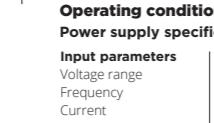


# Bionova® Photon Auto-reader



Operating relative humidity  
Humedad relativa de funcionamiento  
Umidade relativa de funcionamento

Operating temperature  
Temperatura ambiente de funcionamiento  
Temperatura ambiente de funcionamiento

Caution, Warning, Attention - Refer to the instructions for use  
Atenção - Consulte las instrucciones de uso  
Atenção - Consulte as instruções de uso

Important  
Importante  
Importante

Direct current  
Corrente continua  
Corrente contínua

For indoor use only  
Usar solo en interiores  
Apenas para utilização interna

Keep away from sunlight  
Mantener alejado de la luz solar  
Manter afastado da luz solar

Batch code  
Código de lote  
Código do lote

Manufacturer  
Fabricante  
Fabricante

Separate collection for waste of electrical and electronic equipment  
Recolección independiente para el desecho de equipos eléctricos y electrónicos  
Colheita independente para a eliminação de equipamentos elétricos e eletrônicos

## EN Bionova® Photon Auto-reader

### Product description

Terragene Bionova® Photon Auto-reader Incubator (BPH) has been designed for the incubation and automatic readout of the Bionova® Photon line of Self-contained Biological Indicators (SCBIs) appropriate for monitoring Steam Sterilization Cycles.

Bionova® Photon 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 seconds using advanced fluorescence techniques.

Bionova® Photon Auto-reader 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.

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

### Safety Information

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 subjected to shocks, vibrations, temperature or high relative humidity.  
Disconnect the power cord before cleaning.  
Do not use abrasive or 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 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.  
Do not plug any devices into the incubator's USB port other than a personal computer (PC). The PC has to be compliant with IEC60950-1, IEC 62368-1 or comparable, with safety extra-low voltages on its USB ports. Ask a qualified technician to verify device compatibility. Attaching any other device to the USB port may damage the incubator and may not be safe for the user.

To reduce the risk of using incompletely sterilized loads:  
Please read, understand, & follow the instructions for use of each SCBI before its incubation.  
Do not remove the SCBI before the incubator performs 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.  
Do not heat 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 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.

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 range	12	DC Volts
Current	1.5	Amperes

La Auto-leitora Bionova® Photon permite la detección fácil y rápida de SCBIs positivos y negativos. Un resultado positivo también se puede evidenciar por el cambio de color del medio de cultivo al realizar incubaciones extendidas. Lea las instrucciones de uso de cada SCBI para más información. La opción de realizar o no una incubación depende de los protocolos internos de cada laboratorio u hospital. La Auto-leitora Photon presenta opciones de conectividad USB, Wi-Fi y tecnología Bluetooth® incorporadas. Puede accederse a los tickets electrónicos (e-tickets) creados durante cada proceso de lectura utilizando un dispositivo compatible, lo que permite cumplir fácilmente con requisitos documentales y de trazabilidad.

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.

#### Environmental operating conditions

Environmental operating conditions	Operating Conditions	Units
Altitude	3500 (máx.)	Meters
Operating 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® Photon Auto-reader complies with the following standards and directives:

Electrical Safety	IEC 61010-1
	IEC 61010-2-010
Electromagnetic Immunity	IEC 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® Photon 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](http://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 (canals 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/C Council Wireless Compliance: Bionova® Photon Auto-reader complies with applicable FCC/IC directives. Contains certified transmitter module: FCC ID: 2AC72-ESPWR00M32D / IC ID: 21098-ESPWR00M32D.

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 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. 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.

Note with regard FCC "Harmful Interference" definition  
"Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Bionova® Photon 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.

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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.

Designado bajo normas de Sistema de Gestión de Calidad ISO13485:2016/NS-EN ISO 13485:2016. Para obtener más información sobre el cumplimiento de las normativas de seguridad e inalámbricas del dispositivo, consulte el Manual del usuario de la Auto-leitora.

Este dispositivo cumple con la Parte 15, Subparte A de las reglas FCC: 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 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. El funcionamiento está sujeto a las dos condiciones siguientes: (1) este dispositivo no puede causar interferencias y (2) este dispositivo debe aceptar cualquier interferencia, incluidas las interferencias que puedan causar un funcionamiento no deseado del dispositivo.

La Auto-leitora Bionova® Photon no representa riesgo fotobiológico y no genera radiación óptica peligrosa en ninguna de las condiciones de operación normal conforme a los requisitos del estándar IEC 62471.

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016. Para obtener más información sobre el cumplimiento de las normativas de seguridad e inalámbricas del dispositivo, consulte el Manual del usuario de la Auto-leitora.

Este dispositivo cumple con la Parte 15, Subparte A de las reglas FCC: 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 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. El funcionamiento está sujeto a las dos condiciones siguientes: (1) este dispositivo no puede causar interferencias y (2) este dispositivo debe aceptar cualquier interferencia, incluidas las interferencias que puedan causar un funcionamiento no deseado del dispositivo.

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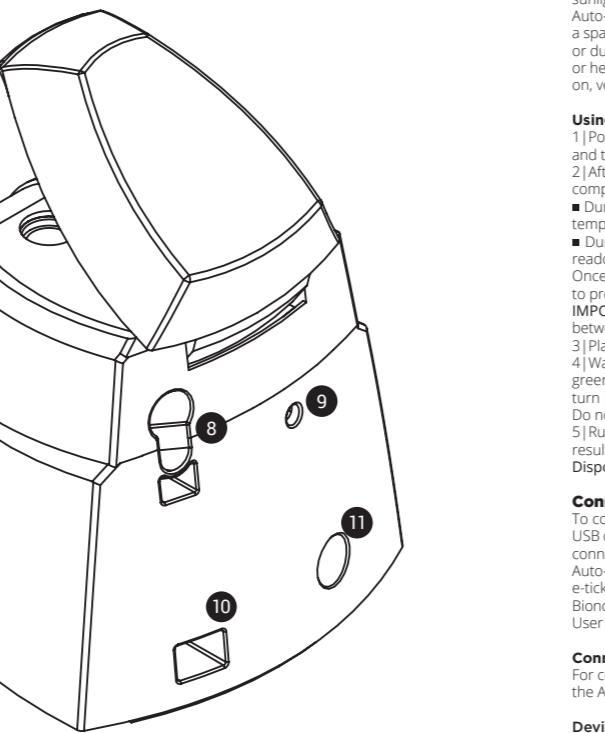
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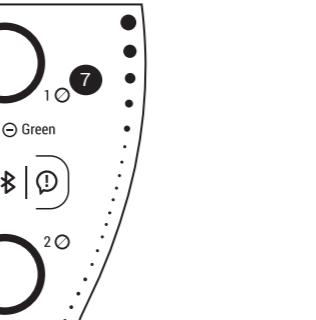
Este dispositivo cumple con la Parte 15, Subparte A de las reglas FCC: 15.247 Operation within the bands 902

# QUICKSTART GUIDE

Guía de inicio rápido

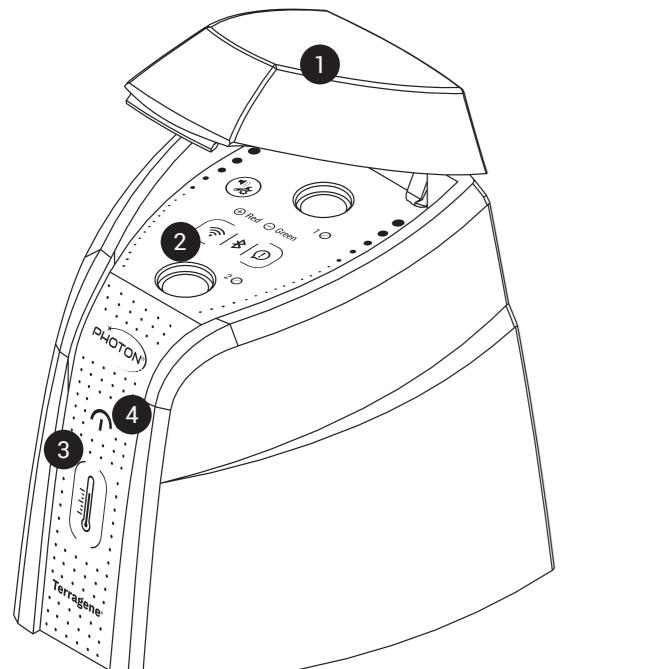


Rev. 7 | June 2023



## References | Referencias | Referências

- ① Protective cover | Cubierta protectora | Tampa protetora
- ② Incubation Positions | Posiciones de incubación | Posições de incubação
- ③ Temperature progress & stability indicator | Indicador de progreso y estabilidad de temperatura | Indicador de progresso e estabilidade da temperatura
- ④ Terragene® logo indicator | Indicador de logo Terragene® | Indicador de logo Terragene®
- ⑤ Configuration & Alarm Cancellation Button | Botón de configuración y Cancelación de Alarma | Botão de configuração e Cancelamento de alarme
- ⑥ Wi-Fi connection indicator - Bluetooth® connection indicator - Connectivity notifications indicator | Indicador de conexión Wi-Fi - Indicador de conexión Bluetooth® - Indicador de notificaciones de conectividad | Indicador de conexão Wi-Fi - Indicador de conexão Bluetooth® - Indicador de notificações de conectividade
- ⑦ Position status indicator | Indicador de estado de posición | Indicador 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)



## EN Instructions for use

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

### Setting Up your Auto-reader

Place the Bionova® Photon Auto-reader incubator on a firm surface, free from vibrations, away from direct sunlight, currents of hot or cold air, chemical and corrosive or flammable substances. Do not place the Auto-reader 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 Auto-reader to the closest wall. Do not move the Auto-reader periodically or during its use. Connect the Auto-reader to a secure and stable electrical mains outlet socket. Do not wet or heat the Auto-reader. If liquid is spilled on the device, disconnect it and dry it immediately. Before turning on, verify that all reading positions are empty.

### Using your Auto-reader

1 | Power on your Bionova® Photon Auto-reader incubator 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. (See image 1)  
2 | After turning on the device, a two steps initialization sequence will start. Please wait until the sequence is complete before using the Auto-reader.  
■ During the first step, the Auto-reader will set and stabilize the incubation temperature. When the correct temperature is reached, the Temperature progress & stability indicator will stop blinking.  
■ During the final step, the Auto-reader will set the readout system of each incubation position. When the readout system is ready for a reading, the Terragene logo will stop blinking. Once both indicators have stopped blinking, the initialization sequence is complete and the device is ready to process a sample.

**IMPORTANT:** The initialization sequence is carried out each time the incubator is turned on and can take between 10 and 30 minutes depending on the Auto-reader's current temperature. Plan accordingly.

3 | Place a SCBI in a readout position. The incubation will start automatically. (See image 2)  
4 | Wait until the incubation is complete. If a negative result is found, the position status indicator will turn green and a short audible sound will be emitted. If a positive result is found, the position status indicator will turn red and an audible alarm will be triggered, press the alarm/configuration button to silence the alarm. Do not remove the SCBI until a result is informed. (See image 3)

5 | Run Bionova® Traceability Software or the Bionova® Wireless Assistant mobile app to check the incubation result e-ticket.  
**Disposal:** Discard the SCBIs following your Country disposal directives.

### Connectivity

To connect your Bionova® Photon Auto-reader incubator to a PC by USB, connect one end of the included USB cable to the rear of the incubator and the other end to a USB port on your PC. Auto-reader to PC Wi-Fi connectivity is also available and can be Set-up using the Bionova® Wireless Assistant. Connecting the Auto-reader to a PC (by USB, or Wi-Fi) allows using Bionova® Traceability Software to save, manage, and print e-tickets reports. Connecting the Auto-reader to an Android device (by Wi-Fi or Bluetooth®) allows using the Bionova® Wireless Assistant APP to check the status of the device, access e-tickets, and more. Check the User Manual for more information.

### Connectivity credentials

For connecting your Auto-reader to the Bionova® Wireless assistant APP please follow the steps detailed on the APP's interactive tutorial. During the connection process, the following credentials can come handy:

**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]

Please check the device user manual for a detailed overview on the connection process.

### Product Compatibility and Incubation programs

**Bionova® Photon Auto-reader Incubation Programs**  
The following incubation programs are available for your Bionova® Photon Auto-reader.

Temperature	Time	Incubation Program
60 °C	7 sec. (Instant)	Instant at 60 °C

**!** Follow each Indicator's Instructions for use before its incubation.

### Bionova® Photon Auto-reader compatible indicators

We develop new Indicators for extending the features of our Auto-readers regularly. Please visit [www.terragine.com/PHOTON](http://www.terragine.com/PHOTON) to access the Compatibility Matrix for Terragene® Auto-readers. The Compatibility Matrix specifies all compatible Indicators developed for your Auto-reader up to date. Stay tuned for new and exciting updates!

### Troubleshooting

Refer to the user manual for a detailed troubleshooting routine.

Please visit [www.terragine.com/PHOTON](http://www.terragine.com/PHOTON) or scan the QR code to access the Auto-reader user manual.

## ES Instrucciones de uso

**IMPORTANTE:** Recuerde setear la fecha y hora local de la Auto-leitora antes de comenzar las incubaciones.

### Instalando su Auto-leitora

Coloque la incubadora Auto-leitora Bionova® Photon sobre una superficie firme, libre de vibraciones, lejos de la luz solar directa, corrientes de aire calientes o frías, sustancias químicas y corrosivas o inflamables. No coloque la Auto-leitora de manera que la desconexión del enchufe de CA de la fuente de alimentación pueda ser difícil. 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 una toma de corriente eléctrica segura 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 su Auto-leitora Bionova® Photon 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 | Luego de encender el dispositivo, se dará comienzo a una secuencia de inicialización de dos pasos. Por favor espere hasta que la secuencia sea completada antes de usar el equipo.

■ Durante el primer paso, la Auto-leitora establecerá y estabilizará la temperatura de incubación. Cuando la temperatura correcta es alcanzada, el Indicador de progreso y estabilidad de temperatura dejará de parpadear.

■ Durante el paso final, la Auto-leitora preparará el sistema de lectura de cada posición de incubación. Cuando el sistema de lectura esté listo para una lectura, el indicador con el logotipo de Terragene dejará de parpadear.

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

**IMPORTANTE:** La secuencia de inicialización se llevará a cabo cada vez que se encienda la Auto-leitora, y puede demorar entre 10 y 30 minutos dependiendo de la temperatura inicial de la Auto-leitora. Tenga en cuenta que.

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

4 | Espere hasta que se complete la incubación. Si se informa un resultado negativo, el indicador de estado de posición se volverá verde y se emitirá un breve sonido. Si se informa un resultado positivo, el indicador de estado de posición se volverá rojo y se activará una alarma audible, presione el botón de configuración y cancelación de alarma para silenciar la alarma. No retire el SCBI hasta que se informe un resultado. (Ver imagen 3)

5 | Ejecute el Software de Trazabilidad Bionova® o la aplicación móvil Bionova® Wireless Assistant para verificar el e-ticket del resultado de incubación.

**Descarte:** Deseche los SCBIs siguiendo las directivas de eliminación de su país.

### Conectividad

Para conectar su Auto-leitora Bionova® Photon a una PC por USB, conecte un extremo del cable USB

incluido a la parte posterior de la incubadora y el otro extremo a un puerto USB de su PC. La opción de conectividad entre Auto-leitora y PC vía Wi-Fi también se halla disponible, la misma se puede configurar empleando la App Bionova® Wireless Assistant. La conexión de la Auto-leitora a un PC (por USB o Wi-Fi) permite utilizar el Software de Trazabilidad Bionova® para guardar, administrar e imprimir e-tickets y reportes. La conexión de la Auto-leitora a un dispositivo Android (mediante Wi-Fi o Bluetooth®), permite usar la App Bionova® Wireless Assistant, para comprobar el estado del dispositivo, acceder a los e-tickets y más. Consulte el Manual del usuario para obtener más información.

### Solución de problemas

Consulte o manual do usuário para obter uma rotina de solução de problemas detalhada. Por favor visite [www.terragine.com/PHOTON](http://www.terragine.com/PHOTON) ou escaneie o código QR para acessar o manual do usuário do Auto-leitora.



Visit [www.terragine.com/PHOTON](http://www.terragine.com/PHOTON) to find all digital content available for your Auto-reader, including Bionova® Cloud Traceability Software, Full User Manuals, and more.

Visit [www.terragine.com/PHOTON](http://www.terragine.com/PHOTON) para acceder a todo el contenido digital disponible para su Auto-leitora, incluyendo o Software de trazabilidad Bionova® Cloud, Manuales de usuario, y mucho más.

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