



Bionova[®] IC10/20FRLCD Auto-reader

for Rapid, Super Rapid and Ultra Rapid
Biological Indicators and Hygiene
Monitoring systems

Rev. 10 | February 2022

WARNING: this product contains dry natural rubber



Index

4 Composition

- 4 Product description
- 4 Indications for use
- 4 Features
- 5 Screen references

5 Safety information

- 5 Symbols
- 6 Operating conditions
- 6 *Power supply specifications*
- 6 *Environment operating conditions*
- 6 Device safety compliance

7 Product Compatibility and Incubation programs

- 7 Bionova® IC10/20FRLCD Incubation Programs
- 7 Bionova® IC10/20FRLCD Auto-reader compatible indicators

7 Instructions for use

- 7 Start-up
- 9 Remaining incubation time
- 9 Cancel reading
- 9 Interpretation of results
- 9 Positive control
- 9 Disposal
- 9 Results history visualization
- 9 Audible alarm
- 9 Temperature monitoring
- 9 Thermal paper specifications
- 10 Replacement of the paper roll
- 10 Time setting mode

10 Auto-reader internal website

- 10 Local Network connection
- 10 Internal website: Homepage
- 10 Results history
- 11 Settings

11 Hygiene monitoring systems

- 11 Readout of PRO1 Indicators
- 13 Interpretation of results of PRO1 indicators
- 14 Disposal
- 14 Audible alarm
- 14 Cancel a reading

14 Additional features

- 14 Firmware update
- 15 Bionova® Wilink connection

15 Bionova® Cloud Environment

- 15 Threshold Mode selection for PRO1 Indicators
- 16 ISO 15883-5:2021 Threshold Mode
- 16 ISO 15883-5 Workflow
- 17 Bionova® Cloud Surface Eye Mobile App advanced features

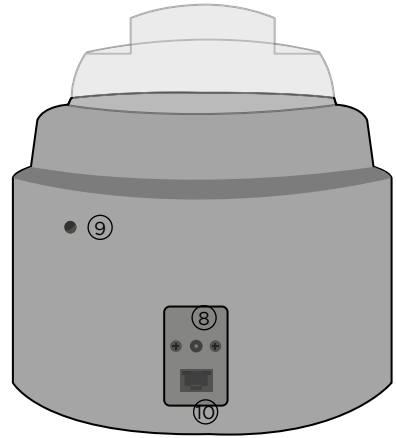
18 Cleaning and maintenance

19 Troubleshooting

20 Warranty

- 20 Term
- 20 Limitation of liability
- 20 Technical assistance

■ Composition



Product description

Bionova® IC10/20FRLCD Auto-reader has been designed for the incubation and automatic readout of Terragene® Rapid, Super Rapid and Ultra Rapid Self-contained biological indicators (SCBIs) appropriate for sterilization and environmental disinfection process control applications, and for the incubation and automatic readout of Hygiene Monitoring System Indicators (Protein pens) appropriate for surface cleaning and contamination control applications.

Bionova® IC10/20FRLCD allows two different incubation temperatures, 37 °C or 60 °C. Microorganisms contained within the SCBIs vary depending on the sterilization process for which they have been designed, therefore, incubation temperatures and incubation times differ depending on the SCBI being used. Bionova® IC10/20FRLCD allows the selection of independent incubation times for each of its positions.

SCBIs for Ethylene Oxide (EO), should be incubated at 37 °C, while those used for the monitoring of the rest of the sterilization processes should be incubated at 60 °C.



Simultaneous incubation of SCBIs for monitoring EO processes along with SCBIs for monitoring other sterilization processes is not possible.

Please check the **Product Compatibility and Incubation programs** section for more information about Incubation Programs and new available Indicators for your Bionova® IC10/20FRLCD.

Bionova® IC10/20FRLCD Auto-reader allows easy and rapid detection of positive and negative SCBIs, using advanced fluorescence techniques. A fluorescence result can also be visually evidenced by culture medium color change when performing extended incubations. Due to the high sensitivity of the fluorescence results, the option to perform or not an extended incubation depends on the internal protocols of each laboratory or hospital. Read the instructions for use of the SCBI for more information.

Bionova® IC10/20FRLCD Auto-reader also provides a printed ticket each time an incubation is completed for recording the results. This allows for easy result management, for documentation compliance and safe-keeping.

Indications for use

United States of America

Terragene® Bionova® Reader Incubators IC10/20FRLCD incubate at 60 °C and 37 °C and read the Terragene® Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Outside the United States

Terragene® Bionova® Reader Incubator IC10/20FRLCD incubate at 60 °C and 37 °C, and read the Terragene® Bionova® SCBIs and the Terragene® Chemdye® Hygiene Monitoring System Indicators at the times prescribed in the User Manuals.

Features















- ① Protective Cover
- ② Incubation Area for 12 SCBIs and 1 Protein pen. Ampoule Crusher
- ③ LCD Touch Screen Display

Composition

- ④ Thermal Printer
- ⑤ Printer's paper indicator light
- ⑥ Paper Traction Button
- ⑦ Cavity for paper
- ⑧ Input for power source plug (12 Volts DC)
- ⑨ Hole for External Temperature Control
- ⑩ Ethernet port (RJ45)

Screen references














-  PRO Configuration Button
-  SCBI Position Configuration Button
-  Position status Indicator
-  13:34 hs.
25/02/16 Date and Time Indicator
-  Remaining Incubation Button
-  Alarm Cancellation Button
-  Incubation Temperature Selection Button
-  Start PRO Button (PRO configuration screen)
-  Cancel PRO Button (PRO configuration screen)
-  Program Configuration Button (SCBI configuration screen)
-  Repeat Selection in all Positions Button (SCBI configuration screen)
-  Incubation Results History Button
-  37 60 Temperature Stability Indicator
-  Bionova® Information Button



Network connection indicator / Bionova® connection indicator

Safety information

Symbols

-  80%
30% Operating relative humidity
-  30 °C
10 °C Operating temperature
-  Caution, Warning, Attention - Refer to the instructions for use
-  Caution: Hot surface
-  Important
-  Direct current
-  For indoor use only
-  Keep away from sunlight
-  Batch code
-  Manufacturer
-  Separate collection for waste of electrical and electronic equipment



To avoid risks and/or damaging the device:

- For indoor use 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 leaned surfaces or on surfaces that are subject to shocks, vibrations, temperature 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 any liquid inside.
- 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 Ethernet cable. Verify that all the included elements are in good condition on daily basis. If any of them is damaged, discontinue their use. 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 Ethernet port other than devices compliant with IEC60950-1, IEC

⚠ Safety information

62368-1 or comparable, with safety extra-low voltages on its Ethernetports. Ask a qualified technician to verify device compatibility. Attaching any other device to the Ethernet port may damage the incubator and may not be safe for the user.

■ Do not attempt to repair the Auto-reader by yourself, that could lead to major and irreversible damages to the device. In case of device malfunction, contact your local distributor for further assistance.



To reduce the risk of using incompletely sterilized loads:

- Please read, understand, and follow the instructions for Use of each SCBI before its incubation.
- Do not remove the SCBI before the incubator reports the final readout result. Check a result ticket is printed.
- Check that culture medium completely wets the spore carrier.



To avoid the risk of injury, related to glass fragments produced when crushing the glass ampoule inside the SCBI tube:

- Cool the SCBI during the indicated time before crushing the ampoule.
- Do not handle the SCBI excessively since this might cause the glass ampoule to burst.
- Wear safety gloves and glasses when removing the SCBI from the sterilizer, pressing the SCBI's cap, and crushing the SCBI's ampoule.
- Do not use your finger for crushing SCBI. Use the Ampoule Crusher instead.



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, inside the incubation positions.
- Place only compatible indicators inside the incubation positions.



To avoid SCBIs from absorbing fluorescent particles:

- Avoid direct contact between the SCBIs and Chemical Indicators or Tapes before the SCBI incubation.



IMPORTANT

Do not use this product in a manner not specified by Terragene® S.A., otherwise the protection provided by the product might be affected.

Only Terragene® S.A. authorized personnel can access or service

the internal components of the Incubator. Parts or components inside the Incubator should not be manipulated by the user.

Operating conditions

Power supply specifications

Input parameters	Operating conditions	Units
Voltage range	(100-240)	AC Volts
Frequency	50/60	Hertz
*Current	0,2	Amperes

Output parameters	Values	Units
Voltage	12	DC Volts
**Current	4	Amperes

* 1 Ampere in USA and Canada.

** 3 Amperes in USA and Canada.

Terragene® S.A. recommends the use of UPS instead of voltage stabilizers, since they fulfill two functions: to stabilize and maintain the energy during a power outage.

Environment operating conditions

Environmental conditions	Operating conditions	Units
Altitude	3500 (máx.)	Meters
Operation temperature	10-30	Celsius
Relative Humidity	30-80	%
Installation/overvoltage	category II	
Degree of contamination	2	
Storage temperature	10-30	Celsius
Voltage	12	DC Volts

Device safety compliance

Bionova® IC10/20FRLCD 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 Compatibility (EMC)	EN 61326-1 EMC Directive 2014/30/EU
European Commission	RoHS Directive 2011/65/EU WEEE Directive 2012/19/EU

Bionova® IC10/20FRLCD Auto-reader do not represent photobiological risk and do not generate dangerous optical radiation in any of its normal operation conditions as per the requirements of IEC 62471 Standard.

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

■ Product Compatibility and Incubation programs

Bionova® IC10/20FRLCD Incubation Programs

The following incubation programs are available for your Bionova® IC10/20FRLCD. Verify which incubation programs are available for your country checking the *Indications for Use* section.

Temperature selection	Incubation time	Incubation program
60 °C	20 min (<i>Ultra</i>)	20 min at 60 °C
	30 min	30 min at 60 °C
	1 h	1 hour at 60 °C
	2 hs	2 hours at 60 °C
	3 hs	3 hours at 60 °C
	PRO (7 min)	PRO at 60 °C
37 °C	4 hs	4 hours at 37 °C

To select the appropriate incubation program for the Indicator you are planning to use, follow each Indicator's Instructions for use.



Select the appropriate incubation program before the incubation of any Indicator.

Bionova® IC10/20FRLCD Auto-reader compatible indicators

We develop new Indicators for extending the features of our Auto-readers regularly. Please check out your Auto-reader's compatibility matrix on www.terragen.com/IC1020FRLCD to find out all compatible indicators for your device.

■ Instructions for use

Start-up

1|Place the Bionova® IC10/20FRLCD Auto-reader on a firm surface, free from vibrations, away from direct sunlight, currents of hot or cold air, chemical and corrosive or flammable substances. Do not place the incubator in a way that disconnection of the power supply's AC plug from mains could be difficult. Leave a space of at least 10 cm from the Incubator to the closest wall. Do not move the Incubator periodically or during its use. Connect the Incubator to a secure and stable electrical mains outlet socket.



Do not wet or heat the device. If liquid is spilled on the Incubator, disconnect it and follow the instructions on the *Cleaning and maintenance* section.

2|Power on your Bionova® IC10/20FRLCD 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 Incubator. The last incubation program used (time and temperature combination) will be selected by default.



Before power on, verify that all incubation positions are empty.



If the Printer's paper indicator light starts blinking after powering on the Incubator, check that the printer's door is tightly closed and that the printer has paper, if not follow the instructions on the *Replacement of the paper roll* section.


3|Set the incubator internal clock to correspond to your local time (see *Settings* from the *Incubator Internal Website* section).



All devices are manufactured with the following settings:



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

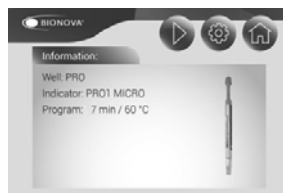
If you want to change the time zone or the printing language, refer to modification of time zone or modification of printing language in the *Set-up mode* section.

4|Select the appropriate incubation temperature for the SCBI you are planning to use, according the SCBI's Instructions for use. Press and hold the  button for 3 seconds to enter the temperature selection to toggle between 37 °C and 60 °C.



Changing the incubation temperature can only be done as long as there is not an ongoing reading.

5|Set the incubation time for the incubation position you are planning to use. Press the incubation position number on the LCD screen (eg. ) press the  button afterwards. Select the SCBI that you are planning to use from the list of compatible SCBIs. After the selection, the Auto-reader will set the right incubation time for the selected SCBI automatically.



To repeat the SCBI selection in all incubation positions press the

Instructions for use

🔍 icon and press the same icon again when it turns into 🚫. This can only be done as long as there is not an ongoing reading.



6 Wait until the temperature stability indicator light stops blinking for the incubator to reach a steady working temperature.



Do not place an indicator in an incubation position before the incubation temperature is stable.

7 Once the temperature stability indicator light remains stable, a one-time automated test to check each position internal status will be carried out (auto-test). Once the test is complete, the position status indicator light will turn green to indicate that the position can be used to perform readings, or it will turn red to indicate that an error has occurred.

When the incubator detects an error in a position, the position will be disabled to guarantee the reliability of the results and it cannot be used to perform any further readings.

To indicate that a position has been disabled, the position status indicator light will turn red and blink indefinitely.



For the correct performance of the auto-test, keep the protective cover closed when the auto-test is running.

8 After the auto-test is complete, readings can be initiated on any incubation position if the position is not disabled. Place an indicator in an SCBI reading position. The reading process will start automatically after placing the SCBI. The incubator will emit an audible notification, indicating that a reading has successfully begun, at the same time the position status lights will start blinking. Close the protective cover and wait until a readout result is obtained.



Read and follow the SCBI's instructions for use. Before placing an SCBI in the incubator, press the top to seal the tube. Crush the internal ampoule (either using the incubator's ampoule crusher or the ampoule crusher included in the SCBI's box). Make sure that culture medium completely wets the spore carrier at the base of the SCBI's tube and agitate.



Do not remove or change the SCBI's placement once a reading process has begun or the reading will be canceled. See the **Canceled reading** section for further details.



If the Auto-reader does not start a reading immediately after placing an SCBI in a reading position, refer to the **Troubleshooting** section for more information.

9 When a positive result is detected in an incubation position, the position status indicator light will turn red, an audible alarm will activate, and a ticket will be printed.

Once the SCBI is removed, the alarm and the red light will turn off automatically after 30 seconds. The position will be available to start a new reading once the position status indicator light turns off. Please refer to the **Interpretation of results** section for more information.



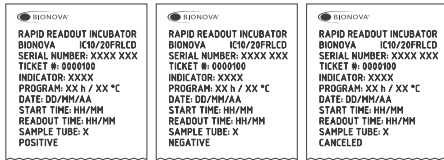
Press the 🚫 button to cancel the audible alarm.

When a negative result is detected in a reading position, the position status indicator light will turn green and a ticket will be printed. Once the SCBI is removed, the green light will turn off automatically after 30 seconds. The position will be available to start a new reading once the position status indicator light has turned off. Please refer to the **Interpretation of results** section for more information.

Note: The incubation time setting defines the upper time limit in which an incubator can inform a fluorescence readout. Nevertheless, the incubator can detect and inform a positive result before the selected time limit as part of its normal operation. Please refer to the product compatibility and incubation settings for more information.

10 Every time the incubator informs a fluorescence result (positive, negative, or canceled), a ticket will be printed to register the result. Pull upward for the paper to be cut with the serrated edge of the printer.

If there is no paper for ticket printing, the printer's paper indicator light will start blinking. To replace the paper, follow the instructions in the **Paper roll replacement** section. The incubator saves the last 208 results. To access them for reprinting, follow the **Results history visualization** section instructions.



POSITIVE

NEGATIVE

CANCELED

Remaining incubation time

Bionova® IC10/20FRLCD Auto-reader allows you to easily verify the remaining incubation time of each reading position. To do this, press the icon. A new screen will open, indicating the remaining readout time of each position that is performing an incubation. In positions where there is no readout initiated, the name of the selected program will be displayed. Press to return to the main screen or wait one minute to return automatically.

Cancel reading

When an SCBI is removed from a position during the incubation process, an audible alarm will be enabled. At the same time, the position status indicator light will turn red and start to blink to indicate that the SCBI should be returned into its original reading position.

If the SCBI is not placed back after 10 seconds of being removed, the reading will be canceled automatically and a ticket will be printed.

Interpretation of results

If a positive result is obtained (red light ●) when incubating an exposed SCBI, this indicates that the sterilization process to which the SCBI was exposed has failed. This result is valid if a positive result is obtained for the positive control SCBI. Take action immediately if a positive result is obtained when incubating an exposed SCBI. Please refer to the sterilizer instructions for use for more information.

If a negative result is obtained when incubating an exposed SCBI (green light ●), this indicates that the sterilization process to which the SCBI was exposed has been successful. This result is valid if a positive result is obtained for the positive control SCBI.



A positive result should always be obtained by the incubator when incubating a positive control SCBI. Refer to the *Positive control* section for more information.

Positive control

A positive control is a non-sterilized SCBI used as a reference during the incubation process. The use of a positive control is

a recommended practice as it helps to ensure:

- The correct incubation temperature is reached.
- Viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals.
- The aptitude of the media to promote rapid growth and fluorescence generation.
- Proper functioning of the incubator.

For the incubation of a positive control SCBI, first press the cap to seal the SCBI and crush the ampoule, making sure the media completely wets the spore carrier. Identify the control SCBI on its label. Place the positive control in an empty incubation position and incubate as described in the SCBI instructions for use.



The positive control and the exposed SCBI should belong to the same batch.



Incubate the positive control SCBI as specified in the SCBI instructions for use.

Disposal

Discard the SCBIs according to your country's sanitary regulations. Positive SCBIs can be sterilized before discarding following the SCBI instructions for use. It is not possible to use or incubate an SCBI more than once.

Results history visualization

IC10/20FRLCD Auto-reader automatically stores the last 208 reading results. These results are accessed by pressing the icon. A screen will be displayed, showing the results in chronological order. The ticket of the desired result can be reprinted by pressing on its corresponding line.

You can also access the visualization of the results by accessing the Home menu of the device (see the *Incubator internal website* section).

Audible alarm

An audible alarm will sound every time a positive result is detected by the incubator. The alarm allows the user to immediately detect a positive result without the need to visually check the device. The alarm can be canceled by pressing the button.

Temperature monitoring

The Bionova® IC10/20FRLCD Auto-reader features an automated internal temperature control. If the incubation temperature falls outside of the specified range of $37 \pm 2 \text{ }^\circ\text{C}$ or $60 \pm 2 \text{ }^\circ\text{C}$, the temperature stability indicator light will start to blink.

Instructions for use

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 device.

Thermal paper specifications

Recommended paper: JUJO AF50KSE3 or similar (order code ICTP).

Paper width : 57 mm

Maximum paper thickness: 60 g/m²

Maximum diameter size: 50 mm

Replacement of the paper roll



1| To replace the paper roll, pull the handle on the printer 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.

Time setting mode




Change the time using the Bionova® Bioupdate*

Connect the incubator via the Ethernet port to a PC as described in the *Local network connection* section and run the program. Select the Auto-reader from the list and press the *Clock Sync* button, to synchronize the auto-reader's internal clock with the PC's clock. Synchronization can only be done as long as there is not an ongoing reading.

Auto-reader internal website

Local Network connection

Bionova® IC10/20FRLCD can be connected to a personal computer (PC) for accessing the Auto-reader home menu and settings, or for connecting the Auto-reader to the Bionova® Cloud traceability software. Follow these instructions to connect the device to your local network.

- 1| Connect the Auto-reader to an ethernet switch or router using a suitable ethernet cable.
- 2| Connect your PC to the same Ethernet switch or router using a suitable Ethernet cable.
- 3| Verify that the Network connection indicator on the LCD screen changes from  to . This indicates that the Auto-reader has connected to your Local Network successfully.
- 4| Press  on the LCD screen to check the Auto-reader's IP Address.


Note: The use of Cat. 5e UTP cable (or superior) with RJ45 connectors is recommended.

Note: The device internal website can be accessed using a Smartphone, Tablet, or any other device that can run a Web Browser, given that the device is connected to the same local network as the Auto-reader.

Internal website: Homepage

After successfully connecting the Auto-reader to your local network, launch a web browser on your PC and enter the Auto-reader's IP in the browser's address bar, to access the Auto-reader home menu and settings. On this screen, you will be able to check the status of each position and the remaining incubation time of all ongoing readings. Also, from this screen, you can access the Auto-reader's settings and the incubation results history screen.

Results history


You can access the results page from the homepage or from any other page, by clicking on the icon . On this page, you

Auto-reader internal website

will find the history of the last 208 results grouped by 10 per page.

By clicking on the previous or next symbol, you will be able to scroll all the results that are stored in chronological order.

Settings

You can access settings page from the homepage or from any other page, by clicking on the icon . On this page, you will find language, date format, time and time zone configuration. These parameters can be configured and synchronized directly with the Auto-reader.

Hygiene monitoring systems

Bionova® IC10/20FRLCD Auto-reader features one incubation position designed for the incubation and automatic readout of Chemdye® Hygiene Monitoring System PRO1 Indicators (PRO1 Protein Pen Indicators) appropriate for surface cleaning and contamination control applications. The use of PRO1 indicators allows you to perform quantitative analysis to determine the amount of residual protein found in sample adjusted by a BSA (Bovine Seric Albumin) reference curve. The protein quantitative analysis method has a detection limit of 1 µg with a sensitivity of 0.5 µg and a maximum detection range of 50 µg. The results are indicated with a resolution of 0.1 µg, with an accuracy greater than 90 % in the whole quantification range (IC95 %).



Refer to *Indications for Use* section to verify which incubation programs and indicators are available for your country.

Readout of PRO1 Indicators

Please follow the instructions below to carry out the incubation and readout of PRO1 indicators on your device.

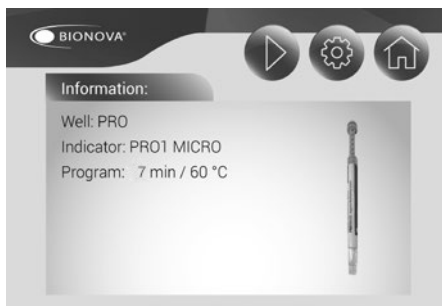
1 Select your preferred Protein Quantification Threshold Mode for your Auto-reader between the two Threshold modes available: Threshold based on HTM01-01 Standard, or Threshold based on ISO 15883-5:2021 standard. For selecting a Threshold Mode and a Threshold value, please follow the indications detailed on Threshold Mode selection on *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




PRO1 incubation position will only be enabled if the temperature of the device is stable at 60 °C and the Temperature Stability Indicator stops blinking. Do not place an indicator until the temperature is stable.

3 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.

4 After a sample from the swabbing surface has been taken, place the 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 on the correct position, the indicator can not be rotated. (Figure 2).




Make sure that the solution is correctly mixed and the reading cone has a sufficient amount of solution before starting an incubation. Make sure that the indicator's swab is not inside the reading cone before starting an incubation.

5 Once the indicator is placed press the  button on the PRO1 indicators setting screen to start the incubation and readout process. Once the process start, the PRO Position status Indicator will start to blink and will keep blinking throughout the whole process. Wait until the incubation and readout process is completed before removing the indicator.



Do not move or 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.

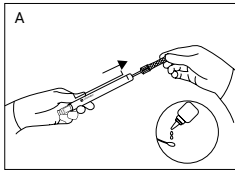
6 Once the incubation and readout process is completed, the PRO Position status Indicator will stop blinking, and a ticket will be printed detailing the µg of protein quantity found in the sample along with other useful information related to the readout process. The protein quantity can also be visualized through the LCD screen, by pressing the  icon.

Hygiene monitoring systems

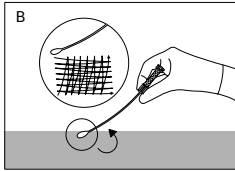
The protein quantity found on the sample is also used to obtain and inform a readout result depending on the Protein Quantification Threshold Mode and threshold values selected on your Auto-reader. Please refer to the *Interpretation of results of PRO1 indicators* section for more information.

Note: The color of the solution on the PRO1 indicator can be used for a qualitative reading only if the protein pen is removed when the program ends. An audible alarm will be set off 30 seconds before the end of the incubation program to warn the operator that the incubation time is close to be completed. If the protein pen is not removed as soon a result is informed the color of the solution will continue to evolve.

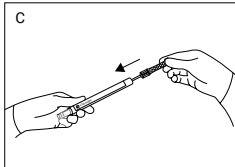
Figure 1



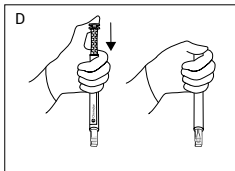
Remove swab and add the moisturizer



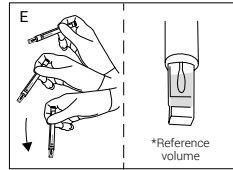
Swab the desired surface by applying a strong pressure



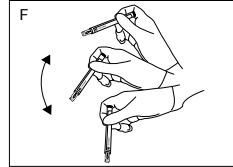
Place the swab back into the device



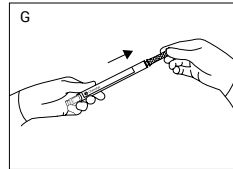
Activate



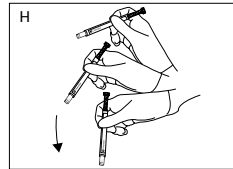
Shake downwards vigorously until the solution turns to green and reaches the readout cone reference volume



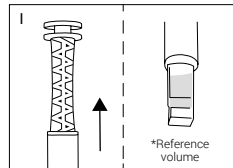
Shake for 15 seconds with the swab inside the readout cone



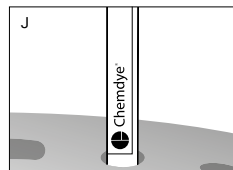
Slide swab upwards without completely removing



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



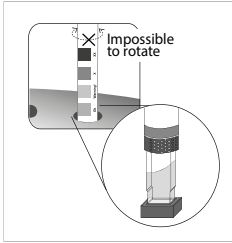
Readout cone without swab



Incubate immediately and read

Hygiene monitoring systems

Figure 2



Insert the pen on the incubation/reading position

Interpretation of 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 Seric Albumin) calibration curve through the LCD screen 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 HTM01-01 Threshold Mode, or Negative, Alert, or Action for ISO 15883-5 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 HTM01-01 Threshold Mode



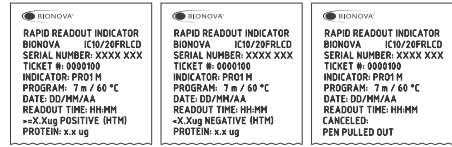
HTM01-01 Threshold Mode is the default Protein Quantification Threshold Mode of your Auto-reader.

HTM01-01 guidelines indicates the use of a single protein quantity threshold to evaluate cleaning efficacy. The guidelines recommends 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.

Important: Refer to the HTM01-01 guidelines for detailed information on how to implement the standard to your processes.

If HTM01-01 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

a printed ticket. The protein quantity can also be visualized through the LCD screen, by pressing the **PRO** icon.



POSITIVE

NEGATIVE

CANCELED

If the protein quantity detected on the sample is lower than the selected threshold, a Negative readout result will be informed and PRO1 position status indicator will turn **GREEN**. If the quantity detected is greater than the selected threshold, a Positive readout result will be informed and the PRO1 position status indicator will turn **RED**. 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 indicate 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 Threshold Mode

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 based thresholds are expressed as ratios in $\mu\text{g}/\text{cm}^2$ units that relates protein quantity found in a sample (μg) and the swabbing surface (cm^2) 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. Recommended threshold value 3 $\mu\text{g}/\text{cm}^2$. 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. Recommended threshold value 6.4 $\mu\text{g}/\text{cm}^2$. Lower values may be recommended for particular applications.

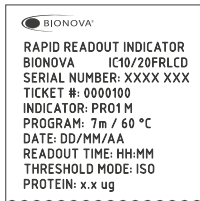
Values between the two thresholds should be investigated, but are considered to pass cleaning requirements.

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

If ISO 15883-5 Threshold Mode is selected as the readout Threshold Mode on your Auto-reader, each time a readout

Hygiene monitoring systems

is completed the protein quantity will be informed through a printed ticket. The protein quantity can also be visualized through the *LCD Screen*, by pressing the  icon.



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

Important: Please keep in mind that according to ISO 15833-5:2021 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 $\mu\text{g}/\text{cm}^2$) that can be comparable with the selected Alarm and Alert thresholds (also in $\mu\text{g}/\text{cm}^2$).

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® Antinova APP. The information is finally linked together by the Bionova® Cloud Environment to inform the readout result. Please refer to *ISO 15833-5:2021 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 ($\mu\text{g}/\text{cm}^2$) is below the Alert Threshold. The readout result will be informed as **NEGATIVE**.

If the protein quantity found on the swabbed surface ($\mu\text{g}/\text{cm}^2$) 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 ($\mu\text{g}/\text{cm}^2$) 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 indicate that the protein quantity found does not comply with the user defined quality standards set for the cleaning process.

Disposal



Discard the PRO1 indicator according to your country's

sanitary regulations. It is not possible to use or incubate a PRO1 indicator more than once. Please refer to the PRO1 instructions for use.

Audible alarm

An audible alarm will sound every time a positive result is detected in your Auto-reader. The alarm allows the user to immediately detect a positive result without the need to visually control the device. The alarm can be canceled by pressing the  button.

Cancel a reading

Press the  icon to access the PRO1 indicators setting screen and press the  button to cancel a reading. The device will cancel the reading and the auto-reader will print out a ticket confirming the cancellation.

Additional features

Firmware update

Bionova® IC10/20FRLCD Auto-reader Incubator allows the update of its firmware (program inside the Incubator that controls and defines its different features) by using the firmware update utility Bionova® Bioupdate. Bionova® Bioupdate connects to the internet to verify, download, and install, the latest firmware version available for your incubator. The update process only lasts a few seconds and is carried out without the loss of any Incubator's data. Please visit www.terragene.com/software to download Bionova® Bioupdate.

Update process

Before updating the device, make sure that the Bionova® Traceability Software is closed. Power Off the Incubator for five seconds, afterwards Power On the Incubator and follow the next steps:

- 1|Connect the Incubator to your Local Network following the instructions on *Local Network connection* section. Make sure your PC is connected to the same network, and that an active internet connection is available.
- 2|Run Bionova® Bioupdate.
- 3|Select the Incubator you want to update, check that the IP is correct. Press the Start button to update.
- 4|Wait until the software indicates that the update process has been completed. The Incubator will print an update confirmation ticket. If it was already up to date, the ticket will not be printed.

Note: This process must be repeated every time that a new firmware version is available, this will be informed in the

Additional features

Terragene® S.A. website.

Note: When it is necessary to update the LCD Screen graphical environment, the update process may take up to 30 minutes. Plan accordingly.

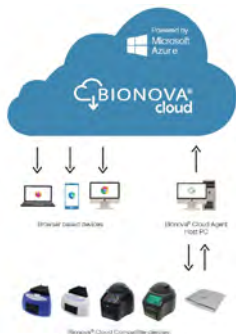
Bionova® Wilink connection

Bionova® Wilink is a Wi-Fi connectivity accessory for Bionova® IC10/20FRLCD. Wilink can be used for connecting the Incubator to a Wi-Fi Network directly, so the incubator connects to your Local Network by Wi-Fi instead of using an Ethernet cable. Please visit www.terrargene.com to learn more about Bionova® Wilink.

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 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.



Bionova® Cloud Traceability Software allows to manage and store the readout results of Self-contained biological indicators and Hygiene Monitoring System Indicators in a secure and user-friendly way.

Bionova® Cloud Traceability Software allows matching the information of an Indicator result with the sterilizer or washing machine used, the operator, cycle characteristics, and all

relevant information for allowing each institution achieve reliable documentation compliance and safe-keeping.

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.

To access to the Bionova® Cloud Environment please visit www.terrargene.com/bionova-cloud.

Threshold Mode selection for PRO1 Indicators

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

Important: Threshold Mode selection is only available for the latests 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 incubator.
- 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: HTM01-01 or ISO 15883-5. 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.

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

ISO 15883-5:2021 Threshold Mode

The new ISO 15883-5:2021 Standard implements new recommendations for taking action based on the findings of hygiene monitoring indicators. One of the major features of this new 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 OS 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 $\mu\text{g}/\text{cm}^2$) that can be compared with ISO 15388:2021 style thresholds.

ISO 15883-5 Workflow

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 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 device.
- Important:** 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 PRO1 Indicator 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

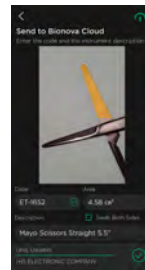
Surface Eye card. Once the position markers are aligned, the App will take a photo automatically.



- 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.

Important: According to ISO 15883-5:2021 Standard, the recommended values for the Alert and Action threshold are $3 \mu\text{g}/\text{cm}^2$ and $6.4 \mu\text{g}/\text{cm}^2$, 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 cm^2 . The use of higher swabbing surfaces ($>7.6 \text{ cm}^2$) imply that the protein


4| Bionova® Cloud Environment

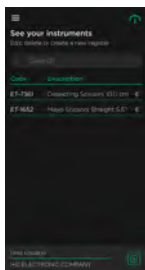
quantity to define the action threshold would be above the 50 µg of the PRO1 Hygiene Monitoring System quantization range and thus cannot be properly used.

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

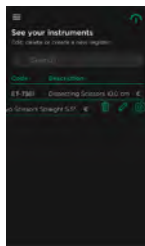
Note: Choose a descriptive code and description for the instrument so its easier to link the surface data with the protein readout information later on the Bionova Cloud Environment.

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 App's 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.

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

Important: 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.

Important: 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

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 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 tapping 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 Ethernet 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 device using a microfiber cloth moistened with a solution of mild dish washing detergent and water. Wring the cloth so it is damp but not dripping before cleaning, and wipe the outer surfaces of the Auto-reader. Afterwards, moisten a clean microfiber cloth with water only, and repeat the procedure until all traces of detergent are removed from the external surfaces of the device. After cleaning, allow the Auto-reader to air dry for at least 1 hour before connecting the power supply cable or the Ethernet cable again.

This cleaning procedure can be followed whenever considered appropriate.

This cleaning procedure must be followed every 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.



Do not clean the internal parts of the device.

Do not pour or immerse the device into any liquid. Do not allow any liquid to run inside the device during its cleaning.

Maintenance

Bionova® IC10/20FRLCD Auto-reader does not require routine maintenance.

■ Troubleshooting

Fault	Possible cause	Action
The Auto-reader does not start.	Power supply is not connected.	Check that the power supply is connected to a proper mains. Check that the DC plug of the power supply is connected to the rear of the Auto-reader.
The Auto-reader informs an error in an incubation position during “Autotest”.	A indicator is placed in the incubation position during the Autotest.	Check that every incubation position is empty during the Autotest.
The Auto-reader informs an error in an incubation position during “Autotest”.	Dust particles might be obstructing the readout mechanism.	Avoid using the Auto-reader in dusty environments. Use air to dust-off inside a position. Do not insert solid objects. Once cleared, restart the Auto-reader.
An incubation can not be run in a SCBI or Protein Pen incubation position (position's red light is on).	Position disabled. Error in that position during “Autotest”.	Make sure that the position is empty when starting the Auto-reader. Once cleared, restart the Auto-reader.
The Auto-reader does not run an incubation in any position.	Incubation temperature is not stable.	Wait until temperature is stable before any incubations.
Is not possible to change temperature and/or time setting.	The printer cover is not tightly closed.	Wait for any incubation to complete, and try again.
The printer does not print (printer blue light blinks quickly).	Printer without paper.	Check that the cover is tightly closed. Place a new paper roll in the right direction.
The printer releases unprinted paper.	Paper roll is not placed correctly.	Place the paper according to the directions on the <i>Replacement of the paper roll</i> section.
The Auto-reader can not be updated.	Bionova® Cloud Agent is running on the PC.	Close Bionova® Cloud Agent and restart the Auto-reader.
The Auto-reader is not detected by Bionova® Cloud Agent.	The Auto-reader is turned off / The Auto-reader is not connected to the PC.	Follow the directions on the <i>Start-up</i> section to set-up the device properly.

■ Warranty

Terragene S.A. guarantees both the quality of the product material components and the quality of its manufacturing process. Should any material or manufacturing faults be detected within the warranty period, the only obligation of Terragene S.A. will be product repairing or substitution.

Term

The warranty period for electronic products marketed by Terragene® will be 1 (one) year from the date of first use of the product, and may never be extended beyond the product's useful life -5 (five) years from its manufacture-.

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

Terragene S.A.
Ruta Nacional N° 9, KM 280 - CP 2130.
Parque Industrial Micropi - Alvear - Santa Fe - Argentina.

