

SCANBO® D8		
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User Manual		
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About this User Manual

This manual shows you how to safely set up and use Scanbo® D8 Device and its accessories. Users should read and understand the instructions and warnings in the manual before using the device. Users must follow the safety instructions in this manual and only use Scanbo® D8 as intended.

For any questions about the manual or product, contact customer support at care@scanbo.com. Understand the following symbols in the manual, labeling, and packaging before using the device:



WARNING – This warns of a potential situation that could cause death or serious injury.



Caution – This warns of potential minor injury or damage to the device or property. It alerts the user to avoid unsafe practices or take extra care.

1. Important Safety Information

1.1. Warnings



WARNING:

The user must operate Scanbo® D8 only after reading these instructions.



WARNING:

DO NOT use Scanbo® D8 for self-diagnosis or standalone diagnosis. Only a healthcare provider can diagnose medical conditions.



WARNING:

DO NOT make treatment decisions on your own. Always consult a healthcare professional.



WARNING:

Always consult a doctor if you have any questions or abnormal readings.



WARNING:

DO NOT use the device near electromagnetic interference or high-frequency surgical equipment.



WARNING:

DO NOT allow the device to contact strong acids or bases. This may affect accuracy and lifespan.



WARNING:

Keep the device away from open flame or excessive heat. This can damage the internal electrical components and battery.



WARNING:

DO NOT use the device during maintenance / charging mode.



WARNING:

DO NOT attempt to calibrate the device by yourself. The device comes fully calibrated. Please contact the Scanbo® for calibration. Calibration is recommended every **2 years**.



WARNING:

DO NOT disassemble, modify, repair or service the device by yourself. Contact Scanbo® if the device is damaged or malfunctions.



WARNING:

Stop using the device and contact customer service if performance changes.

**WARNING:**

DO NOT use unapproved accessories or cables. Use only Scanbo® accessories.

**WARNING:**

DO NOT use the device adjacent to or stacked with other equipment. If it must be, monitor the device to ensure it works properly.

**WARNING:**

Keep the meter and testing supplies out of reach of children and pets. The test strips, lancets, lancet protective covers, and the control solution vial cap, present choking hazards. Do not ingest or swallow any items.

**WARNING:**

Users need to adhere to Standard Precautions when handling or using the SAM. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.



Scanbo® D8 has NOT been validated in Pregnant patients, including pre-eclamptic conditions, for NIBP measurements.

1.2.

**Caution****Caution**

To avoid external disturbances, take measurements in a quiet environment

**Caution**

Only use the accessories supplied by Scanbo®. Using unauthorized accessories NOT specified for the device may damage it and affect the performance. See Section 11.3 to reorder consumables.

**Caution**

The expected service life of the device is 3 years. Contact Scanbo if your device has exceeded the service life.

**Caution**

This device is not for use in the ICU or the emergency room.

**Caution**

The Scanbo® 3.0 App works with devices that have Bluetooth® 4.0+, Android™ 10.0+, or iOS™ 15.0+. Check the mobile phone compatibility before installing.

**Caution**

DO NOT expose the device or accessories to extreme temperatures, humidity, sunlight, or dust. See Section 9 for storage, operation and transportation conditions.

1.3. Contraindications

DO NOT use the Scanbo D8 device:

1. In ICU and emergency room
2. If patient has implanted cardiac devices such as a pacemaker, an automated implantable cardioverter defibrillator, or artificial cardiac valves

1.4. Limitations

- The device works in the Hematocrit range of 10%-65%.
- NOT for diagnosis of or screening of diabetes mellitus.
- DO NOT use on patients with the following conditions – peripheral blood circulation disorders blood circulation, severe dehydration, hypotension, shock, peripheral vascular disease, critical illness, hypoxia, or hyperosmolar state. It may cause inaccurate results.
- NOT for people in a hyperglycemic-hyperosmolar state, with or without ketosis.
- NOT for persons undergoing Oxygen therapy.
- NOT for testing the glucose levels in neonates (children under 4 weeks).
- NOT for testing glucose levels in serum, plasma, arterial or venous blood samples
- NOT for testing glucose from sites other than samples drawn from the fingertip. NOT for Alternative Site Testing (AST)

1.5. Serious Incidents Reporting

If you experience any serious incident while using the device, please report it to Scanbo®. In addition, report it to your national authority.

2. Device Overview

2.1. Product Description

The Scanbo® D8 is a portable, handheld, spot checking device used to measure vital signs and blood glucose level. The device measures and displays Non-Invasive Blood Pressure, Pulse Rate, SpO₂, ECG, Heart Rate, Blood Glucose concentration and Body Temperature...

The measurement is performed by the Signal Acquisition Module (SAM) and the results are displayed on Scanbo 3.0 Mobile App. The SAM is connected to the mobile phone via Bluetooth for measuring the vitals. The measured vitals and patient information can also be displayed on a compatible web browser...

The content of Scanbo® D8 **package** is as follows:

Scanbo® D8 Signal Acquisition Module (SAM) × 1 User Manual/Quick Reference Guide × 1

Accessories as below:

- USB Cable × 1
- NIBP Cuff × 1
- Scanbo® 3.0 App (Installed on the iOS/Android device)

The SAM consists of the parts shown in the **Table 1** below:

Table 1. Signal Acquisition Module

Figure	Figure Description
	Top View - 1 1. SpO₂ Sensor: Located on the top of the device.

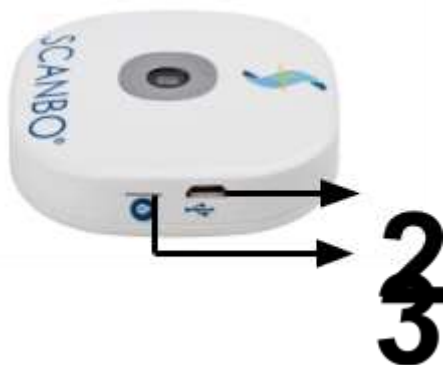
Figure	Figure Description
	Side View - 1 2. USB port: Used to charge the inbuilt battery with the provided USB cable. 3. Glucose strip port: Insert the glucose strip into this port to measure glucose levels.
	Side View - 2 4. Power Button: Used to power the device on and off. It has an LED indicator for battery charging and Bluetooth status.
	Side View - 3 5. Temperature sensor: Located on the front side to measure body temperature.

Figure	Figure Description
	Bottom View 6. NIBP Connector: Located on the back side of the device. It links to the BP cuff for non-invasive blood pressure measurements. 7. ECG Sensor: The bottom has a metal plate for ECG measurements

2.2. Indications for Use:

Scanbo® D8 is a handheld, reusable, and rechargeable device intended for measuring, displaying, and storing non-invasive blood pressure (NIBP), pulse rate (PR), functional oxygen saturation of arterial hemoglobin (SpO2), electrocardiograph (ECG), Heart Rate, and body temperature in adults. The device is intended for use by healthcare professionals and medical service providers in physician's office, endocrinology clinics, and nursing facilities

The blood oxygen measurement is intended for no motion condition.

The blood glucose monitoring function of Scanbo® D8 quantitatively measures glucose concentration in fresh capillary whole blood drawn from the fingertip. It is intended for point-of-care testing, outside the body (in vitro diagnostic use) in a physician's office, endocrinology clinics, and nursing facilities, for multiple patient use. The device is not intended for home use or testing alternative anatomical sites or for neonatal and pediatric use. It should also not be used for the diagnosis or screening of diabetes but is indicated for use in determining dysglycemia.

3. Power on/off

- **Power on** press and hold the power key on the SAM for 2 seconds in the power off state. The SAM vibrates and the LED blinks in blue indicating that the SAM is powered on. See Table 1 for the location of the LED.

Note: The light continues to blink in blue until it's paired with a smartphone.

- **Power off:** press and hold the power key on the SAM for 2 seconds in powered on state. The SAM vibrates and the LED turns off. This confirms that SAM is powered off.

Note: The SAM shuts down automatically when the device is idle for more than 3 minutes.

4. Set up and Use

4.1. Charging the device



Caution:

1. Use only USB power adapters meeting the requirements in Section 9.
2. Charge the device when the low battery warning appears in the Scanbo® 3.0 App.
3. Ensure the power light is blue and flashing while charging.
4. Ensure to check the developer of the app before installing.
5. The device cannot perform the measurements while it is charging.

Fully charge the device for 8h before using it for the first time. Use only the USB cable provided in the package.

The cable has two ends. Connect the micro-USB end to the SAM's USB port (see Table 1). Connect the other end to a 5V USB adapter. Plug the USB adapter into a power source.

Note: The USB cable can be connected to a computer or 5V AC-DC adapter for charging.

4.2. Understanding the Visual indications:

4.2.1. For the Scanbo® D8 device:

The LED indicator provided along with the power button indicates ON/OFF status, Bluetooth connection status, and battery charge status. When used for taking measurements, the LED indicator shows the ON/OFF status of the SAM. When not taking a measurement, the color indicates battery status.

While pairing the SAM to the mobile phone, the LED indicator indicates the Bluetooth connection status.

Table 2. Indicators to show the status of Scanbo device

Status of	LED Feedback		Indication
Charging		Blue LED blinking	Device is charging
		Blue LED Stable	Charging is complete
Bluetooth		Blue LED blinking	Scanning for a device to pair with via Bluetooth

		Blue LED Stable	Device is connected to smartphone via Bluetooth
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4.2.2. For the Scanbo® 3.0 Mobile (iOS / Android) App:

The battery icon color in the Scanbo® 3.0 App also indicates (see Table 3) the available battery backup while the device is connected to the mobile app.

Table 3. Battery icon indicators to show the charge level of the device

 Red: The battery is near to exhausting	 Yellow: Low power of battery
 Green: Sufficient power of battery	 Blue: Full power of battery

4.3. Installing Scanbo® 3.0 Mobile (iOS / Android) App

Install the Scanbo® 3.0 App from Play Store or App Store to use the Scanbo D8 for measurements.

To install the app on your smartphone, search for “Scanbo 3.0” app in **Google Play Store** (Android) or **App Store** (iPhone). Before downloading ensure that you are downloading the app developed by Scanbo Technologies Inc. The Scanbo® 3.0 App is compatible with Android 10.0+ and iOS 15.0+, requiring Bluetooth 4.0+.

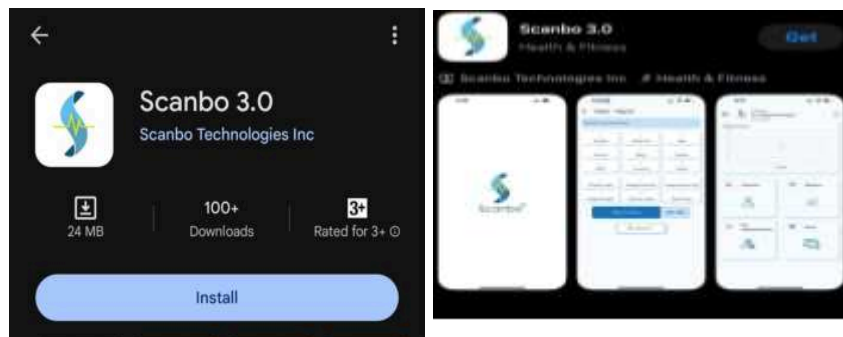


Fig 1: Scanbo® 3.0 mobile application

Once installed, open the app and follow the instructions as per the sections below.

4.4. Setting up your account



Caution:

1. Before downloading the app, make sure your smartphone meets the system requirements.
2. Make sure the device is ON before logging into the app to connect via Bluetooth.

3. If you run into any issues, restart both the device and the app to fix it.

4.4.1. Login/Registration

1. Enter your mobile number. Review the Terms of Use and Privacy Policy.
2. Click "Agree" to confirm your acceptance.
3. Enter the 6-digit OTP sent to your mobile for verification.
4. Choose the role that best suits you from the options provided.
5. Read the Terms and Conditions carefully. Select all required checkboxes before proceeding.

The image shows two side-by-side screenshots from the Scanbo app. The left screenshot is titled 'Verify your phone number' and features the Scanbo logo at the top. Below the logo, it says 'Scanbo will send an SMS message to verify your phone number. Enter your country code and phone number'. There is a text input field for the phone number, a dropdown menu showing 'IN +91' and 'Mobile', and a checkbox labeled 'I have read and agreed to the Terms of use, Privacy policy and Disclaimer'. A blue 'Verify' button is at the bottom. The right screenshot is titled 'Terms & Conditions' and lists four terms, each with a checked checkbox: 'The kit is the property of Scanbo India Pvt. Ltd (Company) and being given to me for use only.', 'Scanbo reserve the right to recall the kit at any time in the event of (a) lapse in renewing the monthly subscription (b) misuse of device (c) sub-leasing the device to third parties or any other event which Scanbo consider to be a violation of company policies.', 'The device is intended for use in primary care for measuring vitals only and not for critical care or in ICU. It is to be used for measurement ONLY.', and 'Scanbo reserve the right to modify device specifications, subscription & test charges and user policies at any time.' At the bottom are 'Cancel' and 'Agree' buttons.

Fig. 2 Phone Number Verification & Terms Acceptance Screen

4.4.2. Creating a new account

1. Select the user type – Hospital, Doctor, or Community Healthcare Worker.
2. Fill in all your personal and medical information in the appropriate fields.
3. Once you enter all the required information, your account will be registered. The entered details will be stored in the cloud server connected via Wi-Fi.
4. You can then go to the Home Screen to access the test menu and other options.

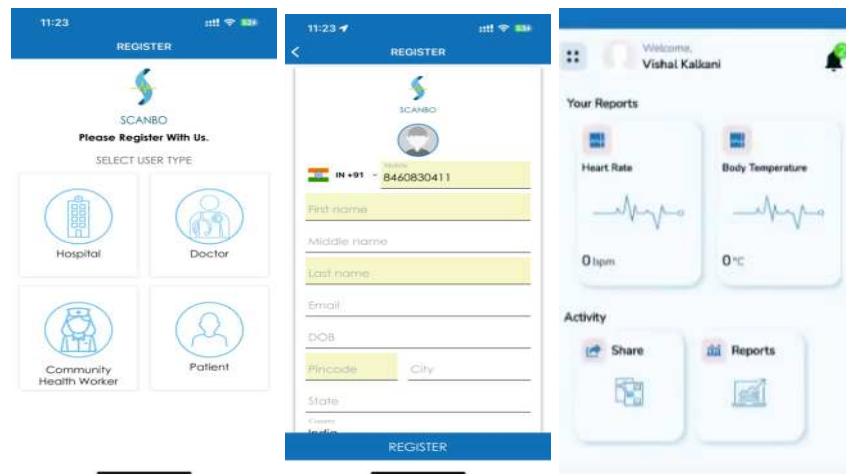


Fig.3 User Type Selection, Registration, and Home Screen

4.5. Pair Scanbo® D8 SAM and Scanbo® 3.0 App

1. Turn on the SAM by holding the power button for 2 seconds. Refer Section 3 for powering ON the SAM.
2. Enable Bluetooth on your smartphone. Open the Scanbo® 3.0 App on your phone after logging in or signing up.
3. Go to the "Vitals" screen. The app will ask for permission to connect to the Scanbo® D8 SAM.
4. Once permission is granted, SAM will connect to your phone automatically. The battery icon will appear in the app once the SAM connects.
5. If the SAM doesn't connect on its own, tap the Bluetooth icon in the Scanbo® 3.0 App to connect.

Note: The LED on the power button of SAM will blink in blue until it pairs with your smartphone. See Table 2 for LED indicators.

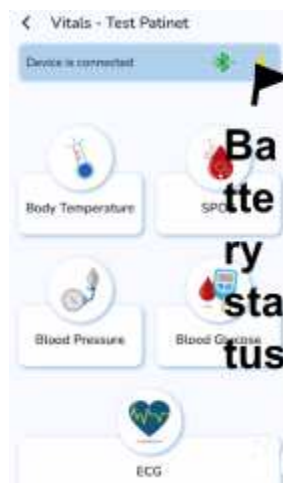


Fig. 4 Battery icon when SAM connects to smartphone

5. Using the Scanbo® 3.0 App

Note: Ensure to use strong and secure Wi-Fi connection on your mobile phone when connecting to the internet.

5.1. Home screen

The Home screen offers quick access to your Account, Vitals screen, Patient List, and their Reports. Additionally, it displays the patient count in a graphical format.

On the top left corner of the Home screen is the Menu icon which provides access to the different features as discussed in the below sections.

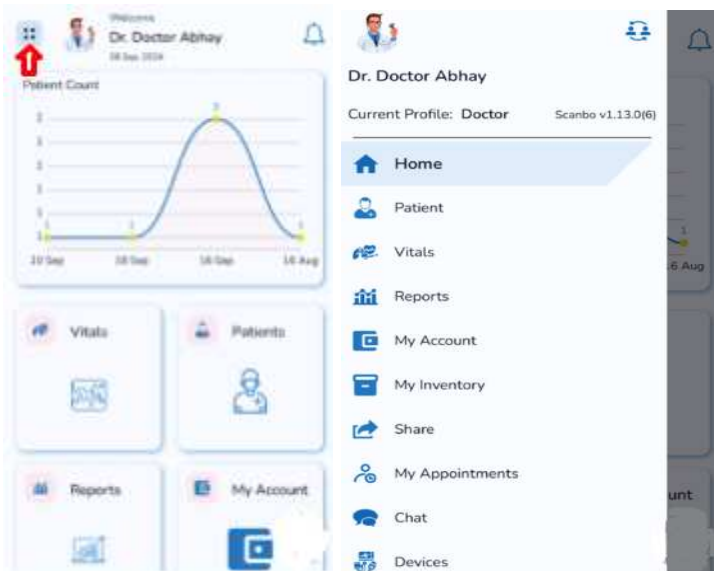


Fig. 5 Menu Screen

5.2. Available Roles

The app offers three distinct user roles: Hospital, Doctor, and Community Healthcare Worker. All user roles can measure vitals and blood glucose levels. Select the user role that best matches your profile.

Note: Doctors and Community Healthcare Workers can create and update patient profiles in their "Patient List." Hospitals can add new doctors to their "Doctor List" and update it as needed.

5.3. Vitals

You can access the vitals and glucose tests from the "Vitals" screen. It gives access to the following options (tiles) :

1. Body Temperature
2. SpO₂
3. ECG
4. Blood Pressure
5. Blood Glucose

Select the parameter you wish to test to proceed to the test screen. Refer Section 6 for detailed instructions on how to perform the tests.

Note: The vitals and glucose measurements cannot be initiated while charging the SAM.

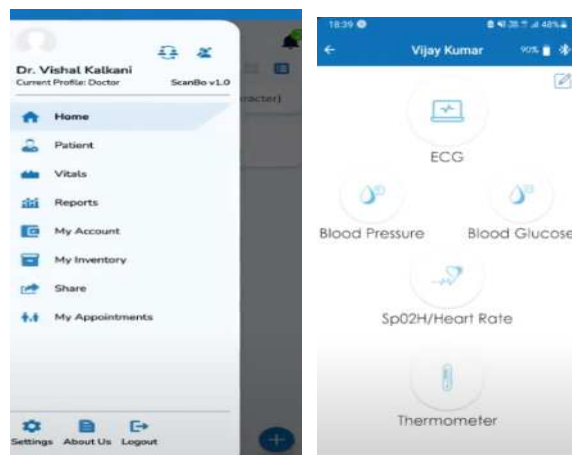


Fig. 6 Vitals Screen

5.4. Reports

The "Report" screen allows the user to view past measurements. Users can view the "Trend" data under the "Report" screen. It shows an overview of the selected vital/blood glucose measurements over a customizable timeframe. View data from the past **7, 14, 30, 60, or 90 days** including the date, trends, normal range, minimum and maximum values.

The "Data" tab allows users to view all the captured measurements over the selected timeframe (7/14/30/60/90 days). Besides, you can view the data for a selected date. Doctors, Community healthcare workers and Hospitals can view the reports for each patient in the "Patient List".

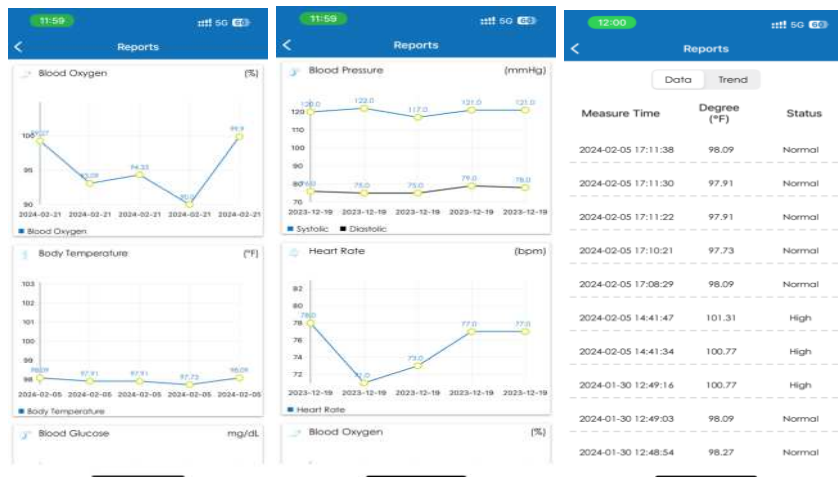


Fig. 7 Reports Screen

The test reports can be shared with the patients, family members as well as other HCPs.

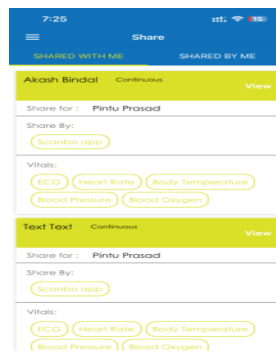


Fig. 8 Data sharing Screen

5.5. Settings

The "Settings" screen allows personalization of your account. On the Home Screen, tap the **Menu icon** (four dots) located at the top left corner. The **Menu screen** will slide out from the left. From the Menu screen, select "Settings" and launch the settings for temperature, ECG, Glucose and language.

1. Temperature settings: Select the preferred temperature unit: **°C (Celsius)** or **°F (Fahrenheit)**.
2. ECG Settings: Choose the desired **Sweep Speed** from the available options.
3. Blood Glucose Unit: Select the preferred glucose unit: **mg/dL** or **mmol/L**.
4. Language: You can switch the default language from "English" to your preferred language.

5.6. Web application

The Scanbo 3.0 web application serves as a secure, user-friendly secondary display. It is an easy-to-use website that helps you keep track of your health. After you use your Scanbo device, your results including vital signs, blood glucose concentration, and associated user information are safely saved online. When you open the website, you can see your latest readings right away, along with your name and basic info. It's a simple and safe way to check how you're doing, anytime and anywhere, using a computer, tablet, or phone. It runs on the following compatible web-browsers:

Google Chrome:

- Version 131.0.6778.204/205
- Version 131.0.6778.139/140

Mozilla Firefox:

- Version 133.0.3
- Version 133.0.2

Microsoft Edge:

- Version 117.0.2045.60
- Version 117.0.2045.55

Safari (macOS only):

- Version 17.1
- Version 17.0

Sections 5.1, 5.2, 5.4, and 5.5 apply to the web application. The web app looks very similar to the mobile app, but it doesn't include "My Account," "My Inventory," or "Vitals" (the screen used to take new readings), because you can only take measurements only with the mobile app.

6. Vitals and Blood Glucose measurement

6.1. Body Temperature

6.1.1. Overview

The device uses infrared technology to measure body temperature. It measures from the **forehead** without direct contact. The measurement range is **34~42°C**.

For the most accurate results, please wait 30 seconds between consecutive measurements.

6.1.2. Safety Information



Caution:

1. Avoid areas with air outlets, fans, air conditioners, or direct sunlight during the measurement.
2. Clean your forehead before measuring body temperature. Sweat, oil, cosmetics or dirt can cause inaccurate results.
3. DO NOT keep the temperature sensor in contact with the forehead during measurement.
4. DO NOT eat, drink alcohol or coffee, bathe, or do physical activities 60 min prior to measurement. Avoid talking during the measurement.

6.1.3. Measuring Body Temperature

1. Pair the SAM with the smartphone and select the "Temperature" option in the "Vitals" screen of the app.
2. Ensure the forehead is dry and clean. Align the temperature sensor perpendicular to the center of the forehead, between the eyebrows. Keep it 1-2 cm from the skin (as shown in the image below).
3. Click the 'Start' button from the Temperature screen to start the measurement.
4. Final temperature value is displayed on the app after the measurement stabilizes within 2-3 seconds.



Fig. 9 Temperature vital screen, positioning of sensor for measurement and measurement area

6.2. Blood Oxygen (SpO₂)

6.2.1. Overview

The device measures the blood oxygen saturation (SpO₂) percentage in continuous mode. It measures the light absorbed and reflected by the blood in the **finger**. The measurement range is **70%~100%**.

6.2.2. Safety Information



WARNINGS:

1. DO NOT look directly into the sensors. This can cause eye damage due to infrared light.
2. Performance Warning: A functional tester can't check the accuracy of Scanbo® D8 SAM.



Caution:

1. DO NOT eat, drink alcohol or coffee, bathe, or do physical activities 60 min before measurement. Avoid talking during the measurement.
2. Place the Scanbo® D8 horizontally on a flat surface during the measurement.
3. Foreign objects between the sensor and fingers can affect results. Clean your fingers and the device before use
4. Avoid applying nail polish on the measuring finger.
5. Measurement may be inaccurate if the finger has thick skin or pigment buildup.
6. Use the middle finger with the nail facing up. Clean your fingers before measuring. .DO NOT move your finger during the measurement.
7. DO NOT take measurements under strong light such as direct sunlight, bright LED lights or excessive ambient lights. This may result in inaccurate or no Blood Oxygen measurement.
8. DO NOT apply excessive pressure on the SpO₂ sensor during the measurement. This may affect the measurement results.
9. Blood pressure can vary between fingers due to circulation and differences in the body. Use the same finger for consistency in Blood Oxygen results...
10. Continuous blood pressure measurements can affect circulation and oximetry values. Wait before measuring blood oxygen after taking blood pressure...
11. Cold fingertips or poor circulation from low temperatures can cause weak, low or no measurement.

6.2.3. Measuring SpO₂

1. Pair the SAM with the smartphone and select the "SpO₂" option in the "Vitals" screen of the app.
2. Patients should be still and remain relaxed for atleast 5mins before the measurement. Place the middle finger on the blood oxygen sensor. Ensure the finger completely covers the sensor. Keep the fingers and wrist flat. DO NOT curve them, as this can affect the accuracy of the readings.
3. Click the 'Start' button from the SpO₂ screen to start the measurement.
4. Final SpO₂ value is displayed on the app after the measurement stabilizes within 15-20 seconds.



Fig. 10 SpO₂ vital screen, proper positioning of fingers and correct posture for measurement

6.3. Blood Pressure

6.3.1. Overview

The SAM uses oscillometry for non-invasive blood pressure measurement. The SAM senses the pressures in the **upper arm** using the BP cuff and converts it into digital readings. The measurement range is:

Table 4. Measurement range of Blood pressure measurement system

Arm circumference of the cuff	22-35 cm
Range of measurable Systolic pressure	60-230 mmHg
Range of measurable Diastolic pressure	40-130 mmHg

Pulse rate measurement range	40- 180 bpm
------------------------------	-------------

6.3.2. Safety Information



WARNINGS:

1. Incorrect placement of the device and BP Cuff may result in inaccurate readings.
2. Kinking in the connection tubing can cause continuous cuff pressure. This can disrupt blood flow and potentially harm the user. Ensure the tubing is properly positioned to avoid this risk.
3. DO NOT wrap the cuff over a wound, as it can worsen the injury and raise the risk of infection.. DO NOT use the device to measure blood pressure on an injured arm.
4. Avoid applying and inflating the cuff on limbs with intravascular access, ongoing therapy, or an A-V shunt. It may block blood flow and harm the patient.
5. Consult the healthcare provider before using the cuff on the arm of a mastectomy or lymph node clearance. This is to avoid potential complications.
6. DO NOT use the BP cuff on the same limb for long periods. Monitor cuff usage to avoid restricting blood circulation for long.



Caution:

1. DO NOT eat, drink alcohol or coffee, exercise, bath, etc. 60 minutes before the measurement. This might affect the measurement.
2. Blood pressure measurements can be affected by posture, physical condition, and the environment. Ensure the cuff and heart are at the same level during measurement. DO NOT interpret the results yourself; always consult a doctor.
3. Make sure your arm's circumference is within the specified range for accurate results. Tighten the arm cuff properly.
4. DO NOT measure the same arm repeatedly. Wait at least 30 seconds between measurements.
5. DO NOT use the device to for NIBP measurements the same arm as other monitoring equipment.

6.3.3. Measuring Blood Pressure

1. The patient should be calm and relaxed 5 minutes prior to the measurement. Avoid talking and movements to ensure accuracy. The arm should be bare or covered with a thin garment.

2. The patient should sit up straight in a comfortable seat. Place the arm on a table or flat surface which is at the same level as the heart. The palm should be facing up and the arm relaxed while legs should be uncrossed, feet flat on the floor, and the back and arm supported.
3. Connect the SAM by gently inserting the NIBP connector on the back of the SAM (See Table 1) into the square-shaped base of the cuff.
4. Wrap the cuff around the patient's upper arm with the device facing up. Follow the arrows on the cuff for correct orientation/positioning of the cuff while wrapping it.
5. Position the cuff 1-2 cm above the elbow joint with a reasonable tightness. Ensure the device is centered on the arm, facing upwards (see image below).
6. Pair the SAM with the smartphone and select the "Blood Pressure" option in the "Vitals" screen of the app.
7. Click the 'Start' button from the Blood Pressure screen to start the measurement. The cuff will inflate, and the measurement will begin. Stay calm during the process.
8. Final Blood Pressure and Pulse Rate values are displayed on the app after the measurement stabilizes within 37 seconds.



Fig. 11 NIBP Cuff and the square-shaped base for connecting the SAM

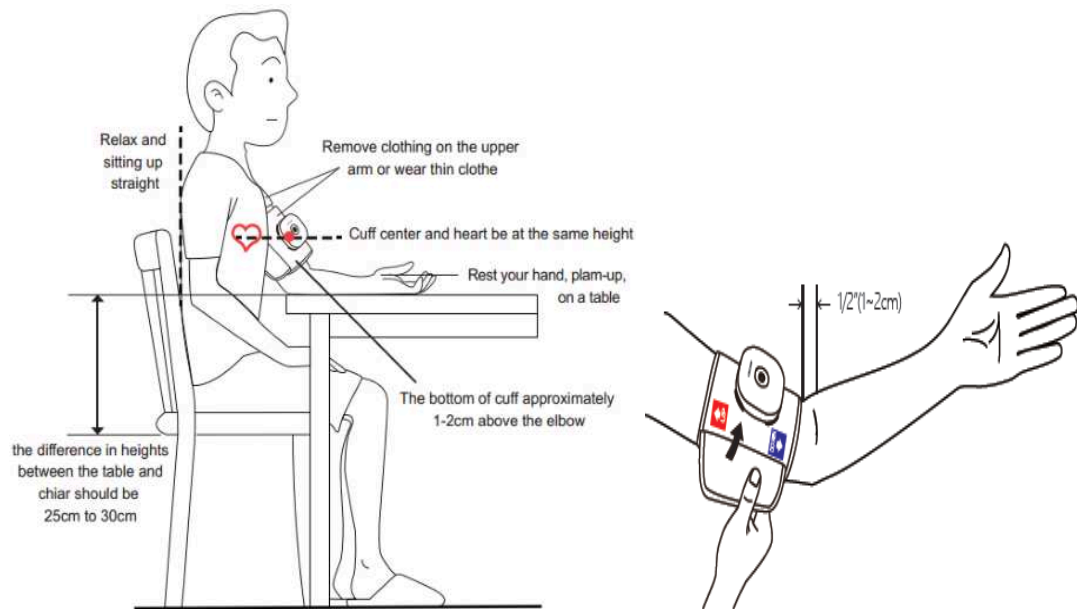


Fig. 12 Correct posture and proper positioning for Blood pressure measurement

6.4. ECG

6.4.1. Overview

The SAM measures the electrocardiogram (ECG) waveforms and calculates Heart Rate (HR) from the ECG. To gather the ECG data, the patient needs to place their **fingers** on the SAM as described in Section 6.4.3. The measurement parameters are as follows:

Table 5. Measurement parameters of ECG measurement system

Heart rate measuring range	30 bpm -240 bpm
Resolution	1 bpm
Sweep speed	25mm or 50 mm/s

6.4.2. Safety Information



Cautions:

1. DO NOT eat, drink alcohol or coffee, bathe, or do physical activities 60 min before measurement.
2. Avoid talking during the procedure. Do the measurement in a quiet place to avoid distractions.

3. DO NOT conduct the measurement while the device is charging.
4. DO NOT conduct measurement with wet hands.
5. Please place both hands in the correct position described in the Section (6.4.3) below. Make sure the ECG, temperature and SpO₂ sensors are fully touching the skin before starting the test.
6. DO NOT let your hands touch each other during the measurement.

6.4.3. Measuring ECG

1. Pair the SAM with the smartphone and select the "ECG" option in the "Vitals" screen of the app
2. Remain still and relaxed 5 minutes prior to the measurement. Hold the device with your left hand, placing your thumb on the blood oxygen sensor. Place your other fingers on the metal plate on the back of the SAM.
3. Ensure the power button faces the patient.
4. Place the index finger of the right hand on the body temperature sensor. Make sure the patient's hands DO NOT touch each other.
5. Click the 'Start' button from the ECG screen to start the measurement.
6. Final ECG waveform, Heart rate, RR_{min}, and RR_{max} values are displayed on the app after the measurement stabilizes within 30 seconds.



Fig. 13 ECG vital screen and proper positioning of hands for measurement

6.5. Blood Glucose

6.5.1. Overview

The blood glucose measurement requires the Scanbo® Glucose test strips to measure the blood glucose levels in fresh capillary blood from the **fingertip** using the lancets to help collect blood samples. The measuring range is **20 – 600 mg/dL**.

Refer to the glucose test strip package insert for more information on the test principle.

6.5.2. Safety Information



WARNINGS:

Potential risks of Biohazards exist with the use of accessories related to blood glucose measuring function. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection (See Section 8.2.2).

Users MUST follow the warnings below to avoid risk of biohazards.

1. Follow Standard Precautions for hand hygiene practices when handling or using the SAM for blood glucose measurements.
2. Operators must remove the gloves, clean their hands, and wear a new pair of clean gloves before testing each patient. Always wash your hands with soap and water and dry them well before and after testing or handling the SAM, lancing device, and test strips.
3. Always wear a new, clean pair of gloves for every blood glucose measurement.
4. DO NOT reuse the lancing device. Use only auto-disabling, single use lancing devices with Scanbo® D8 SAM.
5. Dispose used test strips and lancets as per the local biowaste norms and regulations. Always dispose of used test strips and lancets as medical waste or according to your health institution.
6. The SAM should be cleaned and disinfected as per the instructions in Section 8.2.2 after use on each patient. The SAM may only be used for testing multiple patients when Standard Precautions and the manufacturer's cleaning and disinfection procedures are followed.
7. DO NOT take the vitals measurements right after the glucose measurement. Wait until the blood clots on the finger and then proceed with the measurements.



Cautions:

1. Avoid disinfecting fingers with iodine or chlorinated disinfectant.
2. Only use Scanbo® glucose test strips with the Scanbo® D8 SAM. Always use test strips from a single batch at a time. Finish the strips from one bottle before opening a new one.
3. DO NOT touch the reaction area. Insert the test strip without touching the reaction area.
4. DO NOT press the lanced area or scrape blood on the test strip. DO NOT add blood on both ends of the test strip.

5. Only 0.5 µL of blood is needed. It must fill the sample window in one go—DO NOT add blood repeatedly.
6. Use the test strip within 5 minutes after opening. In high humidity conditions (>80% relative humidity), use it within 3 minutes.
7. DO NOT use the test strips after the expiry date. It can produce inaccurate results. Check the expiration date on the bottle and use it within 60 days after opening the vial. Write the discard date on the bottle as a reminder. Store the test strips in the specified storage conditions (See Section 9).
8. DO NOT reuse the test strips. This can result in inaccurate results. Always use a new test strip.
9. Repeated use of the same sampling site can cause skin trauma and injury. Ensure to rotate sites to minimize injury.

Factors affecting the test result due to improper operation:

1. The initial blood sample was not enough, and the sample window was not fully filled.
2. Blood sample was pressed onto the test strip, or there were air bubbles present.
3. After adding the blood sample, the test strip was removed and reinserted into the device.
4. Test strips were stored at temperatures below 1 °C or above 35 °C.
5. Fingers were disinfected with iodine or chlorinated solutions.
6. fingers were not fully dried after alcohol disinfection.
7. The test strip was exposed to high humidity (>80% RH) for more than 3 minutes.
8. The SAM was not given time to adjust to the room temperature (requires 20 min).

6.5.3. Measuring Blood Glucose

Step 1: Insert the Glucose Test Strip

1. Pair the SAM with the smartphone and select the “Blood Glucose” option in the “Vitals” screen of the app.
2. Choose the time of measuring (meal marker). Then select “Next” to enter the test screen.

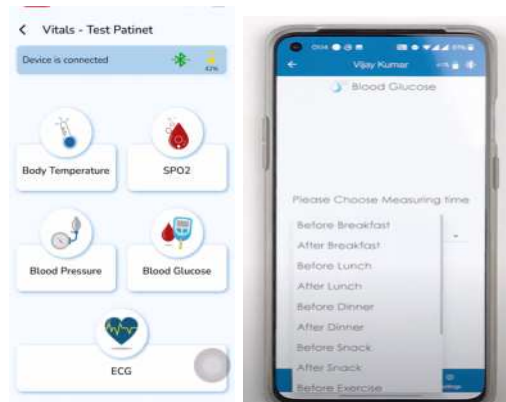


Fig. 14 Vitals screen and Glucose measurement time selection

3. Wash your hands with soap and dry them thoroughly. Wear a new, clean pair of gloves.
4. Take a new test strip from the Scanbo® Glucose test strip bottle. Close the bottle tightly after removing it. The upper side of the strip is green and the backside is white.
5. Insert the end of the test strip with the arrows into the test strip port of SAM. If the test strip isn't inserted correctly, "Test strip not inserted" is displayed.



Fig. 15 Glucose Test Strip and its insertion into the device

Step 2: Obtaining the blood sample

Remember the "PST", i.e., - Prick >> Start >> Touch, sequence.

1. The patient should wash their hands with soap and water and dry them thoroughly.
2. Clean the patient's finger (with an alcohol swab or soap) and gently massage it to stimulate blood flow. The puncture area must be dried before pricking with a lancet.
3. Use only auto-disabling, single use lancing device for blood collection. Remove the protective cap of the sterile single use lancet.
4. Perform the puncture by pressing the lancet firmly against your puncture site
5. DO NOT remove the lancet from the site until an audible click is heard.

6. DO NOT reuse the lancet. Discard the used lancet into a sharps container or according to the local regulatory guidelines
7. Gently squeeze from the base of the finger toward the puncture site to form a drop of blood.
8. Wipe away the first drop and use the second drop as the sample.

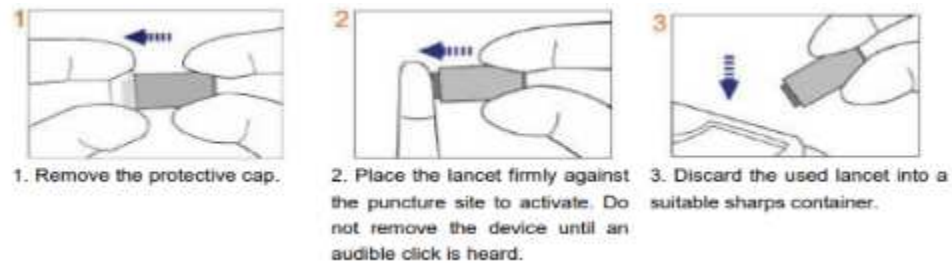


Fig. 16 Lancet usage and Blood sample collection

Step 3: Obtaining the glucose measurement

1. Click the 'Start' button from the Blood Glucose screen to start the measurement.
2. Immediately touch the tip of the test strip to the blood droplet. Observe the glucose test screen on the mobile app for the start of measurement. DO NOT press or smear the blood on the test strip.
3. A small amount of blood is drawn until the sample window fills (see Fig. 17). Then, the "Measuring" message is displayed on the test screen. The patient's finger can be removed now
4. Clean the puncture site with alcohol, or let the patient wash their hands with soap.

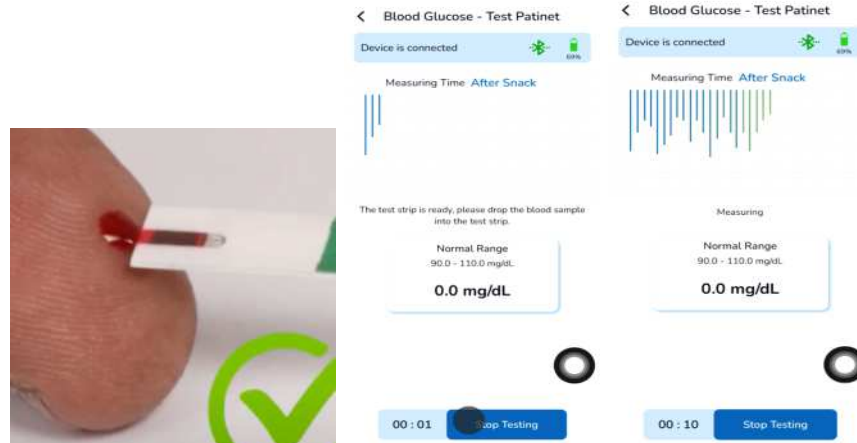


Fig. 17 Blood Application on Test Strip and Glucose Test patient screen

- Final blood glucose value is displayed on the app after the measurement stabilizes within 5–8 seconds.

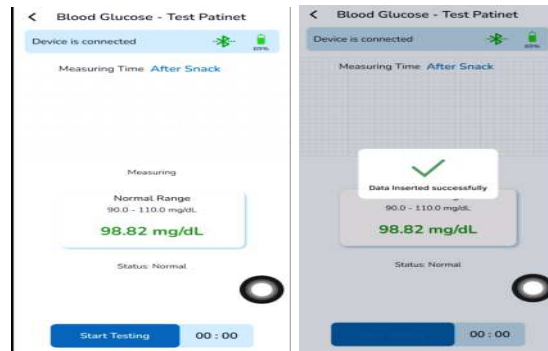


Fig. 18 Results displayed on the Blood Glucose –Test Patient screen

Step 4: Know Your Blood Glucose Results

- Users can view the "Trend" data under the "Report" screen. It shows an overview of the glucose measurements over a customizable timeframe.
- You can view data from the past **7, 14, 30, 60, or 90 days**. Swipe through the entries for easy navigation. In addition, the "Sugar" tab displays the most recent glucose reading. The "History" tab shows the minimum and maximum glucose levels within the selected timeframe.
- The "Data" tab allows users to view all the captured glucose measurements over the selected timeframe (7/14/30/60/90 days).

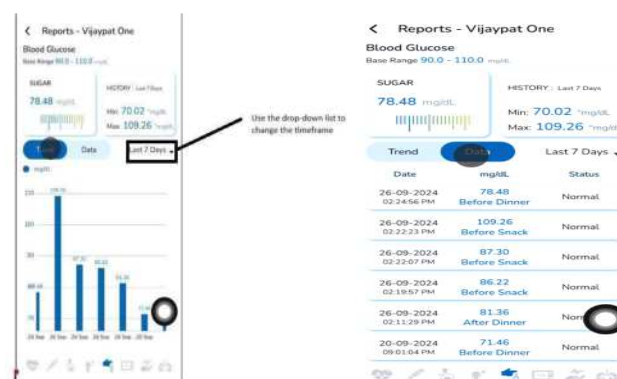


Fig. 19 Glucose Trend Data and History View in Reports screen

Expected Results for people without diabetes¹

- Fasting & before meal: < 100 mg/dL (6.1 mmol/L)
- 2 hours after a meal: < 140 mg/dL (7.8 mmol/L)

¹American Diabetes Association Professional Practice Committee; 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes—2024

Scanbo® D8 SAM is calibrated to provide the blood glucose concentrations that refer to plasma values.

Step 5: Safe Disposal of test strip and lancet

1. After completing the test, remove the test strip from the device.
2. Cover the lancet with the protective cap to cover the tip of the needle. Dispose of the lancet into an appropriate container.
3. Please discard the used test strip and lancet safely, as per the local regulations. DO NOT touch the area with the blood.
4. Dispose off the gloves. Wash your hands with soap and water after using the device, lancets, and test strips.

6.5.4. Control Solution Test for Blood Glucose



Cautions:

- Only use the Scanbo® control solutions with your Scanbo® D8 device.
- Check the expiration date on the control solution bottle and use it within 90 days after opening the vial. Write the discard date on the bottle as a reminder. DO NOT use it if it's expired.
- The control solution's range is listed on the label of the test strip bottle . It is NOT the target range for your blood glucose.
- DO NOT drink or inject the solution.
- DO NOT directly apply a control solution onto the test strip. This is to avoid contaminating the control solution.

A. Why Perform a Control Solution Test:

- To check that your device and test strips are working well together.
- To let you practice testing without using your own blood.

B. When to Perform a Control Solution Test:

- Once a week (to make sure you get accurate results).
- You start using a new vial of test strips.

- Test strips are exposed to extreme conditions outside the specified range (Temperature: 4° C to 35° C; Humidity: <= 93% RH).
- If you drop the device.

C. Performing a Control Solution Test:

1. Wash your hands with soap and water before testing. Make sure to dry them completely.
2. Pair the SAM with the smartphone and select the "Blood Glucose" option in the "Vitals" screen of the app. Next, select the "Control Solution Test" option.
3. Take a new test strip from the Scanbo® Glucose test strip bottle. Close the bottle tightly after removing it.
4. Insert the end of the test strip with the arrows into the test strip port of SAM (See Table 1).
5. Shake the control solution bottle well, then remove the cap. Squeeze the bottle to discard the first drop. Wipe the tip with a clean tissue or cotton.
6. Squeeze the bottle to get a second drop onto a clean, non-absorbent surface.
7. Click the 'Start' button from the control solution test screen to start the measurement.
8. Touch the tip of the test strip to the droplet. The "Measuring" message will be displayed on the test screen. You can now move the test strip away from the droplet.
9. Final glucose value is displayed on the app after the measurement stabilizes within 5-8 seconds. Compare the test result with the range printed on the test strip bottle. Each control solution vial may have a different control solution range. The result should be within the range printed on the test strip bottle.
10. Discard the used test strip properly as medical waste. Tightly close the control solution vial.

If the control result is out of range, DO NOT use the device until the issue is resolved. Please contact Scanbo® customer support. For more information on how to purchase the control solution visit Scanbo® website.

6.5.5. My Inventory

This feature lets you track the number of glucose test strip bottles purchased and used. It also tracks the quantity of test strips used and remaining.



Fig. 20 Glucose Test Strip Tracking and Usage in My inventory screen

7. Error Messages/Troubleshooting

7.1. SAM & Scanbo® 3.0 App

Table 6. SAM & Scanbo® 3.0 App related Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunctions	Reason	Solution
Failure to download the app	- Incompatible smartphone operating system - Not connected to the internet or has a weak connection	- Check the OS version of smartphone - Check you WiFi/Data connectivity
Failure to automatically connect SAM to smartphone	Wrong operation sequence	Turn on the device before logging into the App or tap the Bluetooth icon
Connection or device detection issues	- Bluetooth signal is weak - Bluetooth not turned ON	- Be within the specified signal range i.e., within 3 feet - Turn ON the Bluetooth - Restart Scanbo® D8 and your smartphone
SAM not turning ON	- Low or no battery charge - Adapter or USB cable improperly connected	- Charge the device - Securely connect the adapter/USB cable to the device and the power source.

Device freezes or functions unexpectedly during use	Scanbo® 3.0 App has not been updated	- Update the app if an update is available - Reset Scanbo® D8 to its factory settings and reinstall any updates
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7.2. Body Temperature

Table 7. Temperature Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunction	Reason	Solution
Significant error in measurement	Sweat, water, oil etc on the forehead	Clean the forehead before measurement
	Wrong measuring distance	Keep 1-2 cm distance between the sensor and the forehead

7.3. Blood Oxygen (SpO₂)

Table 8. SpO₂ Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunctions	Reason	Solution
Data fluctuation within a short period	Incorrect measuring technique or body positioning	Refer Cautions and procedure to ensure the instructions are followed. Retake measurement according to the instructions
Unable to obtain measurement results	Finger strained on the sensor	Place your middle finger on the SpO ₂ sensor without applying excessive pressure.
	Finger is too thin	Try using a different finger for the measurement. Ensure it fully covers the sensors.
No SpO ₂ reading	Incorrect finger position on the sensor	Cross check the position of your finger as per the instructions
	Bright ambient light interference	Make sure there are no bright lights while measuring. Cover the sensor and the fingers with an opaque object if the bright lights cannot be avoided.

7.4. Blood Pressure

Table 9. Blood Pressure Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunctions	Reason	Solution
Low or No reading	• Incorrect cuff or device placement • Movement, talking, or improper sitting posture • Inadequate battery	• Wrap the cuff correctly. Place the device properly on the cuff. • Adjust your sitting posture. Remain calm during the measurement. • Check the power level and charge the device
BP Cuff failed to inflate	Air leakage from the cuff or incorrect device positioning	Attach the device properly to the connector on the cuff. Contact Scanbo® if the cuff is damaged

7.5. ECG

Table 10. ECG Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunctions	Reason	Solution
ECG waveform is reverse	The positions of the two hands are switched	Place both hands as per the instructions

7.6. Blood Glucose

Table 11. Blood Glucose Error message/Malfunctions, Possible reasons and Suggested Solutions

Error messages/ Malfunctions	Reason	Solution
Blood sample not added	The blood sample has not been added to the test strip after starting the test	Add the blood sample once you start the test
The test strip is removed	Test strip was removed/removed and reinserted after starting the test.	Once the test starts and blood sample is added to the test strip, DO NOT remove the test strip from the port
The test strip is already used	The timer was stopped midway during the measurement process	DO NOT stop the timer while the device is measuring the glucose levels

	A used test strip was inserted into the device port	DO NOT reuse the test strips. Always use a new strip for each glucose measurement.
Low Glucose level	Blood glucose level is lower than 20 mg/dl (1.1mmol/L)	Repeat the test.
High Glucose level	Blood glucose level is higher than 600 mg/dl (33.3mmol/L)	Repeat the test.

8. Storage & Maintenance

8.1. Storage Condition – Scanbo® D8 device and accessories

- Store the device and accessories in a cool, dry place. Keep them away from sunlight, moisture, and extreme temperatures. The storage temperatures for the device and accessories are specified in Section 9.
- DO NOT fold the cuff tightly.
- Keep the device away from areas of tilting, shaking, or impact.
- Avoid storing heavy objects on top of the device and accessories. This can damage the internal components.
- Store the glucose test strips and the control solution vials in their original airtight container. Store them in a cool, dry place between 4 °C and 35 °C. Keep humidity below 93%. Keep away from direct exposure to light. DO NOT freeze.

8.2. Maintenance



Caution:

1. DO NOT perform cleaning and maintenance while the device is in use.
2. DO NOT drop the device and its accessories from any height.
3. DO NOT sterilize the device or its accessories. Follow the instructions below for maintenance, cleaning and disinfection.

8.2.1. How to care for your Scanbo® D8

1. Regular Inspection:

- The Scanbo D8 SAM is a non-sterile, reusable device. Check the device and accessories regularly for wear or damage. Check for any frayed or loose sensors. Stop using the device if any issues are detected and contact Scanbo®.

- We suggest calibrating the device every **2 years**. Please contact Scanbo® when calibration is needed.

2. Cleaning Instructions

- Regularly clean the device and its accessories after use. Make sure to disconnect the device from the power source before cleaning.
- Use a soft, damp cloth to clean the surface. DO NOT immerse the SAM or accessories in water or liquids. They are not waterproof.
- Clean & disinfect the SAM as per Section 8.2.2 **after every** blood glucose measurement.
- DO NOT wash the NIBP cuff with water. Clean with a soft and clean fabric.
- Ensure the device and accessories are dry before charging.

3. Cord Care

- Check the USB cable regularly for damage. Look for signs like fraying or exposed wires.
- If the cable is damaged, stop use and replace them promptly. Contact Scanbo® for replacement parts (See Section 11.3).

4. Check Controls and Display

- Verify if the control panel and display are functioning correctly in the Scanbo® 3.0 App. Ensure they reflect the chosen settings.

8.2.2. Cleaning & Disinfection



Caution:

1. DO NOT use other solutions or disinfectants with the SAM
2. DO NOT let fluids enter the test strip port, USB port, or Scanbo® D8 SAM.
3. Operators must remove the gloves, clean their hands, and wear a new pair of clean gloves before testing each patient. Always wash your hands with soap and water, then dry them well. Do this before and after testing or handling the SAM, lancets, and test strips.
4. If you notice damage or deterioration on the SAM, contact Scanbo® Customer support. Reach us at care@scanbo.com or +65 3163 7489

Why is this step required?

The cleaning and disinfection procedure is extremely important. It needs to be performed to prevent the transmission of bloodborne pathogens.

- **Cleaning:** process of removing visible soil/dirt from the Scanbo® D8 SAM.

- **Disinfection:** Process of removing most, but not all, bloodborne pathogens. It reduces the risk of infectious diseases.

When to clean and disinfect?

Please ensure to clean and disinfect the SAM **after every** blood glucose measurement.

Items needed:

- Clorox® Disinfecting wipes (EPA Reg #67619-31) - <include or refer instructions on how to obtain/purchase>

Note: The Clorox® Disinfecting wipes (EPA Reg #67619-31) have undergone testing. They are approved for cleaning and disinfecting the SAM. This product can be purchased on the CloroxPro® [website](#). Read this manual and the Clorox Disinfecting Wipes instructions. Make sure to follow both before use.

- Soap and water

How to clean and disinfect the Signal Acquisition Module (SAM)?

1. Wash hands with soap and water and dry thoroughly. Take a Clorox Disinfecting wipe from the container.
2. Turn off the device. Wipe the entire surface with one towelette to clean.
3. Wipe around the test strip port and openings. Ensure no fluid enters.
4. Dispose of the used towelette. Use a new towelette to wipe the device surface. Keep the surface wet for **4 minutes to disinfect**... Let the surface air dry.
5. Dispose of the used towelette and wash your hands with soap and water.

This procedure was validated for the Scanbo® D8 SAM. A total of 1 pre-cleaning and 1 disinfection for 10 patients/day * 365 days (1 year) * 3 years = 10950 pre-cleaning and disinfection cycles were simulated over a 3-year use period.

8.2.3. Updating the Scanbo® 3.0 Mobile App

To update the Scanbo® 3.0 App, navigate Google Play Store (Android) or App Store (iPhone).

8.3. Disposal

If the expected service life period of the Scanbo® D8 SAM is completed, please return the device to Scanbo® Technologies Inc. Follow local regulations for the disposal of the NIBP cuff (post expected service life period), and other accessories. Contact your health department for proper handling and disposal of these components. DO NOT dispose of them with household waste.

9. System Specifications

Table 12. System Specifications

Product name	Scanbo® D8
Product Model	D8
Software	Scanbo® Mobile App (iOS / Android)
Software version	V1.1.2
Power source	400 mAh Li-ion Battery
Battery Nominal Voltage	DC 3.7 V
Charging condition	5 V±0.25 V
Size	70 mm×70 mm×18.4 mm
Net Weight	about 70 g
Wireless protocol	Bluetooth (BLE) 4.0+
Frequency of Bluetooth	2405-2835 Hz
Transmitter power	0 dBm
Intended Range	3 feet
Security measures	AES-128
OS Version	Android - 10.0 or higher iOS - 15.0 or higher
Lifetime of battery	charge-discharge cycles 300 times
Expected service life of product	3 years
Expected service life of NIBP cuff	2 years
Shelf-life of test strip (unopened)	2 years (24 months)
Shelf-life of test strip (opened)	60 days
Shelf-life of Control solutions (opened)	90 days

Radio Compliance	
FCC ID:	2BOXZSCANBO-D8
IC ID:	33813-D8
HVIN:	2.0

Operating conditions for Scanbo® D8 SAM	
Temperature	5°C~40°C
Humidity	15%~93%
Atmospheric Pressure	70~106 kPa
Storage & Transport condition for Scanbo® D8 SAM	
Temperature	-25°C to +40°C
Humidity	≤93%
Atmospheric Pressure	50~106kPa
Storage & Operating condition for Scanbo® Glucose strips and Control Solutions	
Temperature	4° C to 40° C
Humidity	<= 93% RH

Blood oxygen measurement	
Mode of operation	Continuous mode
Site of measurement	Finger
Measurement scope	70%~100%
Accuracy	±4 % for 70 % to 80 % ±2 % for 80 % to 90 % ±1 % for 90 % to 100 %
Red light wavelength	660 nm
Infrared wavelength	900 nm
Pulse Rate (Accuracy)	30~250 bpm (± 2bpm)
Alarm	No alarm

The emitted wavelengths by the pulse oximeter are at 660 nm and 900 nm and the peak optical power is less than 25 mW. Information about the wavelengths can be especially

useful to clinicians. The pulse oximeter updates the mobile app with new valid readings at **1-second intervals**. This data update rate provides a good balance between responsiveness and accuracy, ensuring that users receive timely and stable readings without excessive fluctuation.

Blood pressure measurement	
Site of measurement	Upper arm
Applied arm circumference of cuff	22-35 cm
Resting pressure-rated range	0-300 mmHg
Range of measurable systolic pressure	60-230 mmHg
Range of measurable diastolic pressure	40-130 mmHg
Accuracy	±3 mmHg
Pulse rate measurement range	40 - 180 bpm
Pulse rate accuracy	±5%

Body temperature measurement	
Site of measurement	Forehead
Reference body site	Oral
Measurement scope	34~42°C
Laboratory Accuracy	±0.1° C for 34° C to 42° C
Mode of Temperature measurement	Direct

ECG measurement	
Site of measurement	Hands (handheld)
Calibration voltage	1 mV±5%
Sensitivity error	≤±5%
Polarization resistance voltage	±300 mV
Sensitivity variation	≤±5%
Heart Rate	30-200 bpm
50Hz interference suppression filter	≥20 dB
Waveform sweeping speed	25 mm/s or 50 mm/s

Blood glucose measurement	
Sample volume	0.5 - 0.7 microlitre

Measuring method	Amperometric technology using glucose oxidase
Sample Source	Fresh capillary whole blood from the Fingertip
Model of test strip	Scanbo® D8 Glucose strips
Unit of measurement	mg/dL or mmol/L
Measurement Range	20 to 600 mg/dL (1.1 mmol/L~33.3 mmol/L)
Hematocrit	10% - 65%

10. Symbols Glossary

Symbols	Title of the symbol	Description of the symbol	Source of the symbol
	Prescription Only	Caution: Federal Law restricts this device to sale by or on the order of a physician.	21 CFR 801.109(b)(1)
	Type BF applied part	This symbol indicates Type BF applied part according to the degree of protection against electric shock.	IEC 60417-5840
	WEEE Disposal	Indicate that separate collection for waste electric and electronic equipment (WEEE) is required.	IEC 60417-6414
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021 (Ref. 5.1.1) ISO 7000-3082
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2021 (Ref. 5.1.3) ISO 7000-2497
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2021 (Ref. 5.1.6) ISO 7000-2493
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2021 (Ref. 5.1.7) ISO 7000-2498
	Authorized Representative in the European Community/	Indicates the Authorized Representative in the European Community/ European Union.	ISO 15223-1:2021 (Ref. 5.1.2)

	European Union		
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1:2021 (Ref. 5.7.10)
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021 (Ref. 5.1.4) ISO 7000-2607
	Batch code/ Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021 (Ref. 5.1.5) ISO 7000-2492
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021 (Ref. 5.3.7) ISO 7000-0632
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1:2021 (Ref. 5.3.8) ISO 7000-2620
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1:2021 (Ref. 5.3.9) ISO 7000-2621
IP22	Ingress Protection	Indicates the degree of protection against harmful ingress of particulate matter and water. Protection from ingress of particulates more than 12.5 mm and ingress from water drops when enclosure is tilted up to 15°	IEC 60529
	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	IEC 60417-5031
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read	ISO 7010-M002
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021 (Ref. 5.3.2) ISO 7000-0624

	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1:2021 (Ref. 5.3.4) ISO 7000-0626
	Fragile; handle with care	To indicate that the contents of the transport package are fragile and the package shall be handled with care.	ISO 15223-1:2021 (Ref. 5.3.1) ISO 7000-0621
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1:2021 (Ref. 5.2.8) ISO 7000-2606
	WARNING	This warns of a potential situation that could cause death or serious injury.	ISO 7010-W001
	Caution	This warns of potential minor injury or damage to the device or property. It alerts the user to avoid unsafe practices or take extra care	ISO 15223-1:2021 (Ref. 5.4.4) ISO 7000-0434A
	Alarm inhibit	No SpO ₂ Alarms - To identify the alarm inhibit on control equipment.	IEC 60417-5319
	Medical device	Indicates the item is a medical device.	ISO 15223-1:2021 (Ref. 5.7.7)
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as In vitro diagnostic medical device	ISO 15223-1:2021 (Ref. 5.5.1)

11. Service

11.1. Contact Details

Contact Scanbo® for any feedback, complaints and discrepancies, if any.

For any questions or assistance with set up, use, or maintenance, please contact us using the details below.

Scanbo® Technologies Inc.

Address: 708 Thayer Lane, Unit 304, Foster City, California 94404

Customer Service Tel: +65 3163 7489

Customer service E-mail: support@scanbo.com; care@scanbo.com

Website: <https://www.scanbo.com>

11.2. Reordering Consumables

Contact Scanbo® Customer Service for missing parts or consumable reorders.

Consumable	Part Number/Model No.
Glucose Test strips	SIPL.PKG.ACC.001
Lancets (Needles)	SIPL.PKG.ACC.002
BP Cuff	SIPL.PKG.ACC.004
USB Cable	SIPL.PKG.ACC.005
Control Solutions -Low	SIPL.PKG.ACC.006 (Low)
Control Solutions - High	SIPL.PKG.ACC.007 (high)

12. Guidance on EMC

12.1. FCC Compliance Statement (USA)

Compliance Statement

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



Caution:

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

12.2. Industry Canada (IC) Compliance Statement

Compliance Statement

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause interference.,
2. This device must accept any interference, including interference that may cause undesired operation of the device.
3. A separation distance of **5 mm** must be maintained between the antenna in the Scanbo D8 device and the user. Please note that this distance is maintained inherently by device design. No modifications should be made to the device, as such changes could pose a risk of health hazards from radio-frequency exposure.

Déclarations de conformité:

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.



Caution:

This equipment complies with radio frequency exposure limits set forth by Industry Canada for an uncontrolled environment.



Déclarations de mise en garde:

Cet équipement est conforme aux limites d'exposition aux radiofréquences définies par Industrie Canada pour un environnement non contrôlé.

12.3. Electromagnetic Declaration

Guidance and manufacturer's declaration– electromagnetic emission– for all EQUIPMENT AND SYSTEMS.
Guidance and manufacturer's declaration– electromagnetic immunity – for all EQUIPMENT and SYSTEMS.

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The Scanbo® D8 is intended for use in the electromagnetic environment specified below. The customer or the user of Scanbo® D8 should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment – guidance

4	RF emissions CISPR 11	Group 1	The Scanbo® D8 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Scanbo® D8 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Scanbo® D8 is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanbo® D8 should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Scanbo® D8 requires continued

variations on power supply input lines	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	operation during power mains interruptions, it is recommended that the Scanbo® D8 be powered from an uninterruptible power supply or a battery.
IEC 61000-4-11	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	< 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field	400 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Scanbo® D8 is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanbo® D8 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V (V_1)	Portable and mobile communication equipment should be used no closer to any part of the Scanbo® D8, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF	3 V/m 80 MHz to	10 V/m (E_1)	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$

IEC 61000-4-3	2,5 GHz		800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic energy is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Scanbo® D8 is used exceeds the applicable RF compliance level above, the Scanbo® D8 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Scanbo® D8. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM –for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Scanbo® D8
The Scanbo® D8 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Scanbo® D8 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Scanbo® D8 as recommended below, according to the maximum output power of the communications

equipment.			
Rated maximum output of transmitter [W]	on distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			