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VIGILANTBIOSCIENCES®

BeVigilant™ Reader

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™ Reader is intended to be used only with the Ora-3D. The BeVigilant OraFusion System is intended to be used by qualified health-care providers as a pre-diagnostic test on symptomatic adult patients, specifically those with oral mucosal abnormalities visible to the health-care provider, during the oral cancer exam and risk assessment. The BeVigilant™ Reader provides the summary of the combined test result with clinical risk factors to assess oral abnormalities in patients with lesions.

For professional use only.

For in *vitro* diagnostic use only.

PRINCIPLES OF OPERATION

The Ora-3D is a semi-quantitative point of care device consisting of a single use collection device and a single-use lateral flow immunoassay that measures p16 and EGFR in saliva, which are known to be associated with oral cancer. The BeVigilant™ Reader is the electronic enclosure with integrated electronics and software used to input clinical risk factor and report the result of the test. The clinician initiates a test by selecting 'New Test' on the BeVigilant™ Reader and entering patient data and clinical factors. The clinician then collects a saliva sample from the patient using the Saletto™ Oral Fluid Collection Device (Image 3), which filters the sample. As a last step, the clinician applies it to the specified wells on the test cassette. The cassette is then placed in the positioning tray of the BeVigilant™ Reader (Image 1) and the user reviews the OraFusion Software and taps 'Start Test.' The BeVigilant™ Reader analyzes the sample and provides a test result. The BeVigilant™ Reader is not automated and requires the health-care provider to administer the test and recommend next steps.

MATERIALS PROVIDED IN THE BEVIGILANT® READER TO ADMINISTER A TEST

Component Description	Quantity
BeVigilant™ Reader	1
Power Adapter and Interchangeable Blade Kit	1
Instructions for Use (IFU)	1
Quick Reference Guide (QRG)	1

Image 1-BeVigilant™ Reader

MATERIALS PROVIDED IN THE ORA-3D TO ADMINISTER A TEST

Component Description	Quantity
Ora-3D Pouch	12
Oral Fluid Collection Device	12
Instructions for Use (IFU)	1
Quick Reference Guide (QRG)	1

Image 2 – Ora-3D Cassette

Image 3 – Porex Saletto™ Oral Fluid Collection Device

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ORA-3D & BEVIGILANT® READER WARNINGS AND PRECAUTIONS

- Failure to follow the instructions provided may lead to inaccurate results.
- This test is not intended for diagnosis.
- This test is intended for use by health-care providers in a health-care setting.
- This test should only be used for symptomatic adult patients with oral mucosal abnormalities visible to the health-care provider during the oral cancer exam.
- This test has been developed for use with saliva only. The use of this test with any other specimen type may lead to inaccurate results.
- The use of a saliva specimen with blood, food, alcohol or any other substances present in the oral cavity within 1 hour may lead to false negative/positive results.
- Do not use this device if there is an infection or fungus in the mouth, blood present in the saliva sample, or the patient has an active cancer diagnosis.
- Saliva sample should be used immediately after collection.
- Wear appropriate personal protective equipment and use standard office practices when handling and testing the patient specimen.
- Use the Ora-3D immediately after opening the pouch.
- Stop using immediately if an allergic reaction occurs.
- Insufficient saliva sample volume may lead to inaccurate results.
- This product has not been tested on pregnant women. The OraFusion System has only been tested on adults of age 22 years or older.
- This test is intended to be performed at room temperature (16°C to 30°C); do not use out of this range.
- The recommended storage temperature for the test kit is 4°C to 40°C.
- Use all test devices only once and dispose properly. Do not reuse any of the test devices.
- The BeVigilant™ Reader is not intended to be moved during a test.
- Do not use Ora-3D after the expiration date on the package. Expired devices should be disposed of according to local, state, and federal waste disposal requirements.
- Used Ora-3D are considered a potential biohazard and should be disposed of according to local, state, and federal waste disposal requirements.
- 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™ Reader may cause the battery to lose charge and Reader to not power on.
- Ensure that the Reader 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.
- Ora-3D does not have backward compatibility.
- Use only with recommended consumables, accessories, or medical devices.
- Examine detachable power cord monthly for continued safe usage.
- The BeVigilant™ Reader may be reused until signs of material degradation occur. Do not use the BeVigilant™ Reader 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.
- Ensure the BeVigilant™ Reader is calibrated prior to use.
- Do not use Ora-3D if components are damaged or missing.
- Do not use the BeVigilant™ Reader if unresponsive or components are damaged or missing.
- Discontinue device use in the event of a malfunction.
- Label samples prior to testing to prevent mix-ups.
- Do not write over or damage the QR Code. If damage occurs, the cassette will return an invalid test result.
- Natural rubber latex was not used as a material in the manufacture of a medical product, its container and/or packaging.
- Avoid distractions while administering the test. The patient should remove any lipstick or lip treatment such as lip balm, ointment etc. prior to specimen collection for the administration of the test.

BEVIGILANT™ READER CONTRAINDICATIONS

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

BEVIGILANT™ READER ENVIRONMENTAL CONDITIONS

The permissible environmental conditions of use for proper operation of the BeVigilant™ Reader 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:	81 kPa to 101 kPa

BEVIGILANT™ READER 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™ Reader with care. The BeVigilant™ Reader or its battery may be damaged if disassembled, dropped, bent, burned, crushed, or punctured. Do not use the BeVigilant™ Reader with a cracked screen or damaged enclosure.

Using a damaged device may cause battery overheating or injury. Do not expose the BeVigilant™ Reader 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.

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.

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™ Reader 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™ Reader is intended for use in a clinician's office. The BeVigilant™ Reader 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

DEVICE FREQUENCY BANDS AND POWER
The BeVigilant™ Reader 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™ Reader Maintenance

The BeVigilant™ Reader 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. Avoid USB port and other crevices when cleaning. Do not use any chemical detergent, powder, or other chemical agents to clean the BeVigilant™ Reader or accessories. Do not clean your device while it is charging.

BEVIGILANT™ READER REPAIR AND SERVICE
Do not attempt to repair the BeVigilant™ Reader or any of its accessories. Disassembling the device may cause damage or injury. Contact customer service if the BeVigilant™ Reader is damaged or requires service.

BEVIGILANT™ READER CHARGING
The BeVigilant™ Reader is designed to charge when plugged in. Do not use an alternative charging accessory to charge the device. Do not use the BeVigilant™ Reader 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™ Reader utilizes an AC/DC power adapter to supply the device with AC power. WARNING: do not use any power adapter other than the 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

BATTERY
The BeVigilant™ Reader 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™ Reader 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™ Reader 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™ Reader 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™ Reader 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™ Reader 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™ Reader setup.
- The USB port is for Vigilant use in regard to internal testing and/or accessing data password protection to prevent users from unauthorized access.

BEVIGILANT™ READER PROCEDURE FOR INITIAL SETUP

1. Remove the BeVigilant™ Reader from the box.
2. Place the BeVigilant™ Reader on a flat open surface near a power outlet.
3. Remove the power adapter and Interchangeable Blade Kit from the box.
4. If needed, replace the interchangeable blade on the power adapter by pressing down on the spring-loaded tab, insert the blade adapter at 60° where the top is flat and the bottom has a U-shape. Press the adapter down towards the power supply until it locks in place, a clicking sound will occur. if more information is needed, please visit: http://www.globtek.com/pdf/Instructions-Interchangeable-Blades.pdf.
5. Plug into a power outlet.
6. Plug the power cord into the reader ensuring it is connected securely.
7. Press the power button, located on the back of the device. The power button will illuminate when device is on.
8. Ensure the BeVigilant™ Reader 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).
9. Select the language to be used on the device.
10. Select the Time zone where the device is used.
11. Review the Privacy Policy and tap Accept. Tap CONTINUE to proceed.
12. Review the Terms of Use and tap Accept. Tap CONTINUE to proceed.
13. Connect the reader to a wireless internet network by selecting the network, entering the appropriate network password, and tap CONNECT.
14. 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.
15. 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.
16. Enter the Verification Code in the reader. NOTE: The verification code has a timer associated with email sent and should be entered within that time period.
17. If the correct Verification Code is entered, the reader will prompt the creation of a 4-digit App PIN.
18. Create a 4-digit App PIN for the app to expedite future log in.
19. Re-enter the 4-Digit App PIN to confirm.
20. The reader is now ready to perform the Ora-3D. Setup is complete.

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

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BEVIGILANT™ READER PROCEDURE FOR USE

Perform the following steps to initiate a new Ora-3D test:

1. Place the BeVigilant™ Reader on a flat open surface where the test will be performed. The reader should not be moved while a test is in progress. Movement may invalidate the test.
2. Tap the reader 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 START NEW TEST, then enter Year of Birth and Gender. Record the Test ID for traceability between the Ora-3D test results and the practice's Quality system for future reference.
5. Enter the patient Clinical Risk Factors by tapping the appropriate answer for each factor. For additional information about Clinical Risk Factors, tap the ⓘ
6. Enter if the patient has fasted from food or fluid within 1 hour of the test. If yes, continue; If no, enter if the patient has had any of the cross-reactivity substances listed.
7. Prepare a saliva sample for testing by following the Ora-3D Procedure for Use (next section). After collecting the sample, the BeVigilant™ OraFusion Software will act as a guide through the test steps.

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SPECIMEN COLLECTION PROCEDURE FOR USE

Perform the following steps to prepare a patient sample for Ora-3D.

- Prior to collecting a sample, follow the BeVigilant™ Reader Procedure For Use.
- Gloves must be worn when performing the Ora-3D.

The OraFusion Software will guide user through the following steps.

- Remove a Collection Device and a Test Cassette from the box. Inspect the packaging for damage and do not use items past the expiration date printed on the pouch. Only open the components as needed

Important! Patients should not eat, drink, chew gum, smoke, gargle mouthwash, or put anything in or around the mouth for at least 1 hour before sample collection. Substances in the mouth may cause false test results.

IMPORTANT FOR SALIVA TRANSFER:

1. Place the sponge only on the top of the tongue. DO NOT place the sponge under the tongue.

2. Ensure to POOL saliva prior to placing the sponge in the mouth.

3. Maintain the tongue in one position while the sponge absorbs saliva.

4. DO NOT perform any sucking motion while the sponge is absorbing saliva.

5. DO NOT place your mouth over the plastic body of the collection device.

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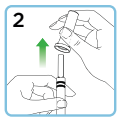
1. Instruct the patient to pool saliva in the mouth for a minimum of 30 seconds.
2. Remove the Push Cap and set aside.
3. Instruct the patient to place the entire Sponge in the mouth and saturate with saliva for a minimum of 90 seconds. Continue to pool and saturate the sponge in the mouth during the 90 seconds.
4. After 90 seconds, check if the indicator has turned solid blue. If the indicator has not turned blue (indicating full saturation), repeat steps 1 through 3.
5. Retrieve the properly filled collection device from the patient. Place the Collection Device cap over the Sponge.
6. Keeping the device upright, push the cap down slowly and smoothly in one motion to filter the saliva into the sample dropper.
7. Saliva should be present in the bottom of the dropper tip. Ensure the minimum volume is up to the top of the purple dropper tip. If there is not enough, repeat steps 1 through 6. The sample is ready for testing. Proceed to the Ora-3D & BeVigilant™ Reader procedure for use.
8. Inspect the filtered saliva in the tube for blood. Select the option on the OraFusion Software to continue.
9. Perform test within 1 hour of saliva collection.

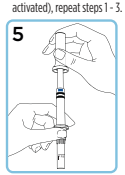
Pool saliva in mouth for 30 seconds.



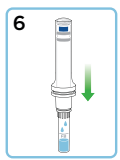
Remove Push Cap and set aside.

Put entire Sponge in mouth and saturate with saliva for 90 seconds. Do not chew or squeeze Sponge.

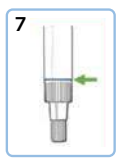
Indicator turns solid BLUE when saturated with saliva.
Remove Sponge from mouth to check Indicator. If it is not solid Blue (fully activated), repeat steps 1 - 3.



Replace Push Cap over Sponge.
Keep device upright.



Keeping device upright, push Push Cap down slowly and smoothly, in one motion.
Compress Sponge completely.



Minimum volume of Saliva shall be to top of the dropper

ORA-3D & BEVIGILANT™ READER PROCEDURE FOR USE

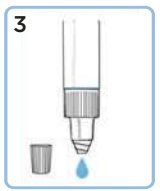
1. Prior to administering a test, follow the BeVigilant™ Reader Procedure For Use and Specimen Collection Procedure for Use.
2. Remove the Ora-3D Test cassette from the packaging and place on flat surface near the BeVigilant™ Reader and prepare to apply the filtered saliva to the cassette.
3. Unscrew the dropper cap from the sample dropper nozzle.

Caution: Some saliva may flow without pressing the dropper tube. Ensure cleaning supplies are available if needed.

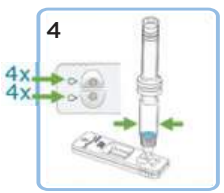
4. Add four drops of the sample into each well of the test cassette (eight drops in total) by squeezing the tube. The sample may pool in the well when first applied. Allow time for the saliva to saturate into the cassette before moving the cassette into the positioning tray.

Important! Do not exceed a 60 second timeframe between dropping the sample into the cassette and beginning the test.

5. Place the test cassette into the positioning tray on the right side of the BeVigilant™ Reader and slide the tray into the reader (do not lift Reader or positioning tray). The positioning tray and cassette have arrows indicating the direction of insertion.
6. Confirm all previous steps have been completed.
7. Tap START TEST on the BeVigilant™ Reader screen. If the elapsed time is greater than 1 hour since the lapse timer started, the sample has expired and an error message will occur.



Remove the dropper cap and set aside



Add a four (4) drops of the sample into each well of the test cassette by squeezing the tube.

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8. When the Sensor Fusion is complete, the BeVigilant™ Reader screen will display a Total Risk Profile result showing LOW RISK, MODERATE RISK, or ELEVATED RISK of oral cancer, based on the analysis of specific biomarkers and individual Clinical Risk Factors.
9. Tap DONE to return to the home screen.
10. Remove the test cassette from the BeVigilant™ Reader and dispose of the cassette and Collection Device according to local, state, and federal waste disposal requirements.

If an error occurs, the screen will display an alert. A new test can be immediately administered using a new Ora-3D.

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

BEVIGILANT™ READER PROCEDURE FOR SHUTDOWN

After completing a test procedure, the BeVigilant™ Reader is ready for the next test. If desired, users may shut down the BeVigilant™ Reader 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.

QUALITY CONTROL PROCEDURE

- Inspect the expiration date on the package for the Ora-3D to ensure the product is not expired.
- 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

Used Ora-3D are considered a potential biohazard and should be disposed of according to local, state, and federal waste disposal requirements. Ensure that the BeVigilant™ Reader 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.

BEVIGILANT™ READER TROUBLESHOOTING

Error	Troubleshooting and mitigation
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. If the device will not power on after troubleshooting, call customer support.
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.
Ora-3D 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.
Sample expiration error	A new saliva sample and test required, use the application to restart the test.
Device is broken or has broken components	Terminate the use and return the device to the vendor.

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.

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		ISO 7010-W001	General warning sign	To signify a general warning

Standard/ Source	Symbol	ISO/IEC symbol number	Title of Symbol	Description of Symbol Per Standard
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	Saliva Drop Well indicator	Indicates where the user is to drop the saliva into the cassette.
N/A	CE	N/A	CE Marking; European Conformity	Indicates that the manufacturer of the product complies with EU legislation and may be sold anywhere in the EEA (European Economic Area).

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QUESTIONS OR CONCERNS?

If you have questions or concerns regarding these instructions for use, please contact your Vigilant Biosciences 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@vigilantbioscineces.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.

REFERENCES

1. “The Science of Earlier: Improving early detection of oral and oropharyngeal cancer”, White Paper, 2018, Vigilant Biosciences, Inc.
2. World Health Organization website. Accessed 2021.
3. Siegel RL, Miller KD, and Jemal A. Cancer statistics, 2019 CA Cancer J Clin 2019;69:7-34.

IVD For in *vitro* diagnostic use only.

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CE

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Revision History

Document Revision	Description of Change	Effective Date
A	Update to include glossary of symbols, contraindications, equipment Class II (electrical safety), warnings and precautions, shutdown procedure, cleaning instructions, temperature, humidity and atmospheric pressure ranges, information regarding detachable supply cord.	03MAR2021
B	Change IFU name from BeVigilant RAPID Test to BeVigilant RAPID Reader. Update operating altitude. Consolidate operational temperature, operating altitude, operational humidity, and storage temperature for the Reader and the phone. Add additional symbols and include contact information to request a replacement.	03MAR2021
C	Update collection method and images; correct branding	13APR2021
D	Remove saline references and update saliva volumes to reflect the change in collection method	21APR2021
E	Update Authorized Representative from Emergo Europe to Vigilant Biosciences GmbH	12MAY2021
F	Updates throughout to reflect product improvements	18APR2022
G	Updates throughout to reflect product improvements	06MAY2022
H	Add warnings and symbol to glossary of symbol	24MAY2022
I	Adjustments to procedure. New symbols added.	28MAR2023
J	Update to warning and precaution, Replace Wizard with OraFusion Software, Formatting Update	26APR2023