BIONOVA®

Bionova® Hyper Auto-reader

for Hyper Rapid Biological Indicators

R05 | June 2025

WARNING: This product contains dry natural rubber.

Terragene®

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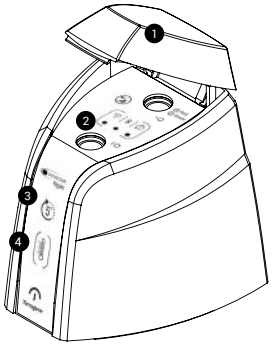
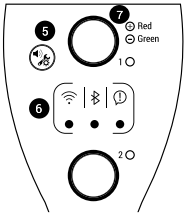
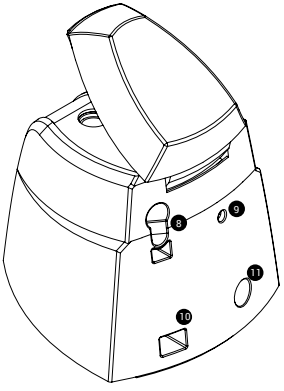
Composition







Product description

The Bionova® Hyper Auto-reader was designed for the incubation and automatic readout of the Bionova® Hyper Self-contained Biological Indicator (SCBI) appropriate for monitoring plasma or vaporized hydrogen peroxide sterilization processes.

The Bionova® Hyper Auto-reader has two independent readout positions. Each position automatically detects when an SCBI has been placed for incubation and delivers a readout result after a few minutes using advanced fluorescence techniques.

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

1. Protective cover
2. Incubation position
3. Hyper indicator light
4. Temperature & stability indicator
5. Configuration & alarm cancellation button
6. Wi-Fi connection - Bluetooth® connection - Connectivity notifications indicator lights
7. Position status indicator light
8. Ampoule crusher
9. Hole for external temperature control
10. Micro USB Port
11. Socket for power supply plug (12 Volts DC)

■ Safety information

Symbols

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

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

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

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

Manufacturer. Indicates the medical device manufacturer.

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

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

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

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

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

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

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

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

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

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

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

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

To avoid risks and/or damaging the device:

- Use indoors only.
- Do not place the auto-reader in a room exposed to direct sunlight or to high luminous intensity lamps.
- Do not place the auto-reader near devices that emit strong electromagnetic fields.
- Do not use the auto-reader on sloping surfaces or on surfaces that may be knocked, that may vibrate, be exposed to high temperatures, or high relative humidity.
- Disconnect the power cord before cleaning.
- Do not use abrasive, corrosive cleaners or disinfectants.
- Do not immerse into any liquid. Do not pour liquid into it.
- Make sure the auto-reader is connected to an appropriate electrical mains outlet socket.
- Use the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable only. Check that all the items included are in good condition every day. If any of them is damaged, discontinue its use. The use of cables, adapters, cords, and/or power supplies different from the ones included may cause fires, electrical shocks, or even physical injuries.
- Do not plug any devices into the auto-reader's USB port other than a personal computer (PC). The PC must be compliant with IEC 60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its USB ports. Ask a qualified technician to check

that the device is compatible. Attaching any other device to the USB port may damage the auto-reader and may not be safe for the user.

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

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To reduce the risk of using incompletely sterilized loads:

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

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

- Cool the SCBI during the indicated time before crushing the ampoule.
- Do not handle the SCBI excessively since this might cause the glass ampoule to explode.
- Wear safety gloves and goggles while removing the SCBI from the sterilizer, pressing the SCBI's cap, and crushing the SCBI's ampoule.
- Do not use your finger to crush the SCBI. Use the ampoule crusher instead.

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To avoid a potentially hazardous situation:

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

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To avoid SCBIs from absorbing fluorescent particles:

- Avoid direct contact between the SCBIs and chemical indicators or tapes before the SCBI incubation.
- Avoid excessive SCBI handling that may lead to fingerprints or glove talc imprinted over the indicator.

Note: Do not use this product other than in the manner specified by Terragene S.A., otherwise the protection provided by the product might be affected.

Note: Only Terragene S.A. authorized personnel may access or service the internal components of the auto-reader. Parts or components inside the auto-reader should not be 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 Uninterruptable Power Supply (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/Over-voltage	Category II	-
Pollution degree	2	-
Storage temperature	5-40	Celsius
Voltage	12	DC Volts

Device safety compliance

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

Electrical Safety	IEC 61010-1 IEC 61010-2-010 Low Voltage Directive 2014/35/EU
Electromagnetic Immunity (EMI)	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: The 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: The 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). The 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: The Bionova® Hyper Auto-reader complies with applicable FCC/IC directives. Contains certified transmitter module: FCC ID: 2AC7Z-ESPWROOM32D / IC ID: 21098- ESPWROOM32D.
This auto-reader 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 Canadian standards: RSS-General Requirements for Compliance of Radio Apparatus, and RSS-247 Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices It may only be used if the following two conditions are met:
1. This auto-reader may not cause interference.
2. This auto-reader must tolerate interference, including interference that may cause undesired operation of the device.

The Bionova® Hyper Auto-reader does not represent photobiological risk and does not generate dangerous optical radiation if used within its normal operating conditions, as per the requirements of IEC 62471 Standard.

Designed under Quality Management System standards ISO 13485:2016/EN ISO 13485:2016.
Note: The auto-reader has been evaluated for conformity for use in business environments. There may be concerns about radio interference if used in home environments. This applies exclusively to the Korean market due to KC certification requirements.

Electromagnetic Compliance

The Bionova® Hyper Auto-reader has been designed to be used in professional healthcare environments.
The Bionova® Hyper Auto-reader 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 auto-reader is suitable for use in domestic settings and in facilities directly connected to a low voltage power supply network, and has no parts that are 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 auto-reader 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.*

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
IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015+A1:2021	EN 61000-4-6 (2014) EN 61000-4-4 (2013)	CI Immunity to conducted disturbances, induced by radiofrequency fields EFT Electrical fast transient/ burst immuty 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
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 Vrms 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 % for 10 ms 100 % for 20 ms 30 % for 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 the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable only.
- Check that all included elements are in good condition every day. If any of them is damaged, stop using it.
- 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 auto-reader near devices that emit strong electromagnetic fields.

RF transmitter specifications

- The 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).
- The 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 considerations table

The Bionova® Hyper Auto-reader contains electronic components. Please dispose of it at an appropriate recycling center.

■ Product compatibility and incubation programs

Available incubation programs

The following incubation program is available for your auto-reader.

Temperature selection	Time selection	Incubation program
60 ºC	5 min (Hyper)	Hyper at 60 ºC

Note: Please read and follow the SCBI Instructions For Use before its use.

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

Compatible indicators

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

■ Instructions For Use

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

Start-up

1|Place the auto-reader on a firm surface, free from vibrations, away from direct sunlight, hot or cold air flows, chemical and corrosive or flammable substances. Do not place the auto-reader in a way that would make it difficult to remove the power supply's AC plug from mains. Leave a space of at least 10 cm from the auto-reader to the closest wall. Do not move the auto-reader periodically or while it is being used. Connect the auto-reader to a secure and stable electrical mains outlet socket.
Note: Do not wet or heat the device. If liquid is spilled on the device, disconnect and clean it. For more information, please refer to the following section: ***Cleaning and maintenance***.

2|Switch on your auto-reader by connecting the power supply's AC plug to the mains and then connect the plug at the other end of power supply to the rear of the auto-reader.
Note: Before switching it on, check that all incubation positions are empty.

3|Set the auto-reader local date and time running the Bionova® Wireless Assistant on a compatible mobile device. For more information, please refer to the following section: ***Connectivity.***
Note: All devices are manufactured with the following settings: *Time zone:* UTC +0:00

4|Wait until the temperature & stability indicator light stops blinking, indicating that the auto-reader has reached a steady working temperature.
Note: Do not place an SCBI on an incubation position before the incubation temperature is stable.

5|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 has been completed, the position status indicator light will turn green to indicate that the position can be used to perform readings, or it will turn red to indicate that an error has occurred. When the auto-reader detects an error in a position, this position will be disabled to guarantee the reliability of the results and no further readings will be possible. To indicate that a position has been disabled, the position status indicator light will turn red and will blink continuously.

Note: To ensure the "Auto-test" works properly, keep the protective cover closed when the automated test is running.

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

7|If a positive result is detected in a reading position, the position status indicator light will turn red and an audible alarm will sound. This indicates that the sterilization process to which the SCBI was exposed, has failed. Once the SCBI has been removed, the alarm and the 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 has turned off.
Note: To cancel the audible alarm, press the button: .
If a negative result is detected in a reading position, the position status indicator light will turn green. This indicates that the sterilization process to which the SCBI was exposed, has been successful. Once the SCBI has been 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.
Note: The incubation time setting defines the upper time limit in which an auto-reader can provide a fluorescence readout. The auto-reader can, however, detect and provide a positive result before the selected time limit under normal operation.

8|Each time a readout is carried out the auto-reader will store the fluorescence readout result along with a uniquely assigned ID identifier in its internal memory. For more information,

please refer to the following section: ***Managing the results***. Positive, Negative, and Canceled Results will be stored in the internal memory.

Remaining incubation time

The remaining incubation time of ongoing incubations can be checked using the Bionova® Wireless Assistant or Bionova® Cloud Environment. Please refer to the following sections: ***Bionova® Wireless Assistant***, ***Bionova® Cloud Enviroment***.

Cancelling a reading

If an SCBI is removed from a position during the incubation process an audible alarm will sound. At the same time, the position status indicator light will turn yellow and start to blink to indicate that the incubation has been canceled.

Interpreting the results

To indicate a positive result, a red light will come on at the incubation position of the auto-reader.
If a positive result is obtained when incubating an exposed SCBI, this indicates that the sterilization process to which the SCBI was exposed has failed. This result is valid if a positive result is obtained for the positive control SCBI.
Act immediately if a positive result is obtained when incubating an exposed SCBI. Please refer to the sterilizer's Instructions For Use for more information.

To indicate a negative result, a green light will come on at the incubation position of the auto-reader.
If a negative result is obtained when incubating an exposed SCBI, this indicates that the sterilization process to which the SCBI was exposed has been successful. This result is valid if a positive result is obtained for the positive control SCBI.
Note: A positive result should always be obtained by the auto-reader when incubating a positive control SCBI. For more information, refer to the following section: ***Positive control.***

Positive control

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

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

For the incubation of a positive control SCBI, 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's Instructions For Use.
Note: The positive control and the exposed SCBI should come from to the same batch.
Note: Incubate the positive control following the SCBI's Instructions For Use.

Disposing of SCBI's

Dispose of the SCBIs in accordance with your country's waste-disposal guidelines. Positive SCBIs can be sterilized before discarding following the SCBI's Instructions For Use. It is not possible to use or incubate an SCBI more than once.

Audible alarm

An audible alarm will sound every time a positive result is detected by the auto-reader. The alarm immediately informs the user that a positive result has been detected without the need to visually check the device. To cancel the alarm press the button: .

Monitoring the temperature

The auto-reader features an automated internal temperature control. If the incubation temperature falls outside of the specified range of 60 ± 2 ºC, the temperature & stability indicator light will start to flash.

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.

Managing the results

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

Managing e-tickets

Figure 1. Positive

BHY BIONOVA HYPER
AUTO-READER INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
POSITIVE

Figure 2. Negative

BHY BIONOVA HYPER
AUTO-READER INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
NEGATIVE

Figure 3. Canceled

BHY BIONOVA HYPER
AUTO-READER INCUBATOR
SERIAL NUMBER: XXXX XXX
TICKET #: 0000084
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XX
CANCELED

The 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 in the internal memory will be deleted.
To make sure your incubation results are not lost, access your e-tickets regularly to print them out, or to create PDF reports to be saved on your preferred device. Keep track of all your e-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 auto-reader.
Note: Make sure you saved/printed your e-tickets before they are delete from the internal memory. This process cannot be undone.
Note: The e-tickets on your device can be accessed by the Bionova® Cloud Environment on personal computers, or by Bionova® Wireless Assistant on mobile devices.

Connecting to your Bionova® Wireless Assistant

After connecting your auto-reader to Bionova® Wireless Assistant Application all ongoing readings can be monitored, the 50 e-tickets stored in the auto-reader can be accessed and PDF reports can be created and saved with one or more e-tickets.

For more information, please refer to the following section: *Connectivity.*

Connecting to Bionova® Cloud Environment

Connecting your auto-reader to the Bionova® Cloud Environment simplifies 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, while adding a whole new layer of features including linking e-tickets and its corresponding incubation results to the sterilizer being used, the operator, a quick search function, a results filter, sterilization process risk (SPR) calculations and more.

If a printer is connected to your computer, you can also print any result or report on Bionova® Cloud Web Application's database to create a hard copy of the information. For more information, please refer to the following section: ***Bionova® Cloud Environment***.

■ Additional features

Firmware update

The auto-reader firmware can be updated (a program inside the auto-reader checks and defines the various features) with the firmware update utility. The firmware update utility connects to the Internet to check, download, and install the latest firmware version available for your auto-reader. The update process only lasts a few seconds and is carried out without the loss of any auto-reader's data.

Please visit www.terragene.com/software to download the firmware update utility.

Update process
Before updating the device, switch off the auto-reader for five seconds, then switch the auto-reader back on and follow the next steps:
1|Using the included USB cable, connect your auto-reader to a PC on which the firmware update utility has been previously. installed. Make sure the PC has a working Internet connection
2|Run the firmware update utility.

3|Select the auto-reader from the list and press the button: *Start.*
4|Wait until the software indicates that update process has been completed.
Note: It is recommended that this process be carried out once a year unless an early update is required by the manufacturer.

■ Connectivity

USB connectivity

To connect your auto-reader to a PC by USB, connect one end of the included USB cable to the rear of the auto-reader and the other end to an USB port on your PC. Follow these recommendations to ensure optimal communication between the auto-reader and your PC:
- Always use the included USB cable.
- Connect the auto-reader to the computer directly, avoiding the use of adapters or a USB HUB.
- Make sure that the USB ports remain connected firmly at both ends.

Bionova® Wireless Assistant Application

To access the extended features of your auto-reader using Wi-Fi or Bluetooth®, please download the ***Bionova® Wireless Assistant application*** to your preferred mobile device.
- *For Android mobile devices:* Download the latest version of Bionova® Wireless Assistant on Google Play.
- *For iOS mobile devices:* Download the latest version of Bionova® Wireless Assistant on the App Store.

Wi-Fi connectivity

Each 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 on the Bionova® Wireless Assistant if the mobile device where the application is running is connected to the same local network.
Note: This auto-reader is only compatible with 2.4 GHz Wi-Fi networks. For more information, refer to the following section: *Safety Information*.
Note: For cybersecurity reasons, the auto-reader will only be able to connect to secure, password-protected Wi-Fi networks and will not support open or public networks.

Wi-Fi connectivity status

The auto-reader Wi-Fi connection indicator light shows the Wi-Fi connectivity status. The indicator light has four different blinking patterns:
- *The Wi-Fi indicator light is on:* The auto-reader is connected successfully to a Wi-Fi network.
- *The Wi-Fi indicator light is blinking slowly:* The auto-reader is not connected to a network.
- *The Wi-Fi indicator light is blinking quickly:* The auto-reader is on connectivity selection mode.
- *The Wi-Fi indicator light is 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 down the following button for 1 second: .
Once you hear a beep, release the button and the pre-selected indicator light will start blinking quickly. Press the button again as many times as necessary until the Wi-Fi connection indicator light is turns back on and starts blinking quickly. This indicates that the Wi-Fi connectivity has been selected.
Wait for a few seconds until you hear a long beep. All connectivity indicator lights will then start to blink, indicating that the Wi-Fi module has been successfully enabled. Then, the auto-reader will reboot automatically.
The Wi-Fi connection indicator light will start to blink slowly or will remain on constantly to indicate the auto-reader connectivity status.
Note: 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.

Device internal Wi-Fi network credentials

The following device internal Wi-Fi network credential may be useful:
- *Wi-Fi network name:* HYPER_[batch][serial number]
- *Wi-Fi network password:* abcd1234

Auto-reader Wi-Fi configuration

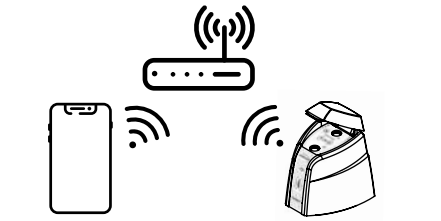
Note: If you are connecting your auto-reader to your local Wi-Fi network for the first time, please carry out the steps provided in this section.
Note: Please make sure your auto-reader's Wi-Fi connectivity has been enabled before carrying out the steps below.
Note: Please make sure to have the name and password of your local Wi-Fi network at hand for the auto-reader to be able to connect to your local Wi-Fi network.

1|Download Bionova® Wireless Assistant Application to a compatible mobile device.
2|Run Bionova® Wireless Assistant Application and access the *FAQs* section: ⓘ.
3|Go to the Wi-Fi connectivity section and follow the instructions to configure the connection between the auto-reader and your local Wi-Fi network. (See figure).

Note: If the auto-reader is not listed on your mobile device, follow the steps detailed on the section: ***Enabling the auto-reader Wi-Fi connectivity***. This will create new internal 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 light will remain on continuously.
Then, connect your mobile device to your local Wi-Fi network as well. Once you have done this, the auto-reader and your mobile device will be connected to the same network.



If the process has been successful, your auto-reader will be listed on the Bionova® Wireless Assistant's Home Screen.

Bluetooth® connectivity

Each auto-reader has a built-in Bluetooth® module that allows you to connect the auto-reader to your Bluetooth® compatible mobile device.

Bluetooth® connectivity status

The auto-reader Bluetooth® connection indicator light informs to the user the Bluetooth® connectivity status. The indicator light has four different blinking patterns:
- *The Bluetooth® indicator light is on:* The auto-reader is connected successfully to a Bluetooth® device.
- *The Bluetooth® indicator light is blinking slowly:* The auto-reader is not connected to a device.
- *The Bluetooth® indicator light is blinking quickly:* It could be that the auto-reader is in connectivity selection mode, searching for a printer, or trying to pair.
- *The Bluetooth® indicator light is off:* The auto-reader Bluetooth® connectivity is not active.

Enabling the auto-reader Bluetooth® connectivity

To enable the auto-reader's internal Bluetooth® module, press and hold down the following button for 1 second: ⓑ.
Once you hear a beep, release the button and the pre-selected indicator light will start blinking quickly. Press the button again as many times as necessary until the Bluetooth® connection indicator light is turned on and blinking fast. This indicates that the Bluetooth® connectivity was selected.
Wait for a few seconds until you hear a long beep, and all connectivity indicator lights start to blink, indicating that the Bluetooth® module was successfully enabled. Then, the auto-reader will reboot automatically.
The Bluetooth® connection indicator light will start to blink slow or will remain turned on steady to indicate the auto-reader connectivity status.
Note: If it is the first time you connect your auto-reader, please carry out the following step.
Once the Bluetooth® connection indicator light starts blinking slowly, press the button again (it must be within one second): ⓑ.
You will hear a short beep. This indicates that the auto-reader is in PAIRING MODE.

↲ **Connectivity**

Note: Please make sure your auto-reader's Bluetooth® connectivity has been enabled for the Bionova® Wireless Assistant to be able to list the device on its Home Screen.

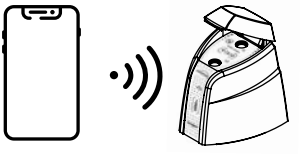
Bluetooth® credentials

The following Bluetooth® credential may be useful:
- *Device Bluetooth® ID:* HYPER_[batch][serial number]

Auto-reader Bluetooth® configuration

Note: If you are connecting your mobile device to your auto-reader via Bluetooth® for the first time, please carry out the steps indicated in this section.
Note: 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 access the ***FAQs*** section: ⓘ.
3|Go to the Bluetooth® connectivity and follow the instructions to configure the connection Bluetooth® (See figure).



Note: If the process has been successful, your auto-reader will be accessible by selecting the device on the Bionova® Wireless Assistant's Home Screen.

Connecting an external printer

It is possible to connect an external printer to the auto-reader via Bluetooth®, which allows to automatically print a ticket with the result after each readout. To use this feature, please refer to the following guide:
https://terragene.com/product/bhy-hyper/
Additionally, for further details, you can visit: ***Bionova® Wireless Assistant Application***.

Resetting wireless settings to factory values

If you reset the wireless connectivity settings to factory setting, all saved Wi-Fi and Bluetooth® configuration settings will be cleared. 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.
To reset the Wi-Fi configuration and Bluetooth® configuration to its factory values, please follow the next steps:
1|Press and hold down the following button for 10 seconds: .
2|After this time a long beep will be heard
3|Release the button: .
4|All connectivity indicator lights will start to blink to indicate that the connectivity settings have been successfully returned to factory settings. 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 indicated in the following section: ***Auto-reader Wi-Fi Configuration.***
To reconnect the auto-reader to your mobile device via Bluetooth® after resetting the connectivity settings, please follow the steps indicated in the following section: ***Auto-reader Bluetooth® Configuration***.

Disabling all wireless Connectivity

To disable all the wireless connectivity features of the auto-reader (Wi-Fi and Bluetooth®), press and hold down the following button for 1 second: .
Press the button again as many times as necessary until the Bluetooth® connection indicator light and the Wi-Fi connection indicator light will turn off at the same time.
Wait for a few seconds until you hear a beep. This means that wireless connectivity has been successfully disabled.
Note: If Wireless connectivity has been disabled, the only auto-reader connectivity method available will be USB.

Recommended wireless security measures

Recommendations for secure Wi-Fi networks:
- Configure your LAN router with a secure authentication method.
- Change the default router passwords and use strong passwords composed of alphanumeric characters.

↲ Connectivity

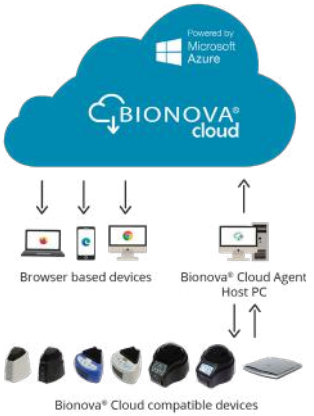
- Keep your passwords secure. Nobody outside your organization should have access to your LAN passwords.

Recommendations for secure workstations (PCs and mobile):

- Install a firewall or enable your OS firewall.
- Make sure to have an installed and updated antivirus program.
- Download software only from trustworthy sources only.
- Keep your OS updated.

■ Bionova® Cloud Environment

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



The Bionova® Cloud Web Application can be used to manage and store the readout results of self-contained biological indicators and hygiene monitoring system indicators in a secure and user-friendly way.
The Bionova® Cloud Web Application matches the information of an indicator result with the sterilizer or washing machine used, the operator, cycle characteristics, and all relevant information so each institution compiles with documentation and archiving regulations.
The Bionova® Cloud Agent handles all communications with Terragene® compatible electronic devices and the Host PC where the Agent Application is operated.
The Bionova® Cloud Agent then acts as an interface between the Terragene® compatible devices and the Bionova® Cloud Web Application and sends the information generated from the devices to the Microsoft™ Azure powered Cloud server where the Web Application is operating and stores the information.
The user can then access to the information saved to the Cloud via any device with a compatible web browser.

To access to the Bionova® Cloud Environment please visit: www.terragene.com/bionova-cloud
The third-party trademarks used herein are the property of their respective owners.

For more information, please refer to the Bionova® Cloud Web Application User Guide.

■ 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 out the cloth so it is damp but not dripping before cleaning and wipe the outer surfaces of the auto-reader. Then, moisten a clean microfiber cloth with just water, 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 each time a spill occurs on any of the external surfaces of the auto-reader.
If further cleaning is required, or if you have doubts about the cleaning agents you may use, please contact your local distributor.
Note: Do not clean the internal parts of the device.
Note: Do not pour liquid on to the device or immerse it in any liquid. Do not allow any liquid to enter device while it is being cleaned.

Maintenance
The auto-reader does not require routine maintenance.

■ Troubleshooting

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

Problem: *The auto-reader is showing an error in an incubation position during the "Auto-test".*
Possible causes: An SCBI is placed in the incubation position during the "Auto- test".
Dust particles might be obstructing the readout mechanism.
Actions: Check that every incubation position is empty during the "Auto- test". Restart the device.
If after restarting the device, the problem persists, use air to remove any dust inside the position. Do not insert solid objects. Once cleared, restart the auto-reader.

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

Problem: *An incubation cannot be run in an SCBI incubation position (the position's red light is on).*
Possible causes: Position disabled. Error in that position during "Auto-test".
Actions: Make sure that the position is empty when starting the auto-reader. Once cleared, restart the auto-reader.

Problem: *The auto-reader will not run an incubation in any position.*
Possible causes: Incubation temperature not stable.
Actions: Wait until temperature is stable before carrying out any incubations.

Problem: *The auto-reader will not update*.
Possible causes: The Bionova® Cloud Web Application is being run.
Actions: Close the Bionova® Cloud Web Application and restart the auto-reader.

Problem: *The auto-reader has not been detected by Bionova® Cloud Web Application.*
Possible causes: The auto-reader is turned off / the auto-reader is not connected to the PC.
Actions: Follow the directions to set up the device properly in the section: ***Instructions For Use***.

Problem: *The auto-reader is not detected by mobile devices.*
Possible causes: The auto-reader's connectivity settings are not properly configured.
Actions: Follow the directions to set up the device properly in the section: ***Connectivity.***

■ Warranty

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

Term

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

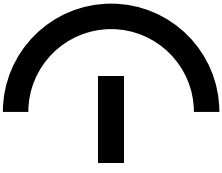
Limitation of liability

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

Technical assistance

For information regarding the functioning or condition of the product, contact Terragene S.A. directly to info@terragene.com or through our website www.terragene.com
In USA, please call +1 844 837 7243.

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



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