



Bionova® IC10/20FR Auto-reader

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

WARNING: This product contains dry natural rubber
R33 / 05.2026



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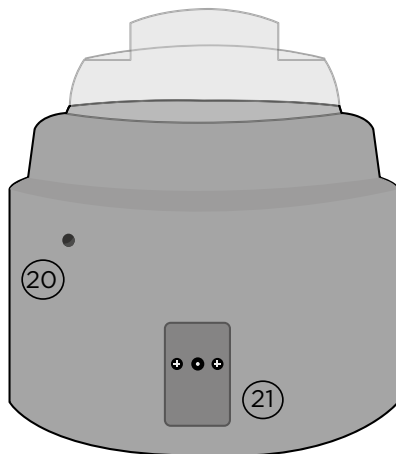
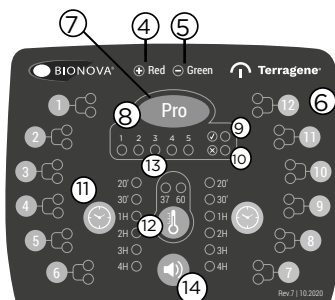
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A detailed line drawing of the Bionova TerraNova Pro machine. The machine is grey with a black control panel. It features a large, clear, dome-shaped lid on top. The control panel includes a digital display, various buttons, and a power switch. The machine has a front-loading slot for documents and a side panel with a power button. Numbered callouts (1-19) point to specific features: 1 points to the lid, 2 points to the top surface, 3 points to the left side, 15 points to the front-loading slot, 16 points to the front panel, 17 points to the front-loading slot, 18 points to the front-loading slot, 19 points to the side panel, and 2 points to the top surface.



The Bionova® iC10/20FR 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 disinfection process control applications, and for the incubation and automatic readout of Terragene® Chemdye® Hygiene Monitoring System Indicators (Protein pens) appropriate for the detection and quantification of surface proteins.

The Bionova® IC10/20FR Auto-reader 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. The Bionova® IC10/20FR Auto-reader allows two independent incubation time selections: One of them for incubation positions 1 to 6, and the other for incubation positions 7 to 12. The 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.

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

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 each SCBI for more information. 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.

Indications for use

Terragenex® Bionova® IC10/20FR Auto-reader incubates at 60 °C and reads the Terragenex® Bionova® SCBLs (BT220, BT221, BT222, and BT223) for fluorescent results at 30 minutes (BT223), 1 hour (BT221, BT222), and 3 hours (BT220).

Terragene® Bionova® IC10/20FR Auto-reader incubates at 60 °C and 37 °C, and reads the Terragene® Bionova® SCBIs and the Terragene® Chemdye® Hygiene Monitoring System Indicators at the times prescribed in this User Manual.

Features

- ① Protective cover
- ② Incubation area for 12 SCBIs and 1 Protein pen / Ampoule crusher
- ③ Control panel
- ④ Positive indicator light (red)
- ⑤ Negative Indicator light (green)
- ⑥ Incubation position number
- ⑦ Start incubation program button
- ⑧ Quantitative protein level indicators
- ⑨ Negative indicator light (green) / Protein level below the selected threshold
- ⑩ Positive indicator light (red) / Protein level above the selected threshold
- ⑪ Incubation time selection buttons
- ⑫ Incubation temperature selection button / Time left button
- ⑬ Temperature & stability indicator light
- ⑭ Alarm cancellation button
- ⑮ Thermal printer
- ⑯ Printer paper indicator light
- ⑰ Paper traction button
- ⑱ Cavity for paper
- ⑲ USB port
- ⑳ Hole for external temperature control
- ㉑ Socket for power supply plug (12 Volts DC)

■ Safety information

Symbols

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



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



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



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



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



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



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



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



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



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



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



Manufacturer. Indicates the medical device manufacturer.



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



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



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



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



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



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



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



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



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



To avoid risks and/or damaging the device:

- Use indoors only.
- Do not place the auto-reader in a room exposed to direct sunlight or to high luminous intensity lamps.
- Do not place the auto-reader near devices that emit strong electromagnetic fields.
- Do not use the auto-reader on sloping surfaces or on surfaces that 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 only the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable. 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 USB port other than a personal computer (PC). The PC must be compliant with IEC 60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its USB ports. Ask a qualified technician to check that the device is compatible. Attaching any other device to the USB port may damage the auto-reader and may not be safe for the user.

■ Do not attempt to repair the auto-reader yourself. This could lead to major and irreversible damages to the device. If the auto-reader malfunctions, contact your local distributor for further assistance.



To reduce the 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 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 goggles 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	Ampere
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: To stabilize and maintain the energy during a power outage.

Environmental operating conditions

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

Device safety compliance

The Bionova® IC10/20FR 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® IC10/20FR 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
37 °C	PRO (7 minutes)	PRO at 60 °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, understand 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 your 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 and corrosive or flammable substances. Do not place the auto-reader in a way that would make it difficult to remove the power supply's AC plug from mains. Leave a space of at least 10 cm from the auto-reader to the closest wall. Do not move the auto-reader periodically or while it is being used. Connect the auto-reader to a secure and stable electrical mains outlet socket.

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

2| Switch on the auto-reader by connecting the power supply's AC plug to mains and then connect the plug at the other end of power supply to the rear of the auto-reader. 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's door is tightly closed and that the printer has paper. 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: **Time setting mode**.

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: **Configuration mode**.

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. Press again to select the desired temperature. After 4 seconds the temperature modification will be accepted automatically.

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. To select the incubation time for incubation positions 1 to 6, press the left incubation time selection button. To select the incubation time for incubation positions 7 to 12, press the right incubation time selection 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 negative indicator light will turn on to indicate that the position can be used to perform readings, or the positive indicator light will turn on 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 positive indicator light will blink continuously.

Note: To ensure the automated test works properly, 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 positive and negative indicator lights will start blinking. Close the protective cover and wait until a readout result has been carried out.

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's box) and make sure that culture medium completely wets the spore carrier at the base of the SCBI's tube. Please, read and follow the SCBI's Instructions for Use before its use.

Note: Do not move, 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: **Canceling 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 positive indicator light will turn on, and an audible alarm will sound. This indicates that the sterilization process to which the SCBI was exposed has failed. Once the SCBI has been removed, the alarm and the positive indicator light will turn off automatically after 30 seconds. The position will be available to start a new reading once the positive indicator light has turned off.

Note: To cancel the audible alarm, press the button: . If a negative result is detected in an incubation position, the negative indicator light will turn on. This indicates that the sterilization process to which the SCBI was exposed has been successful. Once the SCBI has been removed, the negative indicator light will turn off automatically after 30 seconds. The position will be available to start a new reading once the negative indicator light has turned 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 result. 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 it using the printer's 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 13 results. For more information on how to reprint results, please refer to the following section: **Reprinting the results**.

Remaining incubation time

The remaining incubation time of ongoing incubations can be checked by printing a ticket.

To check the remaining time on all incubation positions, press and hold the following button for 5 seconds: . A ticket will be printed informing the remaining time.

```

BIONOVA      IC10/20FR
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
DATE: DD/MM/AA
TIME: HH:MM

PRO X
PROGRAM: X min / X °C
REMAINING TIME: HH:MM h

TUBE 1
PROGRAM: XX h / XX °C
REMAINING TIME: HH:MM h

TUBE 5
PROGRAM: XX h / XX °C
REMAINING TIME: HH:MM h

```

Canceling a reading

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

At the same time, the positive and negative indicator light will start to blink to indicate that the SCBI should be returned into its original incubation 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

BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 000084 PROGRAM: XX h / XX °C DATE: DD/MM/AA START TIME: HH:MM READOUT TIME: HH:MM SAMPLE TUBE: X POSITIVE	BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 000084 PROGRAM: XX h / XX °C DATE: DD/MM/AA START TIME: HH:MM READOUT TIME: HH:MM SAMPLE TUBE: X NEGATIVE	BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 000084 PROGRAM: XX h / XX °C DATE: DD/MM/AA START TIME: HH:MM READOUT TIME: HH:MM SAMPLE TUBE: X CANCELED
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To indicate a positive result, the positive indicator light (red) will turn 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's Instructions for Use for more information.

To indicate a negative result, the negative indicator light (green) will turn 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's Instructions for Use.

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

Note: Incubate the positive control following the SCBI's 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's 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 $37 \pm 2^\circ\text{C}$ or $60 \pm 2^\circ\text{C}$, 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 13 readout results. For reprinting the results, press and hold the following button for 5 seconds: .

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

To replace the paper roll, follow the instructions below:



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



2|Open the cover and remove the empty roll.



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

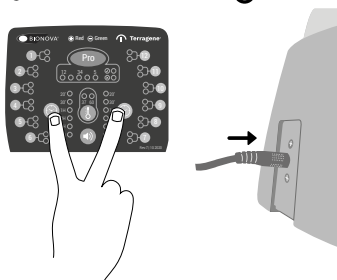


4|Close the printer cover by pressing on the sides of the lid.

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

Configuration mode

The auto-reader features a configuration mode that enables you to set the printing language and the date format and time zone in the device. To access to the configuration mode, turn on the auto-reader while holding both of the following buttons for a few seconds: .

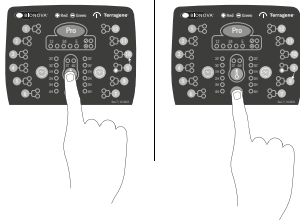


If the auto-reader has successfully entered to the configuration mode, the negative indicator light corresponding to incubation position 1 (one) will start blinking and a ticket will be printed. To change the date format, time zone and printing language, please follow the instructions listed below. To exit the configuration mode, turn off the auto-reader.

Modification of date format and time zone

The date format and time zone modification function allows changing the date format and time zone of the auto-reader to suit better the local characteristics of your country. To select the auto-reader's date format, make sure that the auto-reader is in configuration mode. The current date format will be printed in order to set a reference value and the negative indicator light corresponding to incubation position 1 (one) will start blinking. Three types of date format are available: DD/MM/YY, MM/DD/YY and YY/MM/DD.

To move back and forth between the available options, press the buttons:  or .



After 2 seconds, a ticket with the selected format will be printed to set a reference.

Note: The default date format is DD/MM/YY.

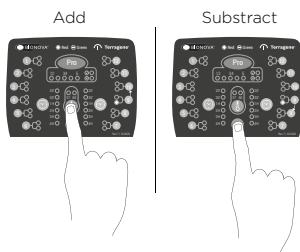
To save the selected date format, press and hold the following button for 3 seconds: .

To discard the changes, turn off the auto-reader.

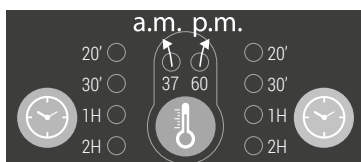
Once the date format has been modified and saved, the auto-reader will enter to the time zone change mode automatically. The current date (with the previously selected format) and the current time will be printed to set a reference.

To add hours, press the button: .

To subtract hours, press the button: .

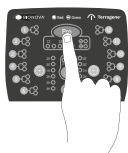


Note: 37 °C light indicates AM. 60 °C light indicates PM.



After 2 seconds, a ticket will be printed, informing the selected time zone.

To confirm the change, press and hold the following button for 3 seconds: .

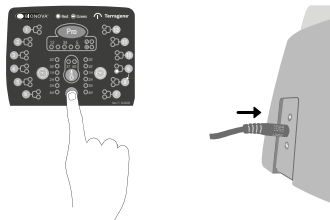


To discard the changes, turn off the auto-reader.

Note: The auto-reader will exit the configuration mode automatically.

Modification of printing language

This functionality allows changing the language that appears on the tickets. To access to the printing language setting mode, switch on the auto-reader while holding the alarm cancellation button for a few seconds, as shown in the figure below:



Each language has a code number assigned:

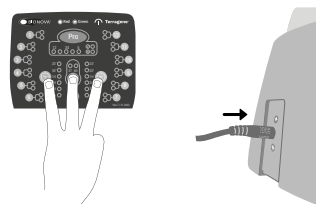
1: English | **2:** Spanish | **3:** Portuguese | **4:** Turkish | **5:** French | **6:** Romanian

To select the code number of the printing language, press the buttons:  or .

To save the changes, press and hold the following button for 3 seconds: . A beep will sound, and a ticket with the new printing language will be printed, confirming that the process was successfully completed. To discard the changes, turn off the auto-reader.

Time setting mode

To access to the time setting mode, switch on the auto-reader while holding both incubation time selection buttons and the incubation temperature selection button for a few seconds, as shown in the figure below:



A ticket will be printed with the current time in order to set a reference.

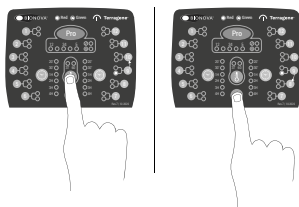
Note: The time format is 24-hour.

Note: The positive and negative indicator lights for incubation positions 1 to 10 represent the digit values being set. Lights 1 to 9 indicate values from 1 to 9 and light 10 indicates 0.

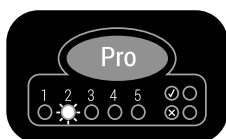
1| The quantitative protein level 1 indicator will turn on, indicating that the tens of hours (Hh:mm) are being adjusted.



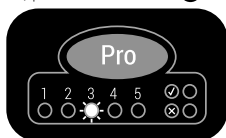
The negative indicator light corresponding to incubation position 10 will also turn on, indicating that the setting process has started. The possible values for the tens of hours are 0, 1 and 2. To increase or decrease the tens of hours value, press the buttons:  and .



2| To adjust the unit hour (hH:mm), press the following button: . The quantitative protein level 2 indicator will turn on. To increase or decrease the unit hour value, press the buttons:  and .



3| To adjust the tens of minutes (hh:Mm), press the following button: . The quantitative protein level 3 indicator will turn on. The possible values for tens of minutes are 0, 1, 2, 3, 4 and 5. To increase or decrease the unit hour value, press the buttons:  and .



4| To adjust the unit minutes (hh:mM), press the following button: . The quantitative protein level 4 indicator will turn on. To increase or decrease the unit hour value, press the buttons:  and .



5| To save the changes, press and hold the following button for 3 seconds: . A beep will sound, and a ticket with the new set time will be printed, confirming that the process was successfully completed.

Note: If the modification was not successful, the auto-reader will emit 3 beeps, and the positive indicator light from the PRO sector will turn on. Repeat the procedure.

Note: To discard the changes, turn off the auto-reader.

Modification of time using Bionova® Bioupdate

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

2| Run Bionova® Bioupdate.

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's current time and date.

Note: The synchronization process can only be done as long as there is not an ongoing reading.

Modification of time using Bionova® Cloud Agent

1| Using the included USB cable, connect your auto-reader to a PC where Bionova® Cloud Agent has been previously installed.

2| Run Bionova® Cloud Agent.

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's current time and date.

Note: The synchronization process can only be done as long as there is not an ongoing reading.

■ 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). The results are indicated with a resolution of 0.1 µg, with an accuracy greater than 90 % in the whole quantification range (IC95 %). 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 below:

1| Select your preferred protein quantification threshold mode for your auto-reader from the two threshold modes available: Threshold based on HTM 01-01 guidelines, or threshold based on ISO 15883-5:2021 standard.

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

To select a threshold mode and a threshold value, please refer to the following section: **Bionova® Cloud Environment**.

All devices are manufactured with the following settings:

■ Default threshold mode: HTM 01-01

■ Default protein threshold: 1 µg

Make sure that the selected protein quantification threshold mode is in accordance with your specifications before performing an incubation. The threshold mode cannot be changed during ongoing readings.

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] Use a compatible 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 in Figure 1.

4] After a sample from the desired surface has been taken, place the PRO1 Indicator fully inside the PRO1 incubation position. 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 correctly mixed and the reading cone has a sufficient amount of solution before starting an incubation.

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

Figure 1

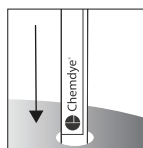
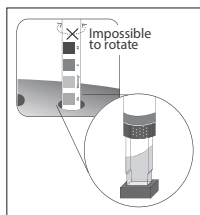


Figure 2



5] Start the incubation and readout process by pressing the following button for 1 second: **Pro**. Once the process starts, the auto-reader will emit an audible notification indicating that a reading has successfully begun, at the same time the positive and negative indicator light will start blinking. Wait until a readout result has been carried out.

Note: Do not remove or change the PRO1 Indicator once a reading process has begun. If you do this, the results may be invalidated.

6] Once the incubation and readout process is completed, the positive and negative indicator light will stop blinking and the auto-reader will indicate the quantity of protein in µg found in the sample by turning on the corresponding quantitative protein level indicator. A ticket will also be printed detailing the protein quantity along with other useful information related to the readout process. The protein quantity found on the sample is also used to obtain and inform a readout result depending on the

protein quantification threshold mode and threshold values selected on your auto-reader. For more information, please refer to the following section: **Interpreting the results of PRO1 Indicators**. After a readout result is informed, remove the indicator from the incubation position and press the button: **Pro** once to reset the incubation position to its stand-by state.

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

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

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

Note: The auto-reader will save the last 13 results. For more information on how to reprint results, please refer to the following section: **Reprinting the results**.

Interpreting the results of PRO1 Indicators

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

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

Note: To select a threshold mode and its values, please refer to the following section: **Bionova® Cloud Environment**.

Readout results for HTM01-01 threshold mode

Note: The HTM 01-01 threshold mode is the default protein quantification threshold mode of your auto-reader.

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

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 the quantitative protein level indicator and a printed ticket:

BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 0000084 PRO1 PROGRAM: 7 min / 60°C DATE: DD/MM/AA TIME: HH:MM ~10ug POSITIVE (HTM) PROTEIN: 3.2ug	BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 0000084 PRO1 PROGRAM: 7 min / 60°C DATE: DD/MM/AA TIME: HH:MM ~10ug NEGATIVE (HTM) PROTEIN: 0.0ug
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POSITIVE

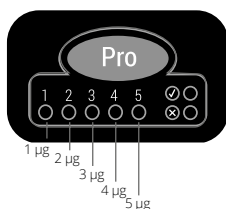
NEGATIVE

If the protein quantity detected on the sample is lower than the selected threshold, a negative readout result will be informed and the auto-reader will turn on the negative indicator light (green).

If the quantity detected is greater than the selected threshold, a positive readout result will be informed and the auto-reader will turn on the positive indicator light (red).

The readout results will be detailed on the printed ticket as well. Furthermore, if the auto-reader is connected to the Bionova® Cloud Environment, the readout results can be found on the *Hygiene Monitoring > Finished* web page of Bionova® Cloud Web interface.

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



Approximate amounts of BSA expressed in µg.

Readout results for ISO 15883-5:2021 threshold mode

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

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

- **Alert threshold:** The alert levels are the target levels of cleaning efficacy that the cleaning process should achieve. The Recommended threshold value is 3 µg/cm². Lower values may be recommended for particular applications.
- **Action threshold:** The action levels are the maximum criteria for acceptable cleaning efficacy during testing of a sample. The recommended threshold value is 6.4 µg/cm². Lower values may be recommended for particular applications. Values between these two thresholds should be investigated, but are considered to pass cleaning requirements described in ISO 15883-5:2021 standard.

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

If ISO 15883-5:2021 threshold mode is selected as the readout threshold mode on your auto-reader, each time a readout is completed the protein quantity will be informed by the auto-reader through the quantitative protein level indicators and through a printed ticket:

BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 0000084 PRO1 PROGRAM: 7 min / 60°C DATE: DD/MM/AA TIME: HH:MM THRESHOLD MODE: ISO PROTEIN: 0ug	BIONOVA IC10/20FR RAPID READOUT INCUBATOR SERIAL NUMBER: XXXX XXX TICKET #: 0000084 PRO1 PROGRAM: 7 min / 60°C DATE: DD/MM/AA TIME: HH:MM THRESHOLD MODE: ISO PROTEIN: x.xug
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Also, as a quick visual cue of the protein quantity found on the sample, the device will turn on the positive indicator light (red) if the protein quantity is above 1 µg, or the negative indicator light (green) if the protein quantity is below 1 µg.

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

Note: To estimate the swabbing surface area, follow the steps detailed at: www.terragence.com/surface-eye.

Note: To obtain the readout result, please refer to the following section: *Bionova® Cloud Environment*.

Depending on the threshold values selected, the informed readout result can be as follows:

- If the protein quantity found on the swabbed surface (µg/ cm²) is below the alert threshold, the readout result will be informed as **NEGATIVE**.
- If the protein quantity found on the swabbed surface (µg/ cm²) is above the alert threshold but below the action threshold, the readout result will be informed as **ALERT**.
- If the protein quantity found on the swabbed surface (µg/ cm²) is above the action threshold, the readout result will be informed as **ACTION**.

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

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:

Canceling a reading

To cancel a reading, press and hold the button: and the following button for 3 seconds: Once the reading is canceled, a ticket will be printed.

■ Additional features

Firmware update

The Bionova® IC10/20FR Auto-reader firmware can be updated with the Bionova® Bioupdate utility. The Bionova® Bioupdate connects to the Internet to check, download, and install the latest firmware version available for your auto-reader. The update process only lasts a few seconds and is carried out without the loss of any auto-reader's data.

Please visit www.terrigen.com/software to download Bionova® Bioupdate.

Update process

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

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

2| Run Bionova® Bioupdate.

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

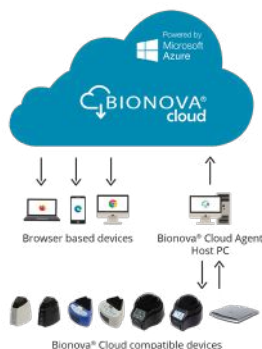
4| Wait until the software indicates that the update process has been completed. The auto-reader will print an update confirmation ticket. If the auto-reader is already up to date, no ticket will be printed.

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

■ Bionova® Cloud Environment

The new Bionova® Cloud Environment is a cloud based solution that integrates the information generated by Bionova® Auto-readers with an easy-to-use Web Application for the traceability of sterilization, disinfection and cleaning 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 washer/cleaner 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 operates.

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 using any device with a compatible web browser. To access to the Bionova® Cloud Environment please visit: www.terrigen.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**.

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 in Configuration menu and select: **Parameters**.

5| Select the threshold working mode for your auto-reader: HTM 01-01 or ISO 15883-5. To confirm your selection, click on the button: **SAVE**.

Note: The ISO 15883-5:2021 threshold mode is only available for Chemdye® 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

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

The ISO 15883-5:2021 standard implements recommendations for taking action based on the findings of hygiene monitoring indicators. One of the major features of this revision of the standard is that the protein quantities measured when swabbing an instrument must be related to the swabbing surface in which the sample was taken, for correct decision-making over decontamination and washing equipment. To obtain an estimation of the swabbing surface area, the new Bionova® Surface Eye Mobile App was designed. The Surface Eye Mobile App is a new proprietary application developed by Terragene® compatible with Android and iOS that allows the user to obtain an estimation of an instrument's swabbed surface using complex machine learning technologies in a few simple steps. The App also implements seamlessly integration with the Bionova® Cloud Environment. Linking protein quantification readout data (in µg) informed by an auto-reader, and swabbing surface data (in cm²) informed by the Surface Eye App, throughout the Bionova® Cloud Environment allows the creation of ratios of protein quantities and swabbing surface area (in µg/cm²) that can be compared with ISO 15883-5:2021 style thresholds.

ISO 15883-5:2021 workflow

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

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

A) Set-up

1| Set-up 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 Bionova® Surface Eye Application from Google Play Store or App Store on your compatible mobile device.

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

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 Bionova® Surface Eye Application 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 and open the Surface Eye Application.
2| Estimate the swabbing surface area by following the instructions at: www.terragene.com/surface-eye.

Note: It is a good practice to standardize the swabbing area for each instrument. Defining and using the same swabbing area for a given instrument allows the

sampling process to be repeatable through time and deliver valuable statistical information.

Note: According to ISO 15883-5:2021 standard, the recommended values for the alert and action threshold are 3 µg/cm² and 6.4 µg/cm², respectively. As both ratios relate protein quantity of a sample to the swabbing surface from which the sample is taken, please make sure to use standardized surfaces on the range of 1 to 7 cm². The use of higher swabbing surfaces (>7,6 cm²) imply that the protein quantity to define the action threshold would be above the 50 µg of the PRO1 Hygiene Monitoring System quantization range and thus cannot be properly used.

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 Apps' home menu swiping the instrument code to the left.

D) PRO1 Indicator incubation and readout

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

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

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

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

E) Linking protein readout information and swabbing surface information

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

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

Note: 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 USB cable from the auto-reader. If the device is hot, wait until it has cooled down before handling it.

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

■ This cleaning procedure can be followed whenever considered appropriate.

■ This cleaning procedure must be followed each time a spill occurs on any of the external surfaces of the auto-reader.

■ If further cleaning is required, or if you have doubts about the cleaning agents you may use, please contact your local distributor.

Note: Do not clean the internal parts of the auto-reader.
Note: Do not pour liquid onto the device or immerse it in any liquid. Do not allow any liquid to enter the device while it is being cleaned.

Maintenance

The 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 proper mains. Check that the DC plug of the power supply is connected to the rear of the auto-reader.

Problem: *The auto-reader is showing an error in an incubation position during the automated test.*

Possible causes: An indicator was placed in the incubation position during the automated test. Dust particles might be obstructing the readout mechanism.

Actions: Check that every incubation position is empty during the automated test. Restart the auto-reader.

If after restarting the auto-reader the problem persists, use air to remove any dust inside a position. Do not insert solid objects. Once cleared, restart the auto-reader.

Note: Do not use the auto-reader in dusty environments.

Problem: *An incubation cannot be run in an SCBI or Protein Pen incubation position (position's positive indicator light is on).*

Possible causes: Position disabled. Error in that position during the automated test.

Actions: Make sure that the position is empty when starting the auto-reader. Once cleared, restart the auto-reader.

Problem: *It is not possible to start a Chemdye® PRO1 Indicator incubation (Pen not valid ticket).*

Possible causes: The protein pen condition is not appropriate for its incubation.

Actions: Make sure that the solution on the reading cone is sufficient. Make sure the indicator solution is not overly saturated or already changing its color (i.e., not green). Do not incubate an indicator twice. Please follow the Instructions for Use before its incubation.

Problem: *The auto-reader will not detect the protein pen (Pen not detected ticket).*

Possible causes: Protein pen is not correctly placed in the incubation position.

Actions: Make sure the indicator is fully placed at the bottom of the incubation position before its incubation.

Problem: *The 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 will not print (printer paper indicator light blinks quickly).*

Possible causes: The printer cover is not tightly closed. The printer is out of paper.

Actions: Check that the cover is tightly closed. Place a new paper roll in the right direction.

Problem: *The printer releases unprinted paper.*

Possible causes: The paper roll is not placed correctly.

Actions: Make sure the paper is placed in the right direction. For more information, please refer to the following section: **Replacement of the paper roll.**

Problem: *The auto-reader cannot be updated.*

Possible causes: Bionova® Bioupdate is not running.

Actions: Install and run Bionova® Bioupdate. For more information, please refer to the following section: **Additional features.**

Problem: *The auto-reader is not detected by Bionova® Cloud Agent.*

Possible causes: The auto-reader is turned off. The auto-reader is not connected to the PC.

Actions: Follow the instructions on the **Start-up** section to set-up the device properly.

■ Warranty

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

Term

The warranty period for the Bionova® IC10/20FR Auto-reader is 1 (one) year from the date of installation and may never be extended beyond 5 (five) years from the product's date of manufacture.

Expected lifetime

The Bionova® IC10/20FR Auto-reader has an expected lifetime of 5 (five) years from the date of manufacture. This period is considered valid under normal operating conditions, provided that the equipment is installed, used, and maintained in accordance with the provisions outlined in this User Manual. Use outside these conditions may affect the product's lifetime.

Limitation of liability

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

Technical assistance

For information regarding the functioning or condition of the product, contact Terragene S.A. directly to info@terragene.com, or through our website www.terragene.com. In USA, please call +1844 837 7243.

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