BIONOVA®

Bionova® IC10/20FR Auto-reader

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

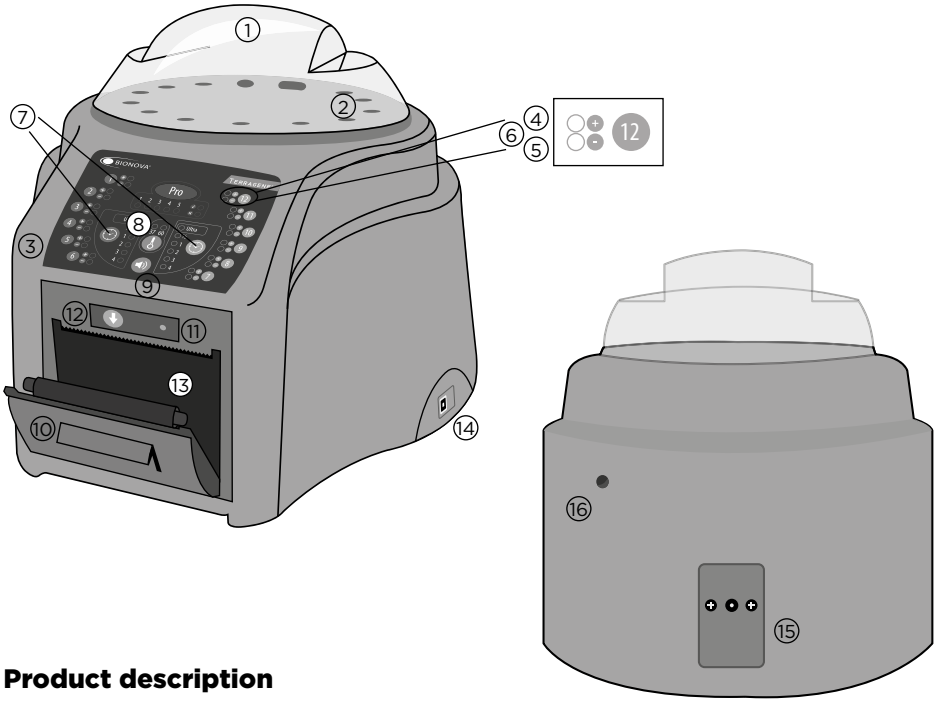
Rev. 31 | February 2022

WARNING: this product contains dry natural rubber

Terragene®

Index

■ Composition



Product description

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

Bionova® IC10/20FR allows two different incubation temperatures, 37 °C or 60 °C. Microorganisms contained within the SCBIs vary depending on the sterilization process for which they have been designed, therefore, incubation temperatures and incubation times differ depending on the SCBI being used. Bionova® IC10/20FR allows two independent time settings selections. One of them for configuring the incubation time for positions 1 to 6, and the other for postions 7 to 12.

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

(!)

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

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

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

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

Please refer to the ***Product compatibility and incubation programs*** section for more information about the incubation settings of your Auto-reader.

Indications for use

United States of America
Terragene® Bionova® IC10/20FR Reader Incubator incubates at 60 °C and reads the Terragene® Bionova® SCBI (BT220, BT221, BT222, and BT223) for fluorescent results at 30 minutes (BT223), 1 hour (BT221, BT222), and 3 hours (BT220).

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

References

① Protective cover

② Incubation Area for 12 SCBIs and 1 Protein Pen. SCBI Ampoule Crusher

③ Control Panel

④ Red Light / Positive Indicator

⑤ Green Light / Negative Indicator

⑥ Incubation Position Number

⑦ Incubation Time Selection Buttons

⑧ Incubation Temperature Selection Button / Time Left

⑨ Alarm Cancellation Button

⑩ Thermal Printer

⑪ Printer's Paper Indicator Light

⑫ Paper's traction button

⑬ Cavity for Paper

⑭ USB Port

⑮ Input for Power Supply Plug (12Volts DC)

⑯ Hole for External Temperature Control

■ Safety information

Symbols

30 % 80 % Operating relative humidity

10 °C 30 °C Operating temperature

Caution, Warning, Attention - Refer to the instructions for use

Caution: Hot surface

Important

Direct current

For indoor use only

Keep away from sunlight

LOT Batch code

Manufacturer

Separate collection for waste of electrical and electronic equipment

To avoid risks and/or damaging the device:
- For indoor use only.
- Do not place the incubator in a room exposed to direct sunlight or to high luminous intensity lamps.
- Do not place the incubator near devices that emit strong electromagnetic fields.
- Do not use the incubator on leaned surfaces or on surfaces that are subject to shocks, vibrations, temperature or high relative humidity.
- Disconnect the power cord before cleaning.
- Do not use abrasive, corrosive cleaners or disinfectants.
- Do not immerse into any liquid. Do not pour any liquid inside.
- Make sure the incubator 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.
- Verify that all the included elements are in good condition on daily basis. If any of them is damaged, discontinue their use. The use of cables, adapters, cords, and/or power supplies different from the ones included may cause fires, electrical shocks, or even physical injuries.
- Do not plug any devices into the Incubator's USB port other than a personal computer (PC). The PC has to be compliant with IEC60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its USB ports. Ask a qualified technician to verify device compatibility. Attaching any other device to the USB port may damage the incubator and may not be safe for the user.
- Do not attempt to repair the incubator by yourself, that could lead to major and irreversible damages to the device. In case of device malfunction, contact your local distributor for further assistance.

To reduce the risk of using incompletely sterilized loads:
- Please read, understand, and follow the Instructions for use

of each SCBI before its incubation.

- Do not remove the SCBI before the incubator reports the final readout result. Check a result ticket is printed.
- Check that culture medium completely wets the spore carrier.

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

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

To avoid a potentially hazardous situation:

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

To avoid SCBIs from absorbing fluorescent particles:

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

IMPORTANT

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

Only Terragene® S.A. authorized personnel can access or service the internal components of the Incubator. Parts or components inside the Incubator should not be manipulated by the user.

Operating conditions

Power supply specifications

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

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

* 1 Ampere in USA and Canada.

** 3 Amperes in USA and Canada.

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

Environment operating conditions

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

Regulatory Compliance

Bionova® IC10/20FR Auto-reader Incubator complies with the following standards and directives:

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

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

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

■ Product Compatibility and Incubation programs

Bionova® IC10/20FR Incubation Programs

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

Temperature selection	Time selection	Incubation program
60 ºC	20 min *(Ultra)*	20 min at 60 ºC
	30 min	30 min at 60 ºC
	1 hs	1 hour at 60 ºC
	2 hs	2 hours at 60 ºC
	3 hs	3 hours at 60 ºC
	PRO (7 min)	PRO at 60 ºC
37 ºC	4 hs	4 hours at 37 ºC

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

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

Bionova® IC10/20FR Auto-reader compatible indicators

We develop new Indicators for extending the features of our incubators regularly. Please visit www.terragene.com/IC1020FR to find out all compatible indicators for your device.

■ Instructions for use

Start-up

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

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

2|Power on your Bionova® IC10/20FR by connecting the power supply's AC plug to mains and then connect the plug at the other end of power supply to the rear of the Incubator. The last incubation program used (time and temperature combination) will be selected by default.

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

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

3|Set the incubator internal clock to correspond to your local time. See configuration methods in the ***Time setting mode*** section.

All devices are manufactured with the following settings:
- Time zone: UTC +0:00
- Printing language: English

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

4| Select the appropriate incubation temperature for the SCBI you are planing to use, according the SCBI's Instructions for use. Press and hold the temperature selection button for 3 seconds to enter the temperature selection mode. Press again to select the desired temperature. After 4 seconds the temperature modification will be accepted automatically.

5| Select the appropriate incubation time for the SCBI you are planning to use by pressing the left incubation time selection button (for selecting the incubation time for incubations positions 1to 6), or the right incubation time selection button ((for selecting the incubation time for incubations positions 7 to 12).
Please refer to the ***Product Compatibility and Incubation programs*** section to know more about the temperature and time combinations (incubation programs) available for your device.

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

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

6|Once the temperature stability indicator light remains stable, a one-time automated test to check each position internal status will be carried out (auto-test). Once the test is complete, the position status indicator light will turn green to indicate that the position can be used to perform readings, or it will turn red to indicate that an error has occurred.
When the incubator detects an error in a position, the position will be disabled to guarantee the reliability of the results and it cannot be used to perform any further readings.
To indicate that a position has been disabled, the position

status indicator light will turn red and blink indefinitely.

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

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

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

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

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

8|When a positive result is detected in an incubation position, the position status indicator light will turn red, an audible alarm will activate, and a ticket will be printed. Once the SCBI is removed, the alarm and the red light will turn off automatically after 30 seconds. The position will be available to start a new reading once the position status indicator light turns off. Please refer to the Interpretation of results for more information.

Press the button to cancel the audible alarm.

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

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

9|Every time the Auto-reader informs a fluorescence readout result (positive, negative, or canceled), a ticket will be printed to register the result. Pull upward for the paper to be cut with the serrated edge of the printer.

Note: If there is no paper for ticket printing, the printer's paper indicator light will start blinking. To replace the paper, follow the instructions in the ***Replacement of the paper roll*** section. The incubator will save the last 13 results, for re-printing, follow the ***Reprinting of the last results*** instructions.

POSITIVE **NEGATIVE** **CANCELED**

Remaining incubation time

The Bionova® IC10/20FR Auto-Reader also allows you to verify the remaining incubation time in every reading position by ticket printing.
Whenever a reading process is in course, press and hold the, press and hold the button for five seconds. A ticket will print, informing reading position, incubation program and remaining incubation time.

Canceling a reading

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

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

Interpretation of results

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

Take action immediately if a positive result is obtained when

incubating an exposed SCBI. Please refer to the sterilizer instructions for use for more information.

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

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

Positive control

A positive control is a non-sterilized SCBI used as a reference during the incubation process. The use of a positive control is a recommended practice as it helps to ensure:

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

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

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

Disposal

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

Reprinting of results

The auto-reader allows reprinting of the last 13 results. For printing the results, press the 🔊 button for 5 seconds.

Audible alarm

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

Temperature monitoring

The Bionova® IC10/20FR Auto-reader features an automated internal temperature control. If the incubation temperature falls outside of the specified range of 37 ± 2 ºC or 60 ± 2 ºC, the temperature stability indicator light will start to blink.

The incubation temperature can be externally monitored by placing an external thermometer in the hole for external temperature control located at the back of the device.

Thermal paper specifications

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

Paper width : 57 mm

Maximum paper thickness: 60 g/m²

Maximum diameter size: 50 mm

Replacement of the paper roll

1|To replace the paper roll, pull the handle of the printer's door.

2|Open the printer's cover and remove the spent 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.

Set-up mode

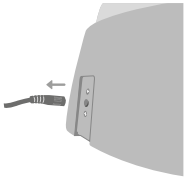
Date format and time zone selection mode

This feature allows to change the date format on the Auto-reader's ticket and to set the auto-reader's internal clock forward or back to adopt a different time zone.

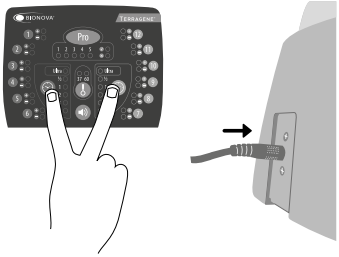
Note: Please note that the time can be synchronized both with the Bioupdate® Software and with Bionova® Traceability Software.

Enabling date format selection mode

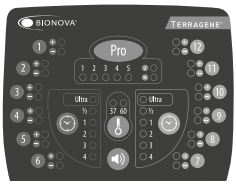
Turn off the device.



Press and hold both buttons simultaneously and Turn on the device.

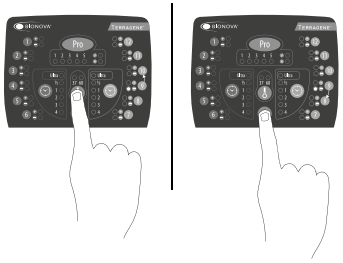


Note: When the date format selection mode has been enabled sucesfully, the green light indicator corresponding to incubation position one will start to blink. In addition, a ticket with the current date will be printed in order to set a reference value.



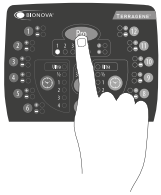
Date format selection

There are three types of date format: DD/MM/YY, MM/DD/YY and YY/MM/DD. Press the or button to move back and forth between each of the 3 available options. After 2 seconds, a ticket with the selected format will be printed to set a reference.



Saving selected date format

To save changes press and hold Pro button for 3 seconds. A beep will indicate that the process has been completed successfully. A ticket with the new date format will be printed. The green light indicator of incubating position one will stop blinking.



Time zone selection mode

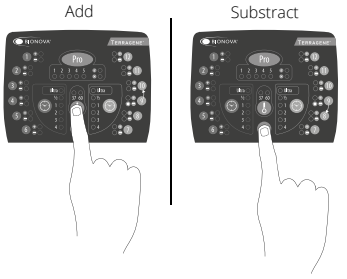
Once the date format has been modified and saved, the incubator will enter Time Zone selection mode automatically. The current date (with the previously selected format) and the current time will be printed to set a reference.

Note: When the Time zone selection mode is enabled, the green light will turn on to the incubation position number corresponding to the current time zone on the device.

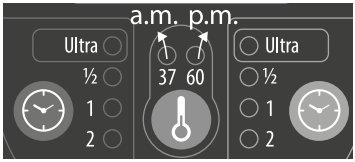
Time zone selection

To add hours, press the button as many times as necessary. To subtract hours, press the button as many

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

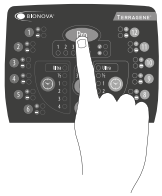


Note: 37 °C light indicates AM. 60 °C light indicates PM.



Save time zone selection

To save changes press and hold Pro button for three seconds. A beep will indicate that process has been completed successfully. A ticket with the new set time will be printed.



Discarding date format selection or time zone selection

To discard the changes, unplug the incubator from the power source.

Time setting mode

Time setting functionality allows you establish a specific time regardless of auto-reader current time.

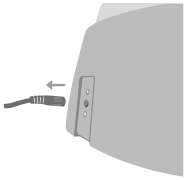
Modification of the time using the Bioupdate® Software

Connect the auto-reader via the USB port to a PC and start-up the program. Select the Bionova® IC10/20FR Auto-reader and press the Clock Sync button, the auto-reader will be synchronized with the PC's clock. Synchronization can only be done as long as there is not an ongoing reading.

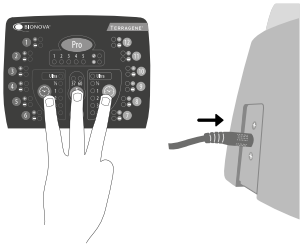
Change the time using the panel

Enabling Time setting mode

Turn off the device.



Press and hold both buttons and button simultaneously and Turn on the device.

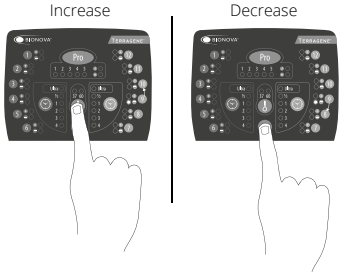


Hours setting

Lights corresponding to 1 to 10 incubation positions indicate the digit value which is set. Lights from 1 to 9 indicate digit value from 1 to 9. Light 10 indicates 0 value.
In time setting mode, light 1 from PRO sector will turn on to indicate ten hour modification and incubation light corresponding to the 10th position will turn on to indicate setting started.

Note: 24-hour format.

To change hours and minutes digits, use and buttons. To increase digit value press ; to decrease press .



↲ Instructions for use

■ Hours setting: Ten hours (H̲h:mm)

The blue light number 1 corresponding to PRO sector should be on. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 1. This indicates ten hour setting.

To increase ten hours value, press button. To reduce ten hours value, press button.

Note: The possible values for ten hour are 0, 1 and 2.

■ Hours setting: Unit hours (hH̲:mm)

Press Pro button to turn on the blue light number 2. This indicates unit hours setting. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 2.

To increase unit hours value, press button. To decrease unit hours value, press button.

Minutes setting

■ Minutes setting: Ten minutes (hh:M̲m)

Press Pro button to turn on the blue light number 3. This indicates ten minutes setting. If any other light from PRO sector is on, press Pro button as many times as necessary to turn on the blue light number 3.

To increase ten minutes value, press button. To decrease ten minutes value, press button.
Note: Possible values for ten minutes are 0, 1, 2, 3, 4 and 5.

■ Minutes setting: Unit minutes (hh:mM̲)

Press Pro button to turn on the blue light number 4. This indicates unit minutes setting. If any other light from Pro sector is on, press Pro button as many times as necessary to turn on the blue light number 4.

To increase unit minutes value, press button. To decrease unit minutes value, press button.

Finish hours setting

To save changes press and hold Pro button for three seconds. A beep will sound, PRO green light will turn on and a ticket with the new set time will be printed to indicate the procedure has been completed successfully.

Note: If the modification has not been done correctly, the auto-reader will emit 3 beeps and the red light from PRO sector will turn on. Repeat the procedure.

Cancel hours setting

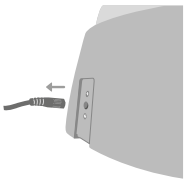
To discard the changes, unplug the incubator from the power source.

Printing language selection mode

This function allows you to change the auto-reader printing language.

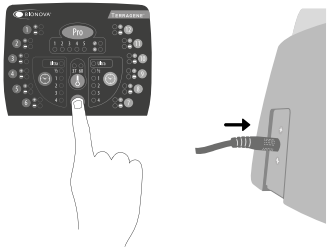
Note: Each language has a code number assigned:
1: English | **2:** Spanish | **3:** Portuguese | **4:** Turkish | **5:** French | **6:** Romanian

Enabling Printing language selection
Turn off the device.

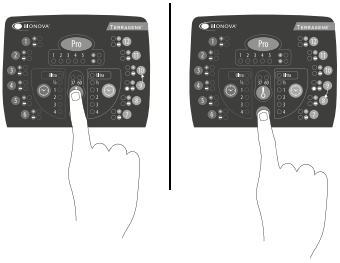


↲ Instructions for use

Press and hold button and turn on the device.



Press and buttons to select the position number corresponding to language code.



Finish printing language selection

To save changes press and hold Pro button for three seconds. A sound will be emitted indicating that process has been completed successfully. A ticket with the new language selection will be printed.

■ Hygiene monitoring systems

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

Verify which incubation programs and indicators are available for your country and application checking the ***Indications for Use*** section.

Readout of PRO1 Indicators

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

1|Select your preferred Protein Quantification Threshold Mode for your Auto-reader between the two Threshold modes available: Threshold based on HTM01-01 Standard, or Threshold based on ISO 15883-5:2021 standard.
For selecting a Threshold mode and a Threshold value, please follow the indications detailed on ***Threshold Mode selection on Bionova® Cloud Environment*** section.
All devices are manufactured with the following settings:

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

Make sure that the selected Protein Quantification Threshold Mode is according to your needs before performing an incubation. The Threshold Mode can not be changed during ongoing readings.

2|Press and hold the Pro button for 1 second to enable the position's readout mode. The Auto-reader will emit a short beeping sound and the 1 µg quantitative protein level led indicator will blink for a moment. After that, two short beeping sounds will be emitted indicating that the incubation position is enabled and ready to start an incubation.

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

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

4|After a sample from the swabbing surface has been taken, place the PRO1 indicator into the enabled incubation position. Insert the indicator fully inside the incubation position, as shown on the Auto-reader's label. When the indicator is on the correct position, the indicator can not be rotated. (Figure 2).

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

5|Once the indicator is placed on the incubation position, press and hold the Pro button for 1 second to start the incubation and readout process. Once the process start, the

↲ Hygiene monitoring systems

positive ⓥ ● and negative ⊗ ● indicators will start to blink and will keep blinking throughout the whole incubation and readout process. Wait until the incubation and readout process is completed before removing the indicator.

⚠

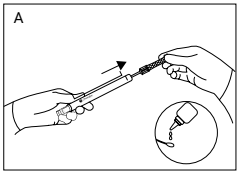
Do not move or remove or change the Indicator placement once a reading process has begun, as it could lead to errors in the incubation and/or readout process.

6| Once the incubation and readout process is completed, the positive ⓥ ● and negative ⊗ ● indicators will stop blinking and the Auto-reader will indicate the µg of protein quantity found in the sample by turning on the corresponding Quantitative Protein Level LED Indicator. A ticket will be printed as well detailing the protein quantity along with other useful information related to the readout process.

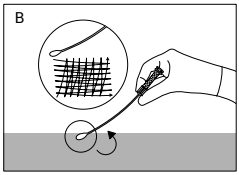
The protein quantity found on the sample is also used to obtain and inform a readout result depending on the Protein Quantification Threshold Mode and threshold values selected on your Auto-reader. Please refer to the ***Interpretation of results of PRO1 indicators*** section for more information.
After a Readout result is informed remove the indicator from the incubation position an press the Pro button once to reset the incubation position to its stand-by state.

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

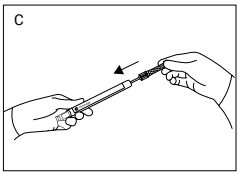
Figure 1



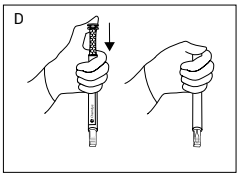
Remove swab and add the moisturizer



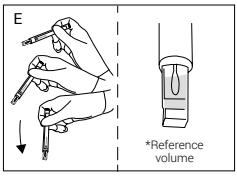
Swab the desired surface by applying a strong pressure



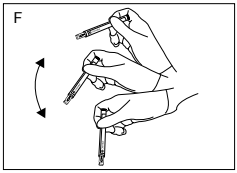
Place the swab back into the device



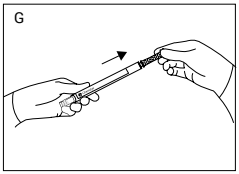
Activate



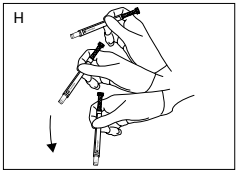
Shake downwards vigorously until the solution turns to green and reaches the readout cone reference volume



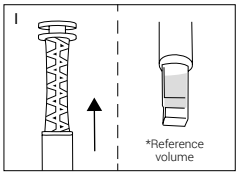
Shake for 15 seconds with the swab inside the readout cone



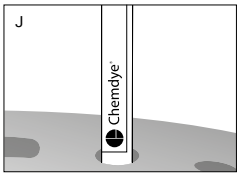
Slide swab upwards without completely removing



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

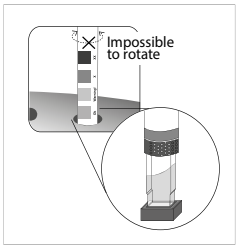


Readout cone without swab



Incubate immediately and read

Figure 2



Insert the pen on the incubation/reading position

Interpretation of results of PRO1 indicators

Once a PRO1 Indicator readout process is finished, the Auto-reader will inform the equivalent µg of protein quantity found on the sample using a BSA (Bovine Seric Albumin) calibration curve through the Quantitative Protein Level LED 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 HTM01-01 Threshold Mode, or Negative, Alert, or Action for ISO 15883-5 Threshold Mode.

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

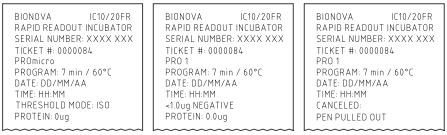
Readout results for HTM01-01 Threshold Mode

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

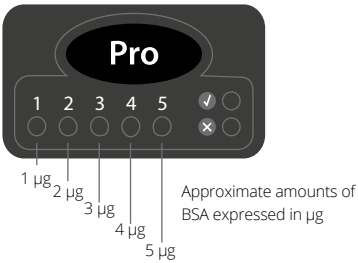
HTM01-01 guidelines indicates the use of a single protein quantity threshold to evaluate cleaning efficacy. The guidelines recommends that the residual protein level upper limit of acceptable protein contamination after processing is 5 µg BSA equivalent per instrument side, indicating as well that lower levels may be recommended for particular applications.

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

If HTM01-01 Threshold Mode is selected as the readout threshold mode on your Auto-reader, each time a readout is completed the protein quantity will be informed through the Quantitative Protein Level LED Indicators and a printed ticket:



POSITIVE **NEGATIVE** **CANCELED**



If the protein quantity detected on the sample is lower than the selected threshold, a Negative readout result will be informed and the Auto-reader will turn on the Green LED indicator. If the quantity detected is greater than the selected threshold, a Positive readout result will be informed and the Auto-reader will turn on the Red LED indicator. The readout result will be detailed on the printed ticket as well.
Furthermore, if the Auto-reader is connected to the Bionova® Cloud Environment, the readout results can be found on the ***Hygiene Monitoring > Finished*** web page of Bionova® Cloud Web interface.
Take action immediately whenever a **POSITIVE** Readout Result is informed as this indicate that the protein quantity found does not comply with the user defined quality standards set for the cleaning process.

↲ Hygiene monitoring systems

Readout results for ISO 15883-5 Threshold Mode

The ISO 15883-5:2021 standard indicates the use of two different protein quantity thresholds to evaluate cleaning efficacy: An Action threshold, and an Alert threshold. ISO 15883-5 based thresholds are expressed as ratios in µg/cm^2 units that relates protein quantity found in a sample (µg) and the swabbing surface (cm^2) on which the sample was taken. According to the standard, each threshold has different implications:

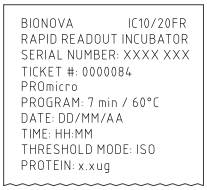
Alert threshold: The alert levels are the target levels of cleaning efficacy that the cleaning process should achieve. Recommended threshold value 3µg/cm^2. Lower values may be recommended for particular applications.

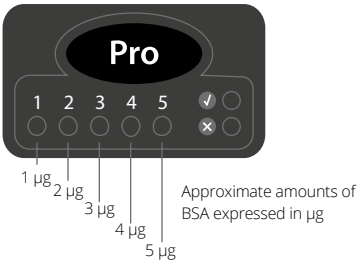
Action threshold: The action levels are the maximum criteria for acceptable cleaning efficacy during testing of a sample. Recommended threshold value 6.4µg/cm^2. Lower values may be recommended for particular applications.

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

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

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





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

Important: Please keep in mind that according to ISO 15833-5:2021 standard the protein quantity found in a sample (in µg) needs to be related to the swabbed surface area to obtain a readout result (in µg/cm^2) that can be comparable with the selected Alarm and Alert thresholds (also in µg/cm^2).

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

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

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

Disposal

Discard the PRO1 indicator according to your country's sanitary regulations. It is not possible to use or incubate a PRO1 indicator more than once. Please refer to the PRO1 instructions for use.

Audible alarm

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

Cancel a reading

The user can cancel a reading by pressing the Pro button and the 🔊 button for three seconds. The device will cancel the reading and the auto-reader will print out a ticket confirming the cancellation.

■ Additional features

Firmware update

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

Update process

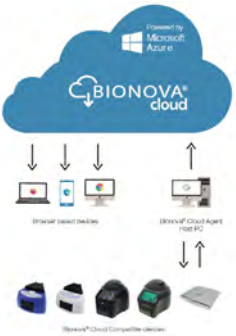
Before updating the device, make sure that the Bionova® Cloud Agent is closed. Power Off the Incubator for five seconds, afterwards Power On the Incubator and follow the next steps:

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 Start button to update.
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: This process must be repeated every time that a new firmware version is available, this will be informed in the Terragene S.A. Website.

■ Bionova® Cloud Environment

The new Bionova® Cloud environment is a Cloud based solution that integrates the information generated by Terragene® electronic devices with an easy-to-use Web App for the traceability of sterilization and disinfection control applications.
The Bionova® Cloud environment is composed by two main components: the Bionova® Cloud Traceability Software which is a Web Based application, and the Bionova® Cloud Agent which is a Microsoft™ Windows App that acts as an interface between the Terragene® compatible devices and the web based application.



Bionova® Cloud Traceability Software allows to manage and store the readout results of Self-contained biological indicators and Hygiene Monitoring System Indicators in a secure and user-friendly way.
Bionova® Cloud Traceability Software allows matching the information of an Indicator result with the sterilizer or washing machine used, the operator, cycle characteristics, and all relevant information for allowing each institution achieve reliable documentation compliance and safe-keeping.
The Bionova® Cloud Agent handles all communications with Terragene® compatible electronic devices and the Host PC where the Agent App runs.
Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Traceability software and sends the information generated from the devices to the Microsoft™ Azure powered Cloud server where the Traceability Software Web App runs and stores the information.
The user can then access to the Cloud saved information through any device with a compatible web browser.

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

Threshold Mode selection for PRO1 Indicators

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

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

1|Connect your Auto-reader to a PC where Bionova® Cloud Agent is installed.
2|Run and Log-in to the Bionova® Cloud Agent. Wait until the Agent lists the incubator.
3|Access as the Administrator user to the Bionova® Cloud Environment Web interface.

↲ Bionova® Cloud Environment

4|Go to the ***Configuration*** > ***Parameters*** section tab on the Bionova® Cloud Web Interface left side menu.
5|Select the Threshold working mode for your Auto-reader: HTM01-01 or ISO 15883-5. Save the selected mode clicking on the ***SAVE*** button.
6|Select the Threshold values for the selected mode. Save the selected Threshold values by clicking on the ***SAVE*** button.

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

ISO 15883-5:2021 Threshold Mode

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

To obtain an estimation of the Swabbing surface area, the new Bionova® Cloud Surface Eye Mobile App was designed. The Surface Eye Mobile App is a new proprietary application developed by Terragene compatible with Android OS that allows the user to obtain an estimation of an instrument's swabbed surface using complex machine learning technologies in a few simple steps. The App also implements seamlessly integration with the Bionova® Cloud Environment. Linking protein quantification readout data (in µg) informed by an Auto-reader, and swabbing surface data (in cm^2) informed by the Surface Eye App, throughout the Bionova® Cloud Environment allows the creation of ratios of protein quantities and swabbing surface area (in $\mu g/cm^2$) that can be compared with ISO 15388:2021 style thresholds.

ISO 15883-5 Workflow

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

A) Set-up
1|Set-up your Auto-reader for ISO 15883-5 Threshold Mode. Please refer to the ***Threshold Mode selection on Bionova® Cloud Environment*** section for more information.
2|Download the Bionova® Cloud Surface Eye APP from Google Play Store on your Android compatible device.
Important: Make sure your Android device has a working camera for the Surface Eye App to work as intended.

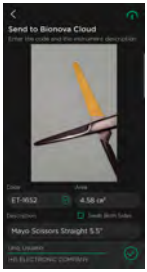
B) Login and authentication
1|Log-in to the Bionova® Cloud Agent on the PC connected to your PRO1 Indicator Auto-reader.
2|Log-in to the Bionova® Cloud Surface Eye APP with the same credentials used on the Bionova® Cloud Agent.
3|Log-in to the Bionova® Cloud Web Interface with the same credentials used on the Bionova® Cloud Agent.

C) Swabbing and surface estimation
1|Set the instrument to be swabbed over the Surface Eye Card. Please keep in mint that the swabbing area must be fully contained on the card for the Surface Eye APP to properly estimate the swabbing surface area.
2|Tap on the icon, and align the 3 position markers from your phone screen with the 3 position markings on the Surface Eye card. Once the position markers are aligned, the App will take a photo automatically.

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

↲ Bionova® Cloud Environment

4|The APP will automatically select and estimate the surface (cm^2) of the selected swabbing area.



It is a good practice to standardize the swabbing area for each instrument. Defining and using the same swabbing area for a given instrument allows the sampling process to be repeatable through time and deliver valuable statistical information.

Important: According to ISO 15883-5:2021 Standard, the recommended values for the Alert and Action threshold are 3 µg/cm^2 and 6,4 µg/cm^2, respectively. As both ratios relate protein quantity of a sample to the swabbing surface from which the sample is taken, please make sure to use standardized surfaces on the range of 1 to 7 cm^2. The use of higher swabbing surfaces (>7,6 cm^2) imply that the protein quantity to define the action threshold would be above the 50 µg of the PRO1 Hygiene Monitoring System quantization range and thus cannot be properly used.

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

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

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

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

8|The surface acquisition details can be edited from the 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.

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

Important: Make sure you swab both sides of the instrument if the ***"Both sides"*** check-box was selected on the Surface Eye APP.

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

E) Linking protein readout information and swabbing surface information

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

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

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

3|Click the ***Confirm*** button to save the details, or the ***Confirm and move to saved*** button to save the details and move the readout to the Bionova® Cloud Database accessible through

↲ **Bionova® Cloud Environment**

Dashboard > *Saved* section tab on the Bionova® Cloud Web Interface left side menu.

Bionova® Cloud Surface Eye Mobile App advanced features

Redefining the swabbing area of an Instrument

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

Editing an instrument code and description

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

Conversion of ISO 15883-5 thresholds

Once a swabbing surface area has been saved and assigned to an instrument on the Surface Eye App, the details of the surface can be accessed by taping the instrument code.
On the details screen, the Alert and Action Thresholds (in µg/cm^2) as defined on the Bionova® Cloud Environment, are converted and shown to the user as protein quantity thresholds (µg) for the selected surface.
This allows for direct visual comparison between the protein quantity found on the sample as informed on the Auto-reader printed ticket, and the protein quantities that correspond to the alert and action thresholds for the defined swabbing area.

■ Cleaning and maintenance

Cleaning and decontamination of external surfaces

Disconnect the power supply cable and the USB cable from the Auto-reader. If the device is hot, wait until it has cooled down before handling it.
Clean the external surfaces of the device using a microfiber cloth moistened with a solution of mild dish washing detergent and water. Wring the cloth so it is damp but not dripping before cleaning, and wipe the outer surfaces of the Auto-reader. Afterwards, moisten a clean microfiber cloth with water only, and repeat the procedure until all traces of detergent are removed from the external surfaces of the device. After cleaning, allow the Auto-reader to air dry for at least 1 hour before connecting the power supply cable or the USB cable again.
This cleaning procedure can be followed whenever considered appropriate.
This cleaning procedure must be followed every time a spill occurs on any of the external surfaces of the Auto-reader.
If further cleaning is required, or if you have doubts about the cleaning agents you may use, please contact your local distributor.

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

Maintenance

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

Troubleshooting

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

Warranty

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

Term

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

Limitation of liability

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

Technical assistance

Terragene S.A.
Ruta Nacional Nº 9, KM 280 - CP 2130.
Parque Industrial Micropi - Alvear - Santa Fe - Argentina.