BIONOVA®

Bionova® Hyper Auto-reader

for Hyper Rapid Biological Indicators

BIONOVA®
Hyper

Terragene®

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Index

◼ Composition

Product description

Terragene® Bionova® Hyper Auto-reader Incubator (BHY) has been designed for the incubation and automatic readout of the Bionova® Hyper line of Self-contained Biological Indicators (SCBIs) appropriate for monitoring plasma or vaporized Hydrogen Peroxide sterilization processes.

Hyper Auto-reader presents two independent readout positions. Each position automatically detects whenever a SCBI is placed for incubation and delivers a readout result after a few minutes using advanced fluorescence techniques.

Terragene® Bionova® Hyper Auto-reader Incubator (BHY) allows easy and rapid detection of positive and negative SCBIs. A positive result can also be evidenced by culture medium color change when performing extended incubations. Read the instructions for use of each SCBI for more information. The option to perform or not an extended incubation depends on the internal protocols of each laboratory or hospital.

Hyper Auto-reader has built-in USB, Wi-Fi, and Bluetooth® technology connectivity capabilities. The electronic tickets (e-tickets) created for each readout process can be accessed using a compatible device thus allowing easy documentation compliance and traceability.
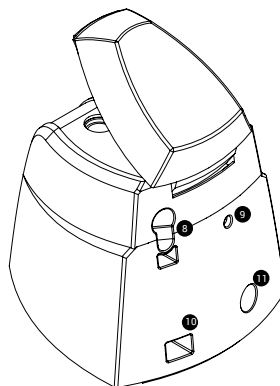
Indications for Use

Terragene® Bionova® Hyper Auto-reader Incubator (BHY) incubates at 60 °C and reads the Terragene® Bionova® Hyper SCBIs at the times prescribed in the User Manual.

Features

❶ Protective Cover

❷ Incubation Position

❸ Hyper Indicator

❹ Temperature progress & stability indicator

❺ Configuration & Alarm Cancellation Button

❻ Wi-Fi connection indicator - Bluetooth® connection indicator - Connectivity notifications indicator

❼ Position status indicator

❽ Ampoule crusher

❾ Hole for external temperature control

❿ Micro USB Port

⓫ Input for power supply plug (12 Volts DC)

■ Safety information

Symbols

80 % 30 % ⌂%	Operating relative humidity
30 ℃ 10 ℃	Operating temperature
⚠	Caution, Warning, Attention - Refer to the Instructions for use
ⓘ	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 Auto-Reader in a room exposed to direct sunlight or to high luminous intensity lamps.

■ Do not place the Auto-Reader near devices that emit strong electromagnetic fields.

■ Do not use the Auto-Reader on leaned surfaces or on surfaces that are subject to shocks, vibrations, temperature or high relative humidity.

■ Disconnect the power cord before cleaning.

■ Do not use abrasive, corrosive cleaners or disinfectants.

■ Do not immerse into any liquid. Do not pour any liquid inside.

■ Make sure the Auto-Reader is connected to an appropriate electrical mains outlet socket.

■ Use only the included power supply (AC power adapter), power supply's AC plug, power supply cords, and 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 Auto-reader and may not be safe for the user.

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

⚠

To reduce the risk of using incompletely sterilized loads:

■ Please read, understand, and follow the Instructions for Use of each SCBI before its incubation.

■ Do not remove the SCBI before the incubator reports the final readout result.

■ Check 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.

↵ Safety information

■ 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.
■ Avoid excessive SCBI handling that may lead to fingerprints or glove talc imprinted over the indicator.

①

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 Auto-reader. Parts or components inside the Auto-reader should not be manipulated by the user.

Operating conditions

Power supply specifications

Input parameters	Operating conditions	Units
Voltage range	(100-240)	AC Volts
Frequency	50/60	Hertz
Current	0,6	Amperes

Output parameters	Values	Units
Voltage	12	DC Volts
Current	1.5	Amperes

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 (max.)	Meters
Operation temperature	10-30	Celsius
Relative humidity	30-80	%
Installation/overvoltage	category II	
Degree of contamination	2	
Storage temperature	5-40	Celsius
Voltage	12	DC Volts

Regulatory Compliance

Bionova® Hyper Auto-reader complies with the following standards and directives:

Electrical Safety	IEC 61010-1
	IEC 61010-2-010
Electromagnetic Immunity	IEC 60601-1-2
	EN 60601-1-2
Electromagnetic Compatibility (EMC)	EN 61326-1
	EN 62311
	RED Directive 2014/53/EU
	47 CFR Part 15
European Commission	RoHS Directive 2011/65/EU
	WEEE Directive 2012/19/EU

EU Wireless Compliance: Bionova® Hyper Auto-reader complies with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following Internet address: www.terragene.com/DOC.
RF transmitter specifications: Wi-Fi transmitter total output power 19.9 dBm E.I.R.P (97.72 mW) in the frequency band of 2.4 GHz ISM band / 2.412 to 2.462 GHz (Channels 1 to 11). Bluetooth® transmitter total output power 4.6 dBm E.I.R.P (2.88 mW) in the frequency band of 2.4 GHz ISM band / 2.402 to 2.480 GHz.

FCC/IC Wireless Compliance: Bionova® Hyper Auto-reader complies with applicable FCC/IC directives. Contains certified transmitter module: FCC ID: 2AC7Z-ESPWROOM32D / IC ID: 21098- ESPWROOM32D.
This device complies with Part 15, Subpart A of the FCC rules: 15.247 Operation within the bands 902-928 MHz, 2400-2483.5 MHz and 5725-5850 MHz, and 15.209 Radiated emission limits - General requirements; and the Canadian standards: RSS-Gen

↵ Safety information

General Requirements for Compliance of Radio Apparatus, and RSS-247 Digital Transmission Systems (DTSs), Frecuency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Bionova® Hyper Auto-reader do not represent photobiological risk and do not generate dangerous optical radiation in any of its normal operation conditions as per the requirements of IEC 62471 Standard.
Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016.

Electromagnetic Compliance

Terragene® Bionova® Hyper Auto-reader Incubator (BHY) has been designed to be used in Professional healthcare environments.
The Bionova® BHY is classified as Group 1 Class B according to EN 55011 / CISPR 11. This means that it generates or uses RF energy only for their internal operations and, therefore, the emissions are low and unlikely to cause interference to nearby electronic equipment.
The ME equipment is suitable for use in domestic establishments and in facilities directly connected to a low voltage power supply network, and has no part directly applied to the patient.
It is user's responsibility to ensure that these conditions are met.

Electromagnetic Immunity

The immunity and basic safety requirements for the equipment were defined and tested according to the applicable standards in each case, as shown in the following tables.

Table 1: *Standard Immunity tests applied to the Auto-reader Incubator.*

Product Test Standard	Test Standard	Requirement Test case
IEC 60601 1 2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	EN 61000-4-3 (2006) / A1 (2008) / A2 (2010)	RI Radiated RF Electromagnetic field immunity test
	EN 61000-4-39 (2017)	PMF Proximity Magnetic Field
	EN 61000-4-6 (2014)	CI Immunity to conducted disturbances, induced by radiofrequency fields

Product Test Standard *(continuation)*	Test Standard	Requirement Test case
IEC 60601 1 2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	EN 61000-4-4 (2013)	EFT Electrical fast transient / burst immunity test
	EN 61000-4-5 (2014) / A1 (2017)	SUR Surge immunity test
	EN 61000-4-11 (2004)	VTE Voltage dips, short interruptions and voltage variations immunity test
	EN 61000-4-2 (2009)	ESD Electrostatic discharge immunity test
	EN 61000-4-8 (2010)	HFI H field immunity test

Table 2: *Frequency ranges and test levels for each immunity test.*

Phenomenon	Basic EMC Standard	Frequency ranges and level tests
Electrostatic Discharges (ESD)	EN 61000-4-2 (2009)	*Direct contact discharge:* ±8 kV
		Indirect contact discharge: ±8 kV
		Air discharge: ±2 kV; ±4 kV; ±8 kV; ±15 kV
Radiated RF Electromagnetic Field	EN 61000-4-3 (2006) / A1 (2008) / A2 (2010)	80 - 2700 MHz: 3 V/m 380 - 390 MHz: 27 V/m 430 - 470 MHz: 28 V/m 704 - 787 MHz: 9 V/m 800 - 960 MHz: 28 V/m 1700 - 1990 MHz: 28 V/m 2400 - 2570 MHz: 28 V/m 5100 - 5800 MHz: 9 V/m
Proximity Magnetic Field	EN 61000-4-39 (2017)	30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m
Electrical fast transient / burst immunity test	EN 61000-4-4 (2013)	*AC power port:* 100 kHz: ±2 kV
Surge immunity test	EN 61000-4-5 (2014) / A1 (2017)	*AC power port:* ±0.5 kV Asymetrical ±0.5 kV Symetrical ±1 kV Asymetrical ±1 kV Symetrical ±2 kV Asymetrical

↵ Safety information

Phenomenon	Basic EMC Standard	Frequency ranges and level tests
Immunity to conducted disturbances, induced by RF fields	EN 61000-4-6 (2014)	150 kHz - 80 MHz: 3 Vrms
		6,765 MHz - 6,795 MHz: 6 Vrms
		13,553 MHz - 13,567 MHz: 6 Vrms
		26,957 MHz - 27,283 MHz: 6 Vms
		40,66 MHz - 40,70 MHz:6 Vrms
		1,8 MHz - 2 MHz: 6 Vrms
		3,5 MHz - 4 MHz: 6 Vrms
		5,3 MHz - 5,4 MHz: 6 Vrms
		7 MHz - 7,3 MHz: 6 Vrms
		10,1 MHz - 10,15 MHz: 6 Vrms
		14 MHz - 14,2 MHz: 6 Vrms
		18,07 MHz - 18,17MHz: 6 Vrms
		21 MHz - 21,4 MHz: 6 Vrms
		24,89 MHz - 24,99 MHz: 6 Vrms
		28 MHz - 29,7 MHz: 6 Vrms
		50 MHz - 54 MHz: 6 Vrms
H field immunity test	EN 61000-4-8 (2010)	50 Hz: 30 A/m
Voltage dips and variations immunity test	EN 61000-4-11 (2004)	*Voltage dips and variations:*
		100 % during 10 ms
		100 % during 20 ms
		30 % during 500 ms
Voltage short Interruptions immunity test	EN 61000-4-11 (2004)	*Voltage interruptions:*
		100 % during 5 s

Warnings and important points to remember

■ Use only the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable.

■ Verify that all 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 place the BHY Auto-reader near devices that emit strong electromagnetic fields.

RF transmitter specifications

■ Wifi transmitter total output power 19.9 dBm e.i.r.p (97.72 mW) in the frequency band of 2.4 GHz ISM band / 2.412 to 2.462 GHz (Channels 1 to 11).

■ Bluetooth transmitter total output power 4.6 dBm e.i.r.p. (2.88 mW) in the frequency band of 2.4 GHz / 2.402 to 2.480 GHz.

Environmental considerationstable

The BHY Auto-reader contains electronic components, please dispose of it at an appropriate recycling center.

■ Product compatibility and incubation programs

Bionova® Hyper Auto-reader incubation programs

The following incubation programs are available for your Bionova® Hyper Auto-reader.

Temperature selection	Incubation time	Incubation program
60 °C	5 min *(Hyper)*	Hyper at 60 °C

(!)

Please read and follow the SCBI instructions for use before its use.

(!)

All SCBIs are single use. Do not use or incubate the same SCBI more than once.

Bionova® Hyper Auto-reader compatible indicators

We develop new Indicators for extending the features of our incubators regularly. Please visit www.terragene.com/HYPER to access the Compatibility Matrix for Terragene® Auto-readers.

■ Instructions for use

Important: Remember to set-up the Auto-reader local date and time before starting incubations. (See item 3)

Start-up

1|Place the Bionova® Hyper Auto-reader on a firm surface, free

↵ Instructions for use

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 Hyper 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.

❗

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

3|Set-up the Auto-reader local date and time running the Bionova® Wireless Assistant on a compatible mobile device. Refer to the *Bionova® Wireless Assistant* section for more information.

❗

All devices are manufactured with the following settings:
■ Time zone: UTC +0:00

4|Wait until the Temperature progress & stability indicator stops blinking for the Auto-reader to reach a steady working temperature.

⚠️

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

5|Once the Temperature progress & stability indicator remains stable, a one-time automated test to check each position internal status will be carried out (Auto-test).
Once the test has been completed, the Position status indicator will turn green to indicate that the position can be used to perform readings, or it will turn red to indicate that an error has occurred. When the Auto-reader detects an error in a position, such position will be disabled to guarantee the reliability of the results and it can not be used to perform

any further readings. To indicate that a position has been disabled, the Position status indicator will turn red and will blink indefinitely.

❗

For the correct performance of the Auto-test keep the Protective Cover closed when the Auto-test is running.

6|After the Auto-test has been completed, readings can be initiated on any incubation position if the position is not disabled. Place an indicator in a SCBI reading position. The reading process will start automatically after placing the SCBI. The Auto-reader will emit an audible notification indicating that a reading has successfully began, at the same time the position status lights will start blinking. Close the Protective Cover, and wait until a readout result is informed.

⚠️

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

⚠️

Do not remove or change the SCBI's placement once a reading process has begun. If this occurs, results may be invalidated. See *Cancelling a reading* section for further details. If the incubator does not start a reading immediately after placing an SCBI in a reading position, refer to the *Troubleshooting* section for more information.

7|When a positive result is detected in a reading position, the Position status indicator will turn red and an audible alarm will activate. This indicates that the sterilization process to which the SCBI was exposed, has failed. 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 has turned off.

❗

Press the 🔇 button to cancel the audible alarm.

When a negative result is detected in a reading position, the Position status indicator will turn green. This indicates that the sterilization process to which the SCBI was exposed, has

been successful. 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 has turned off.

Note: The incubation time setting defines the upper time limit in which an Auto-reader can inform a fluorescence readout. Nevertheless, the Auto-reader can detect and inform a positive result before the selected time limit as part of its normal operation.

8| Each time a readout is carried out the Auto-reader will store the readout result along with an uniquely assigned ID identifier in its internal memory. Refer to the *Results management* section to learn more.

Positive, Negative, and Canceled Results will be stored in the internal memory.

Remaining incubation time

The remaining incubation time of ongoing incubations can be verified using Bionova® Wireless Assistant or Bionova® Traceability Software. Please refer to the *Bionova® Wireless Assistant* section and to the *Bionova® Traceability Software* section.

Cancelling 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 Position status indicator will turn Red and start to blink to indicate that the SCBI should be returned into its original reading position. If the SCBI is not placed back after 10 seconds of being removed, the reading will be canceled automatically.

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. Always retest the Sterilizer. 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 Auto-reader.

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

(!)

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

(!)

Incubate the positive control indicator following the SCBIs Instructions for Use.

Disposal

Discard the SCBIs according to your country's sanitary regulations. Positive SCBIs can be sterilized before discarding following the SCBIs 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 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 🔇.
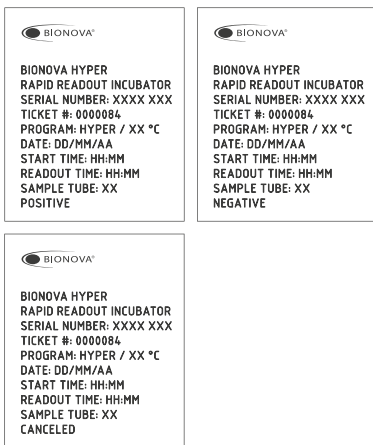
Temperature monitoring

Hyper Auto-reader features an automated internal temperature control. If the incubation temperature falls

outside of the specified range of (60 ± 2) ºC, the Temperature progress & stability indicator will start to blink.

The incubation temperature can be externally monitored placing the Bionova® TB-IC1020 thermometer in the Hole for External Temperature Control located at the back of the device.

Results management

Every time a reading takes place, its result is stored in the Auto-reader's internal memory as an electronic ticket (e-ticket). Each e-ticket has an unique ID numeric identifier and informs incubation information such as the readout result, readout time, and more.

```
● BIONOVA®

BIONOVA HYPER
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: HYPER / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
POSITIVE
```

```
● BIONOVA®

BIONOVA HYPER
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: HYPER / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
NEGATIVE
```

```
● BIONOVA®

BIONOVA HYPER
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: HYPER / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
CANCELED
```

Managing e-tickets

Hyper Auto-reader stores the last 50 e-tickets at any given time. Whenever a new incubation is performed, a new e-ticket will be stored in the Auto-reader's internal memory and, at the same time, the oldest e-ticket of the 50 stored on internal memory will be discarded.

To make sure your incubation results are not lost, access your e-tickets regularly to print them, or to create PDF reports to be saved on your preferred device. Keep track of all your tickets using their ID number as guidance. The e-ticket ID number is a unique identifier assigned to each readout, where ID number 1 corresponds to the first readout ever performed on your Hyper Auto-reader.

(!)

Make sure you saved/printed your e-tickets before they get discarded from internal memory. This process can not be undone. The e-tickets on your device can be accessed by the Bionova® Cloud Environment on Personal Computers, or by Bionova® Wireless Assistant on Android devices.

Bionova® Wireless Assistant integration

Connecting your Auto-reader to Bionova® Wireless Assistant allows the monitoring of all ongoing readings, access to the 50 e-tickets stored in the Auto-reader, and create and save PDF reports with one or more e-tickets. Refer to the *Bionova® Wireless Assistant* section to learn more about the App.

Bionova® Cloud Environment integration

Connecting your Auto-reader to the Bionova® Cloud Environment allows you to simplify the overall e-tickets tracking process by letting the software take care of the details while adding new functionality.

The Bionova® Cloud environment enables you to perform all actions available through the Bionova® Wireless Assistant, but adds a whole new layer of features including linking e-tickets and its corresponding incubation results to the sterilizer being used, the operator, quick search and filtering of results, SPR calculations, and more.

If a printer is connected to your computer, you can also print any result or report on Bionova® Cloud Traceability Software's database to create a hard copy of the information. To learn more about the software refer to the *Bionova® Cloud Environment* section.

■ Additional features

Firmware update

Bionova® Hyper Auto-reader allows the update of its firmware (program inside the Incubator that controls and defines its different features) by using the firmware update utility Bionova® Bioupdate. Bionova® Bioupdate connects to the internet to verify, download, and install, the latest firmware

↵ **Additional features**

version available for your incubator. The update process only lasts a few seconds and is carried out without the loss of any Incubator's data. Please visit www.terragene.com/software to download Bionova® Bioupdate.

Update process

Before updating the device, make sure that the Bionova® 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 Bionova® MiniBio 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 Incubator from the list and press the Start button to update.
4|Wait until the software indicates that update process has been completed. The Incubator will print an update confirmation ticket. If it was already up to date, the ticket will not be printed.

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

■ Bionova® Wireless Assistant

First use

To access the extended features of your Bionova® Hyper Auto-reader, please download the Bionova® Wireless Assistant App to your preferred mobile device.
Once downloaded, run the App and configure a New Auto-reader following the steps detailed on the *Wi-Fi Connectivity* and *Bluetooth® Connectivity* sections to enjoy the Auto-reader's Wireless features.
For Android mobile devices: Go to Google® Play Store and download the latest version of Bionova® Wireless Assistant. Don't forget to rate us!

Home Screen

The Bionova® Wireless Assistant *Home Screen* lists all the devices accessible through your mobile device. From this screen you can easily select any of the devices listed and see their current status, configure color profiles and manage your e-tickets. Tap on any of the devices listed for more information. If no devices are listed, tap on the Configure a new device Button and follow the instructions, refer to the *Connectivity* section for more information.
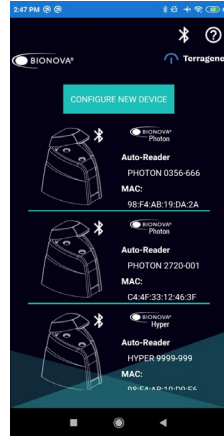
Device information Screen

Once a device is selected from the *Home Screen*, the device information screen will be available. The screen informs all data related to the device, such as device model, device name, device IP, etc. Moreover, the Status of all readout positions is informed in real time.
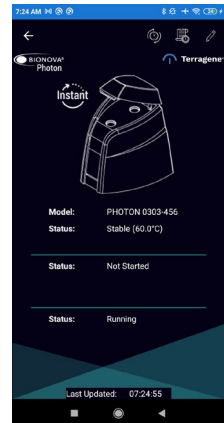
Available actions

■ To synchronize your Bionova® Hyper Auto-reader internal clock with the current date and time of your mobile device tap the button ⊙ .

■ To Access previous readout results e-tickets tap the button 🖥 .

You can also assign a easy to remember name and a color profile for your devices taping the button ✏ .

Accessing e-tickets

For accessing the e-tickets saved internally on your Auto-reader tap the 🖥 on the App's *Home Screen Toolbar*. The 50 last e-tickets internally saved will be displayed on the *Historic Results Screen*.

■ For creating a PDF Report, first select which e-tickets you want to be included and tap the 🖨 . To create a PDF report ready to share via e-mail, Google Drive, Whatsapp, Bluetooth®, or any other sharing platform configured on your mobile device.

■ Tap the button ⤳ for sharing report.

■ Connectivity

USB Connectivity

To connect your Hyper Auto-reader to a PC by USB, connect one end of the included USB cable to the rear of the incubator and the other end to an USB port on your PC. The following recommendations are offered for an optimal communication between the Auto-reader and your PC:

■ Always use the included USB cable.
■ Connect the incubator to the computer directly, avoiding the use of adapters or USB HUB.
■ Make sure that the USB ports remain connected firmly at both ends.

Wi-Fi Connectivity

Each Bionova® Hyper Auto-reader has a built-in Wi-Fi module that allows you to connect the Auto-reader to your Local Wi-Fi Network.

Once the Auto-reader is successfully connected to your local network, it will be visible through Bionova® Wireless Assistant if the mobile device where the App is running is connected to the same local network.

Wi-Fi Connectivity status

The Auto-reader WI-FI connection indicator informs the Wi-Fi connectivity status. The indicator has four different blinking patterns:

■ Wi-Fi indicator On: The Auto-reader is connected successfully to a Wi-Fi local network.
■ Wi-Fi indicator blinking slow: The Auto-reader is not connected to a local network.
■ Wi-Fi indicator bilking fast: The Auto-reader is on connectivity selection mode.
■ Wi-Fi indicator off: The Auto-reader Wi-fi connectivity is not active.

Enabling the Auto-reader Wi-Fi connectivity

To enable the Auto-reader's internal Wi-Fi module, press and hold the 📶 button until you hear a beep (approximately 3 seconds), then release the button.
Press the button again as many times as necessary until the Wi-Fi connection indicator is turned on and blinking fast. This indicates that the Wi-Fi connectivity was selected.
Wait for a few seconds until you hear a beep, this indicates that the Wi-Fi module was successfully enabled. Then, the incubator will reboot automatically.
The Wi-Fi connection indicator will start to blink slow, or will remain turned on steady to indicate the Auto-reader connectivity status.

(!)

Please make sure your Auto-reader's Wi-Fi connectivity is enabled for the Bionova® Wireless Assistant to be able to list the device on its *Home Screen*.
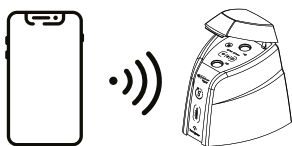
Auto-reader Wi-Fi configuration

(!)

If it is the first time you connect your Auto-reader to your Local Wi-Fi Network please carry out the steps detailed on this section.

↵ **Connectivity**

(!)

Please make sure your Auto-reader's Wi-Fi connectivity is enabled before carrying out the steps below.

1| Download Bionova® Wireless Assistant to a compatible mobile device.
2| Run Bionova® Wireless Assistant and press the *Configure new device* button.
3| Follow the steps detailed on the App's interactive tutorial to connect your mobile device directly to the Auto-reader's internal Wi-Fi network. (See figure).

(!)

If the Auto-reader internal Wi-Fi network is not listed on your mobile device, follow the steps detailed on the *Enabling the Auto-reader Wi-Fi connectivity* section. This will create new internal Wi-Fi network.

4| Follow the steps detailed on the App's interactive tutorial to configure the connection between the Auto-reader and your local Wi-Fi network. (See figure).


(!)

Please make sure to have at hand the name and password of your local Wi-Fi network for the Auto-reader to be able to connect to your local Wi-fi network.

Local Wi-Fi Network connection

Once your Auto-reader has been successfully configured, it will automatically connect to your Local Wi-Fi Network.
Once the Auto-reader connects successfully to the local Wi-Fi network, the WI-FI connection indicator will remain turned on steady.

Afterward connect your mobile device to your Local Wi-Fi Network as well. So both, the Auto-reader and your mobile device are connected to the same Network.
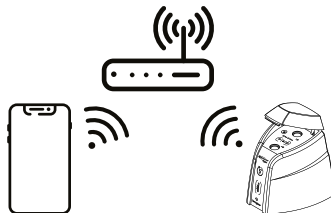
If the process was successful your Hyper Auto-reader will be listed on the Bionova® Wireless Assistant's *Home Screen*.

Bluetooth® connectivity

Each Bionova® Hyper Auto-reader has a built-in Bluetooth® module that allows you to connect the Auto-reader to your Bluetooth® compatible mobile device.
Bionova® Wireless Assistant will find and list all nearby Bluetooth® enabled Auto-readers if the App's Bluetooth® device search is active. Tap the ⬘ button on the App's *Home Screen* to turn-on, or turn-off, devices search.

Bluetooth® connectivity status

The Auto-reader Bluetooth® connection indicator informs to the user the Bluetooth® connectivity status. The indicator has four different blinking patterns:
■ Bluetooth® indicator On: The Auto-reader is connected successfully to a Bluetooth® mobile device.
■ Bluetooth® indicator blinking slow: The Auto-reader is not connected to a mobile device.
■ Bluetooth® indicator bilking fast: The Auto-reader is on connectivity selection mode.
■ Bluetooth® indicator off: The Auto-reader Bluetooth® connectivity is not active.

Enabling the Auto-reader Bluetooth® connectivity

To enable the Auto-reader internal Bluetooth® module, press and hold the (🔇) button until you hear a beep (approximately 3 seconds), then release the button.
Press the button again as many times as necessary until the

↵ Connectivity

Bluetooth® connection indicator is turned on and blinking fast. This indicates that the Bluetooth® connectivity was selected.

Wait for a few seconds until you hear a beep, this indicates that the Bluetooth® module was successfully enabled.
The Bluetooth® connection indicator will start to blink slow, or will remain turned on steady to indicate the Auto-reader connectivity status.

(!)

Please make sure your Auto-reader's Bluetooth® connectivity is enabled for the Bionova® Wireless Assistant to be able to list the device on its *Home Screen*.

Auto-reader Bluetooth® configuration

(!)

If it is the first time you connect your mobile device to your Auto-reader via Bluetooth® please carry out the steps detailed on this section.

(!)

Please make sure your Auto-reader's Bluetooth® connectivity is enabled before carrying out the steps below.

1|Download Bionova® Wireless Assistant to a compatible mobile device.
2|Run Bionova® Wireless Assistant and press the *Configure new device* button.
3|Follow the steps detailed on the App's interactive tutorial to connect your mobile device directly to the Auto-reader. (See figure).
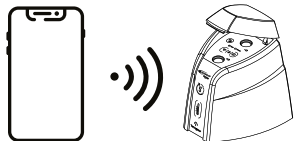
If the process was successful, your Hyper Auto-reader will be accessible by selecting the device on the Bionova® Wireless Assistant's *Home Screen*.

Resetting Wireless settings to factory values

Resetting Wireless connectivity settings to its factory values will clear all saved Wi-Fi and Bluetooth® configuration settings. This process can be useful when trying to connect the Auto-reader to a different local Wi-Fi network from the one previously configured. Or when trying to clear Bluetooth® permissions for any previously connected mobile devices.
For resetting the Wi-Fi configuration and Bluetooth® configuration to its factory values, please follow the next steps.

(!)

Please make sure your Auto-reader's Bluetooth® connectivity is enabled for the Bionova® Wireless Assistant to be able to list the device on its *Home Screen*.

1|Press and hold the (🔊) button until you hear a beep (approximately 3 seconds).
2|Keep the Button **pressed** until you hear a second beep (approximately 8 seconds after the first beep).
3|Release the (🔊) button.
4|All connectivity indicators will start to blink to indicate that the connectivity settings were successfully resetted to factory values. The Auto-reader will reboot automatically.
To reconnect the Auto-reader to your local Wi-Fi network after resetting the connectivity settings, please follow the steps detailed on the *Wi-Fi Connectivity* section.
To reconnect the Auto-reader to your mobile device via Bluetooth® after resetting the connectivity settings, please follow the steps detailed on the *Bluetooth® Connectivity* section.

Disabling all Wireless Connectivity

To disable all Wireless the connectivity capabilities of the Auto-reader (Wi-Fi and Bluetooth®), press and hold the (🔊) button until you hear a beep (approximately 3 seconds), then release the button.
Press the button again as many times as necessary until the Bluetooth® connection indicator and the Wi-Fi connection indicator are turned off simultaneously.
Wait for a few seconds until you hear a beep, this indicates that wireless connectivity was successfully disabled.

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If Wireless connectivity is disabled, the Auto-reader only connectivity method available will be USB.

■ Bionova® Cloud Environment

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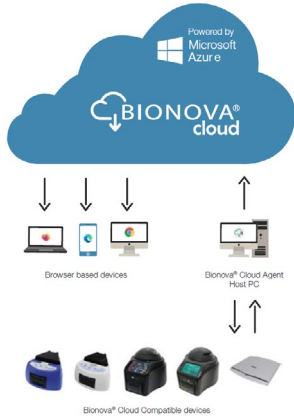
Bionova® Cloud Traceability Software allows to manage and store the readout results of Self-contained biological indicators and Hygiene Monitoring System Indicators in a secure and user-friendly way.

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.

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.

■ 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® Hyper 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 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 not stable.	Wait until temperature is stable before any incubations.
The Auto-reader can not be updated.	Bionova® Traceability Software is being run.	Close Bionova® Traceability Software and restart the Auto-reader.
The Auto-reader is not detected by Bionova® Traceability Software	Auto-reader is turned off / Auto-reader is not connected to the PC.	Follow the directions on the Start-up section to set up the device properly.
The Auto-reader is not detected by Android devices.	The Auto-reader's connectivity settings are not properly configured.	Follow the directions on the *Connectivity* 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.
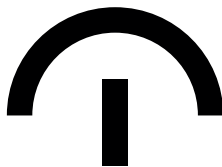
Term

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.