Contains or presence of natural rubber latex. Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical or the packaging of a medical device.

Polarity of d.c. power connector. To identify the positive and negative connections (the polarity) of a d.c. power supply, or the positive and negative connections on a piece of equipment to which a d.c. power supply may be connected.

⚠ To avoid risks and/or damaging the device:

- Use indoors only.
- Do not place the auto-reader in a room exposed to direct sunlight or to high luminous intensity lamps.
- Do not place the auto-reader near devices that emit strong electromagnetic fields.
- Do not use the auto-reader on sloping surfaces or on surfaces that might be knocked, that may vibrate, be exposed to high temperatures, or high relative humidity.
- Disconnect the power cord before cleaning.
- Do not use abrasive, corrosive cleaners or disinfectants.
- Do not immerse into any liquid. Do not pour liquid into it.
- Make sure the auto-reader is connected to an appropriate electrical mains outlet socket.
- Use only the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable. Check that all the included items are in good condition every day. If any of them is damaged, stop using them. The use of cables, adapters, cords, and/or power supplies different from the ones included may cause fires, electrical shocks, or even physical injuries.
- Do not plug any devices into the auto-reader's USB port other than a personal computer (PC). The PC must be compliant with IEC 60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its USB ports. Ask a qualified technician to check that the device is compatible. Attaching any other device to the USB port may damage the auto-reader and may not be safe for the user.
- Do not attempt to repair the auto-reader yourself. This could lead to major and irreversible damages to the device. If the auto-reader malfunctions, contact your local distributor for further assistance.

⚠ To reduce the risks associated with contaminated surfaces with protein levels outside the user-defined threshold:

- Please read, understand, and follow the Instructions for Use of each Protein Pen before its incubation.
- Do not remove the Protein Pen before the auto-reader shows the final readout result. Check a result ticket is printed.

⚠ To avoid a potentially hazardous situation:

- Avoid contact with the hot metal block inside each incubation position.
- Do not insert your fingers, or any other element, into the incubation positions.
- Place only compatible indicators inside the incubation positions.

Note: Do not use this product other than in the manner specified by Terragene S.A., otherwise the protection provided by the product might be affected.

Note: Only Terragene S.A. authorized personnel may access or service the internal components of the auto-reader. Parts or components inside the auto-reader should not be handled by the user.

Operating conditions

Power supply specifications

Input parameters	**Operating conditions**	**Units**
Voltage range	(100-240)	AC Volts
Frequency	50/60	Hertz
Current	1	Ampere

Output parameters	**Values**	**Units**
Voltage	12	DC Volts
Current	3	Amperes

Terragene S.A. recommends the use of Uninterruptible Power Supply (UPS) instead of voltage stabilizers since they fulfill two functions: To stabilize and maintain the energy during a power outage.

Environmental operating conditions

Environmental conditions	**Operating conditions**	**Units**
Altitude	3500 (max.)	Meters
Operation temperature	10-30	Celsius
Relative humidity	30-80	%
Installation/Over-voltage	Category II	
Pollution degree	2	
Storage temperature	5-40	Celsius
Voltage	12	DC Volts

Device safety compliance

The Bionova® MiniPro Auto-reader complies with the following standards and directives:

Electrical Safety	IEC 61010-1
	IEC 61010-2-010
	Low Voltage Directive 2014/35/EU
Electromagnetic	EN 61326-1
Compatibility (EMC)	EMC Directive 2014/30/EU
European Commission	RoHS Directive 2011/65/EU
	WEEE Directive 2012/19/EU

The Bionova® MiniPro Auto-reader does not represent photobiological risk and does not generate dangerous optical radiation if used within normal operation conditions as per the requirements of IEC 62471 standard.

Designed under Quality Management System standards ISO 13485:2016/ EN ISO 13485:2016.

Note: The auto-reader has been evaluated for conformity for use in business environments. There may be concerns about radio interference if used in home environments. This applies exclusively to the Korean market due to KC certification requirements.

■ Product compatibility and incubation program

The Bionova® MiniPro Auto-reader incubation program

The following incubation program is available for your auto-reader:

Temperature	Time	Incubation program
60 °C	4 minutes	PRO1 (4 minutes at 60 °C)

Follow the Protein Pen Instructions for Use before its incubation.

■ Instructions for use

Note: Remember to set-up the auto-reader to your local date and time before starting incubations.

Start-up

1| Place the Bionova® MiniPro Auto-reader on a firm surface, free from vibrations, away from direct sunlight, hot or cold air flows, chemical and corrosive or flammable substances. Do not place the auto-reader in a way that would make it difficult to remove the power supply's AC plug from mains. Leave a space of at least 10 cm from the auto-reader to the closest wall. Do not move the auto-reader periodically or while it is being used. Connect the auto-reader to a secure and stable electrical mains outlet socket.

Note: Do not wet or heat the device. If liquid is spilled on the auto-reader, disconnect it and clean it. For more information, please refer to the following section: *Cleaning and maintenance.*

2| Switch on the auto-reader by connecting the power supply's AC plug to mains and then connect the plug at the other end of power supply to the rear of the auto-reader.

Note: Before switching it on, verify that all incubation positions are empty.

Note: If the attention indicator light starts blinking after switching on the auto-reader, check that the printer's door is tightly closed and that the printer has paper. For more information, please refer to the following section: *Paper roll replacement.*

3| Set the auto-reader internal clock to match your local date and time. For more information, please refer to the following section: *Time setting mode.*

All devices are manufactured with the following settings:

- Time zone: UTC +0:00
- Printing language: English

Note: You can change the time zone or the printing language. For more information, please refer to the following section: *Configuration mode.*

4| Select your preferred Protein Quantification Threshold Mode for your auto-reader from the two Threshold modes available: Threshold based on HTM 01-01 guidelines or Threshold based on ISO 15883-5:2021 standard.

Note: The ISO 15883-5:2021 Threshold Mode is available exclusively for the Chemdye® PRO1 MICRO Indicator.

For the selection of a Threshold mode and a Threshold value, please follow the indications detailed in the *Threshold Mode Selection* section on the *Bionova® Cloud Environment* section.

All devices are manufactured with the following settings:

- Default Threshold Mode: HTM 01-01
- Default Protein Threshold: 1 µg

Make sure that the selected Protein Quantification Threshold Mode is in accordance with your specifications before performing an incubation. The Threshold Mode cannot be changed during ongoing readings.

5| Wait until the temperature stability indicator stops blinking for the auto-reader to reach a steady working temperature.

Note: Do not place an indicator on an incubation position before the incubation temperature is stable.

6| Once the temperature stability indicator remains stable, a one-time automated test to check each position internal status will be carried out.

Once the test has been completed, the Green light will turn on to indicate that the position can be used to perform readings. Otherwise, the Red light will turn on to indicate that an error has occurred.

When the auto-reader detects an error in a position, the position will be disabled to guarantee the reliability of the results and no further readings will be possible.

To indicate that a position has been disabled, the Red light will blink continuously.

Note: To ensure the automated test works properly, keep the protective cover closed when the automated test is running.

7| Once the automated test has been completed, the readings can be initiated on any incubation position if the position has not been disabled. Place a Chemdye® PRO1 Indicator in an incubation position to start an incubation. Press and hold the button of the chosen

position for 1 second to enable the position's readout mode. The auto-reader will emit an audible notification and the 1 µg quantitative protein concentration indicator will blink for a moment. After that, two short beeping sounds will be emitted indicating that the incubation position is enabled and ready to start an incubation.

An incubation position cannot be enabled before the incubation temperature is stable and the automated test has been carried out successfully. Please wait until both processes are completed before placing an indicator on an incubation position.

8| Use a compatible Chemdye® PRO1 Indicator to take a sample from the surface to be analyzed. Make sure to follow the indicator's Instructions for Use while taking the sample. A summary of the swabbing process is also detailed on Figure 1.

9| After a sample from the desired surface has been taken, place the Chemdye® PRO1 Indicator into the enabled incubation position. Insert the indicator fully inside the incubation position, as shown on the auto-reader's label. When the indicator is in the correct position, the indicator cannot be rotated. (Figure 2).

Note: Make sure that the solution is correctly mixed and the reading cone has a sufficient amount of solution before starting an incubation.

Note: Make sure that the indicator's swab is not inside the reading cone before starting an incubation.

10| Once the indicator is placed on the incubation position, press and hold the button Pro for 1 second to start the incubation and readout process. Once the process starts, the Red and Green lights will start to blink and will continue blinking throughout the whole incubation and readout process. Wait until the incubation and readout process is completed before removing the indicator.

Note: Do not move, remove or change the indicator placement once a reading process has begun, as it could lead to errors in the incubation and/or readout process.

11| Once the incubation and readout process is completed, the Red and Green lights will stop blinking and the auto-reader will indicate the quantity of protein in µg found in the sample by turning on the corresponding Quantitative protein concentration indicator. A ticket will also be printed detailing the protein quantity along with other useful information related to the readout process.

The protein quantity found on the sample is also used to obtain and inform a readout result depending on the Protein Quantification Threshold Mode and threshold values selected on your auto-reader. For more information, please refer to the section: ***Interpreting the results of PRO1 Indicators.*** After a readout result is informed, remove the indicator from the incubation position and press the: Pro button once to reset the incubation position to its stand-by state.

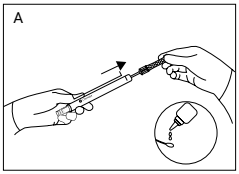
Note: The color of the solution in the Chemdye® PRO1 Indicator can be used for a qualitative reading only if the pen is removed immediately when the incubation program ends. An audible alarm will sound 30 seconds before the program finishes to alert the operator that completion is near. If the protein pen is not removed promptly after the result is indicated, the solution color will continue to change.

12| To save the printed ticket, pull the paper upward to cut it using the printer's serrated edge.

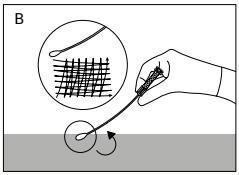
Note: If there is no paper for ticket printing, the attention indicator light will start blinking. For more information on how to change the paper roll, please refer to the following section: ***Paper roll replacement.***

Note: The auto-reader will save the last 3 readout results. For more information on how to reprint results, please refer to the following section: ***Reprinting the results.***

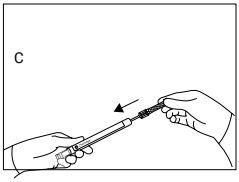
Figure 1



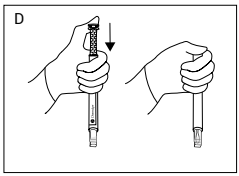
Remove swab and add the moisturizer



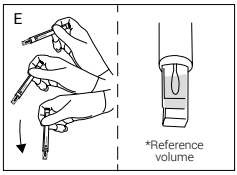
Swab the desired surface by applying a strong pressure



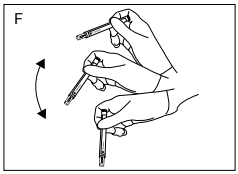
Place the swab back into the device



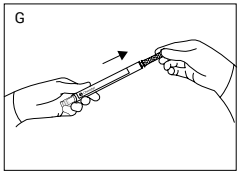
Activate



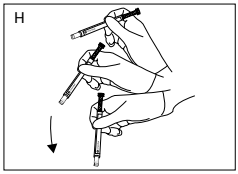
Shake downwards vigorously until the solution turns to green and reaches the readout cone reference volume



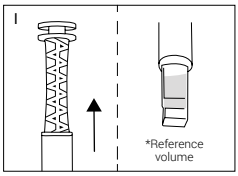
Shake for 15 seconds with the swab inside the readout cone



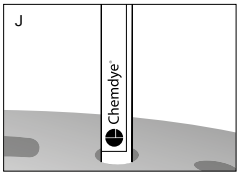
Slide swab upwards without completely removing



Again, shake downwards vigorously and reach the readout cone reference volume

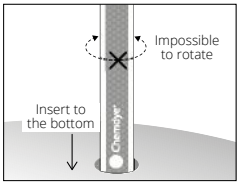


Readout cone without swab



Incubate immediately and read

Figure 2



Insert the pen on the incubation/reading position

Interpreting the results of PRO1 Indicators

Once a PRO1 Indicator readout process is finished, the auto-reader will inform the equivalent µg of protein quantity found on the sample using a BSA (Bovine Serum Albumin) calibration curve through the Quantitative Protein Concentration Indicators and through a printed ticket.

The protein quantity found on the sample is also used to obtain and inform a readout result depending on the Threshold mode and threshold values selected on your auto-reader. Such readout result can be either Positive or Negative for HTM 01-01 Threshold Mode, or Negative, Alert, or Action for ISO 15883-5:2021 Threshold Mode.

Note: To select a Threshold mode and its values please refer to the *Threshold Mode selection on Bionova® Cloud Environment section.*

Readout results for HTM 01-01 Threshold Mode

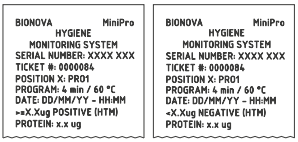
Note: The HTM 01-01 Threshold Mode is the default Protein Quantification Threshold mode of your auto-reader.

HTM 01-01 guidelines indicate the use of a single protein

quantity threshold to evaluate cleaning efficacy. The guidelines recommend that the residual protein level upper limit of acceptable protein contamination after processing is 5 µg BSA equivalent per instrument side, indicating as well that lower levels may be recommended for particular applications.

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

If HTM 01-01 Threshold Mode is selected as the readout threshold mode on your auto-reader, each time a readout is completed the protein quantity will be informed through the Quantitative Protein Concentration Indicators and a printed ticket:



POSITIVE **NEGATIVE**

If the protein quantity detected on the sample is lower than the selected threshold, a negative readout result will be informed and the auto-reader will turn on the Green light. If the quantity detected is greater than the selected threshold, a positive readout result will be informed and the auto-reader will turn on the Red light. The readout result will be detailed on the printed ticket as well. Furthermore, if the auto-reader is connected to the Bionova® Cloud Environment, the readout results can be found on the *Hygiene Monitoring > Finished web page of Bionova® Cloud Web interface.*

Take action immediately whenever a POSITIVE readout result is informed as this indicates that the protein quantity found does not comply with the user defined quality standards set for the cleaning process.

Readout results for ISO 15883-5:2021 Threshold Mode

Note: This mode is only valid for the Chemdye® PRO1 MICRO Indicators.

The ISO 15883-5:2021 standard indicates the use of two different protein quantity thresholds to evaluate cleaning efficacy: An Action threshold, and an Alert threshold. ISO 15883-5:2021 based thresholds are expressed as ratios in µg/cm² units that relates protein quantity found in a sample (µg) and the swabbing surface (cm²) on which the sample was taken. According to the standard, each threshold has different implications:

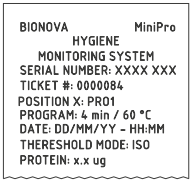
Alert threshold: The alert levels are the target levels of cleaning efficacy that the cleaning process should achieve. The recommended threshold value is 3 µg/cm². Lower values may be recommended for particular applications.

Action threshold: The action levels are the maximum criteria for acceptable cleaning efficacy during testing of a sample. The recommended threshold value is 6.4 µg/cm². Lower values may be recommended for particular applications.

Values between the two thresholds should be investigated, but are considered to pass cleaning requirements described in ISO 15883-5:2021 standard.

Note: Refer to the ISO 15883-5:2021 standard for detailed information on how to implement the standard to your processes.

If ISO 15883-5:2021 Threshold Mode is selected as the readout threshold mode on your auto-reader, each time a readout is completed the protein quantity will be informed by the auto-reader through the Quantitative Protein Concentration Indicators and through a printed ticket:



Also, as a quick visual cue of the protein quantity found on the sample, the device will turn on the Red light if the protein quantity is above 1 µg, or the Green light if the protein quantity is below 1 µg.

Note: Please keep in mind that according to ISO 15883-5:2021 standard the protein quantity found in a sample (in µg) needs to be related to the swabbed surface area to obtain a readout result (in µg/cm²) that can be comparable with the selected Alert and Action thresholds (also in µg/cm²).

Once the protein quantity in the sample has been obtained by the auto-reader, and the swabbed surface information has been obtained with the Bionova® App, the information is finally linked together by the Bionova® Cloud Environment to inform the readout result. Please refer to ISO 15883-5:2021 on *Bionova® Cloud Environment* section for a step by step guide to upload and link data on *Bionova® Cloud Environment.*

Once the data has been linked, the readout result will be shown on the *Hygiene Monitoring > Finished tab of Bionova® Cloud Web Interface.* Depending on the threshold values selected, the informed readout result can be as follows:

If the protein quantity found on the swabbed surface (µg/cm²) is below the Alert Threshold, the readout result will be informed as *NEGATIVE.*

If the protein quantity found on the swabbed surface (µg/cm^2) is above the Alert Threshold but below the Action Threshold, the readout result will be informed as *ALERT.*
If the protein quantity found on the swabbed surface (µg/cm^2) is above the Action Threshold, the readout result will be informed as *ACTION.*
Take action immediately whenever an ACTION readout result is informed as this indicates that the protein quantity found does not comply with the user defined quality standards set for the cleaning process.

Disposal

Dispose of the PRO1 Indicator in accordance with your country's waste-disposal guidelines. It is not possible to use or incubate a PRO1 Indicator more than once. Please refer to the PRO1 Indicator Instructions for Use.

Reprinting the results

The auto-reader allows reprinting of the last 3 readout results. For reprinting the results, press and hold the following button for 3 seconds: .

Remaining incubation time

The remaining incubation time of ongoing incubations can be checked by printing a ticket.
To check the remaining time in a single reading position, press and hold the following button for 3 seconds: Pro.
To check the remaining time on all reading positions, press and hold simultaneously and for 3 seconds two of the buttons: Pro.
In each case a ticket will be printed informing the remaining time as shown below:

```
BIONOVA              MiniPro
        HYGIENE
    MONITORING SYSTEM
SERIAL NUMBER: XXXX XXX
DATE: DD/MM/AA
TIME: HH:MM

POSITION 1: PRO1
PROGRAM: 4 min / 60°C
REMAINING TIME: MM:SS

POSITION 3: PRO1
PROGRAM: 4 min / 60°C
REMAINING TIME: MM:SS
```

Audible alarm

An audible alarm will sound every time a positive result is detected by the auto-reader. The alarm immediately informs the user that a positive result has been detected without the need to visually check the device. The alarm can be canceled by pressing the button: .

Cancelling a reading

To cancel the reading of any of the 3 positions, press and hold the button: Pro of the chosen position and the following button for 3 seconds: .
Once the reading is canceled, a ticket will be printed.

```
BIONOVA              MiniPro
        HYGIENE
    MONITORING SYSTEM
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
POSITION X: PRO1
PROGRAM: 4 min / 60 °C
DATE: DD/MM/YY - HH:MM
CANCELED:
PEN PULLED OUT
```

Monitoring the temperature

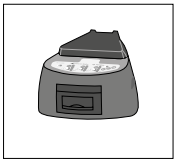
The auto-reader features an automated internal temperature control. If the incubation temperature falls outside of the specified range of 60 ± 2 °C, the temperature stability indicator will start to flash.
The incubation temperature can be externally monitored by placing an external thermometer in the hole for external temperature control located at the back of the auto-reader.

Thermal paper specifications

Recommended paper: JUJO AF50KSE3, or equivalent (order code ICTP MINI).
Paper width: 57 mm
Maximum paper thickness: 60 g/m^2
Maximum diameter size: 23 mm

Paper roll replacement

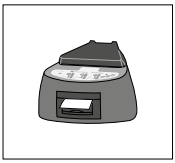
To replace the paper roll, follow the instructions below:



1 | Pull the handle of the printer's door.

2 | Open the cover and remove the empty roll.

3| Place the new paper roll with the outer side up.



4| Close the printer cover by pressing on the sides of the lid.
Note: To feed the paper, press the button: .

Configuration mode

The auto-reader features a configuration mode that enables you to set the printing language and the date format and time zone in the device.
To access the configuration mode, turn on the auto-reader while holding the button: .
If the auto-reader has successfully entered the configuration mode, the Red and Green lights in all incubation positions will turn on and a ticket will be printed. To change the date format, time zone and printing language, please follow the instructions listed below. To exit the configuration mode, turn off the auto-reader.

Modification of date format and time zone

The date format and time zone modification function allows changing the date format and time zone of the auto-reader to suit better the local characteristics of your country.
To select the auto-reader's date format, make sure that the device is in configuration mode and press the button: .
The current date format will be printed in order to set a reference value and the Green light corresponding to incubation position 1 will start blinking.
Three types of date format are available: DD/MM/YY, MM/DD/YY and YY/MM/DD.
To move back and forth between the available options, press the buttons: or .
After 2 seconds, a ticket with the selected format will be printed to set a reference.
Note: The default date format is DD/MM/YY.
To save the selected date format, press and hold the following button for 3 seconds: .
To discard the changes, turn off the auto-reader.
Once the date format has been modified and saved, the auto-reader will enter to the time zone change mode automatically.
The current date (with the previously selected format) and the current time will be printed to set a reference.
To subtract hours, press the button: .
To add hours, press the button: .
After 2 seconds, a ticket will be printed informing the selected time zone.
To confirm the change, press and hold the following button for 3 seconds: .
To discard the changes, turn off the auto-reader.
Note: The Green light corresponding to incubation position 1 will stop blinking once both, the date format, and time zone modifications are saved.

Modification of printing language

This functionality allows changing the language that appears on the tickets.
To select the printed ticket's language, make sure that the auto-reader is in configuration mode and press the button: .
The current language and list of available languages will be printed to establish a reference. To move back and forth between the available options, press the buttons: or .
After 2 seconds, a ticket will be printed informing the selected language. To confirm the change, press and hold the following button for 3 seconds: .
To discard the changes, turn off the auto-reader.

Time setting mode

Modification of the time using Bionova® Bioupdate

1| Using the included USB cable, connect your auto-reader to a PC where Bionova® Bioupdate has been previously installed. Make sure the PC has a working internet connection.

2| Run Bionova® Bioupdate.

3| Select the auto-reader from the list and press the button: *Clock Sync.*

4| The auto-reader's internal time and date will be synchronized with the PC's current time and date. Wait until the software indicates that the syncronization process has been completed.
Note: The synchronization process can only be done as long as there is not an ongoing reading.

Modification of the time using Bionova® Cloud Agent
1| Using the included USB cable, connect your auto-reader to a PC where Bionova® Cloud Agent has been previously installed. Make sure the PC has a working internet connection.

2| Run Bionova® Cloud Agent.

3| Select the auto-reader from the list and press the button: *Clock Sync.*

4| The auto-reader's internal time and date will be synchronized with the PC's current time and date.
Note: The synchronization process can only be done as long as there is not an ongoing reading.

■ Additional features

Firmware update

The Bionova® MiniPro Auto-reader firmware can be updated with the Bionova® Bioupdate utility. The Bionova® Bioupdate connects to the Internet to check, download, and install the latest firmware version available for your auto-reader. The update process only lasts a few seconds and is carried out without the loss of any auto-reader's data.
Please visit **www.terragene.com/software** to download Bionova® Bioupdate.

Update process

Before updating the auto-reader, switch off the auto-reader for five seconds. Then, switch the auto-reader back on and follow the next steps:
1| Using the included USB cable, connect your auto-reader to a PC where Bionova® Bioupdate has been previously installed. Make sure the PC has a working Internet connection.

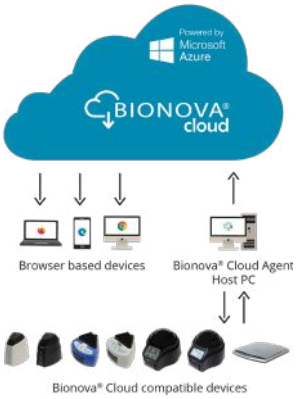
2| Run Bionova® Bioupdate.

3| Select the auto-reader from the list and press the button: *Start.*

4| Wait until the software indicates that update process has been completed. The auto-reader will print an update confirmation ticket. If the auto-reader is already up to date, no ticket will be printed.
Note: It is recommended that this process be carried out once a year unless required by the manufacturer.

■ Bionova® Cloud Environment

The new 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, disinfection and cleaning control applications.
The Bionova® Cloud Environment comprises two main components: The Bionova® Cloud Traceability Software which is a web-based application, and the Bionova® Cloud Agent which is a Microsoft™ Windows Application that acts as an interface between the Terragene®compatible devices and the web-based application.



The Bionova® Cloud Traceability Software can be used to manage and store the readout results of Hygiene Monitoring System Indicators in a secure and user-friendly way.
The Bionova® Cloud Traceability Software matches the information of an indicator result with the sterilizer or washing machine used, the operator, cycle characteristics, and all relevant information so each institution complies with documentation and archiving regulations.
The Bionova® Cloud Agent handles all communications with Terragene® compatible electronic devices and the Host PC where the Agent App is operated.
The Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Traceability Software and sends the information generated by the devices to the Microsoft™ Azure powered Cloud server where the Traceability Software Web App is operating and stores the information.
The user can then access to the information saved to the Cloud via any device with a compatible web browser.

To access to the Bionova® Cloud Environment, please visit: **www.terragene.com/bionova-cloud**

Threshold Mode selection for PRO1 Indicators

The Bionova® Cloud Environment allows the selection of the Protein Quantification Threshold Mode and Threshold values throughout its web interface.

Note: The Threshold Mode selection is only available for the latest firmware versions. Update your auto-reader's firmware before carrying out any of the steps below. Please refer to the *Firmware update* section for more information.

1| Connect your auto-reader to a PC where Bionova® Cloud Agent is installed.

2| Run and Log-in to the Bionova® Cloud Agent. Wait until the Agent lists the auto-reader.

3| Access as the Administrator user to the Bionova® Cloud Environment Web interface.

4| Go to the *Configuration > Parameters* section tab on the Bionova® Cloud Web Interface left side menu.

5| Select the Threshold working mode for your auto-reader: HTM 01-01 or ISO 15883-5:2021. Save the selected mode clicking on the SAVE button.

6| Select the Threshold values for the selected mode. Save the selected Threshold values by clicking on the SAVE button.

Note: If the process is carried out successfully your auto-reader will print a ticket detailing the selected Threshold Mode.

ISO 15883-5:2021 Threshold Mode

Note: This mode is only valid for the Chemdye® PRO1 MICRO Indicators.

The ISO 15883-5:2021 standard implements recommendations for taking action based on the findings of hygiene monitoring indicators. One of the major features of this revision of the standard is that the protein quantities measured when swabbing an instrument must be related to the swabbing surface in which the sample was taken for correct decision-making over decontamination and washing equipment.

To obtain an estimation of the swabbing surface area, the new Bionova® Cloud Surface Eye Mobile App was designed. The Surface Eye Mobile App is a new proprietary application developed by Terragene® compatible with Android and iOS that allows the user to obtain an estimation of an instrument's swabbed surface using complex machine learning technologies in a few simple steps. The App also implements seamlessly integration with the Bionova® Cloud Environment.

Linking protein quantification readout data (in µg) informed by an auto-reader, and swabbing surface data (in cm^2) informed by the Surface Eye App, throughout the Bionova® Cloud Environment allows the creation of ratios of protein quantities and swabbing surface area (in $\mu g/cm^2$) that can be compared with ISO 15883-5:2021 style thresholds.

ISO 15883-5:2021 workflow

Note: This workflow is only valid for the Chemdye® PRO1 MICRO Indicators.

Take the following steps for linking protein quantification readout data and swabbing surface data through the Bionova® Cloud Environment.

A) Set-up

1| Set-up your auto-reader for ISO 15883-5:2021 Threshold Mode. Please refer to the *Threshold Mode selection* on *Bionova® Cloud Environment* section for more information.

2| Download the Bionova® Cloud Surface Eye App from Google Play Store on your Android compatible mobile device.

Note: Make sure your Android device has a working camera for the Surface Eye App to work as intended.

B) Login and authentication

1| Log-in to the Bionova® Cloud Agent on the PC connected to your Bionova® MiniPro Auto-reader.

2| Log-in to the Bionova® Cloud Surface Eye App with the same credentials used on the Bionova® Cloud Agent.

3| Log-in to the Bionova® Cloud Web Interface with the same credentials used on the Bionova® Cloud Agent.

C) Swabbing and surface estimation

1| Set the instrument to be swabbed over the Surface Eye Card. Please keep in mind that the swabbing area must be fully contained on the card for the Surface Eye App to properly estimate the swabbing surface area.

2| Tap on the icon, and align the 3 position markers from your phone screen with the 3 position markings on the Surface Eye card. Once the position markers are aligned, the App will take a photo automatically.

3| Select the area of the instrument to be swabbed and tap on the icon.

4| The App will automatically select and estimate the surface (cm^2) of the selected swabbing area. It is a good practice to standardize the swabbing area for each instrument. Defining and using the same swabbing area for a given instrument allows the sampling process to be repeatable through time and deliver valuable statistical information.

Note: According to ISO 15883-5:2021 standard, the recommended values for the Alert and Action threshold

are 3 µg/cm² and 6.4 µg/cm², respectively. As both ratios relate protein quantity of a sample to the swabbing surface from which the sample is taken, please make sure to use standardized surfaces on the range of 1 to 7 cm². The use of higher swabbing surfaces (>7.6 cm²) imply that the protein quantity to define the action threshold would be above the 50 µg of the PRO1 Hygiene Monitoring System quantization range and thus cannot be properly used.

5| Define an instrument code and a description to fully identify the swabbing area and the surface acquisition details.

Note: Choose a descriptive code and description for the instrument so it is easier to link the surface data with the protein readout information later on the Bionova® Cloud Environment.

6| Check the Both sides check-box if you plan to swab both sides of the instrument. Checking the button will duplicate the selected swabbing area to account for the double sided swabbing procedure.

7| Once ready, tap the icon. The App will upload all the surface information to your Bionova® Cloud Environment account.

8| The surface acquisition details can be edited from the Apps' home menu swiping the instrument code to the left.

D) PRO1 Indicator incubation and readout

1| Follow the Instructions for Use of your PRO1 Indicator to take a protein sample of the selected instrument.

Note: Make sure to swab evenly the same surface area that was selected on the Surface Eye App.

Note: Make sure you swab both sides of the instrument if the Both sides check-box was selected on the Surface Eye App.

2| Carry out the incubation and readout of the PRO1 Indicator as described on the *Instructions for Use* section of this manual. Wait for a readout result to be informed.

E) Linking protein readout information and swabbing surface information

1| Once the readout result is informed by the auto-reader. Go to the *Hygiene Monitoring > Finished* tab on the Bionova® Cloud Web Interface right side menu and fill in the PRO1 Indicator readout information.

2| Click on the *Assign Area* button and select the surface acquisition data details of the swabbed surface.

Note: Make sure the surface acquisition information corresponds to the protein readout data so that the correct ratios can be obtained. To check if the surface information is the correct one, click on the magnifying glass to view the swabbing surface image saved on the Bionova® Cloud Environment.

3|Click the *Confirm* button to save the details, or the *Confirm and move to saved* button to save the details and move the readout to the Bionova® Cloud Database accessible through *Dashboard > Saved* section tab on the Bionova® Cloud Web Interface left side menu.

Bionova® Cloud Surface Eye Mobile App advanced features

Note: The Surface Eye Mobile App is only compatible with the Chemdye® PRO1 MICRO Indicators.

Redefining the swabbing area of an instrument

You can redefine a previously saved surface area of an instrument on the Surface Eye App, and take a new photo to assign a new swabbing area to the instrument. For this swipe left on the instrument code, and tap the icon. Take a new photo and select the new swabbing area.

Editing an instrument code and description

You can edit the details of any of the instrument codes previously saved on the Surface Eye App. For this swipe left on the instrument code, and tap the icon.

Conversion of ISO 15883-5:2021 Thresholds

Once a swabbing surface area has been saved and assigned to an instrument on the Surface Eye App, the details of the surface can be accessed by typing the instrument code.

On the details screen, the Alert and Action Thresholds (in µg/cm²) as defined on the Bionova® Cloud Environment, are converted and shown to the user as protein quantity thresholds (µg) for the selected surface.

This allows for direct visual comparison between the protein quantity found on the sample as informed on the auto-reader printed ticket, and the protein quantities that correspond to the alert and action thresholds for the defined swabbing area.

■ Cleaning and maintenance

Cleaning and decontamination of external surfaces

Disconnect the power supply cable and the USB cable from the auto-reader. If the device is hot, wait until it has cooled down before handling it.

Clean the external surfaces of the auto-reader using a microfiber cloth moistened with a solution of mild dish washing detergent and water. Wring out the cloth so it is damp but not dripping before cleaning and wipe the outer surfaces of the auto-reader. Then, moisten a clean

microfiber cloth with just water, and repeat the procedure until all traces of detergent are removed from the external surfaces of the auto-reader. After cleaning, allow the auto-reader to air dry for at least 1 hour before connecting the power supply cable or the USB cable again.
This cleaning procedure can be followed whenever considered appropriate.
This cleaning procedure must be followed each time a spill occurs on any of the external surfaces of the auto-reader.
If further cleaning is required, or if you have doubts about the cleaning agents you may use, please contact your local distributor.
Note: Do not clean the internal parts of the auto-reader.
Note: Do not pour liquid onto the device or immerse it in any liquid. Do not allow any liquid to enter the device while it is being cleaned.

Maintenance

The Bionova® MiniPro Auto-reader does not require routine maintenance.

■ Troubleshooting

Problem: *The auto-reader will not start.*
Possible causes: Power supply is not connected.
Actions: Check that the power supply is connected to proper mains. Check that the DC plug of the power supply is connected to the rear of the auto-reader.

Problem: *The auto-reader is showing an error in an incubation position during the automated test.*
Possible causes: An indicator was placed in the incubation position during the auto-test. Dust particles might be obstructing the readout mechanism.
Actions: Check that every incubation position is empty during the auto-test. Restart the auto-reader.
If after restarting the auto-reader the problem persists, use air to remove any dust inside a position. Do not insert solid objects. Once cleared, restart the auto-reader.
Note: Do not use the auto-reader in dusty environments.

Problem: *An incubation cannot be run in an incubation position (position's Red light is on).*
Possible causes: Position disabled. Error in that position during the the automated test.
Actions: Make sure that the position is empty when starting the auto-reader. Once cleared, restart the auto-reader.

Problem: *The auto-reader will not run an incubation in any position.*
Possible causes: The incubation temperature is not stable.
Actions: Wait until temperature is stable before any incubations.

Problem: *It is not possible to start a Chemdye® PRO1 Indicator incubation (Pen not valid ticket).*
Possible causes: The protein pen condition is not appropriate for its incubation.
Actions: Make sure that the solution on the reading cone is sufficient. Make sure the indicator solution is not overly saturated or already changing its color (i.e., not green).
Do not incubate an indicator twice. Please follow the Instructions for Use before its incubation.

Problem: *The auto-reader will not detect the Protein Pen (Pen not detected ticket).*
Possible causes: Protein pen is not correctly placed in the incubation position.
Actions: Make sure the indicator is fully placed at the bottom of the incubation position before its incubation.

Problem: *The printer will not print (attention indicator light blinks quickly).*
Possible causes: The printer cover is not tightly closed. The printer is out of paper.
Actions: Check that the cover is tightly closed. Place a new paper roll in the right direction.

Problem: *The printer releases unprinted paper.*
Possible causes: The paper roll is not placed correctly.
Actions: Make sure the paper is placed according to the directions on the *Paper roll replacement* section.

Problem: *The auto-reader cannot be updated.*
Possible causes: Bionova® Bioupdate is not running.
Actions: Install and run Bionova® Bioupdate. For more information refer to section: *Additional features.*

Problem: *The auto-reader is not detected by Bionova® Cloud Agent.*
Possible causes: The auto-reader is turned off. The auto-reader is not connected to the PC.
Actions: Follow the directions on the *Start-up* section to set-up the device properly.

■ Warranty

The products are guaranteed to be free from material and workmanship defects when properly installed, maintained and used for their intended purpose as indicated in the applicable product label and/or the User Manual. The warranty only applies to the original purchaser.

Term

The warranty period for the Bionova® MiniPro Auto-reader is 1 (one) year from the date of installation and

may never be extended beyond 5 (five) years from the product's date of manufacture.

Expected lifetime

The Bionova® MiniPro Auto-reader has an expected lifetime of 5 (five) years from the date of manufacture. This period is considered valid under normal operating conditions, provided that the equipment is installed, used, and maintained in accordance with the provisions outlined in this User Manual. Use outside these conditions may affect the product's lifetime.

Limitation of liability

Terragene S.A. shall not be held liable for any loss or damage that result from the unsuitable use of the equipment, negligence, or user's full responsibility.

Technical assistance

For information regarding the functioning or condition of the product, contact Terragene S.A. directly to **info@terragene.com** or through our website **www.terragene.com**

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