ALVEO
TECHNOLOGIES, Inc.

Alveo Analyzer

User Manual

REF A-FIN-000039 Alveo Analyzer

For use with the
Alveo Sense Mobile App

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 +1 833-239-3550.

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Chapter 1:
General Information

Welcome to Alveo's System

The Alveo System is a rapid molecular testing system for performing diagnostic 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 Analyzer with the System, which consists of:

Alveo Analyzer


Cartridge Test Kit

(Sample collection and preparation materials may vary by test type and are not pictured below.)



Alveo Sense Mobile App

Alveo Sense

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 +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 System correctly and safely.



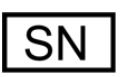
Caution:
A Caution message provides information to prevent damage to your Alveo System.

Note:
A note provides additional information to make the instructions clearer.

Within this document, procedural steps that apply to the Mobile App are **bolded**, sequentially numbered and should be performed in the order reflected.

Symbols Guide

The following symbols may be found on Alveo product packaging and labeling:

	Manufacturer
	Date of manufacture
	Consult instructions for use
	CE mark of conformity
	Customer support
	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 Alveo System

Before beginning a test, review this User Manual to help properly set up the Alveo System (or "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 Alveo Analyzer is an instrument that accepts test-specific Cartridges and executes nucleic acid amplification and detection of analytes according to assay definitions associated with the inserted Cartridge. The Alveo Analyzer is designed for use with Alveo's Cartridges, allowing users to run specific tests on the platform using pre-defined assays.

System Description

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

The Analyzer is a standalone instrument that is capable of running Cartridges from the Test Kits. The 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, Canceled) on the screen of the user's mobile smart device, and are saved to the registered user's Alveo Sense Account. Descriptions of each of the System components are included in Chapter 2.

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

Storage and Handling Conditions



Use all System components within a temperature range of 15-30 °C (59-86 °F).

Store the Analyzer between 15-30 °C (59-86 °F).

Note: For more information on storing and operating the Analyzer, see "Chapter 7: Technical Information and Specifications".

General Warnings & Precautions

- Always operate the Analyzer on a stable, flat, and level surface while running a test. Do not move or tilt the Analyzer while a test is in progress.
- Operation of the System should occur at the temperature ranges referenced in this User Manual and the respective 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 Cartridge Test Kits for applicable precautions and guidance.

- Do not insert anything into the Analyzer port other than Test Cartridges and only when prompted by the Alveo Sense Mobile App.
- Do not use any damaged or opened System components.
- If the Analyzer gets wet, immediately wipe the outside of the Analyzer and the opening of the Analyzer port with a clean paper towel or cloth and leave to dry.
- Do not immerse the Analyzer in water or cleaning solutions. Unplug the Analyzer before cleaning and clean only as indicated in this User Manual.
- Store all 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 Cartridge that is inserted into the Analyzer.

- Making changes to any of the parts of your System or using any parts that did not come with the System may cause harm to yourself or the System, and will also void your warranty.
- Charge the Analyzer before using the device after being stored for long periods.
- **For the purpose of security and data privacy, the mobile device used must not be rooted or jailbroken. Use of a rooted or jailbroken mobile device is a violation of the end-user software license agreement.**

Chapter 2: System Overview and Features

The Alveo System consists of:

- Alveo Analyzer
- Cartridge Test Kit
- Alveo Sense Mobile App

Descriptions of each System component are included below.

NOTE: Analyzer and Test Kits sold separately.

Alveo Analyzer

The Analyzer is a stand-alone instrument that is required to run Cartridges. The Analyzer communicates with the Alveo Sense Mobile App via Bluetooth and also interfaces with test-specific Cartridges that are directly inserted into the Analyzer port.

Each Analyzer package includes the following components:

- One (1) Alveo Analyzer
- One (1) USB charging cable
- Two (2) power adapters (pre-assembled)

Cartridge Test Kit

Cartridge Test Kits contain the components and materials needed to run a pre-defined diagnostic test. Cartridges included in each Test Kit are inserted into the Analyzer port when directed by the Mobile App and should be used before their expiration date. Test Kit contents vary based on the specific product type.

Alveo Sense Mobile App

The Alveo Sense Mobile App (or Mobile App) is a software application that runs on a compatible mobile smart device, providing the user interface to the Analyzer, retrieving test-specific information for the inserted Cartridge, viewing of results, and retrieval of results from a secured, cloud-based database.

The Mobile App communicates with to the Analyzer via Bluetooth. An Account is required to run a test and to 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 Account in a secure cloud-based database.

The "Alveo Sense" Mobile App is available for download onto a mobile device.

System requirements for the Alveo Sense Mobile App:

iOS™ 15.0 and later
Android 13.0 and later

Chapter 3: Alveo System Set Up

Unpacking the Alveo Analyzer

Inspect the packaging for obvious damage prior to opening. Unpack the contents, placing the 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 Alveo Analyzer

Figures 1, 2 and 3 identify the components of the Alveo Analyzer.

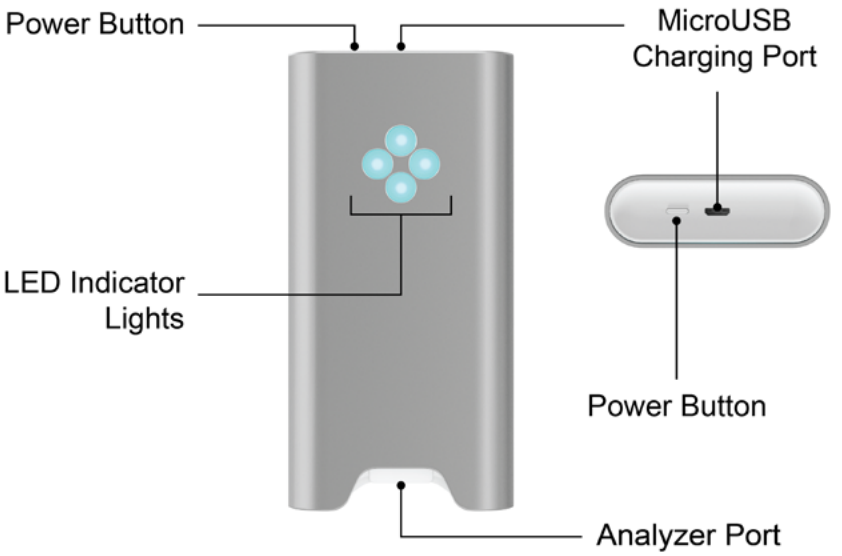
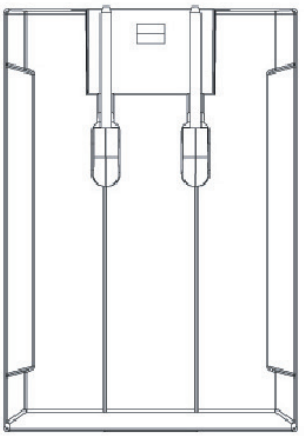


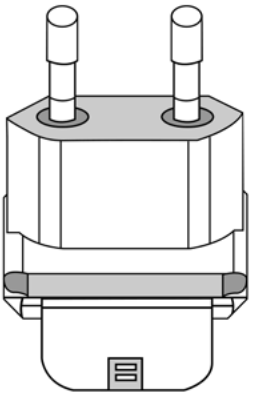
Figure 1. View of Analyzer face (front) and locations of power button, USB charging port and Analyzer port.

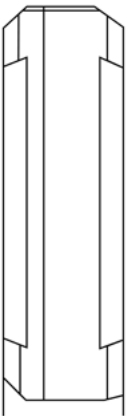


Figure 2. View of Analyzer back and associated device label.

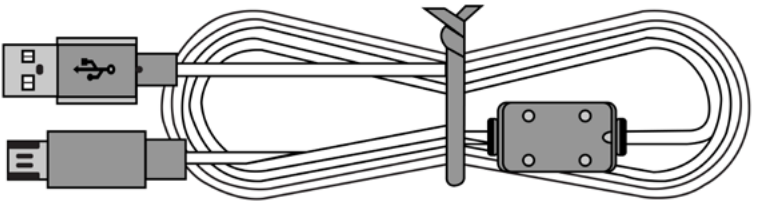


US ADAPTER





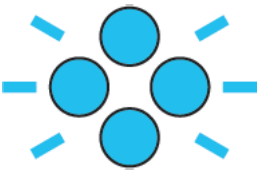
EU + US ADAPTER



USB CHARGING CABLE

Figure 3. View of US power adapter, EU power adapter (couples with US adapter and is pre-assembled), and USB charging cable. Power adapter included with kit may vary by region.

LED Indicator Lights on the Analyzer



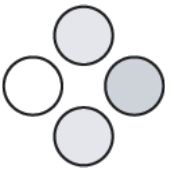
Blinking Blue lights indicate that the Analyzer is sufficiently charged and is ready to pair with a mobile device.



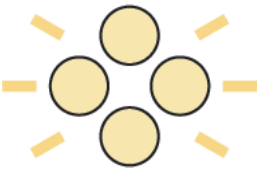
Solid Blue lights indicate that the Analyzer is paired with a mobile device and is ready to run a test.



Spinning Blue lights indicate that a test is in progress.



Spinning White lights indicate that a test is in progress, but the connection between the Analyzer and app is inactive because the app is closed or out of Bluetooth® range.



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



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



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 Analyzer



Caution:

- *Place and operate the Analyzer on a stable, flat, and level surface while running a test.*
- *Do not move or tilt the* Analyzer *while a test is in progress.*
- *Do not place the* Analyzer *in a location that is subject to vibrations, such as near machines that vibrate, shake or spin.*
- *Do not place the* 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* Analyzer *near a source of electromagnetic interference.*

Charging the Analyzer

Charge the Analyzer battery by plugging the respective ends of the Micro USB charging cable into the charging port on the end of the 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 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 Analyzer is left inactive for 10 minutes, it will go into a power save mode and turn off its LED Indicator Lights. To turn the 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 Analyzer in to charge as it likely has a depleted battery.



Caution: Only use the charging cable provided with the Analyzer.

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

Downloading and Installing the Mobile App

Download the Alveo Sense Mobile App onto the mobile smart device (*internet connectivity required*).

To download the Alveo Sense Mobile App:

1. Turn on the mobile smart device.
2. Confirm the mobile smart device has internet connectivity.

3. Search for and download "**Alveo Sense**" on the mobile smart device.
4. Follow the mobile smart device's prompts to install.

The Alveo Sense app is supported on iPhone iOS 15 and above and Android OS 13 and above. Certain features may be limited or unavailable on devices running on iOS 14 and below and Android OS 12 and below. Compatibility with other devices or OS versions is not guaranteed. Bluetooth must be enabled to pair the analyzer.

NOTES:The Alveo Sense Mobile App needs to be installed on each mobile smart device intended for use.
Refer to the respective test-specific Cartridge Instructions for Use (IFU) and Quick Reference Instructions (QRI), which include visual aids and instructions for many of the soft-ware-related steps and procedures described in this user manual.

Creating and Registering an Account in the Alveo Sense Mobile App

Users must create an Account via the Mobile App before running a test. To do so:

1. After installing the Mobile App on your mobile smart device, **tap the icon to open the app**.
2. Tap "**Register.**"
3. **Enter the user information to create an Account, then tap "Confirm Information."**
4. **Read the Terms of Use, including the Privacy Policy,** scroll to the end and tap "**I agree.**"
5. **Check 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 spam folder.

6. Once you receive the “Registration Successful!” notice on the Alveo Technologies account set up page, **Tap “Log In” in the Alveo Sense Mobile App, enter email address and password, and tap “Log In” again to land on the home page**.

NOTE: To delete your account, please contact Alveo Customer Support at (+1 833-239-3550) or support@alveotechnologies.com.

Logging in to Your Account on the Alveo Sense Mobile App

If you have already created your Account, log in as follows:

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

Review Cartridge Test Kit Materials & Instructions

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

Power On

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

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

Pairing the Analyzer With a Mobile Smart Device

Pair the Analyzer via Bluetooth with the mobile smart device. Instructions to connect the Analyzer will display on-screen after you tap “**Start a New Test**” and enter location and testing details. Next, tap **"+Pair New Analyzer,"** then **"Begin Pairing,"** then select the Analyzer to pair for testing.

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

Check that the Analyzer serial number that is displayed on the “Pairing Successful!” screen matches the serial number and lot number on the back of the Analyzer. If you wish to pair a different Analyzer, tap the back arrow, then tap **"+Pair New Analyzer"** at the bottom of the screen and follow the instructions.

Tap “**Next**” when connected with the

intended Analyzer.

The Mobile App will notify you at this step if your Analyzer requires an update. Follow the prompts to update your 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 Analyzer will still run to completion. View the test result by logging back into the Mobile App once the mobile smart device is charged or reconnected to the Analyzer via* Bluetooth*.*

Sample Collection & Insertion of Cartridge into Analyzer Port

Follow the test-specific instructions on how to collect and prepare the sample(s) and insert the Cartridge into the Analyzer.

View Test Results

Test results are displayed (e.g. Positive, Negative, Invalid,

Canceled) on the screen of the user's mobile smart device and are saved to the registered user's Account.

Understanding Invalid Results

Invalid test results may be reported if:

- An insufficient amount of sample was collected.
- Test Kit components were used after their expiration date.
- Test Kit components were not stored in temperatures or conditions indicated in the respective test kit's Instructions for Use.
- 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 Analyzer was moved or tilted during testing.
- The Analyzer or Test Kit components are damaged.

- The instructions found in the test-specific Instructions For Use (IFU) were not correctly followed.

Alveo Sense Mobile App Menu

To access your Account menu, launch the Alveo Sense Mobile App on your mobile smart device. Then:

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

Managing Analyzer(s) From Your Mobile Smart Device

Tap “**Manage Analyzers**” in the Mobile App menu to:

Check the battery level of an Analyzer

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

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

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

Connect a New Alveo Analyzer to A Mobile Smart Device

There are two ways to connect a new Analyzer with your mobile smart device:

1. Start a new test (see “Pairing Your Analyzer With Your Mobile Smart Device” in Chapter 4).
2. Add up to 6 Analyzers on a single Mobile Device via the “**Manage Analyzers**” menu tab by tapping “**+ Pair New Analyzer**” and follow the instructions to connect the new device.

NOTE: If the mobile smart device is unable to locate your Analyzer, it’s possible that the Analyzer is out of Bluetooth range of the 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 the Alveo Analyzer

In the "**Manage Analyzers**" menu tab, tap on the Analyzer you wish to name, then tap "**Edit Name**" and enter preferred name for Analyzer.

Check the Product Specific Detailed Information of a Connected Analyzer

Tap the Analyzer icon in the "**Manage Analyzers**" menu tab to view the selected Analyzer's information, including the Serial Number, Lot Number, and UDI.

Disconnect Your Analyzer From A Mobile Smart Device

In the "**Manage Analyzers**" menu tab, tap the Analyzer you wish to disconnect, then tap "**Forget this Analyzer.**"

Retrieving a Forgotten Password

If you forgot your password, open

the 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

A digital copy of the Instructions for Use (IFU) and other related documents may be accessed via the “**Documentation**” option in the Mobile App menu.

Tap “**View Terms of Use**” in the Mobile App menu to view the Software License Agreement.

Chapter 6: Cleaning and Disinfecting the Alveo System

At the end of each test or if the Analyzer becomes dirty, clean the outside surface and visible part of the Analyzer port and allow to air dry. Do not spray cleaning or disinfectant directly on the Analyzer. Use external wipe for disinfecting external components of the Analyzer.

Disinfectants that have been validated and are acceptable for use on the 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 Analyzer in water or other liquids. If part of the analyzer becomes wet, wipe off all moisture and allow sufficient time for drying before use.*
- *Do not spray solution or insert anything into the Analyzer port.*

Chapter 7: Technical Information and Specifications

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 Cartridge technical specifications, refer to the respective Instructions for Use (IFU).

Compliance With International Standards

The Alveo 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 system (Battery Mode) tested to: EN/IEC 60601-1-2:2015
Electromagnetic Compatibility of the system (AC Charge Mode) tested to: EN/IEC 60601-1-2:2015 – 2014+AMD1:2020
Electromagnetic Compatibility of the system tested to: EN 61326-1:2013
Electromagnetic Compatibility of the 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 Alveo 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 Alveo system tested to: ETSI EN 300328 for Intentional Radiators
EMC Wireless compliance of the 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 Alveo 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 Alveo System Components



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

The lights on the Analyzer are not on:

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

How to reset the Analyzer:

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

The Analyzer and mobile smart device will not pair:

- Ensure the mobile smart device's Bluetooth is on and within range

of the Analyzer.

- Ensure the Analyzer is powered on, charged, and ready to pair (indicator lights flashing blue).
    - If the lights are solid blue, it means the Analyzer is already paired with a nearby mobile smart device. Follow the steps in the section “Unpair 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 Analyzer and release. If the lights do not turn on, plug your Analyzer in to charge.

Battery too low to run a test:

- The Analyzer must have at least 34% battery to run a test. The Mobile App will provide a notification that the battery is too low to run a test.
- When the battery is sufficiently charged enough to run a test, the

LED Indicator Lights will be blue. The lights will turn yellow when the battery percentage drops below 34%.

- To maintain charge, the Analyzer may remain 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 Alveo System. A notification will appear in the Alveo Sense Mobile App and the Analyzer LED Indicator Lights will turn red.
- To resolve:
  - Remove Cartridge from the Analyzer if one is inserted.
  - Reset the Analyzer (see above) up to three times until the red lights revert back to blue.

- OR: Go to Mobile App menu and tap Manage Analyzers. Tap on the analyzer with the error, then tap "Clear error". Alternatively, start new test. Proceed to the Manage Analyzer screen. Tap the analyzer with the error, tap "Clear error", and then continue by tapping "Next".

- **If the lights remain red after resetting and attempting to clear in the Mobile App:**
  - Go into settings and forget the Analyzer (see “Disconnect Analyzer From Your Mobile Smart Device” in Chapter 5).
  - If the red lights still appear, re-pair your mobile smart device and Analyzer (see “Connect a New Alveo Analyzer to A 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 Alveo Sense Mobile App

Analyzer not detected
⚠ **Please ensure that your Analyzer is turned on and not connected to another phone.** User cannot connect with Analyzer.
Make sure Analyzer lights are on and check that the Mobile App is connected to the right Analyzer by going to “**Manage Analyzers**” in the app.

Application update needed
⚠ **The Alveo Sense app must be updated before you can continue.** A newer version of the Mobile App has been released.
Click "Ok" to clear the notification, then go to the App Store to update the “Alveo Sense” Mobile App.

Invalid credentials
⚠ **Please, check your e-mail address and password and try again. You may use the “Forgot password” option to request a new password.** Login credentials are invalid.
For an existing Alveo Sense account, enter a valid e-mail address and password, or request a new password. If you do not have an account, create and register an account (see Chapter 3).

Maintenance mode
⚠ **System is under maintenance for next {number} minutes, please try login again.** Maintenance is being performed on the System.
Please wait until the time has passed, then try to log in again.

Update failed
⚠ **The software on the Analyzer failed to update. Please reset your Analyzer and try again.** The update failed to download or install.
Reset the Analyzer (see Chapter 8), then follow the prompts to update the analyzer when they appear in the Alveo Sense Mobile App.

Pairing failed
⚠ **Please check that the blue lights on the Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth settings and forget the device(s).** Unsuccessful pairing.
Check that the blue lights on the Analyzer are flashing and try pairing again. If this problem persists, go to the phone's Bluetooth settings and "Forget" the device(s) and pair again.

Network error
⚠ **Please check your internet connection and try again.** No internet service.
Check WiFi or cellular service connection, turn off and turn on to reconnect and try again.

Location services
⚠ **This app requires location services to be enabled in order to scan for Bluetooth devices and connect to the Alveo Analyzer.** **Turn on Location services to continue.** Location permission not authorized by user.
Go to settings on mobile device and enable location services.

Location permission
⚠ **This app requires the location permission to be provided in order to scan for Bluetooth devices and connect to the Alveo Analyzer.** Location permission not authorized by user.
Go to settings on mobile device and enable location services.

Bluetooth permission
⚠ **This app requires Bluetooth permission to be provided in order to communicate with the Alveo Analyzer.** Bluetooth permission has not been authorized.
Go to settings on mobile device and enable Bluetooth services.

Bluetooth services
⚠ **This app requires Bluetooth to be enabled in order to communicate with the Analyzer. Turn on Bluetooth to continue.** Bluetooth permission has not been authorized.
Go to settings on mobile device and enable Bluetooth services.

⚠ **This field is required* is shown below a field.** A required field is not entered.
Enter required field.

⚠ **"Please, enter a valid email address" is shown below the Email ID field.** Invalid email ID entered.
Enter correct email ID.

Please check e-mail
⚠ **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 must 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.

⚠ **Password must satisfy the conditions below.**
Conditions for the password are not met.
Enter a password that meets the conditions.

Test failed: Cartridge removed
⚠ **Your test could not finish. The cartridge was removed before the test was finished.** User removes Cartridge before the test is completed.
Collect sample and run another test according to the instructions.

Scan failed: Expired cartridge
⚠ **Your cartridge is expired Please get a new cartridge and start over.** Expired Cartridge scanned.
Use a new Cartridge that is not expired and restart the test.

Scan failed: Invalid QR/Barcode
⚠ **Wrong bar code. Please scan the bar code on the cartridge label or the cartridge packaging.** User scans an invalid QR code or barcode.
Scan the correct QR code on the Cartridge.

Test failed: Unscanned cartridge
⚠ **Your test cannot be run. The cartridge was loaded without scanning a barcode first.** **Get a new Cartridge and follow the steps in the app for scanning the Cartridge.** Cartridge not scanned before loading into the Analyzer.
Follow the instructions and scan the Cartridge before starting the test. If Cartridge was inserted, get a new Cartridge and follow the instructions for running a test.

Test failed: System error
⚠ **Your test could not finish. There was a system error and your test results were lost. Please get a new cartridge and start your test again.** Test fails while running.
Remove the Cartridge from the Analyzer, get a new Cartridge, collect patient sample and restart the test.

Scan failed: Used cartridge
⚠ **Your cartridge has already been used for a test. Please get a new cartridge and start over.** Used Cartridge inserted into the Analyzer.
Insert a new Cartridge that has not been used and restart the test.

Phone storage full
⚠ **You do not have enough storage to use the Alveo Sense app.** 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, free up space by deleting content you no longer use.

Remove cartridge
⚠ **Please remove the cartridge from the Analyzer before you start a new test.** User attempts to start a new test with a Cartridge already inserted.
Remove the Cartridge from the Analyzer port, then scan the new Cartridge and start the test.

Test in Progress
⚠ **A test is in progress on this Analyzer. Please wait for test 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.

Communication failure
There has been an error in configuring your Analyzer. Please ensure you are within 3 feet of the Analyzer and try again. User sees an error while configuring the Analyzer
Make sure that the 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 Analyzer. If this doesn't resolve the issue, restart the Analyzer by pressing the button on top of the Analyzer for 5 seconds and then attempt to start the test again.

Operation Timeout
Cartridge insertion has timed out. Please restart the test. User is informed the time to insert the cartridge to start the test has expired
Make sure to initiate test on the Mobile App at the time of sampling and sample preparation, not in advance.

Too hot to run test
⚠ **Your room is too hot to run a test. Please move the Analyzer to a cooler place so the test can run.** Room temperature is too hot to run a test.
Move the Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended temperature range, wait for the Analyzer to cool down and then start the test.

Too cold to run test
⚠ **Your room is too cold to run a test. Please move the Analyzer to a warmer place so the test can run.** Room temperature is too cold to run a test.
Move the Analyzer and mobile device to a room/location where the temperature is in accordance with the recommended temperature range, wait for the Analyzer to achieve normal temperature and then start the test.

Chapter 9: Limited Warranty and Supplies

Limited Warranty

Unless otherwise agreed upon in writing by Alveo, the Alveo Analyzer will be subject to the limited warranty as set forth in your applicable Terms of Sale and Software License.

Supplies

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

NOTE: Analyzer and Cartridge Test Kit sold separately.

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Product Descriptions

REF A-FIN-000039 Alveo Analyzer

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