

be.well™ Analyzer

User Manual

For use with the Alveo be.well™ System

Important Notice

Please read this User Manual fully. If you have any questions or comments, please contact Alveo Customer Support at support@alveotechnologies.com or call (+1) 833-BE-WELL-O (+1 833-239-3550).

This user manual, as well as the be.well™ System components and software programs described herein, should be used in accordance with their stated purpose. The information in this manual is furnished for the purpose of instruction and guidance only, is subject to change, and should not be construed as an alternative to qualified medical advice.



For *In Vitro* Diagnostic Use



Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium



Alveo Technologies, Inc.
1000 Atlantic Ave
Alameda, CA 94501, USA
alveotechnologies.com

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Chapter 1: General Information

Welcome to Alveo's be.well™ System

The be.well™ System is a rapid molecular diagnostic testing system for performing *In Vitro* Diagnostic (IVD) medical tests. Individual results are delivered and saved to Alveo's secure, cloud-based system. This User Manual will guide you through the proper setup and use of the be.well™ Analyzer with the be.well™ System, which consists of:

be.well™ Analyzer	be.well™ Test Kit (Sample collection and preparation materials may vary by test type and are not pictured below.)	be.well™ Mobile App
		

Alveo Contact Information

If you have any questions regarding the use of this product, please contact Alveo Customer Support at support@alveotechnologies.com or call toll-free at (+1) 833-BE-WELL-0 (+1 833-239-3550).

Formatting, Labels and Symbols Utilized in This User Manual

This User Manual includes two types of important messages: ***Cautions*** and ***Notes***. “*Caution*” and “*Notes*” messages are written in *italics*. It is important to pay close attention to these messages to make sure you use the be.well™ System correctly and safely.



Caution:

A Caution message provides information to prevent damage to your be.well™ System.

Note:

A note provides additional information to make the instructions clearer.

Within this document, procedural steps that apply to the be.well™ Mobile App are **bolded**. Steps that are sequentially numbered should be performed in the order indicated.

Symbols

The following symbols may be found on be.well™ product packaging and labeling:

	Manufacturer		<i>In vitro</i> diagnostics
	Date of manufacture		Consult instructions for use
	European conformity		Customer Support
	Authorized representative in the European Community/ European Union		Temperature limit
	Electrical and Electronic Equipment Waste: Discard product at separate collection facility for recovery and recycling.		Serial number
	Catalog number		Batch code
	Caution		Keep dry
	MET Certification Mark		Compliance to FCC Part 15 Subpart B
	Input rating		

Before Testing With the be.well™ System

Before beginning a test, review this User Manual to help properly set up the be.well™ System and familiarize yourself with its many features, including detailed information needed to use the system correctly and safely. It is important that you follow the instructions in this manual.

Intended Use

The be.well™ Analyzer is an *In Vitro* Diagnostic (IVD) instrument that accepts test-specific be.well™ Cartridges and executes nucleic acid amplification and detection of analytes according to assay definitions associated with the inserted be.well™ Cartridge. The be.well™ Analyzer is designed exclusively for use with Alveo's be.well™ Cartridges, allowing healthcare providers to run specific tests on the platform using pre-defined assays.

System Description

The be.well™ System consists of the be.well™ Analyzer, be.well™ Test Kits (test-specific kits) and be.well™ Mobile App (software) that must be installed on a compatible mobile smart device.

The be.well™ Analyzer is a stand-alone instrument that is capable of running be.well™ Cartridges from the be.well™ Test Kits. The be.well™ Cartridges include internal process controls to help ensure that tests are run properly and that test results are valid. Test results are displayed to the user (e.g. Positive, Negative, Invalid) on the screen of the user's mobile smart device, and are saved to the registered user's be.well™ Account. Descriptions of each of the be.well™ System components are included in Chapter 2.

All test results in the be.well™ System are stored on a secured, cloud-based database.

Storage and Handling Conditions



- Use all be.well™ System components within a temperature range of 15-30°C (59-86 °F).
- Store the be.well™ Analyzer between 15-30 °C (59-86 °F).

Note: For more information on storing and operating the be.well™ Analyzer, see “Chapter 7: Technical Information and Specifications”.

General Precautions

- Always operate the be.well™ Analyzer on a stable, flat, and level surface while running a test. Do not move or tilt the be.well™ Analyzer while a test is in progress.
- Operation of the be.well™ System should occur at the temperature ranges referenced in this User Manual and the respective be.well™ Test Kit Instructions for Use (15° – 30°C). Do not run a test if the room temperature is outside of the testing conditions stated in the test-specific Instructions for Use (IFU). Testing in room temperatures that are too high or too low may cause an incorrect or invalid result.
- Refer to the test-specific Instructions for Use (IFU) found in be.well™ Test Kits for applicable precautions and guidance.

- The be.well™ Analyzer is only compatible with be.well™ Cartridges.
- Do not insert anything into the be.well™ Analyzer Port other than be.well™ Cartridges and only when prompted by the be.well™ Mobile App.
- Do not use any damaged or opened be.well™ System components.
- If the be.well™ Analyzer gets wet, immediately wipe the outside of the be.well™ Analyzer and the opening of the be.well™ Analyzer port with a clean paper towel or cloth and leave to dry.
- Do not immerse the be.well™ Analyzer in water or cleaning solutions. Unplug the be.well™ Analyzer before cleaning and clean only as indicated in this User Manual.
- Store all be.well™ System components as described in this User Manual and in the test-specific Instructions for Use (IFU).
- Avoid touching the electrical contacts located on the end of the be.well™ Cartridge that is inserted into the be.well™ Analyzer.
- Making changes to any of the parts of your be.well™ System or using any parts that did not come with the be.well™ System may cause harm to yourself or the be.well™ System, and will also void your warranty.
- Charge the be.well™ Analyzer before using the device after being stored for long periods.

Chapter 2: be.well™ System Overview and Features

The be.well™ System consists of:

- be.well™ Analyzer
- be.well™ Test Kit
- be.well™ Mobile App

Descriptions of each be.well™ System component are included below.

NOTE: be.well™ Analyzer and be.well™ Test Kits sold separately.

be.well™ Analyzer

The be.well™ Analyzer is a stand-alone instrument that is required to run be.well™ Cartridges. The be.well™ Analyzer communicates with the be.well™ Mobile App via Bluetooth® and also interfaces with test-specific be.well™ Cartridges that are directly inserted into the be.well™ Analyzer port. Each be.well™ Analyzer package includes the following components:

- One (1) be.well™ Analyzer
- One (1) USB charging cable
- Two (2) power adapters (pre-assembled)

be.well™ Test Kit

be.well™ Test Kits contain the components and materials needed to run a pre-defined diagnostic test. be.well™ Cartridges included in each be.well™ Test Kit are inserted into the be.well™ Analyzer Port and should be used before their expiration date. be.well™ Test Kit contents may vary based on the specific product type (test), though the following components are typically included with most be.well™ Test Kits:

- Test-specific, single-use be.well™ Cartridge
- Sample collection component (e.g. Nasal Swab)

- Instructions for Use (Package Insert)
- Quick Reference Instructions

be.well™ Mobile App

The be.well™ Mobile App is a software application that runs on a compatible mobile smart device, providing the user interface to the be.well™ Analyzer, retrieving test-specific assay definitions for the inserted be.well™ Cartridge, viewing of results, and archival and retrieval of results to a secure cloud-based database. The be.well™ Mobile App connects to the be.well™ Analyzer via Bluetooth® and is required to create a be.well™ Account, run a test, and view or share test results.

Test results are displayed on the screen of the user's mobile smart device and are saved to the registered user's be.well™ Account in a secure cloud-based database.

The be.well™ Mobile App is available for download onto a mobile smart device in the Apple® App Store.

System requirements for the be.well™ Mobile App:
iOS™ 12.0 and later

Chapter 3: be.well™ System Set Up

Unpacking the be.well™ Analyzer

Inspect the packaging for obvious damage prior to opening. Unpack the contents, placing the be.well™ Analyzer upright on a dry, stable, and level surface. Carefully examine it for damage. Check that all components are provided and are in good condition. In case of damage or any missing parts, contact Alveo Customer Support.

Identifying Parts of the be.well™ Analyzer

Figures 1, 2 and 3 identify the components of the be.well™ Analyzer.

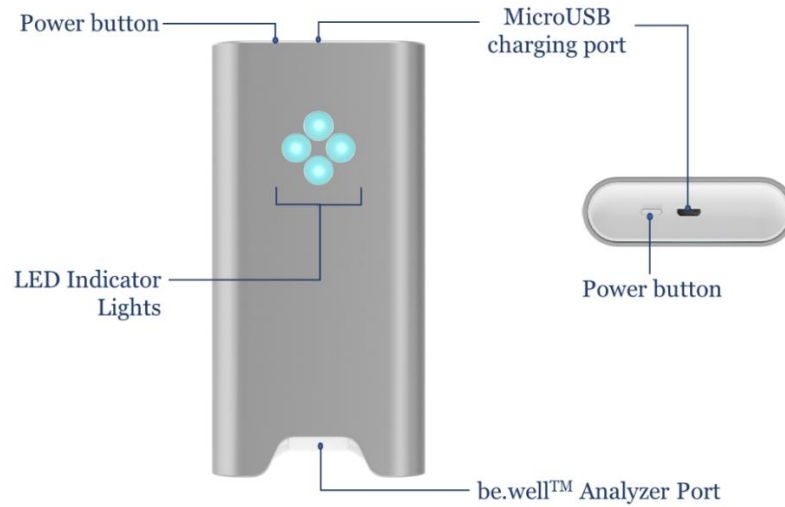


Figure 1. View of be.well™ Analyzer face (front) and locations of power button, USB charging port and be.well™ Analyzer port (assay port)

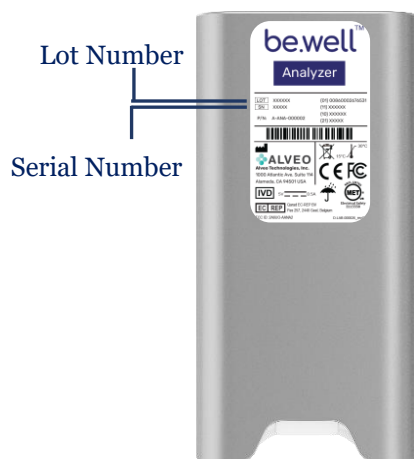


Figure 2. View of be.well™ Analyzer back and associated device label

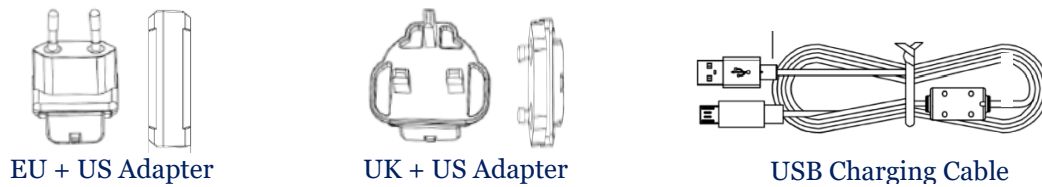
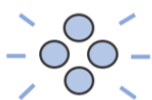


Figure 3. View of EU and UK power adapters (each couples with US adapter and is pre-assembled), USB charging cable

LED Indicator Lights on the be.well™ Analyzer



Blinking Blue lights indicate that the Analyzer is sufficiently charged and is ready to pair with a mobile device.



Blinking Yellow lights indicate that the Analyzer has insufficient battery. Connect Analyzer to power source.



Solid Blue lights indicate that the Analyzer is paired with a mobile device and you are ready to run a test.



Spinning Yellow lights indicate that the Analyzer has insufficient battery and is charging.



Spinning Blue lights indicate that a test is in progress.



Solid Red lights indicate that the Analyzer is in an error state. Reset Analyzer and follow troubleshooting guide to clear error state.

Placement of the be.well™ Analyzer



Caution:

- *Place and operate the be.well™ Analyzer on a stable, flat, and level surface while running a test.*
- *Do not move or tilt the be.well™ Analyzer while a test is in progress.*
- *Do not place the be.well™ Analyzer in a location that is subject to vibrations, such as near machines that vibrate, shake, or spin.*
- *Do not place the be.well™ Analyzer in a location that will subject it to sources of direct airflow that can affect the instrument's ability to maintain proper temperature.*
- *Do not place the be.well™ Analyzer near a source of electromagnetic interference.*

Charging the be.well™ Analyzer

Charge the be.well™ Analyzer battery by plugging the respective ends of the Micro USB charging cable into the charging port on the end of the be.well™ Analyzer and the pre-assembled power adapters, then plug-in to a power source. It may take up to 75 minutes to sufficiently charge the battery if fully depleted. When the be.well™ Analyzer has enough charge to run a test, the LED Indicator Lights will flash blue.

Note: If the pre-assembled power adapters become disengaged from each other, the components may be reconnected by aligning the connection points and re-engaging.

If the be.well™ Analyzer is left unattended for 10 minutes, it will go into a power save mode and turn off its LED Indicator Lights. To turn the be.well™ Analyzer on, momentarily press the power button next to the charging port. Within a few seconds, all four dots should begin to flash blue if sufficiently charged, or yellow if low on battery. If no lights flash, plug the be.well™ Analyzer in to charge as it likely has a depleted battery.



Caution: Only use the charging cable provided with the be.well™ Analyzer.

Note: If running multiple tests, it is recommended that you keep the be.well™ Analyzer plugged in during a test as well as when not in use.

Downloading and Installing the be.well™ Mobile App

You can download the be.well™ Mobile App onto your mobile smart device from the Apple App Store (*internet connectivity required*). The be.well™ Mobile App is free of charge and may be downloaded and installed the same way as other apps on your mobile smart device.

To download the be.well™ Mobile App:

1. Turn on your mobile smart device.
2. Confirm your mobile smart device has internet connectivity.
3. Launch the Apple App Store.
4. Search for the “**be.well™ Mobile App**” and tap on the app icon.
5. Follow your mobile smart device’s prompts to install.

Notes:

- *The be.well™ Mobile App needs to be installed on each mobile smart device intended for use.*
- *be.well™ Mobile App updates must be downloaded from the Apple App Store when a new version is available. You may check the current be.well™ Mobile App version in the “About the app” menu option.*
- *Refer to the respective test-specific be.well™ Cartridge Instructions for Use (IFU) and Quick Reference Instructions (QRI), which include visual aids and instructions for many of the software-related steps and procedures described in this user manual.*

Creating and Registering a be.well™ Account in the be.well™ Mobile App

Users must create a be.well™ Account via the be.well™ Mobile App before running a test.

To do so:

1. After installing the be.well™ Mobile App on your mobile smart device, **tap the icon to open the app.**
2. Tap “**Register**”.
3. **Read the Terms of Use, including the Privacy Policy**, scroll to the end and tap “**I agree**”.
4. **Enter the required user information to create a be.well™ Account, then tap “Save Account”.**
5. **Check your email for a security confirmation message from Alveo Technologies (alvcloud@alvcloud.net). Click on the link in the email to verify your email address and complete registration.** If you do not see a confirmation email, check your spam folder.
6. Once you receive the “Registration Successful!” notice on the Alveo Technologies account set up page, **Tap “Log In” in the be.well™ Mobile App, enter your email address and password, and tap “Log In” again to land on the home page.**

Logging in to Your be.well™ Account on the be.well™ Mobile App

If you have already created your be.well™ Account, log in as follows:

1. **Open the be.well™ Mobile App on your mobile smart device.**
2. **Enter your email and be.well™ Account password on the Log In screen.**
3. Tap “**Log In**”.

Creating and Updating Patient IDs in the be.well™ Mobile App

Each individual being tested must have their own Patient ID to run a test. Previous test results are saved under each individuals' Patient ID.

Multiple Patient IDs can be created and stored under one be.well™ Account, however, only one ID will appear on the home screen at a time.

To create a new Patient ID:

1. Tap “**Add Patient ID**” at the bottom of the home screen.
2. Follow the prompts to enter the ID of the Patient manually or by scanning a barcode using the camera of the mobile device.
NOTE: If using Health Passport Worldwide (HPW), use the scanning feature to scan the client's personal HPW QR Code or enter it manually as described above.
3. Tap “**Save**” and then “**Yes**” to finish.

Chapter 4: Running a Test

Review be.well™ Test Kit Materials & Instructions

Read the Quick Reference Instructions found in your be.well™ Test Kit and follow the on-screen prompts in the be.well™ Mobile App for test-specific instructions on how to collect a sample and set up and run a be.well™ Cartridge. It is recommended that you review these instructions before powering up the be.well™ Analyzer.

Power On

Press the power button to turn on the be.well™ Analyzer. Ensure the be.well™ Analyzer is turned on and the LED Indicator Lights are flashing blue.

NOTE: If the LED Indicator Lights are yellow, your be.well™ Analyzer is low on battery charge and you will not be able to run a test. Charge the device until the lights turn blue. Refer to “Indicator Lights on Your be.well™ Analyzer” section in Chapter 3.

Pairing the be.well™ Analyzer With a Mobile Smart Device

Pair the be.well™ Analyzer via Bluetooth® with your mobile smart device. Instructions to connect your be.well™ Analyzer will display on-screen after you tap “**Start New Test**” under the individual's Patient ID. Next tap “**Begin Pairing**”. When your mobile smart device locates the be.well™ Analyzer, a prompt to pair it will appear on-screen. Tap “**Pair**” in the pop-up notification.

NOTE: If you have paired the same two devices in the past, you may not receive the “Pair” notification.

Bluetooth® uses the 2.4 GHz ISM spectrum band (2400 to 2483.5 MHz)

Maximum RF Output Power is set to 0 dBm

Check that the be.well™ Analyzer serial number that is displayed on the “**Pairing Successful!**” screen matches the serial number and lot number on the back of your be.well™ Analyzer. If you wish to pair a different be.well™ Analyzer, tap “**Connect a different be.well™ Analyzer**” at the bottom of the screen and follow the instructions.

Tap “**Next Step**” when connected with the intended be.well™ Analyzer.

The be.well™ Mobile App will notify you at this step if your be.well™ Analyzer requires an update. Follow the prompts to update your be.well™ Analyzer and proceed with the test.

NOTE: If the mobile smart device loses power or goes out of Bluetooth® range while the test is in progress, the test on the be.well™ Analyzer will still run to completion. View the test result by logging back into the be.well™ Mobile App once the mobile smart device is charged or reconnected to the be.well™ Analyzer via Bluetooth® and re-enter the Patient ID exactly as it was originally entered.

Sample Collection & Insertion of be.well™ Cartridge into be.well™ Analyzer Port

Follow the test-specific instructions on how to collect a sample and insert the be.well™ Cartridge into the be.well™ Analyzer.

View Test Results

Test results are displayed (e.g. Positive, Negative, Invalid) on the screen of the user’s mobile smart device and are saved to the registered user’s be.well™ Account.

Understanding Invalid Results

Invalid test results may be reported if:

- An insufficient amount of sample was collected.
- be.well™ Test Kit components were used after their expiration date.
- be.well™ Test Kit components were not stored in temperatures or conditions indicated in the respective test kit’s Instructions For Use.
- be.well™ Test Kit components were not at room temperature (15° – 30°C) at the time of testing. See “Storage and Handling Conditions” in Chapter 1 for more details.
- The be.well™ Analyzer was moved or tilted during testing.
- The be.well™ Analyzer or be.well™ Test Kit components are damaged.
- The instructions found in the test-specific Instructions For Use (IFU) were not correctly followed.

Chapter 5: be.well™ System Management

be.well™ Mobile App Menu

To access your be.well™ Account menu, launch the be.well™ Mobile App on your mobile smart device. Then:

1. Log in to your be.well™ Account.
2. Tap on the three horizontal lines in the upper right corner of the screen. This will open the menu.
3. The be.well™ Mobile App menu features:
 - Home
 - Manage be.well™ Analyzers
 - Documentation
 - i. Access various reference documents including the Instructions For Use (IFU) and other helpful resources
 - About the app

- About us
- Contact Us
- View Terms of Use
- Log Out function

Managing Your be.well™ Analyzer(s) From Your Mobile Smart Device

Tap “**Manage be.well™ Analyzers**” in the be.well™ Mobile App menu to:

Check the battery level of a be.well™ Analyzer

When in the “**Manage be.well™ Analyzer**” screen, all paired be.well™ Analyzers will be listed.

To see the battery level of any device, ensure the be.well™ Analyzer is turned on (LED Indicator Lights are on) and connected to the be.well™ Mobile App. Once connected, the battery level will be displayed.

You can also check the battery level of the be.well™ Analyzer after successfully connecting with your mobile smart device when starting a new test. On the “Success!” page, the paired be.well™ Analyzer will appear on the screen, with the battery level shown on the left side of the marker.

Connect Additional be.well™ Analyzers to Your Mobile Smart Device

There are two ways to connect an additional be.well™ Analyzer with your mobile smart device:

1. Start a new test (see “Pairing Your be.well™ Analyzer With Your Mobile Smart Device” in Chapter 4)
2. Add additional be.well™ Analyzers via the “**Manage be.well™ Analyzers**” menu tab by tapping “+ **Add a New be.well™ Analyzer**” and follow the instructions to connect the new device as you would when starting a new test.

NOTE: If your mobile smart device is unable to locate your be.well™ Analyzer, it’s possible that the be.well™ Analyzer is out of Bluetooth® range of your mobile smart device, its battery is depleted, or it has fallen asleep. See “Chapter 8: Troubleshooting” for more information.

Edit the Name That Appears for Your be.well™ Analyzer

In the “**Manage be.well™ Analyzers**” menu tab, tap on the be.well™ Analyzer you wish to name, then tap “**Edit Name**”. Enter a new name for the be.well™ Analyzer selected, then tap “**Save**”.

Check the Unique Device Identifier (UDI) of a Connected be.well™ Analyzer

Tap the be.well™ Analyzer icon in the “**Manage be.well™ Analyzers**” menu tab to view the selected be.well™ Analyzer’s information, including the UDI.

You can also view the be.well™ Analyzer’s UDI from the “**Success!**” pairing screen. Tap the be.well™ Analyzer you connected with to view information.

Disconnect Your be.well™ Analyzer From Your Mobile Smart Device

In the “**Manage be.well™ Analyzers**” menu tab, tap the be.well™ Analyzer you wish to disconnect, then tap “**Forget This be.well™ Analyzer**”.

Retrieving a Forgotten Password

If you forgot your password, open the be.well™ Mobile App on your mobile smart device and tap “**Forgot Password**” on the log in screen. Then enter your email address and tap “**Send Email**”. A temporary password to use to log in will be emailed to you. After logging in, you will be instructed to change your password. Tap “**Save Changes**” and then log in with your new password.

Accessing Product Documentation

You may access a digital copy of this be.well™ Analyzer User Manual and other related documents via the “**Documentation**” option in the be.well™ Mobile App menu.

Tap on “**View Terms of Use**” in the be.well™ Mobile App menu to view the Terms of Use and Privacy Policy.

Chapter 6: Cleaning and Disinfecting the be.well™ System

At the end of each test or if the be.well™ Analyzer becomes dirty, clean the outside surface and visible part of the be.well™ Analyzer Port and allow to air dry.

Disinfectants that have been validated and are acceptable for use on the be.well™ Analyzer include:

- Commercial bleach (10%)
- Hand sanitizer (>60% ethanol)
- Isopropyl alcohol (70%)
- Hydrogen peroxide (3%)

Note: Do not use products containing quaternary ammonium compounds.



Caution:

- *Do not place the be.well™ Analyzer in water or other liquids. If part of your device becomes wet, wipe off all moisture and allow sufficient time for drying before use.*
- *Do not spray solution or insert anything into the be.well™ Analyzer Port.*

Chapter 7: Technical Information and Specifications

be.well™ Analyzer Technical Specifications

Power Supply	Input: 90 ~ 264 VAC, 47 ~ 63Hz Output: 5VDC, 1A, 5W
Dimensions	130.25 mm x 65 mm x 21.20 mm
Weight	174 grams

Operational Conditions		15°C - 30°C, uncontrolled relative humidity, non-condensing
Storage and Shipping Conditions		15°C - 30°C, uncontrolled relative humidity
Operational Altitude		0 m (0 ft) - 2000 m (6561 ft)
Storage Altitude		0 m (0 ft) - 2000 m (6561 ft)

Note: For test-specific be.well™ Cartridge technical specifications, refer to the respective Instructions for Use (IFU).

Compliance With International Standards

The be.well™ Analyzer has been tested to the following standards:

- IEC 60101-1-2 (ED. 4.1) - 2014 +
- AMD1:2020
- EN 61326-1:2013
- FCC Part 15 Subpart B
- IEC/EN 61010-1, 3rd edition

Electromagnetic (EMC) and Electrical Safety Testing

Electromagnetic Compatibility of the be.well™ system (Battery Mode) tested to: EN/IEC 60601-1-2:2015
Electromagnetic Compatibility of the be.well™ system (AC Charge Mode) tested to: EN/IEC 60601-1-2:2015 – 2014+AMD1:2020
Electromagnetic Compatibility of the be.well™ system tested to: EN 61326-1:2013
Electromagnetic Compatibility of the be.well system tested to: ETSI EN 301 489-1 with ETSI EN 301 489-17 (Article 3.1(b) of R&TTE Directive)
Electromagnetic Compatibility of the be.well system tested to: FCC Part 15 Subpart B Innovation, Science, and Economic Development (ISED) Canada ICES-003 Issue 7
Environmental Simulation tested to: IEC 60529, Edition 2.2 – 2013-08
Compliant to IEC 61010-1:2010, Third Edition, AMD1:2016, and EN 61010-1:2010, Third Edition, +A1:2019, Safety requirements for electrical equipment for Measurement, Control and Laboratory Use, Part 1; IEC 61010-2-010:2019, Fourth Edition, and EN 61010-2-010, Fourth Edition, Part 2-010: Particular requirements for laboratory equipment for the heating of materials; IEC 61010-2-101:2018, Third Edition, and EN 61010-2-101:2018, Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

**MET Mark Certification
Safety Standards**

- UL61010-1/CSA22.2 No. 61010-1 Third Edition: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use -Part 1: General Requirements
- UL61010-2-010/CSA22.2 No. 61010-2-010, Fourth Edition: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use -Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Materials
- UL61010-2-101/CSA22.2 No. 61010-2-101, Third Edition: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use -Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment

Wireless compliance of the be.well system tested to:
ETSI EN 300328 for Intentional Radiators

EMC Wireless compliance of the be.well system tested to:
Title 47 of the CFR, Ch. 1 (10-1-06 ed.), Part 15 Subpart C for Intentional Radiators

RF Exposure compliance of the be.well system tested to:
RSS-102 Issue 5 (2015-03) IEEE C95.3 -2002

RF Exposure compliance of the be.well system tested to:
47 CFR FCC Part 2. 1093

Disposing of be.well™ System Components



Dispose of be.well™ System components according to applicable regulations and guidelines in your country or locality.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is

connected.

-Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

Chapter 8: Troubleshooting

The lights on your be.well™ Analyzer are not on:

- If the lights on your be.well™ Analyzer are not on, the battery may be depleted or the be.well™ Analyzer may have gone to sleep (occurs after 10 minutes of inactivity).
- To turn on the be.well™ Analyzer, press the power button located next to the charging port on the end of the be.well™ Analyzer. If no lights flash, plug in the be.well™ Analyzer to charge.

How to reset the be.well™ Analyzer:

- Press and hold the power button next to the charging port on the end of the be.well™ Analyzer for approximately 10 seconds and release. The lights should flash and then turn back on.

The be.well™ Analyzer and mobile smart device will not pair:

- Ensure the mobile smart device's Bluetooth® is on and within range of the be.well™ Analyzer.
- Ensure the be.well™ Analyzer is powered on, charged, and ready to pair (indicator lights flashing blue).
 - If the lights are solid blue, it means the be.well™ Analyzer is already paired with a nearby mobile smart device. Follow the steps in the section "Unpair Your be.well™ Analyzer From Your Mobile Smart Device" in Chapter 5 to "Forget" all devices.
 - If no LED Indicator Lights are on, press the power button on the end of the be.well™ Analyzer and release. If the lights do not turn on, plug your be.well™ Analyzer in to charge.

Battery too low to run a test:

- The be.well™ Analyzer must have at least 34% battery to run a test. The be.well™ Mobile App will give you a notification informing you that your battery is too low and will not allow you to run the test.
- You will know the battery is sufficiently charged (enough to run a test) because the LED Indicator Lights will be blue. The lights will turn yellow when the battery percentage drops below 34%.
- To maintain charge, you can keep the be.well™ Analyzer plugged in when not in use.
NOTE: It may take up to 75 minutes to regain charge from a fully depleted battery.

Resolving Red Light Error State:

- A Red Light Error State occurs when there is an error with any part of the be.well™ System. A notification will appear in the be.well™ Mobile App and the be.well™ Analyzer LED Indicator Lights will turn red.
- To resolve:

- Remove the be.well™ Cartridge from the be.well™ Analyzer if one is inserted.
- Reset the be.well™ Analyzer (see above) up to three times until the red lights revert back to blue.
- **If the lights remain red after the third reset:**
 - Go into settings and forget the be.well™ Analyzer (see “Disconnect Your be.well™ Analyzer From Your Mobile Smart Device” in Chapter 5).
 - If the red lights still appear, re-pair your mobile smart device and be.well™ Analyzer (see “Connect Additional be.well™ Analyzers to Your Mobile Smart Device” in Chapter 5). The lights should resolve once paired again. If they do not, contact Alveo Customer Support.

Notifications when Using the be.well™ Mobile App

Notification	Description of Issue	Solution
Please ensure that your be.well™ Analyzer is turned on and not connected to another phone	User cannot connect with be.well™ Analyzer.	Make sure be.well™ Analyzer lights are on and check that the be.well™ Mobile App is connected to the right be.well™ Analyzer by going to “ Manage be.well™ Analyzers ” in the app.
be.well™ Analyzer not working	be.well™ Analyzer is not powering on or responding.	Charge the be.well™ Analyzer.
Please check that the blue lights on the be.well™ Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth® settings and Forget the be.well™ device(s)	Unsuccessful pairing.	Check that the blue lights on the be.well™ Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth® settings and “ Forget ” the be.well™ device(s) and pair again.
Please check your internet connection and try again	No internet service.	Check Wi-Fi® or cellular service connection, turn off and turn on to reconnect and try again.
Please try again after some time. Contact issues@alveotechnologies.com if this issue persists.	Error persists after multiple login attempts.	Check Bluetooth® connections, confirm that be.well™ Analyzer is turned on and mobile device is paired with the correct be.well™ Analyzer, then try again.
This be.well™ Mobile App requires location services to be enabled in order to scan for Bluetooth® devices and connect to the be.well™ Analyzer.	Location service may be disabled.	Go to settings on mobile device and enable location services.
This be.well™ Mobile App requires the location permission to be provided in order to scan for Bluetooth® devices and connect to the be.well™ Analyzer.	Location permission not authorized by user.	Go to settings on mobile device and enable location services.
This be.well™ Mobile App requires Bluetooth® permission to	Bluetooth® permission has not been authorized.	Go to settings on mobile device and enable Bluetooth® services.

be provided in order to communicate with the be.well™ Analyzer.		
Patient ID is required * is shown below the Patient ID field	No Patient ID entered.	Enter Patient ID.
Invalid Email * is shown below the Email ID field	Invalid email ID entered.	Enter correct email ID.
Please check your e-mail for the validation message and click the link before logging in.	User tries to login before authenticating via email.	Refer to the email received and click on the confirmation link to login.
Passwords do not match *	Password entered does not match password entered in the "confirm password" field.	Check the password entered in both fields to confirm that they match.
Your test could not finish. The be.well™ Cartridge was removed before the test was finished.	User removes be.well™ Cartridge before the test is completed.	Collect patient sample and run another test according to the instructions.
Scan failed: expired be.well™ Cartridge	Expired be.well™ Cartridge scanned.	Use a new be.well™ Cartridge that is not expired and restart the test.
Scan failed: Invalid QR/Barcode	User scans an invalid QR code or barcode.	Scan the correct QR on the be.well™ Cartridge.
Your test cannot be run. The be.well™ Cartridge was loaded without scanning a barcode first. Get a new be.well™ Cartridge and follow the steps in the be.well™ Mobile App. The barcode tells the be.well™ Analyzer what kind of test to run.	be.well™ Cartridge not scanned before loading into the be.well™ Analyzer.	Follow the instructions and scan the be.well™ Cartridge before starting the test. If be.well™ Cartridge was inserted, get a new be.well™ Cartridge and follow the instructions for running a test.
Wrong bar code. Please scan the bar code on the be.well™ Cartridge label or the be.well™ Cartridge packaging.	Wrong barcode is scanned.	Scan the correct QR code on the be.well™ Cartridge.
Test failed: System error Your test could not finish. There was a system error and your test results were lost. Please get a new be.well™ Cartridge and start your test again.	Test fails while running.	Remove the be.well™ Cartridge from the be.well™ Analyzer, get a new be.well™ Cartridge, collect patient sample and restart the test.
Scan failed: used be.well™ Cartridge. Your be.well™ Cartridge has already been used for a test. Please get a new be.well™ Cartridge and start over.	Used be.well™ Cartridge inserted into the be.well™ Analyzer.	Insert a new be.well™ Cartridge that has not been used and restart the test.
Your be.well™ Cartridge is expired. Please get a new be.well™ Cartridge and start over.	Expired be.well™ Cartridge inserted into the be.well™ Analyzer.	Get a new be.well™ Cartridge that is not expired and restart the test.

Phone storage full. You do not have enough storage to use the be.well™ Mobil App. Free up space by deleting unneeded apps, videos or music.	Mobile device storage space is full.	Check to make sure there is enough storage on the mobile device for the test to run. If necessary, delete unneeded videos, apps, music or photos and then start the test.
Cannot add be.well™ Analyzer. You cannot add a new be.well™ Analyzer while running a test. Please wait for the test to complete.	User tries to add another be.well™ Analyzer while there is a test in progress.	Wait for the test to complete and then add the desired be.well™ Analyzer.
Test failed: be.well™ Cartridge removed	Test be.well™ Cartridge removed while test is in progress.	Do not remove the be.well™ Cartridge while testing is in progress; this will lead to loss of data and results. If be.well™ Cartridge is removed accidentally, get a new be.well™ Cartridge, patient sample and start a new test.
Please remove the be.well™ Cartridge from the be.well™ Analyzer before you start a new test.	User attempts to start a new test with a be.well™ Cartridge already inserted.	Remove the be.well™ Cartridge from the be.well™ Analyzer port, then scan the new be.well™ Cartridge and start the test.
Another test is running on this be.well™ Analyzer. Please wait for it to complete.	User tries to start another test while a test is in progress.	Wait for the current test to complete before starting a new test.
There has been an error in configuring your be.well™ Analyzer. Please ensure you are within 3 feet of the be.well™ Analyzer and try again.	User sees an error while configuring the be.well™ Analyzer.	Make sure that the be.well™ Analyzer is close to the mobile device and try again to start the test. Also check that the mobile device is paired with the correct be.well™ Analyzer. If this doesn't resolve the issue, restart the be.well™ Analyzer by pressing the button on top of the be.well™ Analyzer for 5 seconds and then reattempt to start the test again.
The be.well™ Analyzer you are trying to connect to is being used by someone else. Do you still want to connect?	Another user tries to connect with a be.well™ Analyzer on which testing is already in progress.	Choose "Yes" or "No" and follow the on-screen prompts. Check that you are connecting to the correct be.well™ Analyzer, not one that is already in use. Note: Connecting to a be.well™ Analyzer on which testing is in-progress will interrupt the test in-progress and result in a system error that will end the test in-progress.
Your room is too hot to run a test. Please move the be.well™ Analyzer to a cooler place so the test can run.	Room temperature is too hot to run a test.	Move the be.well™ Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended

		temperature range, wait for the be.well™ Analyzer to cool down and then start the test.
Your room is too cold to run a test. Please move the be.well™ Analyzer to a cooler place so the test can run.	Room temperature is too cold to run a test.	Move the be.well™ Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended temperature range, wait for the be.well™ Analyzer to achieve normal temperature and then start the test.

Chapter 9: Limited Warranty and Supplies

Limited Warranty

Alveo Technologies Inc. warrants your new be.well™ Analyzer will be free from defects in materials and workmanship for a period of one (1) year from the date of the original purchase. If during this time the be.well™ Analyzer does not work properly because of a defect in materials or workmanship, Alveo Technologies Inc. agrees to replace free of charge any and all parts proven to be defective and subject to warranty. This warranty only applies to the original purchaser of the be.well™ Analyzer and may not be transferred.

This Limited Warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by Alveo Technologies to perform such repairs.

Warranty is void on product sold, or resold, outside the country or region of original purchase.

Supplies

be.well™ System supplies are available by calling Alveo Technologies at (+1) 833-BE-WELL-o (+1 833-239-3550) or email Alveo Customer Support at support@alveotechnologies.com.

NOTE: be.well™ Analyzer and be.well™ Test Kit sold separately.

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For In Vitro Diagnostic Use



Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium



Alveo Technologies, Inc.
1000 Atlantic Ave, Suite 114
Alameda, CA 94501, USA
alveotechnologies.com

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