INSTRUCTIONS FOR USE

VOCxi Health MyBreathPrint® (MBP-001)

This “Instructions for Use” contains information on how to operate the MyBreathPrint® (MBP) Breath Analyzer system.

MyBreathPrint® Overview:

The MyBreathPrint® system is provided in two different kits. One kit includes a mobile phone and connecting cable. The second kit includes the MyBreathPrint® breath analyzer with a disposable breathing mask and IFU card. The physical system is paired with an application for the mobile phone and a web portal. The mobile application provides instructions as well as information for the procedure. The results of the procedure, patient information, site information, and provider information can be viewed on the web portal.

MyBreathPrint® connects to the mobile phone via the USB-C port. The breathing mask provided is equivalent to generic anesthesia breathing masks. The breathing mask is

assembled on the MyBreathPrint® hand-held device. The patient will remove the pull tab from the MyBreathPrint® device and breath into the mask (preferably inhale through nose and exhale through the mouth, depending on the patient's ability). Following the breathing period, the results of the procedure will be available to the provider via the web portal. The results consist of 5 potential outcomes: a high risk or low risk of malignancy, undetermined risk, invalid, or pending analysis. Following the procedure, MyBreathPrint® should be packaged in the return packaging provided by Vocxi health, and the phone and USB-C cable should be stored in a secure location. It is recommended to keep the phone battery charged for future use.

Indication for Use:
The MyBreathPrint® is intended to analyze the exhaled breath of adult patients, ages 50-75, with pulmonary nodules 8mm or greater in diameter identified after LDCT evaluation.

The MyBreathPrint® system will identify those patients with a high probability of malignancy and provide the clinician with a result that classifies patients as either 'High Risk [or Positive Indication]' or 'Low Risk [or Negative Indication]' or 'Undetermined [outcome could not be classified into high or low]'. If the procedure data was collected with errors, the mobile app will prompt the user to repeat the procedure with a new device and the results will be listed as 'Invalid [insufficient data to classify]'.

Note: The output of MyBreathPrint® is not a stand-alone diagnosis; the information provided is meant as clinical decision support and should be considered in the context of other clinical information. MyBreathPrint® uses a data set that can be classified using machine learning models (Breathprint TM) to support data analytics and provide feedback to the user.

Contraindications for Use:

MyBreathPrint® is not intended to be used by patients undergoing active cancer treatments. The device is not intended to be used as a stand-alone diagnostic.

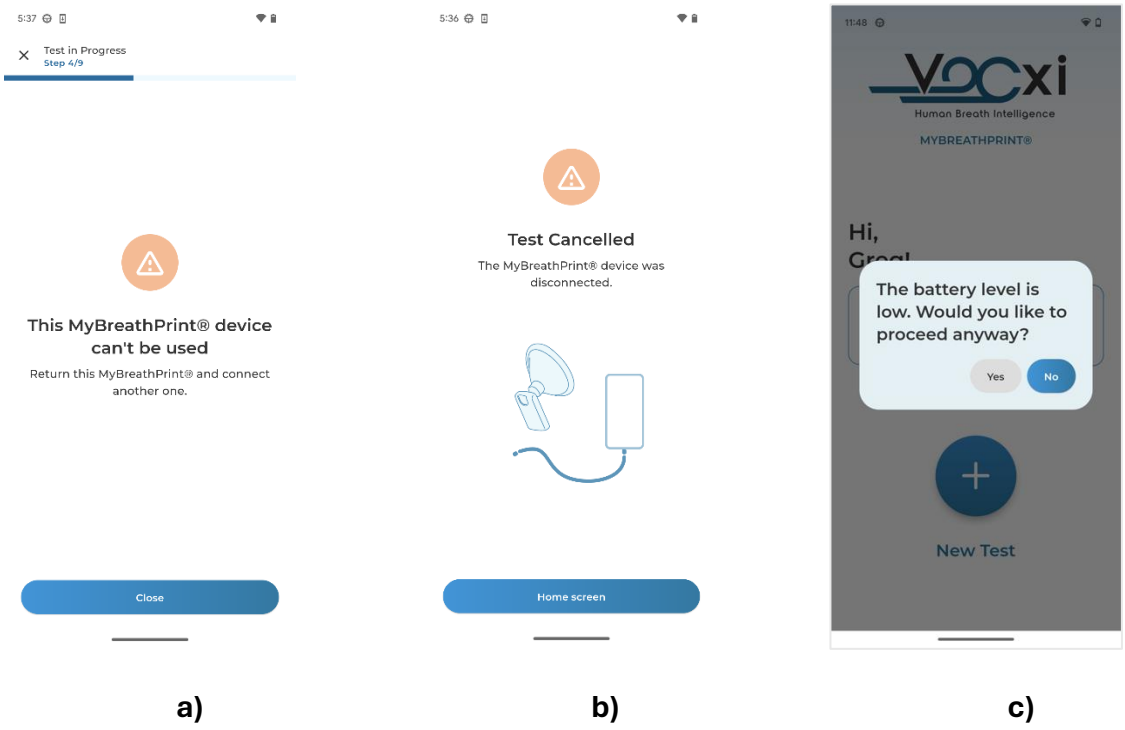
Labeling Symbology

	Contents		**Manufacturer**
	Warning	UDI	**Unique Device Identification**
	Expiration Date		**Separate Collection**
GTIN	**Global Trade Item Number**		**Do not use if package is damaged**
REF	**Reference Number**		**Single use. Do not re-use.**
SN	**Serial Number**		**Consult instructions for use**

General Warnings:

- Do not open MyBreathPrint® foil pouch until the patient is ready to begin the procedure.
- If the pull tab has been removed, do not use the device.
- Confirm the expiration date has not passed prior to using the device.
- A warning will be displayed if the software identifies a predetermined reason to restart the procedure (Figure 1, a).
- Do not disconnect the MBP breath analyzer from the phone until the exhale collection is complete and the on-screen instructions state that the data collection is complete. If the device is disconnected prematurely, the procedure will be canceled (Figure 1, b).

- The mobile phone should have 25% of battery life remaining or greater (Figure 1, c).
- Ensure the USB-C cable has been connected correctly between MyBreathPrint® and the mobile phone.



a) **b)** **c)**

Figure 1: MyBreathPrint® Phone Application

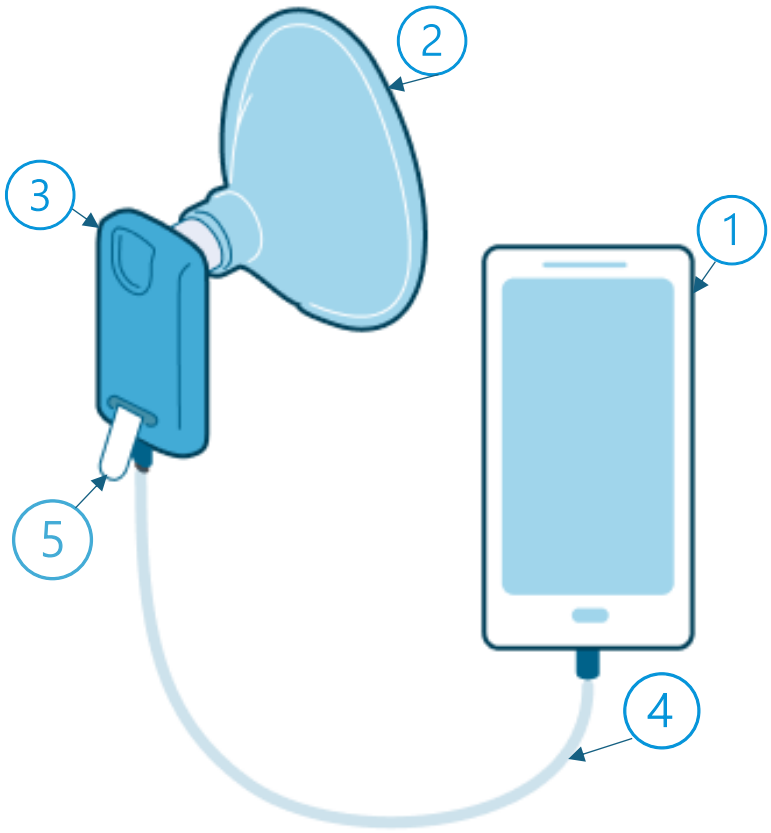


Figure 2: MyBreathPrint® System

1. Google Pixel 6a (On-screen Instructions via MyBreathPrint® App)
2. Breathing Mask
3. MyBreathPrint® (Handheld MBP breath analyzer)
4. USB-C cable
5. Pull Tab (To expose the sensor die)

Directions for Use

Precautions:

To capture a successful exhale, ensure the following:

- Patient has not eaten 60 minutes prior to the exhale.
- Patient has not smoked 2 hours prior to the exhale.

- Remove glasses or other face accessories that could prevent a secure seal around the breathing mask.
- Hold the mask tightly against the face (especially if facial hair is present)
- Advise the patient to inhale normally through the nose and exhale through the mouth, if possible.

Preparation

Collect required materials:

- Cell Phone (Google Pixel 6a)
    - With pre-installed application
- Cable (USB-C)
- Breathing Mask
- MyBreathPrint® packaged breath analyzer

Assembly preparation:

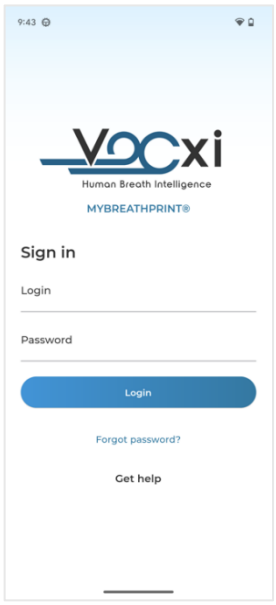
- Assemble the breathing mask to the handheld device.
    - The breathing mask will have a slight press fit to the port on MyBreathPrint®.
- Open the Vocxi application on the mobile phone.
- Follow the set-up prompts directed by the application.
- Enter patient survey data using the web portal.

Note: If internet connectivity is not available, you may proceed with the data collection for up to ten (10) procedures using a unique handheld breath analyzer for each procedure. Once connectivity is established, the procedure data will be automatically uploaded to the web portal.

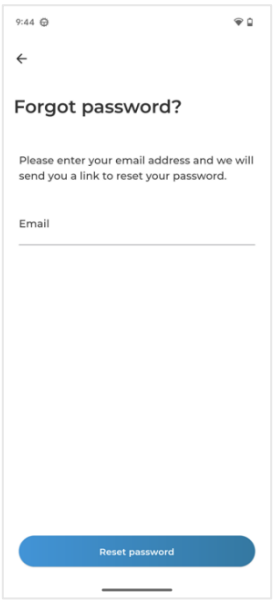
On-Screen Instruction:

Login Screen

a) Login and password prompt
b) Forgot Password
    a. Enter linked email address to reset your password



Login Screen



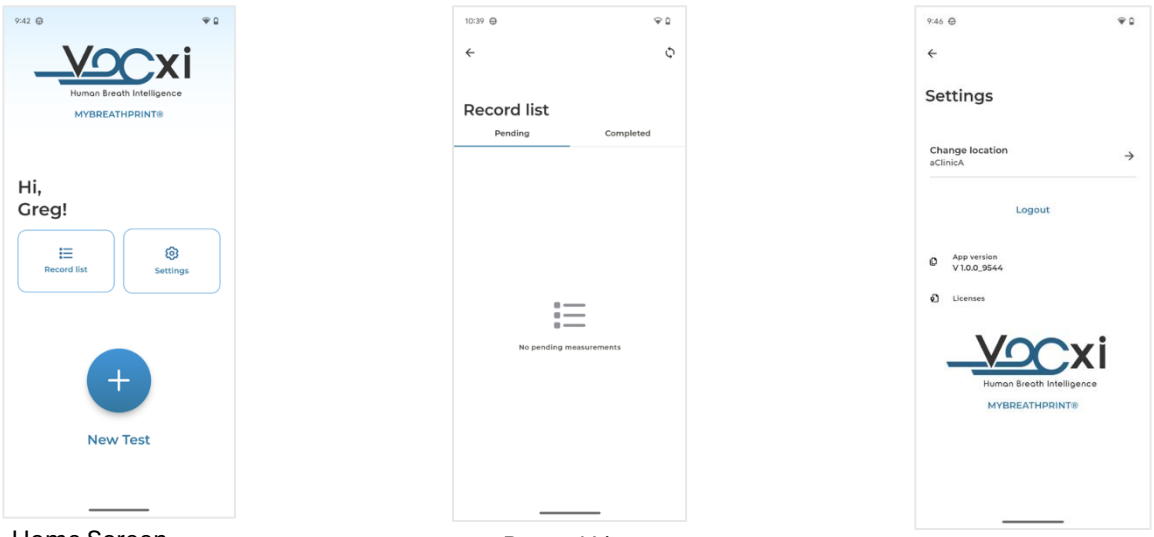
Forgot Password

Figure 3: MyBreathPrint® Login Screen

Home Screen

The home screen on the mobile device has the following options:

a. Record List: Indicates status of pending and completed procedures by the user on the mobile phone.
b. Setting: Allows user to change location or identify app version.
c. Start New Test: Select New Test when ready to start the procedure.

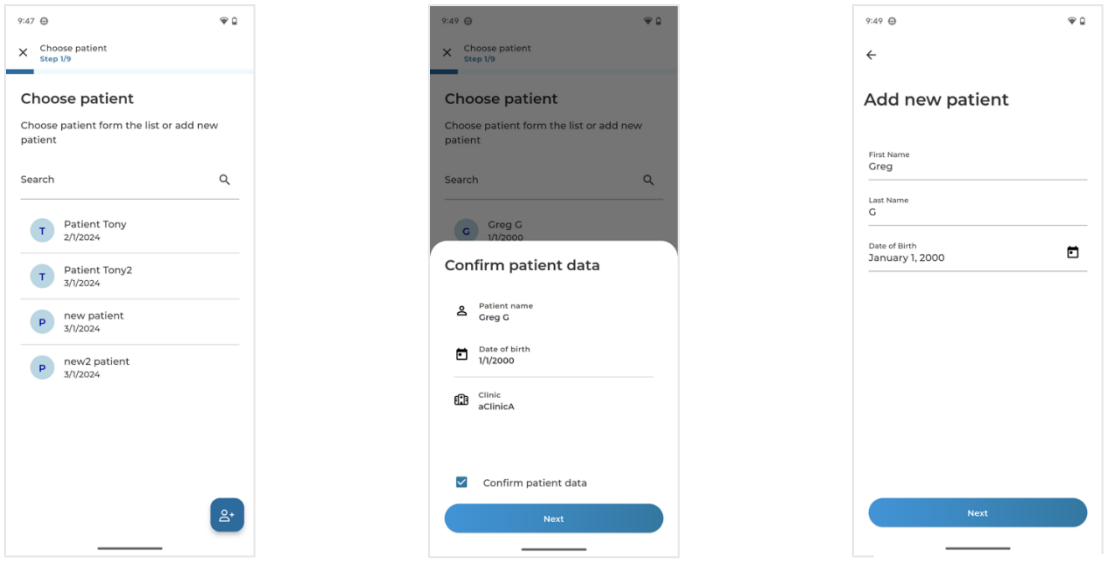


Home Screen Record List Setting

Figure 4: MyBreathPrint® Navigation

When ‘Start New Test’ is selected, you are prompted to ‘Choose Patient’ or select the icon for adding a new patient.

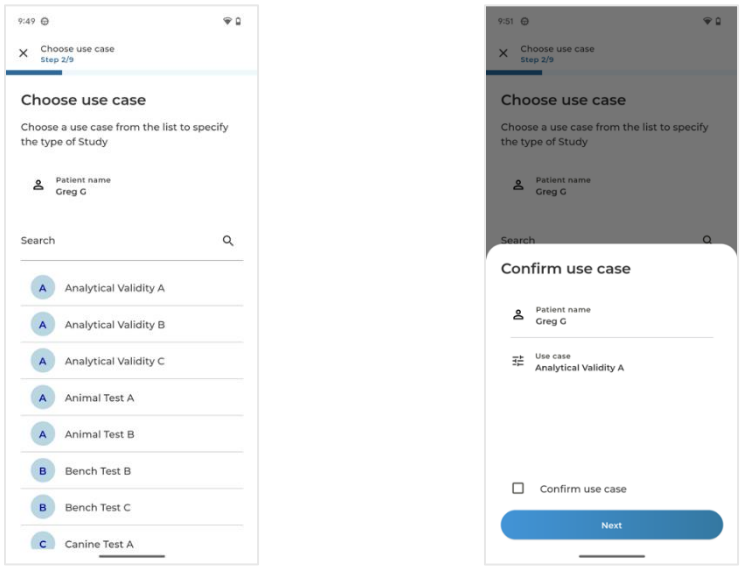
a. Choose Patient
    a. Confirm Patient Data
b. Add New Patient



Choose Patient | Confirm Patient Data | Add New Patient

Figure 5: MyBreathPrint® "Start New Test" Options

Next the provider will be prompted to assign and confirm the use case.



Assign Use Case | Confirmation

Figure 6: MyBreathPrint® Use Case and confirmation Menus

After the patient and use case are confirmed, they are prompted to connect the MyBreathPrint® handheld breath analyzer to the mobile phone with the USB-C cable. The user will be notified by the app that the connection between the mobile phone and MyBreathPrint® have been made and the device is ready to start the procedure. Continue to follow the onscreen instructions. Following 'Start Test' being selected, the screen will show that the device is preparing by heating the sensors. Then the device will notify the user that a baseline air sample is being taken. After the baseline data has been collected, the user will be instructed to practice exhaling into the device.

Once the user feels comfortable to perform the official exhale, the mobile app will prompt the user to remove the pull tab from the device. If needed, the mask can be temporarily removed while pulling the tab, before replacing the mask and resuming breathing as instructed. The user will place and hold the mask tightly over their nose and mouth and breathe normally. The MyBreathPrint® app will prompt the user to keep the device connected to the mobile phone and to remove the mask upon completion of procedure. The MyBreathPrint® app will notify the user when the test has been completed.

Web Portal Instruction:

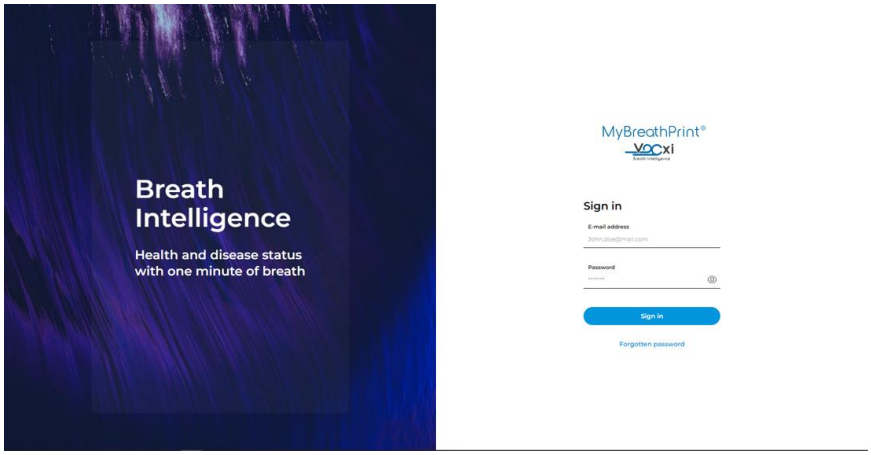
Login Screen:

a) Login and password prompt.

b) Forgot Password

    a) Enter linked email address to reset your password

    b) Set new password meeting criteria on screen.

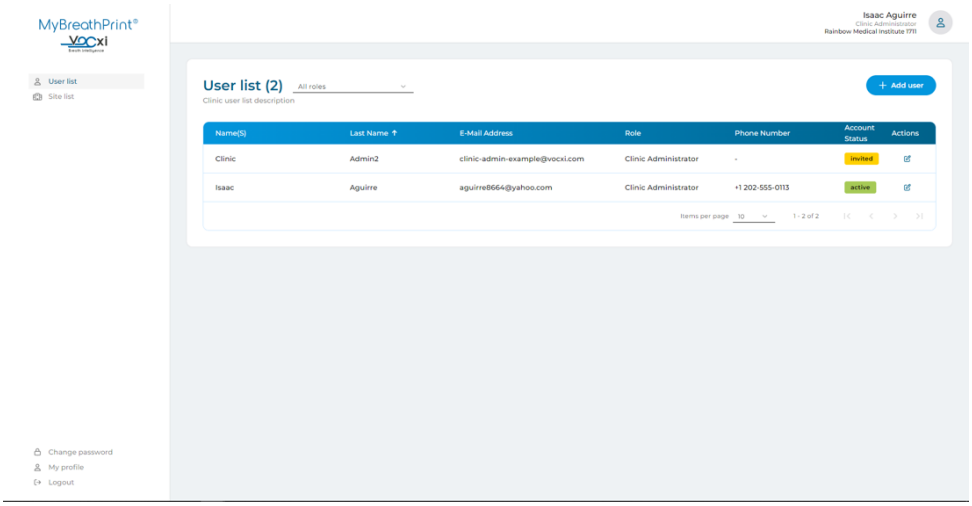


Login Screen

Figure 7: MyBreathPrint® Web Portal Login

Clinical Administrator:

The clinical administrator is assigned to a particular clinic and provided access to the health care professional (HCP) information, site information, and the clinical administrator profile associated with that clinic. The HCP list can be viewed. The HCP and HCP details can be viewed, edited, added, and/or removed. The clinic site list can be viewed, added, and/or removed. The personal, contact, role, and language information can be updated in the clinical administration profile.



Clinical Administrator Portal

Figure 8: Clinical Administrator Portal

Health Care Professional (HCP):

The HCP is provided access to the patient information, enrollment requests, and the HCP profile. The patient list can be viewed. The patient and patient details can be viewed, edited, and/or added. The HCP can request removal of a patient. The enrollment requests can be viewed. The personal, contact, specialization, and language information can be updated in the HCP profile.

Web Portal – Surveys

Three surveys are provided on the web portal. These surveys are the biopsy survey, the ovarian cancer survey, and the lung cancer survey. The biopsy survey requests information pertaining to cancer history, current cancer status, type of cancer, treatment history, nodule(s) location(s), size of nodule, and cancer stage. The ovarian cancer survery requests information pertaining to demographic information, current medical treatment, medical history, and vital signs. The lung cancer survey requests information pertaining to demographic information, current medical treatment, pulmonary history, current medications (oral, injected, or inhaled), smoking history, breathing issues assessment, and vital signs.

Benefits:

Office Based Procedure

Non-invasive, no radiation

Easy to Administer

Compared to Standard of Care (Routine MRI or Tissue Extraction)

Patient Records

Track and monitor breath print status across multiple patients, referring clinicians, and clinics.

Quick Results

Test complete within 5 minutes

Handling and Storage:

- Store the MyBreathPrint® device in a facility between -30°C to 60°C.
- Prior to use, ensure the MyBreathPrint® is not damaged or altered in any way.
- If the pull tab has been removed, do not utilize the device for the procedure.
- Store the mobile phone (Pixel 6a) in a secure location and ensure the device is charged to a minimum of 25% for each use.

Device Disposal and Return:

- Following execution of procedure, dispose of breathing mask, pull tab, and packaging.
- Utilizing the return packaging provided by VOCxi Health, package two used MyBreathPrint® breath analyzers together following the return packaging work instruction.
- Ship the return packaging back to VOCxi Health.
- Store the mobile phone (Pixel 6a) and the USB-C in a secure location for future use.

Troubleshooting

In the event that assistance is needed, reach out to VOCxi Health at info@vocxi.com or 507-301-6866.

Error messages that might be encountered:

- Test canceled: there is an issue with the sensor device. The measurement cannot proceed. Please retry the measurement using a new sensor device
- Test canceled. There was an issue with the firmware or USB channel. Please retry the measurement using a new sensor device
- Invalid Test. Please retry the measurement using a new sensor device

Regardless of when during the process the errors occur, restart the procedure with a new device, do not restart the procedure with the same device.

Manufactured for:
Vocxi Health, Inc.
4100 Hamline Ave N, A-200
Arden Hills, MN 55112

Made in US:
1275 Red Fox Rd
St Paul, MN 55112