

Bionova® Photon Auto-reader



Symbols | Símbolos | Símbolos

You may see one or more of these symbols on the packaging or labeling of this product. | Es posible que vea uno o más de estos símbolos en el envase o el etiquetado de este producto. | Poderá ver um ou mais destes símbolos na embalagem ou rotulagem deste produto.

Humidity limitation
Límite de humedad
Límite de umidade

Temperature limit
Límite de temperatura
Límite de temperatura

Caution
Precaución
Precaução

CE Mark
Marca CE
Marcagem CE

Direct current
Corriente continua
Corrente direta

For indoor use only
Solo se debe usar en interiores
Apenas para uso interior

Keep away from sunlight
Mantener alejado de la luz solar
Evitar exposição à luz

LOT
Código de lote
Código do lote

Manufacturer
Fabricante
Fabricante

Recycle electronic equipment
Reciclar equipos electrónicos
Reciclagem de equipamento eletrônico

EN Bionova® Photon Auto-reader
The 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

EU Wireless Compliance: The 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.terragine.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.

FC/C Wireless Compliance: The Auto-reader complies with applicable FCC/C directives. Contains certified transmitter module FCC ID: 2AC72-ESPVR00M32D / IC ID: 21098-ESPVR00M32D.

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 Requirements for Compliance of Radio Apparatus, and RSS-247 Digital Transmission Systems (DTS), Frequency Hopping Systems (FHS) 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.

The 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. For more information, please refer to the user manual.

Indication for Use

Terragene Bionova® Photon Auto-reader Incubator (BPH) incubated at 60 °C and reads the Terragene Bionova® Photon SCBs at the times prescribed in the User Manual.

Safety Information

⚠ To avoid risks and/or damaging the device:

Do not 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 subjected to shocks, vibrations, temperature or high relative humidity.

Disconnect the power cord before cleaning.

Do not use abrasives or desinfectants.

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

Do not plug any devices into the Auto-reader'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.

⚠ 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 Auto-reader reports the final readout.

Check that culture medium completely wets the spore carrier.

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

Cool the SCBI during the indicated time before crushing the ampoule.

Do not handle the SCBI excessively since this might cause the glass ampoule to burst.

Wear safety gloves and glasses when removing the SCBI from the sterilizer, pressing the SCBI's cap, and crushing the SCBI's ampoule.

Do not use your finger for crushing the SCBI. Use the Ampoule Crusher instead.

⚠ To avoid a potentially hazardous situation:

Avoid contact with the hot metal block inside each incubation position.

Do not insert your fingers, or any other element, inside the incubation positions.

Place only compatible indicators inside the incubation positions.

⚠ To avoid SCBs from absorbing fluorescent particles:

Avoid direct contact between the SCB 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 in a manner not specified by Terragene S.A., otherwise the protection provided by the product might be affected.

Note: 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 Uninterruptable Power Supply (UPS) instead of voltage stabilizers, since they fulfill two functions: to stabilize and maintain the energy during a power outage.

Environmental operating conditions

Environmental conditions

Operating conditions

Units

Altitude 3500 (max.) Meters

Operation temperature 10-30 Celsius

Relative Humidity 30-80 %

Installation/Over-voltage Category II

Degree of contamination 2

Storage temperature 5-40 Celsius

Voltage 12 DC Volts

Device safety compliance

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European Commission

RoHS Directive 2011/65/EU

WEEE Directive 2012/19/EU

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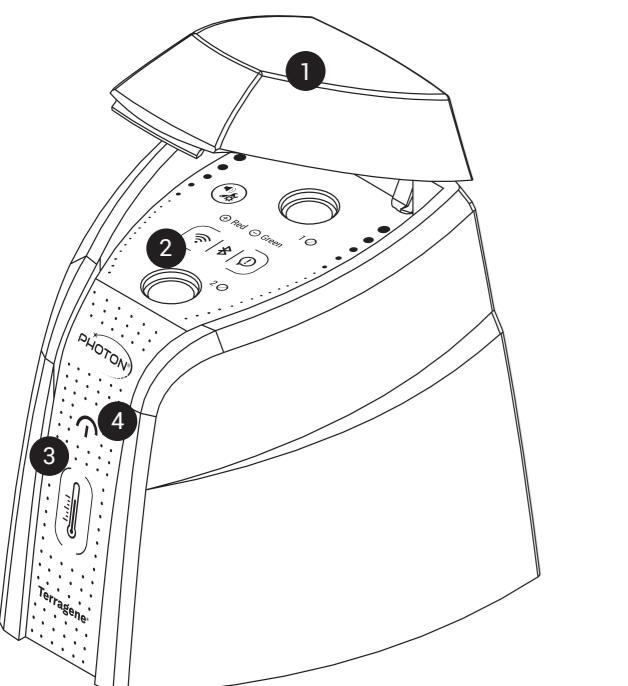
QUICKSTART GUIDE

Guía de inicio rápido



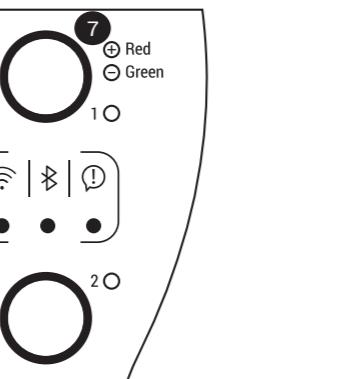
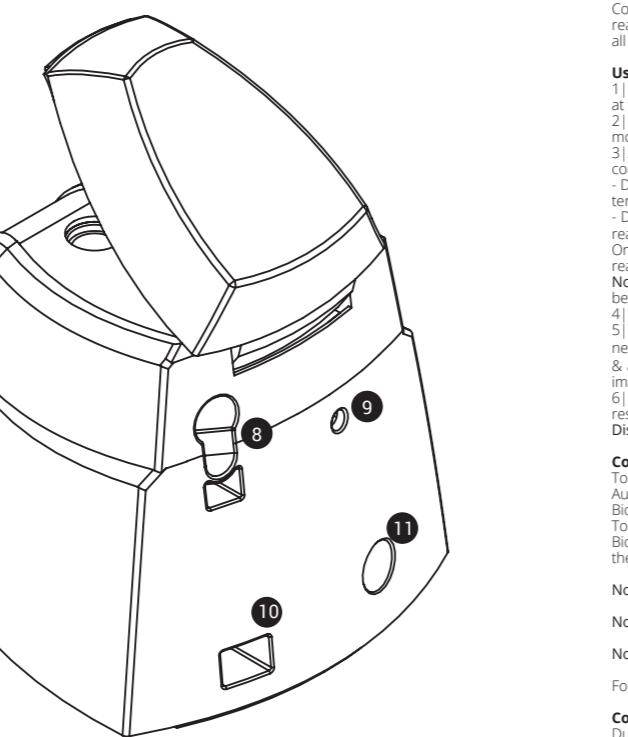
Terragene®

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References | Referencias | Referências

- ① Protective cover | Cubierta protectora | Tampa protetora.
- ② Incubation Positions | Posiciones de incubación | Posições de incubação.
- ③ Temperature progress & stability indicator light | Luz indicadora de progreso y estabilidad de temperatura | Luz indicadora de progresso e estabilidade da temperatura.
- ④ Terragene® indicator light | Luz indicadora Terragene® | Luz indicadora Terragene®
- ⑤ Configuration & alarm cancellation button | Botón de configuración y cancelación de alarma | Botão de configuração e cancelamento de alarme.
- ⑥ Wi-Fi connection - Bluetooth® connection - Connectivity notifications indicator lights | Luces indicadoras de conexión Wi-Fi - conexión Bluetooth® - de notificaciones de conectividad | Luzes indicadoras de conexão Wi-Fi - conexão Bluetooth® - de notificações de conectividade.
- ⑦ Position status indicator light | Luz indicadora de estado de posición | Luz indicadora de status da posição.
- ⑧ Ampoule crusher | Rompe ampollas | Quebra ampolas.
- ⑨ Hole for external temperature control | Orificio para control externo de temperatura | Orifício para controle externo de temperatura.
- ⑩ Micro USB Port | Puerto Micro USB | Porta Micro USB.
- ⑪ Input for power supply plug (12 Volts DC) | Entrada para clavija de fuente de alimentación (12 Voltios CC) | Entrada ficha de fonte de alimentação (12 Volts CC).



ES Instrucciones de uso

Nota: Recuerde configurar la fecha y hora local de la Auto-leitora antes de comenzar las incubaciones.

Instalando su Auto-leitora

Coloque la Auto-leitora sobre una superficie firme, libre de vibraciones, alejado de la luz solar directa, corrientes de aire frío o caliente, sustancias químicas y corrosivas o inflamables. No coloque la Auto-leitora de manera que pueda resultar difícil desconectar el enchufe de CA de la fuente de alimentación de la red. Deje un espacio de al menos 10 cm desde la Auto-leitora hasta la pared más cercana. No mueva la Auto-leitora periódicamente o durante su uso. Conecte la Auto-leitora a un tomacorriente seguro y estable. No moje ni caliente la Auto-leitora. Si se derrama líquido sobre el dispositivo, desconéctelo y séquelo inmediatamente. Antes del encendido, verifique que todas las posiciones de incubación estén vacías.

Usando su Auto-leitora

1| Encienda la Auto-leitora conectando el enchufe de CA de la fuente de alimentación a la red eléctrica y luego conecte la clavija en el otro extremo de la fuente de alimentación a la parte posterior de la Auto-leitora. (Ver imagen 1)

2| Configure la fecha y hora local de la Auto-leitora ejecutando Bionova® Wireless Assistant en un dispositivo móvil compatible.

3| Despues de encender el dispositivo, se iniciará una secuencia de inicialización de dos pasos. Espere hasta que se complete la secuencia antes de usar la Auto-leitora.

- Durante el primer paso, la Auto-leitora establecerá y estabilizará la temperatura de incubación. Cuando se alcance la temperatura correcta, la luz indicadora de progreso y estabilidad de la temperatura dejará de parpadear.

- Durante el paso final, la Auto-leitora configurará el sistema de lectura de cada posición de incubación. Cuando el sistema de lectura esté listo para realizar una lectura, la luz indicadora Terragene® dejará de parpadear.

Una vez que ambas luces indicadoras hayan dejado de parpadear, la secuencia de inicialización está completa y el dispositivo está listo para procesar una muestra.

Notas: La secuencia de inicialización tarda entre 10 y 30 minutos, dependiendo de la temperatura actual de la Auto-leitora. Planifique en consecuencia.

4| Coloque un SCBI en una posición de lectura. La incubación comenzará automáticamente. (Ver imagen 2)

5| Espere hasta que se complete la incubación. La luz indicadora de estado de posición se pondrá verde para indicar un resultado negativo o roja para indicar un resultado positivo. Si se informa un resultado positivo, presione el botón de Configuración y cancelación de alarma para silenciar la alarma. No retire el SCBI hasta que se informe el resultado. (Ver imagen 3)

6| Ejecute la aplicación web Bionova® Cloud o la aplicación móvil Bionova® Wireless Assistant para verificar el e-ticket del resultado de incubación.

Eliminación: Deseche los SCBI de acuerdo con las normas sanitarias de su país.

Conectividad

Para conectar su Auto-leitora a una PC mediante USB, conecte uno de los extremos del cable USB en la parte posterior de la Auto-leitora y el otro extremo al puerto USB de su PC. La conexión de la Auto-leitora a una PC permite utilizar la aplicación web Bionova® Cloud. Para más información, consulte el manual del usuario.

EN Instructions for use

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

Setting Up your Auto-reader

Coloque la Auto-leitora sobre una superficie firme, libre de vibraciones, alejado de la luz solar directa, corrientes de aire frío o caliente, sustancias químicas y corrosivas o inflamables. No coloque la Auto-leitora de manera que pueda resultar difícil desconectar el enchufe de CA de la fuente de alimentación de la red. Deje un espacio de al menos 10 cm desde la Auto-leitora hasta la pared más cercana. No mueva la Auto-leitora periódicamente o durante su uso. Conecte la Auto-leitora a un tomacorriente seguro y estable. No moje ni caliente la Auto-leitora. Si se derrama líquido sobre el dispositivo, desconéctelo y séquelo inmediatamente. Antes del encendido, verifique que todas las posiciones de incubación estén vacías.

Using your Auto-reader

1| Encienda la Auto-leitora por conectando la clavija en la parte posterior de la Auto-leitora y luego conecte la clavija en el otro extremo de la fuente de alimentación a la parte posterior del dispositivo.

2| Configure la fecha y hora local de la Auto-leitora ejecutando Bionova® Wireless Assistant en un dispositivo móvil compatible.

3| Despues de encender el dispositivo, se iniciará una secuencia de inicialización de dos pasos. Espere hasta que se complete la secuencia antes de usar la Auto-leitora.

- Durante el primer paso, la Auto-leitora establecerá y estabilizará la temperatura de incubación. Cuando se alcance la temperatura correcta, la luz indicadora de progreso y estabilidad de la temperatura dejará de parpadear.

- Durante el paso final, la Auto-leitora configurará el sistema de lectura de cada posición de incubación. Cuando el sistema de lectura esté listo para realizar una lectura, la luz indicadora Terragene® dejará de parpadear.

Una vez que ambas luces indicadoras hayan dejado de parpadear, la secuencia de inicialización está completa y el dispositivo está listo para procesar una muestra.

Notas: La secuencia de inicialización tarda entre 10 y 30 minutos, dependiendo de la temperatura inicial de la Auto-leitora. Consecuentemente, tenha em consideração esse período de tempo.

4| Coloque un SCBI en una posición de lectura. La incubación será iniciada automáticamente. (Ver imagen 2)

5| Aguarde até que a incubação seja concluída. A luz indicadora de estado da posição ficará verde para indicar um resultado negativo ou vermelha para indicar um resultado positivo. Se o resultado for positivo, pressione o botão de configuração e cancelamento de alarme para silenciar a alarma. Não retire o SCBI até o resultado ser informado. (Ver imagem 3)

6| Inicie o aplicativo web Bionova® Cloud ou o aplicativo móvel Bionova® Wireless Assistant para verificar o e-ticket do resultado da incubação.

Eliminación: Elimine los SCBI de acuerdo con las normas sanitarias de su país.

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. Connecting the Auto-reader to a PC allows using Bionova® Cloud Web Application. For more information, please refer to the user manual.

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 and follow the steps detailed on the Application's tutorial.

Note:

This Auto-reader is only compatible with 2.4 GHz WiFi networks.

Note: Due to cybersecurity reasons, the Auto-reader will only be able to connect to WPA2-PSK WiFi networks.

Note: Bluetooth® connection mode is not available for iOS mobile devices.

For a detailed overview on the connection process, please refer to the user manual.

Connectivity credentials

During the connection process, the following credentials can come useful:

Device Internal Wi-Fi network credentials

Wi-Fi network name: PHOTON_[batch][serial number]
Wi-Fi network password: abcd1234

Bluetooth® credentials

Device Bluetooth® ID: PHOTON_[batch][serial number]

Product Compatibility and Incubation Programs

Auto-reader Incubation Programs

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

Temperature selection

60 °C

Time selection

Instant (7 sec.)

Incubation program

Instant at 60 °C

Note: Follow each Indicator's Instructions for use before its incubation.

Compatible indicators

We develop new indicators 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 indicators for your device.

Troubleshooting

Refer to the user manual for a detailed troubleshooting routine.

Please visit www.terragine.com/PHOTON or scan the QR code to access the Auto-reader user manual.

Para acceder a las funciones extendidas de su Auto-leitora mediante Wi-Fi o Bluetooth®, descargue la aplicación Bionova® Wireless Assistant en su dispositivo móvil de preferencia y siga los pasos detallados en el tutorial de la aplicación.

Nota: Esta Auto-leitora es compatible únicamente con redes WiFi de 2.4 GHz.

Nota: Por razones de ciberseguridad, la Auto-leitora solo podrá conectarse a redes WiFi con seguridad WPA2-PSK.

Nota: El modo de conexión Bluetooth® no se encuentra disponible para dispositivos móviles iOS.

Para obtener una descripción detallada del proceso de conexión, consulte el manual del usuario.

Credenciales de conectividad

Durante el proceso de conexión, las siguientes credenciales pueden resultar útiles:

Información de la red Wi-Fi interna del dispositivo

Nombre de la red Wi-Fi: PHOTON_[lote][número de serie]

Contraseña de la red Wi-Fi: abcd1234

Información de Bluetooth®

ID de dispositivo de Bluetooth®: PHOTON_[lote][número de serie]

Compatibilidad de productos y programas de incubación

Programas de incubación de la Auto-leitora

Los siguientes programas de incubación están disponibles para su Auto-leitora.

Selección de temperatura **Selección de tiempo** **Programa de incubación**

60 °C Instant (7 seg.) Instant at 60 °C

Nota: Siga las Instrucciones de uso de cada Indicador antes de su incubación.

Indicadores compatibles

Regularmente desarrollamos nuevos Indicadores para ampliar las características de nuestras Auto-leitoras. Consulte la matriz de compatibilidad de su Auto-leitora para obtener más información sobre todos los indicadores compatibles con su dispositivo.

Solución de problemas.

Consulte el manual del usuario para obtener una rutina detallada de resolución de problemas.

Por favor visite www.terragine.com/PHOTON o escanee el código QR para acceder al manual del usuario de la Auto-leitora.



Visit www.terragine.com/PHOTON to find all digital content available for your Auto-reader. Including Bionova® Cloud Web Application, Full User Manuals, and more.

Visite www.terragine.com/PHOTON para accesar todo o conteúdo digital disponivel para su Auto-leitora. Inclui o Aplicativo Web Bionova® Cloud, Manuales de usuario, e muito mais.

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