

Instructions for Use

For additional product information, visit www.vigilantbiosciences.com

Users must read this package insert in its entirety before using the product. Follow the instructions carefully when conducting the test. Failure to do so may cause inaccurate test results.

PRODUCT NAME AND INTENDED USE

The BeVigilant™ Sali-Mark Analyzer is an instrument specifically to be used to provide quantitative in-vitro determination of photometric immunochromatographic test. The BeVigilant™ Sali-Mark Analyzer quantifies the optical output from the lateral flow device intended to be used only in combination with lateral flow tests indicated for use with the Sali-Mark Analyzer.

PRINCIPLES OF OPERATION

The BeVigilant™ Sali-Mark Analyzer, an electro-optical device, is used to read the lateral flow test cassette. The lateral flow test cassette is placed into the positioning tray on the BeVigilant™ Sali-Mark Analyzer. The camera on the analyzer captures the image of the test cassette. The software processes the image and measures the test line optical intensities. The device displays the result in absorbance units (AU).

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MATERIALS PROVIDED IN THE BEVIGILANT™ SALI-MARK ANALYZER

Component Description (9000014)	Quantity
BeVigilant™ Sali-Mark Analyzer	1
Power Adapter & Interchangeable Kit	1



A lateral flow immunoassay is required to use the device but not provided with the device. The BeVigilant™ Sali-Mark Analyzer is to be used only in combination with lateral flow tests indicated for use with this device.

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BEVIGILANT™ SALI-MARK ANALYZER WARNINGS AND PRECAUTIONS

- Failure to follow the instructions provided may lead to inaccurate results.
- This device is not intended for diagnosis or as a standalone test.
- The device is intended to be used by trained qualified professional personnel within a hospital setting or in an outpatient setting such as in a physician's office.
- Wear appropriate personal protective equipment and use standard office practices when handling and testing the patient specimen.
- Stop using immediately if an allergic reaction occurs.
- This device is intended to be performed at room temperature (16°C to 30°C); do not use out of this range.
- The BeVigilant™ Sali-Mark Analyzer is not intended to be moved during a test.
- Clinical judgment and experience by clinician are required to recommend next steps.
- Do not position the equipment in a way that would make it difficult to reach the external power supply.
- Not properly plugging the charging cable into the BeVigilant™ Sali-Mark Analyzer may cause the battery to lose charge and Analyzer to not power on.
- Ensure that the Analyzer is plugged into the appropriate power source.
- Do not expose ports to liquids; this can cause a short circuit and overheating.
- Maintain the environmental conditions explained in Safety Warnings for proper equipment operation.
- Modification of this device is not allowed.
- Use only with recommended consumables, accessories, or medical devices.
- Examine detachable power cord monthly for continued safe usage.

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- The BeVigilant™ Sali-Mark Analyzer may be reused until signs of material degradation occur. Do not use the BeVigilant™ Sali-Mark Analyzer if the device shows signs of ageing, wear, fatigue or any degradation as suggested by changes in its appearance that may affect performance.
- Install software updates immediately upon notification.
- Do not use the BeVigilant™ Sali-Mark Analyzer if unresponsive or components are damaged or missing.
- Discontinue device use in the event of a malfunction.
- Natural rubber latex was not used as a material in the manufacture of a medical product, its container and/or packaging.

BEVIGILANT™ SALI-MARK ANALYZER CONTRAINDICATIONS

There are no contraindications that would prevent the BeVigilant™ Sali-Mark Analyzer from being used on a patient's test.

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BEVIGILANT™ SALI-MARK ANALYZER ENVIRONMENTAL CONDITIONS

The permissible environmental conditions of use for proper operation of the BeVigilant™ Sali-Mark Analyzer are:

Operational temperature:	16°C to 30°C
Operational Humidity:	10% to 85% relative humidity, non-condensing
Storage Temperature:	-20°C to 40°C
Operating Altitude:	2000 Meters
Atmospheric Pressure:	70 kPa to 106 kPa

BEVIGILANT™ SALI-MARK ANALYZER SAFETY WARNINGS



WARNING: HEALTH AND SAFETY INFORMATION; READ BEFORE USE TO REDUCE THE RISK OF PERSONAL INJURY, DISCOMFORT, PROPERTY DAMAGE, INCLUDING DAMAGE TO THE DEVICE AND OTHER POTENTIAL HAZARDS

Handle the BeVigilant™ Sali-Mark Analyzer with care. The BeVigilant™ Sali-Mark Analyzer or its battery may be damaged if disassembled, dropped, bent, burned, crushed, or punctured. Do not use the BeVigilant™ Sali-Mark Analyzer with a cracked screen or damaged enclosure.

Using a damaged device may cause battery overheating or injury. Do not expose the BeVigilant™ Sali-Mark Analyzer to liquids, which can cause a short circuit and overheating. If the device gets wet, do not attempt to dry it using an external heat source.

When removing the device from temperatures at or below freezing, allow the device to acclimate to room temperature for 1 hour before use. Failure to allow the device to acclimate may cause the device to provide inaccurate test results or failure.

Do not leave the device in places where the temperature may exceed 40°C, such as near a heating vent, as this may damage the product, overheat the battery, or pose a risk of fire. Keep the device away from heat sources and out of direct sunlight. If the device becomes too hot, it will temporarily shut down. If this occurs, disconnect the device from the power source if it is plugged in, move it to a cooler place, and do not use it until it has cooled. Contact customer service and do not use the device if it is not working properly or has been damaged.

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**ELECTROMAGNETIC COMPATIBILITY (EMC) EQUIPMENT IS CLASS II
(ELECTRICAL SAFETY)**

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary,

This equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BeVigilant™ Sali-Mark Analyzer including cables specified by the manufacturer. Otherwise, degradation of equipment performance could result.

- The operator could experience display flicker if the unit is exposed to excessive EMI.
- The operator shall ensure, as a precaution to be taken to prevent adverse events to the Patient and Operator due to electromagnetic disturbances, that the device is kept away from RF communications equipment. Device is designed to be immune to the external EMI as per IEC 60601-1-2. There were no deviations from the standards used.
- RF emissions are very low and are therefore unlikely to cause any interference in nearby electronic equipment. There is no evidence of any issues associated with the use of the device in healthcare establishments.

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ELECTROMAGNETIC IMMUNITY

The BeVigilant™ Sali-Mark Analyzer is intended for use in a hospital setting or in an outpatient office. The BeVigilant™ Sali-Mark Analyzer user should assure that it is used in such an environment.

Immunity Test	Compliance Level
IEC 61000-4-2 Electrostatic Discharge	±8 kV Contact, ±2kV, ±4kV, ± 8kV, ±15 kV Air
IEC 61000-4-3 Radiated RF Electromagnetic Fields	3 V/m, 80 MHz to 2.7 GHz, 80% AM at 1 kHz
IEC 61000-4-3 Proximity Fields from RF Wireless Communications Equipment	Refer Section 8.10 of IEC 60601-1-2
IEC 61000-4-8 Rated Power Frequency Magnetic Fields	30 A/m 50 Hz or 60 Hz
IEC 61000-4-4 Electrical Fast Transients / Bursts	±2 kV for power-supply lines, 100 kHz repetition frequency
IEC 61000-4-5 Surges	± 0,5 kV, ± 1 kV line to line, ± 0,5 kV, ± 1 kV, ±2 kV line to earth
IEC 61000-4-6 Conducted Disturbances Induced by RF Fields	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
IEC 61000-4-11 Voltage Dips, Short Interruptions and Voltage Variations	0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle
IEC 61000-4-39 Proximity to Magnetic Fields	30 kHz continuous wave 134.2 kHz 50% Pulse at 2.1 kHz 13.56 MHz 50% Pulse at 50 kHz

ELECTROMAGNETIC EMISSIONS

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Immunity Test	Compliance Level
IEC 61000-3-2 Harmonic Distortion	Compliant
IEC 61000-3-3 Voltage Fluctuations and Flicker	Compliant
CISPR 11, Radiated Emissions, Class A, Group 1	Compliant
CISPR11, Conducted Emissions, Class A, Group 1 (100VAC and 240 VAC)	Compliant

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DEVICE FREQUENCY BANDS AND POWER

The BeVigilant™ Sali-Mark Analyzer utilizes the Raspberry Pi Compute Module for Wi-Fi capabilities with connectivity through Wi-Fi 2.4 GHz + 5.0 GHz 802.11b/g/n/ac. The Frequency Bands and Power data provided below is the maximum radio frequency power transmitted in the frequency band(s) in which the radio equipment operates.

Frequency	Power
2400 to 2500 MHz	+21dBm
4900 to 5845 MHz	+18.5dBm

BEVIGILANT™ SALI-MARK ANALYZER MAINTENANCE

The BeVigilant™ Sali-Mark Analyzer may be used until signs of material degradation occurs.

CARE AND CLEANING

Unplug the device before cleaning, during lightning storms, or when unused for extended periods of time. Avoid solvent and abrasive materials that may cause damage to the product surface. CaviWipes™ are recommended for cleaning the device as needed. Avoid USB port and other crevices when cleaning. Do not use any chemical detergent, powder, or other chemical agents to clean the BeVigilant™ Sali-Mark Analyzer or accessories. Do not clean your device while it is charging.

BEVIGILANT™ SALI-MARK ANALYZER REPAIR AND SERVICE

Do not attempt to repair the BeVigilant™ Sali-Mark Analyzer or any of its accessories. Disassembling the device may cause damage or injury. Contact customer service if the BeVigilant™ Sali-Mark Analyzer is damaged or requires service.

BEVIGILANT™ SALI-MARK ANALYZER CHARGING

The BeVigilant™ Sali-Mark Analyzer is designed to charge when plugged in. Do not use an alternative charging accessory to charge the device. Do not use the BeVigilant™ Sali-Mark Analyzer if any of the cables, connectors, or power adapter are damaged or when moisture is present due to possible fire, electric shock, injury, or damage to the device and other property. Do not charge or use the device if it appears damaged.

AC ADAPTER

The BeVigilant™ Sali-Mark Analyzer utilizes an AC/DC power adapter to supply the device with AC power. **WARNING:** do not use any power adapter other than Vigilant Supplied, incorrect power adapters may lead to damage to the device. Specifications: GlobTek, Wall Plug-in, Regulated Switch mode AC-DC Power Supply AC Adaptor, Input Rating: 100-240V~, 50-60 Hz, with Interchangeable Blades <http://en.globtek.com/interchangeable-blades.php>, Output Rating: 36W, 12.0V@3.0A, Output Configuration: 1200 mm, 16/2 Cond, UL 2468, Female Barrel 5.5*2.1*11mm w/ Spring Clip & Locking Notch

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BATTERY

The BeVigilant™ Sali-Mark Analyzer contains a rechargeable lithium-ion battery, which is a sensitive component that can cause injury if damaged. Do not attempt to remove the battery. Contact Vigilant Biosciences® Customer Service if you have a problem with the battery. Replacement by unqualified professionals can damage the device. Using an unqualified battery may pose a risk of fire, explosion, leakage, or other hazards. If the battery leaks, do not allow the leaking fluid to come into contact with eyes, skin, or clothing. If battery fluid makes contact with the eyes, do not rub. Rinse the eyes with clean water immediately and seek medical advice.

Dispose of the BeVigilant™ Sali-Mark Analyzer and accessories according to local environmental regulations. Do not dispose in normal household waste. Improper disposal may lead to fire, explosion, and/or other hazards. Do not open, crush, heat above 45°C, or incinerate.

Specifications: Rated output voltage 7.2V; Rated current or power 2A; Rated Capacity 3.2 Ah; Rated Energy 23 Wh

ENVIRONMENTAL RESTRICTIONS

To prevent damage to the BeVigilant™ Sali-Mark Analyzer parts or internal circuits, do not use or store the device or its accessories in dusty, smoky, damp, or dirty environments, or near magnetic fields. Keep it away from heat sources and out of direct sunlight. Do not leave the BeVigilant™ Sali-Mark Analyzer inside a vehicle or in places where the temperature may exceed 40°C, such as on a car dashboard, windowsill, near a heating vent, or behind glass that is exposed to direct sunlight or strong ultraviolet light for extended periods of time.

EXPLOSIVE ATMOSPHERES

Do not use, store, or transport the BeVigilant™ Sali-Mark Analyzer where flammables are stored or used. Sparks in such areas could cause an explosion or fire resulting in bodily injury or even death. Please observe all notices and signs where these hazards might be present.

ROHS COMPLIANCE

The BeVigilant™ Sali-Mark Analyzer is in compliance with Directive 2015/863 of the European Parliament and of the Council of 31 March 2015, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and its amendments.

HARDWARE, IT NETWORK CHARACTERISTICS, AND IT SECURITY MEASURES

- Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity, or exposure of other connected devices or networks to security threats.
- Limit access to devices through user authentication.
- Wi-Fi is required for the BeVigilant™ Sali-Mark Analyzer setup.
- The USB port is for Vigilant use in regard to internal testing and/or accessing data. Each analyzer is password protected to prevent users from unauthorized access.

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Emergency Procedures for Cybersecurity Incidents

What to Do in a Cybersecurity Incident

If you suspect or detect a security issue with the device, please follow these steps immediately:

Disconnect device from network.

Notify your IT department.

Immediately contact Vigilant Biosciences support team at customerservice@vigilantbiosciences.com.

Handling of Forensic Evidence

Logs on device operations are being registered and saved. In case of any issue, please turn off the device and send it to Vigilant Biosciences for inspection.

Retaining and Recovering Device Settings

Vigilant does not retain or recover the settings on the software.

Protecting the Device from Cyber Threats Communication Interfaces and Protocols

Active interfaces used by the device (physical): External USB

Disabled interfaces and why they are disabled: Internal USB is disabled by design.

Network Ports and Connectivity

Ports Open for communication: HTTPS (443), SSH (22)

Cybersecurity Best Practices

Please always consider following cybersecurity best practices, like using an up-to-date antivirus or firewall.

1. The device should be accessible to trained intended users only.
2. Connect the device to a private secure network in the intended use environment.

Built-in Security Features

Security features included:

1. Encrypted Storage
2. HTTPS (Secure communications protocol) Network Communication
3. USB port configured only for syncing test data (Keyboard and mouse are locked and unavailable for use)
4. Password/PIN protected access
5. Device blacklisting capability to disable device

Setting Up the Device in Your Practice

Expected Setup Environments

Optimal environments for the device: healthcare setting

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Handling Connectivity Issues

Managing cloud and network connections:

1. Ensure Wi-Fi network is operational.
2. Ensure Wi-Fi signal is strong.
3. Ensure Wi-Fi router name and password is correct.
4. If connection issues persist, turn analyzer off/on and try to connect again.
5. Sometimes Wi-Fi can be available but the internet connection to Wi-Fi is down, please contact your Internet Service Provider (ISP) to ensure stable internet connection.

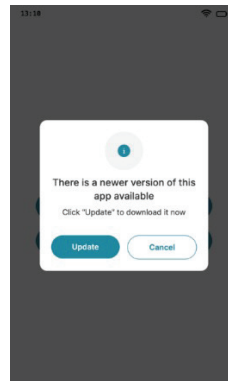
Risk Management Overview

Software is not an interoperable device, therefore no specific risks related to cybersecurity threats are identified. Please review Warning section for more information on related risks.

Updating the Device

Software Updates

Vigilant recommends connecting the device to an active Wi-Fi network at least once a week to allow the system to automatically check for updates. Once updates are available a system pop-up will appear, if an update is available.



Technical Information for Users

Operating System Details

Raspberry Pi Operating System

Software Components Lists

A copy of software bill of material can be obtained by emailing a request to Vigilant Biosciences at customerservice@vigilantbiosciences.com.

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BEVIGILANT™ SALI-MARK ANALYZER PROCEDURE FOR INITIAL SETUP

1. Remove the BeVigilant™ Sali-Mark Analyzer from the box.
2. Place the BeVigilant™ Sali-Mark Analyzer on a flat open surface near a power outlet.
3. Remove the power adapter from the box.
4. Plug into a power outlet.
5. Plug the power cord into the analyzer ensuring it is connected securely.
6. Press the power button, located on the back of the device. The power button will illuminate when device is on.
7. Ensure the BeVigilant™ Sali-Mark Analyzer is powered on (if the screen does not light up after the power button is activated, check all connections and ensure the outlet being used is functioning properly).
8. Select the language to be used on the device.
9. Select the Time zone where the device is used.
10. Review the Privacy Policy and tap Accept. Tap CONTINUE to proceed.
11. Review the Terms of Use and tap Accept. Tap CONTINUE to proceed.
12. Connect the analyzer to a wireless internet network by selecting the network, entering the appropriate network password, and tap CONNECT.
13. Create an account for the practice by entering the Practice Name, Email Address, and Password (enter the password twice for confirmation) and tap CREATE ACCOUNT.
14. An automated message will be sent to the email address used to create the account. Check the email (if it is not in the inbox, check any spam filters) to get the Verification Code.
15. Enter the Verification Code in the analyzer. NOTE: Verification code is valid for a limited time.
16. If the correct Verification Code is entered, the analyzer will prompt the creation of a 4-digit App PIN.
17. Create a 4-digit App PIN for the app to expedite future log in.
18. Re-enter the 4-Digit App PIN to confirm.
19. The analyzer is now ready to perform the testing procedure. Setup is complete.

PLEASE NOTE: The USB is for Vigilant use in regard to internal testing and/or accessing data. Each Analyzer is password protected in order to prevent unauthorized access.

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BEVIGILANT™ SALI-MARK ANALYZER PROCEDURE FOR USE

Perform the following steps to initiate a new test:

1. Place the BeVigilant™ Sali-Mark Analyzer on a flat open surface where the test will be performed. The analyzer should not be moved while a test is in progress. Movement may invalidate the test.
2. Tap the analyzer screen to ensure it is powered on. If the screen doesn't respond, press the power button on the back of the device for 1 second.
3. Enter the App PIN to log into the app.
4. Tap NEW TEST. Record the Test ID for traceability between the test results and the practice's Quality system for future reference.
5. The software will act as a guide through the test steps.
6. Place the test cassette into the positioning tray on the right side of the BeVigilant™ Sali-Mark Analyzer and slide the tray into the analyzer (do not lift Analyzer or positioning tray). The positioning tray and cassette have arrows indicating the direction of insertion.
7. Confirm all previous steps have been completed .
8. Tap START TEST on the BeVigilant™ Sali-Mark Analyzer screen.
9. When the test is complete, the BeVigilant™ Sali-Mark Analyzer will display a result.
10. Remove the test cassette from the BeVigilant™ Sali-Mark Analyzer.



If you wish to view the test again, it can be displayed through the home screen by selecting "FIND TEST" and entering the Test ID previously recorded in the practice's Quality system.

If an error occurs, the screen will display an alert. A new test can be immediately administered using a new test cassette.

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BEVIGILANT™ SALI-MARK ANALYZER PROCEDURE FOR SHUTDOWN

After completing a test procedure, the BeVigilant™ Sali-Mark Analyzer is ready for the next test. If desired, users may shut down the BeVigilant™ Sali-Mark Analyzer by pressing and holding the power button on the back of the device for 3 seconds. The device will take 15 seconds to power down completely and the illuminated power button will go off.

BEVIGILANT™ SALI-MARK ANALYZER PROCEDURE FOR SHUTDOWN

- Examine detachable power cord monthly for continued safe usage.
- Ensure the most recent software is installed prior to use if the device has been unused for an extended period of time.

DISPOSAL

Ensure that the BeVigilant™ Sali-Mark Analyzer is handled in accordance with WEEE and Batteries Directive.

WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) AND BATTERIES DIRECTIVE

The Waste Electrical and Electronic Equipment (WEEE) directive requires that all Electrical and Electronic Equipment (EEE) must be marked with the symbol of the crossed-out wheeled bin. This symbol means that the equipment must not be disposed of as unsorted municipal waste. Disposing of WEEE together with normal waste may pose a risk to the environment and to human health, due to certain substances used in EEE and their batteries.











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Analytical Performance Characteristic	p16 Result
Device will not power on	Check the device's battery life. If the battery is low, ensure the power adapter is plugged into the device and the cord is plugged into the wall. If the device is fully discharged, wait for 10 minutes before powering on the device.
User cannot remember application PIN	Use the "Forgot PIN" feature in the Application. The Application will walk you through the instructions. Internet access and user's email will be required.
Tray position error	Ensure positioning tray is inserted fully and flush against the main body of the device. Ensure the silver dot on the positioning tray is present. Ensure there is no debris on the positioning sensor. If the device will not function after troubleshooting, call customer support.
Test error	Ensure the test's expiration date, to ensure it is within use by date. Ensure the test's QR is present and not damaged. If either of these scenarios are present, a new test is required. If the device will not function after troubleshooting, call customer support.
Device is broken or has broken components	Terminate the use and return the device to the vendor.

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
GLOSSARY OF SYMBOLS

Standard/ Source	Symbol	ISO/IEC symbol number	Title of Symbol	Description of Symbol Per Standard
ISO 15223-1:2021 5.1.1		ISO 7000- 3082	Manufacturer	Indicates the medical device manufacturer
ISO 15223-1:2021 5.1.2		N/A	Authorized representative in the European Community/ European Union manufacturer	Indicates the authorized representative in the European Community/ European Union
ISO 15223-1:2021 5.1.3		ISO 7000- 2497	Date of Manufacture	Indicates the date when the medical device was manufactured
ISO 15223-1:2021 5.1.4		ISO-7000- 2607	Use-by-date	Indicates the date after which the medical device is not to be used.
ISO 15223-1:2021 5.1.6		ISO 7000- 2493	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
ISO 15223-1:2021 5.1.7		ISO 7000- 2498	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
ISO 15223-1:2021 5.3.4		ISO 7000- 0626	Keep Dry	Indicates a medical device that needs to be protected from moisture.
ISO 15223-1:2021 5.3.7		ISO 7000- 0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

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Standard/ Source	Symbol	ISO/IEC symbol number	Title of Symbol	Description of Symbol Per Standard
ISO 15223-1:2021 5.3.8		ISO 7000- 2620	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
ISO 15223-1:2021 5.3.9		ISO 7000- 2621	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
ISO 15223-1:2021 5.4.2		ISO 7000- 1051	Do not reuse	Indicates a medical device that is intended for one single use only.
ISO 15223-1:2021 5.4.3		ISO 7000- 1641	Consult instructions for use	Indicates that the user needs to consult the instructions for use.
ISO 15223-1:2021 5.5.1		N/A	In Vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
IVD Regulation 2017/746/EU		Annex I, Chapter III, 20.1h	Device for near-patient testing	Indication of near-patient testing
IVD Regulation 2017/746/EU		Annex I, Chapter III, 20.1h	Device not for self-testing	Explicit exclusion for assays not intended for self-testing or near-patient testing
IEC 60601- 1:2005 +AMD1:2012 +AMD2:2020		IEC 60417- 5032	Alternating current	Indicates that the equipment is suitable for alternating current only.
IEC 60601- 1:2005 +AMD1:2012 +AMD2:2020		IEC 60417- 5032	Alternating current	Indicates that the equipment is suitable for alternating current only.

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Standard/Source	Symbol	ISO/IEC symbol number	Title of Symbol	Description of Symbol Per Standard
IEC 60601-1:2005 +AMD1:2012 +AMD2:2020		ISO 7010-W001	General warning sign	To signify a general warning
Waste from Electrical and Electronic Equipment (WEEE) Directive		IEC 60417-6414	Waste Electrical and Electronic Equipment	Indicates that separate collection for waste electric and electronic equipment is required.
N/A		N/A	Illuminated Momentary Power Button	Indicates the power button on the back of the device. (Illuminated - Device is on / Light off - Device is off)
N/A		N/A	Prescription Use Only	Indicates prescription use only

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QUESTIONS OR CONCERNS?

If you have questions or concerns regarding these instructions for use, please contact your Sales Representative or Vigilant Biosciences at customerservice@vigilantbiosciences.com.

If you have any issues with the external power supply, please contact Vigilant Biosciences for a replacement at customerservice@vigilantbiosciences.com.

For additional product information, visit www.vigilantbiosciences.com

If any serious incident occurs in relation to the device, please report to Vigilant Biosciences, US Food & Drug Administration, and/or the competent authority of the Member State in which the user and/or the patient is established.

The Summary of Safety and Performance is available upon request.

IVD For in *vitro* diagnostic use only.

PATIENT DATA PRIVACY

Vigilant Biosciences respects the privacy rights of individuals and is committed to handling and protecting personal information in compliance with the EU-U.S. and Swiss-U.S. Privacy Shield Frameworks. For our full Privacy Policy, visit our website at www.vigilantbiosciences.com. For complaints or concerns, contact our Privacy Administrator at privacy@vigilantbiosciences.com.

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LIMITATION OF WARRANTY AND LIABILITY

Use of BeVigilant™ products constitutes an acceptance of all terms and conditions of this limitation of warranty and liability.

1. BeVigilant™ products are warranted to meet product descriptions and specifications in effect on the time of shipment and to be free from defects in materials and workmanship for the products' shelf life. User assumes all risk and liability resulting from the use of BeVigilant™ products, whether used singly or in combination with other products. The foregoing warranty is in lieu of all other warranties or obligations, express or implied. Vigilant Biosciences expressly disclaims all implied warranties, including without limitation, the warranties of merchantability, fitness for a particular purpose, and noninfringement. Accordingly, the distributor covenants not to assert, and not to permit to be asserted, any claim whatsoever against Vigilant Biosciences or any affiliate of Vigilant Biosciences based thereto.
2. Distributor's sole and exclusive remedy for defective product, including any claims by third parties made against distributor, shall be refund, credit or replacement. In no event shall Vigilant Biosciences be liable for cost of procurement of substitute goods, loss of profits, or for any other special, consequential, indirect, or incidental damages, however caused, even if Vigilant Biosciences has been advised of the possibility of such damages. If the foregoing limitation shall be found inapplicable for any reason, Vigilant Bioscience's liability under this agreement shall not exceed the price paid for the defective product.

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Revision History

Document Revision	Description of Change	Effective Date
A	Initial Production Release	01 Nov 2024