BIONOVA®

Bionova® IC10/20FRLCD Auto-reader

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

WARNING: this product contains dry natural rubber

R11 | May 2025

Terragene®

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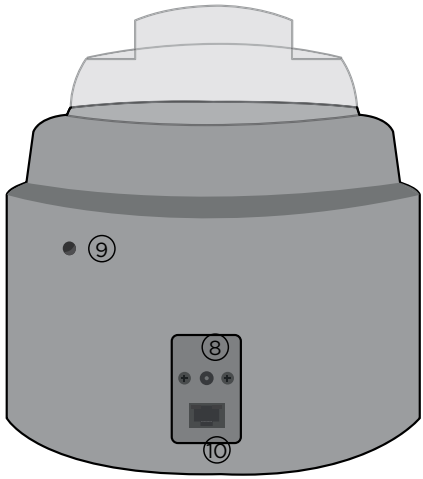
■ Composition



Product description

The Bionova® IC10/20FRLCD Auto-reader was designed for the incubation and automatic readout of Terragene® Bionova® Rapid, Super Rapid and Ultra Rapid Self-contained Biological Indicators (SCBIs) for sterilization and environmental disinfection process control applications, and for the incubation and automatic readout of Terragene® Chemdye® Hygiene Monitoring System Indicators (Protein pens) for cleaning control applications.

The Bionova® IC10/20FRLCD Auto-reader incubates at two different temperatures, 37 °C or 60 °C. The microorganisms within SCBIs vary depending on the sterilization process they were designed for; therefore, incubation temperatures and times differ accordingly. The Bionova® IC10/20FRLCD Auto-reader allows independent incubation time selection for each incubation position.

SCBIs designed for ethylene oxide (EO) sterilization are incubated at 37 ºC, while those used for monitoring other sterilization processes are incubated at 60 ºC.

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

The Bionova® IC10/20FRLCD Auto-reader detects positive and negative SCBIs easily and quickly, using advanced fluorescence techniques. A positive result can also be shown by a change in the culture medium color when extended incubations are carried out. Read the Instructions For Use of the SCBI for more information. The option to perform or not an extended incubation depends on the internal protocols of each laboratory or hospital.

The Bionova® IC10/20FRLCD Auto-reader generates a printed ticket each time an incubation program has been completed enabling 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® SCBI for fluorescent results at the times prescribed in the User Manuals.

Outside the United States of America

Bionova® Auto-reader Incubators IC10/20FRLCD incubate at 60 °C and 37 °C, and read the Bionova® SCBIs and the 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

④ Thermal printer

↲ Composition

⑤ Printer paper indicator light

⑥ Paper traction button

⑦ Cavity for paper

⑧ Socket for power supply plug (12 Volts DC)

⑨ Hole for external temperature control

⑩ Ethernet port (RJ45)

Main screen features

PRO configuration button

SCBI position configuration button

Position status indicator light

Temperature selection button

37 60 Temperature & stability indicator light

Remaining time button

13:34 hs. 25/02/16 Current date and time

Alarm cancellation button

Results history button

Bionova® information button

Network connection indicator

Main screen 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)

■ Safety information

Symbols

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

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.

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

REF **Catalogue number.** Indicates the manufacturer's catalogue number so that the medical device can be identified.

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

Manufacturer. Indicates the medical device manufacturer.

AR **Country of manufacture.** To identify the country of manufacture of products.

Date of manufacture. Indicates the date when the medical device was manufactured. This shall be expressed in accordance with ISO 8601-1 [year-month-day].

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

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

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

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.

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

Consult instructions for use or consult electronic instructions for use. Indicates the need for the user to consult the instructions for use.

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

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

Safety information

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.

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

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

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.

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

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 may 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 the included power supply (AC power adapter), power supply's AC plug, power supply cords, and Ethernet cable only. Check that all the items included are in good condition every day. 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 IEC 60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its Ethernet ports. Ask a qualified technician to check that the device is compatible. Attaching any other device to the Ethernet 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 risk of using incompletely sterilized loads:

- Please read, understand, and follow the Instructions for Use of each SCBI before incubating it.
- Do not remove the SCBI before the auto-reader shows the final readout result. Check a result ticket is printed.
- Check that the spore carrier has been wetted completely by the culture medium.

To avoid the risk of injury by 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 explode.
- 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 to crush the 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, into 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.
- Avoid excessive SCBI handling that may lead to fingerprints or glove talc imprinted over the indicator.

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

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

Environment operating conditions

Environmental conditions	Operating conditions	Units
Altitude	3500 (maximum)	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® 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

The Bionova® IC10/20FRLCD Auto-reader does not represent photobiological risk and does not generate dangerous optical radiation if used within its normal operating 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 programs

Available incubation programs

The following incubation programs are available for your auto-reader.

Temperature selection	Time selection	Incubation program
60 °C	20 minutes	20 minutes at 60 °C
	30 minutes	30 minutes at 60 °C
	1 hour	1 hour at 60 °C
	2 hours	2 hours at 60 °C
	3 hours	3 hours at 60 °C
	7 minutes (PRO)	PRO at 60 °C
37 °C	4 hours	4 hours at 37 °C

To select the appropriate incubation program for the SCBI or PRO1 indicator you are planning to use, follow each SCBI/ PRO1 indicator Instructions For Use.

Note: Please read and follow the SCBI/ PRO1 indicator Instructions For Use before using it.
Note: All SCBIs and PRO1 indicators are single use. Do not use or incubate the same SCBI/ PRO1 indicator more than once.

Compatible SCBIs

We develop new SCBIs for extending the features of our auto-readers regularly. Please check out your auto-reader's compatibility matrix to find out more about all compatible SCBIs for your auto-reader.

■ Instructions for use

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

Start-up

1.Place the auto-reader on a firm surface, free from vibrations, away from direct sunlight, hot or cold air flows, chemical, 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 during its use. 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 the mains and then connect the plug at the other end of power supply to the rear of the suto-reader. The last used incubation program (time and temperature combination) will be selected by default.
Note: Before switching it on, check that all incubation positions are empty.
Note: If the printer paper indicator light blinks after switching on the auto-reader, check that the printer door is tightly closed and that there is paper in the printer. For more information, please refer to the following section: ***Replacement of the paper roll.***

3.Set the auto-reader local date and time. For more information, please refer to the following section: ***Auto-reader internal website.***
Note: All devices are manufactured with the following settings:
- Time zone: UTC +0:00
- Printing language: English

You can change the time zone and the printing language. For more information, please refer to the following section: ***Auto-reader internal website.***

4.Select the appropriate incubation temperature for the SCBI you are planning to use, according to the SCBI Instructions For Use. To change the incubation temperature, press and hold the temperature selection button for 3 seconds: . The temperature modification will automatically be accepted.
Note: To return to the main screen, press the button: .
Note: Do not place an SCBI on an incubation position before the incubation temperature is stable.
Note: Changing the incubation temperature can only be done as long as there is not an ongoing reading.

5.Select the appropriate incubation time for the incubation position you are planning to use. Press the SCBI position configuration button on the main screen (e.g.). Then, press the program configuration button ( ) and choose the SCBI from the list of compatible SCBIs. Once selected, the auto-reader will automatically set the incubation time for the chosen SCBI.

Note: To repeat the SCBI selection in all incubation positions, press the repeat selection in all positions button ( ) in the SCBI configuration screen, and this will change to: . Then, select the SCBI that you are planning to use from the list of compatible SCBIs. This can only be done as long as there is not an ongoing reading.

Note: To return to the main screen, press the button: .

6.Wait until the temperature & stability indicator light stops blinking, indicating that the auto-reader has reached a steady working temperature.
Note: Do not place an SCBI 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.
Once the test has been completed, 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 auto-reader detects an error in a position, this 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 position status indicator light will turn red and will blink continuously.
Note: To ensure the automated test, keep the protective cover closed when the automated test is running.

8.Once the automated test has been completed, the readings can be initiated on any incubation position if the position has not been disabled. Place an SCBI in an incubation position. The reading process will start automatically after placing the SCBI. The auto-reader will emit an audible notification, indicating that a reading has successfully began, at the same time the position status indicator light will start blinking. Close the protective cover and wait until a readout result has been carried out.
Note: To return to the main screen, press the button: .
Note: Before placing an SCBI in the auto-reader, press the top to seal the tube, crush the internal ampoule (either using the auto-reader's ampoule crusher or using the ampoule crusher included in the SCBI box) and make sure that culture medium completely wets the spore carrier at the base of the SCBI's tube and agitate. Please, read and follow the SCBI Instructions For Use.
Note: Do not remove or change the position of the SCBI once the reading process has begun. If you do this, the results may be invalidated. For more information, please refer to the following section: ***Cancelling a reading.***

If the auto-reader does not start a reading immediately after placing an SCBI in an incubation position, please refer to the following section: ***Troubleshooting.***

9.If a positive result is detected in an incubation position, the position status indicator light will turn red, and an audible alarm will sound.

Note: To cancel the audible alarm, press the button: .

If a negative result is detected in an incubation position, the position status indicator light will turn green. Once the SCBI has been removed, the position status indicator 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. For more information, please refer to the following section: ***Interpreting the results.***

Note: The incubation time setting defines the upper time limit in which an auto-reader can provide a fluorescence readout. The auto-reader can, however, detect and provide a positive result before the selected time limit under normal operation. For more information, please refer to the following section: ***Product compatibility and incubation programs.***

10. Each time a readout is carried out, the auto-reader will store the fluorescence result (positive, negative, or canceled) in its internal memory and a ticket will be printed to record it. Pull the paper upward to cut using the printer serrated edge.

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

Note: The auto-reader will save the last 208 results. For more information on how to reprint results, refer to the following section: ***Results history visualization.***

Remaining incubation time

The remaining incubation time of ongoing incubations can be checked by pressing the remaining time button: .

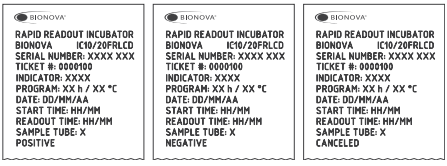
A new screen will appear, showing the remaining incubation time of each position currently incubating. For positions without an initiated readout, the name of the selected program will be displayed. Press the main screen button to return to the main screen or wait one minute to an automatic return.

Cancelling a reading

If an SCBI is removed from a position during the reading process, an audible alarm will sound.

At the same time, the position status indicator light will turn orange 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.

Interpreting the results



POSITIVE **NEGATIVE** **CANCELED**

To indicate a positive result, a red light will come on at the incubation position of the auto-reader.

If a positive result is obtained 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.

Act immediately if a positive result is obtained when incubating an exposed SCBI. Please refer to the sterilizer Instructions For Use for more information.

To indicate a negative result, a green light will come on at the incubation position of the auto-reader.

If a negative result is obtained when incubating an exposed SCBI, 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.

Note: A positive result should always be obtained by the auto-reader when incubating a positive control SCBI. For more information, please refer to the following section: ***Positive control.***

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.
- The viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals.
- The media is able to promote rapid growth and generate fluorescence.
- The auto-reader is operating correctly.

For the incubation of a positive control SCBI, press the top to seal the tube 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.

Note: The positive control and the exposed SCBI should come from the same batch.

Note: Incubate the positive control following the SCBI Instructions For Use.

Disposing of SCBIs

Dispose of the SCBIs in accordance with your country's waste-disposal guidelines. 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.

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 auto-reader. The alarm can be canceled by pressing the button: .

Monitoring the temperature

The auto-reader features an automated internal temperature control. If the incubation temperature falls outside of the specified range of 37±2 °C or 60±2 °C, the temperature & stability indicator light 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.

Reprinting the results

The auto-reader allows reprinting of the last 208 readout results. For reprinting the results, press the button: .
A screen will be displayed, showing the results in chronological order. To reprint the ticket of a specific result, press its corresponding line.
You can also view the readout results by navigating to the Home menu of the auto-reader. For more information, refer to the following section: ***Auto-reader internal website.***

Thermal paper specifications

- Recommended paper: JUJO AF50KSE3 or similar (order code ICTP).
- Paper width: 57 mm.
- Maximum paper thickness: 60 g/m^2.
- Maximum diameter size: 50 mm.

Replacement of the paper roll

To replace the paper roll, follow the instructions bellow:

1|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.
Note: To feed the paper, press the button:

Time setting mode

Modification of the time using the firmware update utility

1.Connect the auto-reader via the Ethernet port to a PC where the firmware update utility has been previously installed. For more information, please refer to the following section: ***Local network connection.***
2.Run the firmware update utility.
3.Select the auto-reader from the list and press the button: *Clock Sync.*
4.The auto-reader internal time and date will be synchronized with the PC current time and date.
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 Ethernet cable, connect your auto-reader to a PC where the Bionova® Cloud Agent has been previously installed. For more information, please refer to the following section: ***Local network connection.***
2.Run the Bionova® Cloud Agent.
Note: Check that the network connection indicator on the LCD screen changes to:
3.Select the auto-reader from the list and press the button: *Clock Sync.*
4.The auto-reader internal time and date will be synchronized with the PC current time and date.

Modification of the time using the Auto-reader internal website

1.Connect the auto-reader via the Ethernet port to a PC. For more information, please refer to the following section: ***Local network connection.***
2.Access the home menu and settings of the auto-reader by launching a web browser on your PC and entering the auto-reader's IP address in the browser's address bar.
Note: To check the Auto-reader's IP Address, press the button: BIONOVA.
3.Access the time settings by pressing the button: . For more information, please refer to the following section: ***Auto-reader internal website.***

■ Auto-reader internal website

Local Network connection

To connect the auto-reader to a personal computer (PC), follow the instructions below:

1.Connect the auto-reader to an Ethernet switch or router using a suitable Ethernet cable.
Note: The use of Cat. 5e UTP cable (or superior) with RJ45 connectors is recommended.
2.Connect your PC to the same Ethernet switch or router using the suitable Ethernet cable.
3.Check that the network connection indicator on the LCD screen changes to: . This indicates that the auto-reader has successfully connected to your Local Network.
Note: The local network connection may take between 1 and 2 minutes to establish.
Note: The auto-reader's internal website can be accessed using a smartphone, tablet, or any other device capable of running a web browser, as long as the device is connected to the same local network as the auto-reader.

Internal website: Homepage

Note: To check the auto-reader's IP address, press the button: BIONOVA .
After successfully connecting the auto-reader to your local network, launch a web browser on your PC and enter the auto-reader's IP address in the browser's address bar to access the home menu and settings. This screen allows to check the status of each position and the remaining incubation time of all ongoing readings. Additionally, you can access the auto-reader's settings and the incubation results history.
Note: To access the history results, click on the button: . On this page, you will find the last 208 results stored in the auto-reader in chronological order.
Note: To access the settings page, click on the button: . On this page, you will find language, date format, time and time zone configuration.

■ Hygiene monitoring systems

The auto-reader has one incubation position designed for the incubation and automatic readout of Chemdye® Hygiene Monitoring System PRO1 Indicators for protein detection and quantification. The readout of PRO1 indicators allows the detection and quantification of residual proteins after the cleaning process. The protein quantitative analysis has a quantification range from 1 to 50 µg of protein with a limit of detection (LOD) of 0.5 µg and a quantification range from 1 to 50 µg BSA (bovine serum albumin). For more information, please refer to the following section: ***Product Compatibility and Incubation programs.***
Note: Please read and follow the PRO1 Instructions For Use before using it.

Reading of PRO1 Indicators

To incubate and readout PRO1 indicators, follow the instructions bellow:

1.Select one protein quantification threshold mode for your auto-reader.
There are two threshold modes available:
- Threshold based on HTM 01-01 standard,
- Threshold based on ISO 15883-5:2021 standard.

To select a threshold mode and a threshold value, please refer to the following section: ***Bionova® Cloud Environment.***
Note: All auto-readers are manufactured with the following settings:
- Threshold mode: HTM 01-01
- Protein threshold: 1 µg

Note: Make sure that the selected protein quantification threshold is according to your needs before performing an incubation. The threshold mode cannot be changed during ongoing readings.
Note: The ISO 15883-5:2021 Threshold Mode is available only for PRO1 MICRO indicators.
2.Access the PRO1 configuration screen by pressing the button: Pro.
Note: The PRO1 incubation position will only be enabled when the temperature of the auto-reader has stabilized at 60 °C and the temperature & stability indicator light has stopped blinking. Do not place a PRO1 indicator until the temperature is stable.
3.To take a sample for analysis, use a compatible PRO1 indicator and follow its Instructions For Use.
4.Once the sample has been taken, place the PRO1 indicator fully inside the PRO1 incubation position, as shown in Figure 1. When the PRO1 indicator is in the correct position, it cannot be rotated, as shown in Figure 2.
Note: Make sure that the solution is mixed correctly and that the reading cone has a sufficient amount of solution before starting an incubation.
Note: The incubation should be performed with the swab out of the solution (reading cone) and immediately after activation.

Figure 1

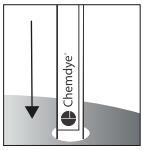
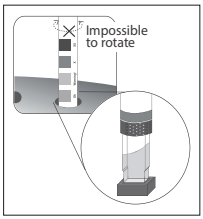


Figure 2



5.Start the incubation and readout process by pressing the button: ▷. Once the process start, the auto-reader will emit an audible notification indicating that a reading has successfully began, at the same time the position status indicator light will start blinking. Wait until the readout result has been carried out.

Note: Do not remove the PRO1 indicator once the reading process has begun. If this occurs, the results may be invalidated.

6.Once the incubation and readout process has been completed, the position status indicator light will stop blinking, and a ticket will be printed detailing the µg of protein quantity with other useful information. To check the protein quantity on the LCD screen, press the button: Pro. For more information, please refer to the following sections: ***Interpreting the results of PRO1 MICRO indicators, Interpreting the results of PRO1 ENDO indicators.***

Note: The color of the solution in 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 sound 30 seconds before the end of the incubation program to warn the operator that the incubation time is about to be completed. If the protein pen is not removed as soon as the result is informed, the color of the solution will continue to change.

Interpreting the results of PRO1 MICRO indicators

Once a readout process has been finished, the auto-reader will inform the equivalent µg of protein quantity using a BSA (Bovine Seric Albumin) calibration curve through the LCD screen and a ticket will be printed.

The protein quantity detected in a sample is also used to generate and inform a readout result based on the threshold mode and threshold values selected on your auto-reader. The readout result can be either positive or negative in HTM 01-01 Threshold Mode, or negative, alert, or action in ISO 15883-5:2021 Threshold Mode. To select a threshold mode and its values, please refer to the following section: ***Bionova® Cloud Environment.***

Note: The ISO 15883-5:2021 Threshold Mode is only available for PRO1 MICRO indicators.

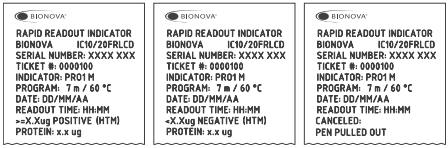
Note: The HTM 01-01 Threshold Mode is the default protein quantification threshold mode.

Readout results in HTM 01-01 Threshold Mode

The 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: For detailed information on how to implement the standard in your processes, please refer to the HTM 01-01guidelines.

If the 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 a printed ticket. To check the protein quantity on the LCD screen, press the button: Pro.



POSITIVE **NEGATIVE** **CANCELED**

To indicate a negative result, the position status indicator light will turn green. If a negative result is obtained when incubating a PRO1 MICRO indicator, this indicates that the protein quantity detected on the sample is lower than 5 µg BSA.

To indicate a positive result, the position status indicator light will turn red. If a positive result is obtained when incubating a PRO1 MICRO indicator, this indicates that the protein quantity detected is greater than 5 µg BSA.

Act immediately if a positive result is obtained when incubating a PRO1 MICRO indicator. This indicates that the protein quantity does not comply with the user defined quality standards set for cleaning process.

Readout results in ISO 15883-5:2021 Threshold Mode

Note: The ISO 15883-5:2021 Threshold Mode is available only for PRO1 MICRO indicators.

The ISO 15883-5:2021 standard establishes two protein quantity thresholds for evaluating cleaning efficacy: an action threshold, and an alert threshold. These thresholds are expressed as ratios in µg/cm², relating the protein quantity detected in a sample (µg) to the swabbed surface area (cm²). Each threshold has different implications:

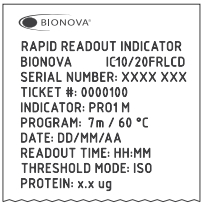
- *Alert threshold:* Represents the target level of cleaning efficacy that the process should achieve. The recommended threshold value is 3 µg/cm², though lower values may be recommended for specific applications.
- *Action threshold:* Represents the maximum acceptable level of residual protein during testing. The recommended threshold value is 6.4 µg/cm², thought lower values may be recommended for specific applications.

Values between these two thresholds should be investigated but are considered acceptable for cleaning requirements.

Note: Refer to the ISO 15883-5:2021 standard for detailed information on its implementation the standard in your processes.

If the ISO 15883-5:2021 Threshold Mode is selected, the detected protein quantity will be printed on a ticket after each readout.

To check the protein quantity on the LCD screen, press the button: Pro.



Note: The position status indicator light will turn green if the protein quantity detected is lower than 1 µg BSA.
Note: The position status indicator light will turn red if the protein quantity detected is greater than 1 µg BSA.

According to ISO 15833-5:2021, the protein quantity detected in a sample (in µg) must be related to the swabbed surface area to obtain a readout result (in µg/cm²) comparable to the selected Alert and Action thresholds.

Note: To estimate the swabbing surface area, follow the steps detailed at: www.terragene.com/surface-eye
Note: To obtain the readout result, please refer to the following section: ***Bionova® Cloud Environment.***

The readout result can be as follows, based on the threshold values selected:

- If the protein quantity on the swabbed surface (µg/cm²) is below the Alert threshold, the readout result will be reported as: **NEGATIVE**.
- If the protein quantity on the swabbed surface (µg/cm²) is above the Alert threshold but below the Action threshold, the readout result will be reported as: **ALERT**.
- If the protein quantity on the swabbed surface (µg/cm²) is above the Action threshold, the readout result will be reported as: **ACTION**.

Act immediately whenever an ACTION readout result is reported as it indicates that the detected protein quantity does not comply with the user-defined quality standards for the cleaning process.

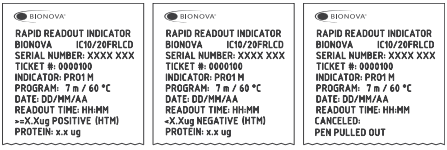
Interpreting the results of PRO1 ENDO indicators

The PRO1 ENDO indicator has been developed based on one of the methods described in Annex C of the ISO 15883-5:2021 standard, specifically designed for detecting and evaluating residual protein contamination.
Currently, there is no specific standard that defines acceptance limits for residual protein in cannulated instruments. Therefore, we recommend using the HTM 01-01 Threshold Mode as a reference.

Readout results in HTM 01-01 Threshold Mode

The 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: For detailed information on how to implement the standard in your processes, please refer to the HTM 01-01 guidelines.

Each time a readout is completed, the protein quantity will be informed through a printed ticket.
To check the protein quantity on the LCD screen, press the button: Pro.



POSITIVE **NEGATIVE** **CANCELED**

To indicate a negative result, the position status indicator light will turn green. If a negative result is obtained when incubating a PRO1 ENDO indicator, this indicates that the protein quantity detected on the sample is lower than 5 µg BSA.
To indicate a positive result, the position status indicator light will turn red. If a positive result is obtained when incubating a PRO1 ENDO indicator, this indicates that the protein quantity detected is greater than 5 µg BSA. This indicates that the protein quantity does not comply with the user defined quality standards set for the cleaning process.

Disposing of PRO1 indicators

Dispose of the PRO1 indicators in accordance with your country's waste-disposal guidelines. It is not possible to use or incubate a PRO1 indicator more than once. For more information, please refer to the PRO1 indicator Instructions For Use.

Audible alarm

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

Cancelling a reading

To cancel a reading, enter to the PRO configuration screen and press and hold the following button for 4 seconds: □. Then, the auto-reader will cancel the current readout process and generate a printed ticket to confirm the cancellation.

■ Additional features

Firmware update

The auto-reader firmware can be updated (a program inside the auto-reader checks and defines the various features) with the firmware update utility. The firmware update utility 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.

To download the firmware update utility, please visit: www.terragene.com/software

Update process

Before updating the device, switch off the auto-reader for five seconds, then switch the auto-reader back on and follow the next steps:

1.Connect the auto-reader to your Local Network. For more information, please refer to the following section: ***Auto-reader internal website.*** Make sure the PC has the same network connection and a working Internet connection.

2.Run the firmware update utility.

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 it was already up to date, the ticket will not be printed.

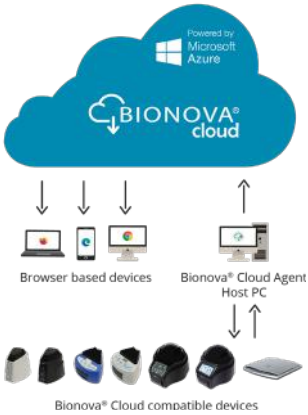
Note: It is recommended that this process is carried out once a year unless required by the manufacturer.

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

■ Bionova® Cloud Environment

The new Bionova® Cloud Environment is a cloud based solution that integrates the information generated by Terragene® auto-readers with an easy-to-use Web Application for the traceability of sterilization and disinfection control applications.

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



The Bionova® Cloud Web Application can be used to manage and store the readout results of Self-contained Biological Indicators and Hygiene Monitoring System Indicators in a secure and user-friendly way.

The Bionova® Cloud Web Application 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 devices and the Host PC where the Agent Application operated.

The Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Web Application and sends the information generated by the devices to the Microsoft™ Azure powered Cloud server where the web application is operating and stores the information.

The user can then access 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

For more information, please refer to the Bionova® Cloud User Manual.

Threshold mode selection for PRO1 Indicators

The Bionova® Cloud Web Application can be used to select the protein quantification threshold mode and threshold values for your auto-reader.

Note: The threshold mode selection is only available for the latest firmware versions. To update your auto-reader's firmware, please refer to the following section: ***Additional features***.

To select or change the protein quantification threshold mode and the threshold values, please follow the next steps:

1.Connect your auto-reader to a PC on which the Bionova® Cloud Agent is installed.

Note: To connect the auto-reader to a PC, please refer to the following section: ***Auto-reader internal website***.

↲ Bionova® Cloud Environment

2.Run and Log-in to the Bionova® Cloud Agent. Wait until the Agent lists the auto-reader.
Note: Check that the Network connection indicator on the LCD screen changes to: 

3.Log-in to the Bionova® Cloud Web Application as: ***Administrator.***

4.Go to the left side Configuration menu and select: ***Parameters.***

5.Select the threshold working mode for your Auto-reader: HTM 01-01 or ISO 15883-5:2021. To confirm your selection, click on the button: ***SAVE.***
Note: The ISO 15883-5:2021 Threshold Mode is only available for Chemdye® Hygiene Monitoring System PRO1 Micro Indicators.

6.Enter the threshold values for the selected mode. To store the values, click on the button: ***SAVE.***
If the process is successfully completed, your auto-reader will generate a printed ticket detailing the selected threshold mode.

ISO 15883-5:2021 Threshold Mode

The ISO 15883-5:2021 standard implements new recommendations for taking action based on hygiene monitoring indicators findings. One of the major features in this revision is the requirement to relate the measured protein quantities from a swabbed instrument to the surface area from which the sample was taken, ensuring accurate decision-marking regarding decontamination and washing equipment.
To estimate the swabbing surface area, the new Surface Eye Application was designed. This Mobile Application, developed by Terragene S.A. utilizes advanced machine learning technologies to provide a quick and accurate estimation of an instrument's swabbed surface in just a few simple steps. The application also implements seamlessly integration with Bionova® Cloud.
By linking protein quantification readout data (in µg) from an auto-reader with swabbing surface data (in cm^2) from the Surface Eye Application via Bionova® Cloud, users can generate protein-to-surface ratios (in $\mu g/cm^2$) that align with ISO 15883-5:2021 thresholds recommendations.

ISO 15883-5:2021 Workflow

To link protein quantification with surface estimation, follow the next steps:

A) Set-up

1.Configure your auto-reader for ISO 15883-5:2021 Threshold Mode. For more information, please refer to the following section: ***Threshold Mode selection for PRO1 indicators.***
2.Download the Surface Eye Application from Google Play Store or App Store on a compatible mobile device.
Note: Make sure your mobile device has a functional camera for the Surface Eye Application to work properly.

B) Log-in and authentication

1.Log-in to the Bionova® Cloud Agent on the PC connected to your auto-reader.
2.Log-in to the Surface Eye Application with the same credentials as in the Bionova® Cloud Agent.
3.Log-in to the Bionova® Cloud Web Application with the same credentials.

C) Swabbing and surface estimation

1.Place the instrument to be swabbed over the Surface Eye Card and open the Surface Eye Application.
2.Estimate the swabbing surface area by following the instructions at: www.terragene.com/surface-eye
Note: Standardizing the swabbing area for each instrument ensures repeatability over time and provides valuable statistical information.
Note: According to ISO 15883-5:2021 Standard, the recommended threshold values are:
- *Alert threshold:* 3 $\mu g/cm^2$
- *Action threshold:* 6.4 $\mu g/cm^2$

For accurate results, use standardized swabbing surfaces between 1 cm^2 and 7 cm^2. Using surfaces larger than > 7,6 cm^2 may exceed the 50 µg quantification limit of the PRO1 Hygiene Monitoring System, making results unreliable.
3.Once ready, the Surface Eye Application will upload the surface data to your Bionova® Cloud account.
Note: The surface acquisition details can be edited from the Surface Eye Application'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.
Note: For instruments, make sure to swab evenly the same surface area that was selected on the Surface Eye Application.
2.Carry out the incubation and readout of the PRO1 Indicator. Wait for a readout result to be informed. For more information, please refer to the following section: ***Hygiene monitoring system***.

E) Linking protein readout information and swabbing surface information

For instruments, once the readout result is informed by the auto-reader, go to Bionova® Cloud Web Application and fill in the PRO1 Indicator readout information to select the surface acquisition data details of the swabbed surface.
Note: To select the surface acquisition data details of the swabbed surface, follow the instructions at:
www.terragene.com/surface-eye

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 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 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 in air 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 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 device.
Note: Do not pour liquid onto the device or immerse it in any liquid. Do not allow any liquid to enter device while it is being cleaned.

Maintenance

The auto-reader does not require routine maintenance.

Troubleshooting

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

Problem: *The auto-reader informs an error in an incubation position during automated test.*
Possible causes: An SCBI was placed in the incubation position during the automated test.
Dust particles might be obstructing the readout mechanism.
Actions: Check that every incubation position is empty during the Automated test. Restart the device.
If after restarting the device, the problem persists, use air to remove any dust inside the 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 SCBI or Protein Pen incubation position (position's red light is on).*
Possible causes: Position disabled. Error in that position during 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 change temperature and/or time setting.*
Possible causes: Ongoing reading.
Actions: Wait for any incubation to complete, and try again.

Problem: *The printer does not print (printer paper indicator light blinks quickly).*
Possible causes: The printer cover is not tightly closed.
The printer has not 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: Paper roll is not placed correctly.
Actions: Follow the instructions to place the paper properly. For more information, please refer to the following section: *Replacement of the paper roll.*

Problem: *The auto-reader will not be update.*
Possible causes: The Firmware update utility is not running.
Actions: Install and run the Firmware update utility. For more information, please refer to the following section: *Additional features.*

Problem: *The auto-reader has not been 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 instructions to set up the device properly. For more information, please refer to the following section: *Instructions for use.*

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® IC10/20FRLCD 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.

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. In USA, please call +1 844 837 7243.

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