

Purpose:

The purpose of this document is to outline how to take a measurement with the BIOSENSE device for trial participants of MBL949A12201.

Setup:

Both the Biosense device and the MBL949A12201 app are required to take a measurement. Preparation time for the device can take anywhere from 30 seconds to 5 minutes for a measurement to properly warm-up depending on the state of the sensor.

When Should Measurements be Taken:

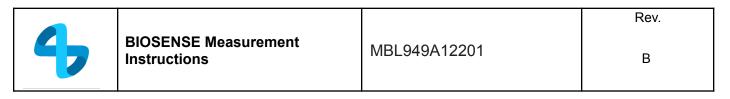
The breath meter will be administered daily at the following 4 times; in the morning after an overnight fast, before lunch, before dinner, and before bedtime.

Tips for Successful Measurements

The device should always be kept in an environment free from solvents like hand sanitizer, perfume, nail polish remover and other aromatics. These can permanently damage the device.

For best results, wait 60 minutes to take a measurement after:

- Eating
- Smoking/Vaping
- Drinking sodas or flavored drinks
- Consuming any of item with flavorings:
 - Toothpaste
 - Mouthwash
 - Cough Drops
 - Breath Mints/Chewing Gum
 - Lip Balm



- Artificial Sweeteners
- Any other flavored consumables

Do not test after consuming alcohol. If consuming alcohol, the device should not be used until the following morning.

Procedure For Taking A Measurement:

- I. First Measurement
 - A. Download and open the MBL949A12201 from google play/apple store
 - B. Open the app on your smartphone.
 - C. Turn on the BIOSENSE device by holding the check button until the BIOSENSE Logo appears.
 - D. A screen will appear saying to Pair to the App to Set Time
 - 1. On the Home screen of the App click the red X.
 - 2. When the device list appears, click on the Serial Number that matches the Serial Number of your device.
 - DO NOT CLOSE THE APP DURING THE MEASUREMENT
 CYCLE (The device will check that you are paired and will prompt you again if the app closes).
 - 4. You will know that you are paired because the app will replace the red X on the app with a green check mark. A blue dot will also appear next to the battery indicator on the device.
 - E. The device will begin preparing, and the blue bars will fill up as the sensor warms up.
 - F. After the device is done preparing, press the check button on the home screen. The screen will say "get ready". Wait for the progress bar to complete.



BIOSENSE Measurement Instructions

MBL949A12201

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- G. A screen appears stating "Blow", Inhale normally and place your lips around the mouthpiece. Steadily exhale with medium force. Do not stop blowing until the device vibrates twice.
- H. BIOSENSE will take 15 seconds to measure your breath. After the measurement is calculated, the device will show a large green check mark that indicates "Success". At this moment the device will send the measurement to the app. The phone will vibrate when measurement is sent.
- I. Once the appropriate circle fills up and turns blue in the app, you may close the app.
 - 1. IF THE CIRCLE IS NOT FILLING UP ATTEMPT A

 MEASUREMENT AGAIN AND VERIFY THAT THE APP HAS NOT

 CLOSED DURING THE CYCLE.
- J. Repeat the same steps above for subsequent measurements at the times specified by the app.
- K. For further information on how to take a measurement using BIOSENSE go to mybiosense.com/novartis/