Auto-reader
for Hygiene Monitoring Systems

Innovation in technologies for Infection Control

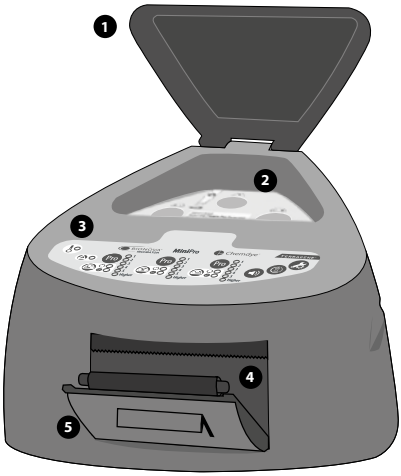
BIONOVA®

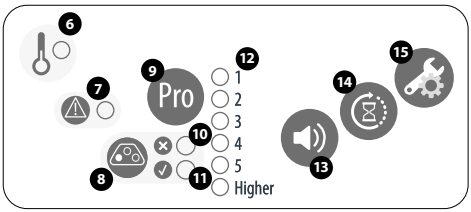
MiniPro

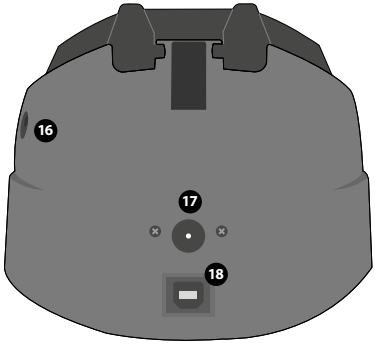
TERRAGENE®

Rev.7 | February 2019

Composition







Use description

Bionova® MiniPro Auto-reader has been designed with 3 positions to perform 3 simultaneous quantitative readings of hygiene indicators, intended for the control of surface cleaning and disinfection.
Bionova® MiniPro device can perform a quantitative analysis of Chemdye® PRO1 MICRO Hygiene Monitoring System, adjusted by a reference curve constituted with BSA (Bovine Seric Albumin). This analysis allows the traceability of the surface cleaning control.
The method has a detection limit of 1 µg and a sensitivity of 0.3 µg. The result is indicated with a resolution of 0.1µg, and its accuracy is ± 0.5µg (IC95%), in the range of 0 to 5µg, and ±0.7µg (IC95%), in the range of 5 to 10 µg with a range of 10 µg.

The reading will be able to initiate once the incubation temperature has been reached. The light corresponding to the selected temperature (37 ºC or 60 ºC) will blink until the temperature is stable. PRO1MICRO readings must be performed at 60 ºC.

Bionova® MiniPro Auto-reader not only allows the detection of results, it also provides a printed ticket for your registration. In addition, Bionova® MiniPro Auto-reader can be connected to a PC via a USB port. This allows linking the results with the *Bionova® Traceability Software* for the Automatic Reading and Traceability of Rapid, Super Rapid and Ultra Rapid Biological Indicators and Hygiene Monitoring System. To download the latest version of the software, go to: http://www.terragene.com.ar/productos/infection-control/incubators/software-downloads/?lang=en, from there you can also download the user manual.

Safety information

References

1. Protective Cover.
2. Incubation area.
3. Control panel.
4. Cavity for paper.
5. Thermal printer.
6. Temperature stability indicator.
7. Attention indicator light.
8. Incubation position.
9. Start incubation program button / Time left.
10. Red light / Protein concentration above the selected threshold
11. Green light / Protein concentration below the selected threshold
12. Quantitative indicators of protein concentration.
13. Cancellation of audible alarm.
14. Reprinting of results.
15. Configuration button / Paper Traction Button.
16. Hole for external temperature control.
17. Input for power supply plug (12 Volts DC).
18. USB port.

Symbols

Operating/storage relative humidity.

Operating/storage environmental temperature.

Caution, warning.

Important, attention.

Direct current.

Correct disposal of this product
(Electrical and electronic equipment waste)

LOT Batch number.

To avoid risks and damaging the equipment
-Do not place the auto-reader in an environment exposed to direct sunlight or high intensity light lamps.
-Do not place the auto-reader near devices that emit electromagnetic fields.
-Do not use the equipment on vibrating surfaces.
-Do not pour any liquid inside.
-Do not immerse into any liquid.
-Use indoors only.
-Disconnect the power cord before cleaning.
-Do not use abrasive, corrosive cleaners or disinfectants.
-In case of technical fault, contact the manufacturer for support. Please, do not try to open or repair the auto-reader on your own, since this will imply the loss of product warranty and could lead to a major and irreversible damage.
-Make sure that the auto-reader is connected to a properly rate power cord.
- Do not remove the hygiene indicator until the auto-reader reports the final result of the reading, check the printing of the result ticket.

Safety information

To avoid a potentially hazardous situation: avoid contact with the hot surface of the metal incubator block.

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

Do not replace the power supply cord for other not provided within the product.

Only personnel authorized by Terragene® S.A can access the inside of the incubator and its components. Parts or components inside the machine should not be manipulated by the user.

Power supply specifications

Input parameters	**Operating conditions**	**Units**
Voltage range	(100-240)	Volts
Frequency	50/60	Hertz
Current	0,5	Ampers
Output parameters	**Values**	**Units**
Voltage	12	DC Volts
Current	2	Ampers

Terragene® recommends using a UPS instead of stabilizers, since the former has two functions: it stabilizes and provides a continual power source during energy cutoff.

Environment operating conditions

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

Serial/Batch Number

For easy identification, each Bionova® MiniPro Auto-reader has a unique serial number and a batch number printed on a label found at the bottom of the auto-reader and on its packaging. Please, register your serial number and batch number in this manual for future reference:

Serial number: _____

Batch number: _____

Record Table

Use the following table to record firmware updates.

NOTE: manufacture firmware is printed on a label found at the bottom of the auto-reader and on its packaging.

Please, register your manufactory firmware in this manual for future reference:

Manufacture Firmware: _____

Fecha	Versión	Operador

Instructions for use

Start-up

1-Place the auto-reader on a firm surface, free from vibrations, away from sunlight, currents of hot or cold air, chemical and corrosive or flammable substances. Do not place the equipment in a way that disconnection of the plug from the power supply could be difficult. Leave a gap of at least 10 cm from the wall. Do not move the auto-reader periodically or during its use. Connect the auto-reader to a secure and stable electrical power source.

⚠ Do not wet or heat the auto-reader. If liquid is spilled on the auto-reader, disconnect it and dry it immediately. Before turning on, verify that all reading positions of the MiniPro auto-reader are empty.

2-Turn on the auto-reader by connecting the end of the AC of the power supply to the power source and then connect the other end of the source (plug) on the rear of the Bionova® MiniPro unit. The equipment will start by running the last program set-up.
3-Synchronize the Bionova® MiniPro Auto-reader with local time, using Bionova® software available in: http://http://www.terragene.com.ar/productos/infection-control/incubators/software-downloads/?lang=en. Connect the device USB port to the computer and start the program. Bionova® MiniBio will be synchronized with the time and time zone in the PC. Synchronization can be done as long as there is not an ongoing reading. See other 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, refer to *Modification of time zone* section. If you want to change the print language, refer to *Modification of print language* section.
4- Wait until the temperature of the equipment stabilizes. When this happens, the temperature indicator will remain fixed.

⚠ Do not place any hygiene indicator for protein detection in reading positions until the equipment indicates that the temperature is stable.

5-Reading can be initiated when the temperature blue light remains stable, indicating that the incubation temperature was reached. When the equipment is turned on and the temperature remains stable, an automatic check of the status of the 3 reading positions will be carried out. The indicator lights of each position will light up to indicate the result of the test: the green light ✓ ● will indicate that it was satisfactory and the red light ⊗ ● will indicate that an error has occurred.
When the equipment detects an error in some position, it will print a receipt indicating the date, time and positions with error. To guarantee the reliability of the results, these positions will be deactivated avoiding their use. To indicate that this position has been disabled, the red light of that position will remain blinking indefinitely.

⚠ For the correct performance of the automatic check, it should be done with the protective cover closed.

6-Press and hold the key Pro of the chosen position for 1 second to enter the reading mode. The device will emit a sound, the led indicator of quantitative results corresponding to 1 will blink quickly, the Auto reader will emit two sounds and the led will light indicating that the time program corresponding to a reading of a Chemdye®PRO1 MICRO pen has been selected. Auto-reader will keep the selected program in position during the entire reading process. The system does not allow the program to be modified once the reading has begun, unless it has been completed.
7- Use Chemdye® PRO1 MICRO pen to take the sample from the surface to be analyzed. To do this, follow the instructions described in Figure 1 (also explained in the Instructions for use of Chemdye® PRO1 MICRO hygiene monitoring system).
8- Once the solutions contained in the device have been correctly mixed, proceed with the incubation (remember that reading cone should not contain the swab). To do this, place the pen in the incubation / reading position (Figure 2) making sure to orient it as indicated on the label of the auto-reader. Insert the pen making sure that it stops at the bottom of the reading position, if it is in the correct position, check that it cannot be rotated (Figure 2).
9- Press the key Pro of the chosen position for 2 seconds to start the incubation and reading process (10 minutes at 60 °C). The lights ✓ ● and ⊗ ● of the position will become intermittent.

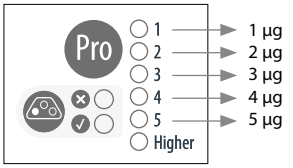
⚠ Do not move or remove the pen from its position during the reading process, this may cause mistaken readings or even the cancellation of it.

NOTE: If the incubation does not start, it may be due to the fact the Auto-reader has not yet stabilized the temperature (to confirm that the temperature light is stable) or the position used is disabled due to an error in the initial auto test.

10- Once the incubation process ends, a sound alarm indicates the end of the program. The sample is read and the

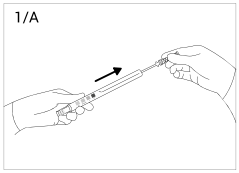
protein concentration is calculated using a calibration curve with BSA (Bovine Seric Albumin). Then, a ticket is printed with the calculated protein concentration. If the value is below the selected threshold, a green light ✓ will appear, indicating a **negative** result, if it is by above the selected threshold, a red light ✗ will appear, indicating a **positive** result. In both cases, one of the lights of the PRO panel will indicate the approximated rank of concentration calculated between 1 to 5 µg; if the value exceeds the 5 µg all the lights on the panel they will light up. The threshold to determine a positive or negative result can be configured using the Bionova® traceability software. The configuration process is outlined in the Bionova® traceability software manual. The factory-set threshold is 1µg.

NOTE: 30 seconds before the end of the program, the auto-reader will emit an alarm that will last until the end of the reading to warn the operator that the incubation time will be completed. The color of the solution can be used for a qualitative reading only if the protein pen is removed when the program ends. If the protein pen is not removed at that time the color of the solution will continue to evolve.

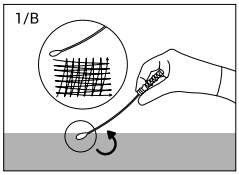


Approximate amounts of BSA expressed in µg.

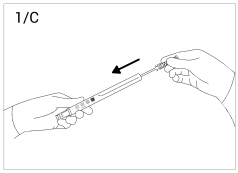
Figure 1



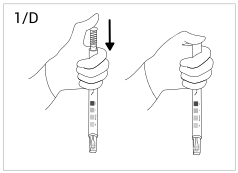
Remove the swab from the device. Carefully apply 2 drops of moisturizer on the swab or surface to be tested.



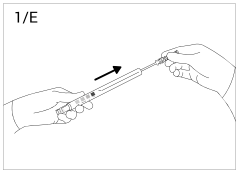
Swab thoroughly the desired surface.



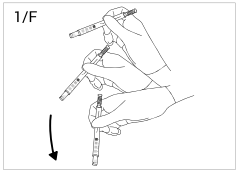
Place swab back into the device.



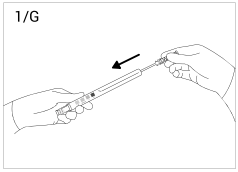
Place swab downwards firmly to activate.



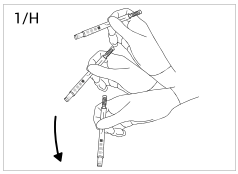
Slide swab upwards.



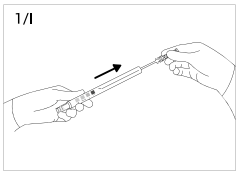
Shake vigorously and collect solution in the readout cone.



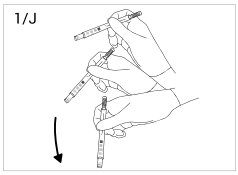
Slide swab downwards.



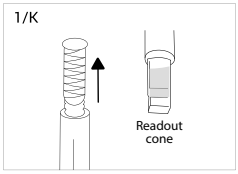
Shake for 15 seconds.



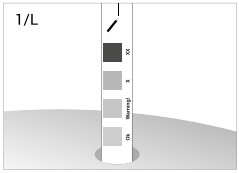
Slide swab upwards.



Shake vigorously and collect solution in the readout cone.

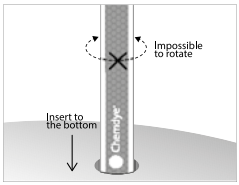


Readout cone without swab.



Incubate and read.

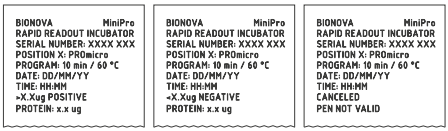
Figure 2



Insert the pen on the incubation/reading position.

11-Each time a result is available, it is informed with the impression of the corresponding ticket and with an audible alarm.
12- To register the ticket, take the paper and pull it up so that it cuts on the serrated edge of the printer.

NOTE: If the paper for ticket printing is finished, the blue attention light will flash rapidly. To replace the paper, follow the instructions in *Replacing the paper roll in the printer*. The machine will save the last 3 results, for its reprint, follow the instructions of *Reprinting of results*.



POSITIVE **NEGATIVE** **CANCELED**

Disposal

After reading, discard the hygiene indicators according to the sanitary regulations of your country. The hygiene indicators used cannot be reused (read the Instructions for use of Chemdye® PRO1 MICRO Hygiene Monitoring System).

Reprinting of results

Auto-reader allows reprinting of the last 3 results. For printing the results, press the button for 3 seconds.

Remaining incubation time

Bionova® MiniPro allows to verify the remaining incubation time of every reading position by printing a ticket. Whe-

never a reading process is in course, press and hold the button Pro for 3 seconds, a ticket will then be printed informing reading position, incubation program and remaining incubation time.
To verify remaining incubation time of 2 or more readings in course press 2 buttons Pro simultaneously; the device renders a ticket informing remaining incubation time of all positions.

```
BIONOVA              MiniPro
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
DATE: DD/MM/AA
TIME: HH:MM:SS

POSITION 1: PROmicro
PROGRAM: 10 min / 60°C
REMAINING TIME: HH:MM h

POSITION 3: PROmicro
PROGRAM: 10 min / 60°C
REMAINING TIME: HH:MM h
```

Audible alarm

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

Cancellation of a reading

The user can cancel a reading of any of the 3 positions by simultaneously pressing the button Pro of the chosen position and the button for 3 seconds. The device will cancel the reading and the cancellation will be informed by printing a ticket.

Temperature monitoring

Bionova® MiniPro Auto-reader contains an internal temperature control. If the temperature falls outside of the specified range 60±2 ºC, the blue temperature led light will start to twinkle.
Temperature can be externally monitored by using a Bionova® TB-IC1020 thermometer or other similar. MiniPro Auto-reader has a special hole for placing the thermometer which is located at the right side of the device.

Thermal paper specifications

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

Paper width : 58 mm

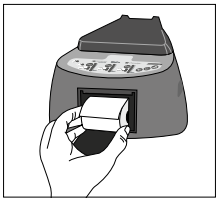
Maximum paper thickness: 60 g/m2

Maximum diameter size: 23 mm

Replacement of the paper roll

The printer uses thermal paper rolls.

1. To replace the paper roll, pull the handle of the printer's door. Open the printer's cover and remove the spent roll.



2. Place the new paper roll with the outer side up.

3. Close the printer cover by pressing on the sides of the lid.

NOTE: You can check the correct paper replacement by pressing , this button will force the advance of the paper a few centimeters.

Care and cleaning

Clean the outer surface of the Bionova® MiniPro Auto-reader with a damp cloth moistened with a small amount of detergent. Do not clean interior components. If additional cleaning of the internal components of the equipment is required, contact your distributor or manufacturer.

⚠ Always unplug the MiniPro Auto-reader and allow it to cool before cleaning. Do not immerse the unit in liquid.

NOTE: Bionova® MiniPro Auto-reader does not need routine maintenance.

Firmware update

Bionova® MiniPro Auto-reader allows updating the firmware periodically (program that controls the device and defines its different features) through the use of the Bioupdate Software. This software verifies, by using the internet, the latest firmware version available for MiniPro Auto-reader; downloads it and installs it in a few seconds without the loss of any device data.
The Bioupdate Software must be downloaded, only once, from the web site: http://www.terragene.com.ar/productos/infection-control/incubators/software-downloads/?lang=en.
Download file: **Download Bioupdate program**

UPDATE PROCEDURE:
Before starting the process, make sure that the Bionova® software is closed. Turn off the auto-reader for five seconds, then turn it on and follow these steps:
1-Connect the auto-reader to a PC using a USB cable and make sure to have an internet connection.
2-Open Bioupdate program.
3-Select the device and press Start button to update.

4-Wait until the software indicates that the upgrade process is complete. The auto-reader prints an update confirmation ticket. If it was already up to date, it will print nothing.

NOTE: This process must be repeated every time that a new firmware version is available; this will be informed in the website.

Calibration

The equipment calibration procedure is described in the attached software manual (*Bionova® Traceability Software* for Automatic Reading and Traceability of Rapid, Super Rapid and Ultra Rapid Biological Indicators and Hygiene Monitoring System). You can also download it from http://www.terragene.com.ar/productos/infection-control/incubators/software-downloads/?lang=en.

Setup Mode

Bionova® MiniPro has a setup mode from which, the equipment time zone and the print language can be set up. To enter Setup Mode, turn on the auto-reader while holding down the button . The red and green LEDs in the three positions will remain on, indicating that the device is in this mode. The printer will render a ticket indicating that it is in Setup Mode.
To change the time zone and the print language, follow the instructions below. When finished, restart the computer to exit Setup Mode.

Modification of time zone

The time zone modification function allows changing the time zone of the device to suit the time zone of your country.
To make this change, the auto-reader must be started in Setup Mode (see Setup Mode), then press the button . The current time will be printed to set a reference.
To subtract hours, press the button as many times as necessary. To add hours, press the button as many times as necessary. After 2 seconds, a ticket will be printed informing the selected time.
To confirm the change hold down the button for 3 seconds. To discard the changes, unplug the auto-reader from the power source.

Modification of printing language

This functionality allows changing the language in which the auto-reader printer renders the tickets.
To make this change, the device must be started in Setup Mode (see *Setup Mode*), then press the button .
The current language and list of available languages will be printed to establish a reference. Press the button to scroll up and to scroll down. After 2 seconds, a ticket will be printed informing the selected language.
To confirm the change, press and hold the button for 3 seconds. To discard the change, unplug the auto-reader from the power source.

Time setting mode

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® MiniPro 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 Bionova® traceability software.

Connect the auto-reader via the USB port to a PC and start-up the program. The Bionova® MiniPro Auto-reader will be synchronized with the PC's clock. Synchronization can only be done as long as there is not an ongoing reading.

Troubleshooting chart

Fault	Possible cause	Action
The auto-reader does not start.	Power source is not connected.	Check that the power source is connected to the power supply according to its characteristics and that the plug is connected to the auto-reader.
The auto-reader gives an error in one position during "Auto test".	A hygiene indicator is placed in the position at the moment of starting the auto-reader.	Check that every position is empty at the moment of starting the device.
The auto-reader gives an error in the "Auto test".	Soil particles might be obstructing the light path between the sensors.	Ensure cleanliness of the incubation position. Use of air is recommended. Do not use solid objects that could damage internal components. Restart the auto-reader.
The auto-reader does not run a hygiene indicator reading. The red light of that position is blinking.	The "Auto test" gives an error in that position, which becomes disabled.	Make sure that the position is empty when starting the device. Restart the auto-reader.
The auto-reader does not run a hygiene indicator readout in any position.	The incubation temperature is not stable.	Wait for temperature to be stable.
The auto-reader does not allow changing the program.	Ongoing reading.	Wait for the reading of corresponding position to finish.
The printer does not print and attention indicator light blinks quickly.	The printer cover is not tightly locked.	Check that the cover is tightly closed.
	Printer without paper.	Place a new paper roll in the right direction.
The printer releases unprinted paper.	Paper roll is placed in the wrong direction.	Check the paper roll direction.
The Bionova® traceability software does not detect the auto-reader.	The auto-reader is turned off or the USB cable is disconnected.	Check that the auto-reader is turned on, the USB cable is connected and the COM port is correctly installed and accepted by the operative system.
The update of the auto-reader fails.	The auto-reader is connected to the Bionova® traceability software.	Close the program, restart the auto-reader and try again.

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 (1 year from the time of purchase), the only obligation of Terragene® S.A. will be product repairing or substitution.

Limitation of liability

Terragene® S.A. shall not be held liable for any loss or damage that may 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.