

## **Indicor™ Instructions for Use: Rev A, For Clinical Validation Study**

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**NOTICE:** This Instructional Manual is specifically intended for use by hospital(s) participating in the Vixiar clinical trial. The Indicor device is not FDA cleared and is for investigational use only.

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**Introduction:**

The Indicor™ is non-invasive system for estimating elevated cardiac filling pressures (“LVEDP”) by analyzing the patient’s pulse response to a controlled Valsalva maneuver. The system includes three main components: 1. A Bluetooth® enabled handheld device (“Handheld”) for performing a standardized Valsalva maneuver. 2. A finger photoplethysmography sensor (“PPG”) for capturing the patient’s waveform pulse response to the maneuver. 3. A computer tablet containing the Indicor Navigator App (“App”) which provides the patient with visual guidance and coaching as well as the algorithm that calculates and provides a numeric, estimated LVEDP estimate for the clinician.

**Intended Use:**

The Indicor Device is intended to generate PPG and pressure waveforms and provide algorithmic analysis of pulse amplitudes for calculating a patient’s pulse response to the Valsalva maneuver, a controlled exhalation against a closed device system with pressure sensor. The operators of the device are intended to be physicians, nurses, physician’s assistants, medical assistants and other health care professionals.

**Indications for Use:**

The Indicor is indicated for use in providing a noninvasive, indirect estimate of left ventricular end diastolic pressure (LVEDP). This calculated estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected.

**Contraindications:**

The Indicor is contraindicated for patients with: The Indicor is contraindicated for patients with: Weight <88 pounds (40 kilograms), atrial flutter or atrial fibrillation with an irregular ventricular response; significant atrial or ventricular ectopy; history of paradoxical emboli; hypertrophic obstructive cardiomyopathy; history of paradoxical emboli; known intracardiac shunt; known severe aortic valve stenosis or known severe mitral valve stenosis; history of embolic CVA; clinically unstable; uncontrolled hypertension (systolic BP >160mmHg or diastolic BP> 100mmHg); hypotension (systolic BB <90mmHg); symptomatic bradycardia; known cholesterol emboli; poor LV function with known LV thrombus.

**Latex Statement**

The Indicor device including disposables, hardware and accessories contain no latex.

**Symbols and Definitions:**

	WARNING: The warning statements in this manual identify conditions or actions that could lead to illness, injury, or death. Warning statements appear with a grey background in a black and white document.
	CAUTION: The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data
	Instructions/Directions for Use (IFU/DFU)

	Do not reuse. Single patient use only.
	Manufacturer
	Manufactured Date
	Keep Device Dry
	Storage/Operating Temperature
	Bluetooth® low energy (v4.1) device
	WiFi/WLAN Wireless Local Area Network
	Rx/Prescription Required
	Reference, Product Identifier
	Power-On Button
	Serial Number, for capital devices.
Bar Code  	UDI – Unique Device Identifier (Bar Code & Number); Includes both: DI-Device Identifier: Model/Version Number PI-Production Identifier: Serial Number, Lot Number, Expiration, or Manufacturing Date
	Lot Number, for disposable and limited reusable parts. Indicates when built.
	Do not dispose of in trash

	Lithium Battery, Recycle
	No Latex used in the product
	Use By Date



### Warnings and Cautions:

- WARNING:** Patient injury risk. Reuse of mouthpieces could result in cross contamination. Mouthpieces are single patient use items and should be disposed of after each use.
- WARNING:** Patient injury risk. Device shall be disconnected from charger/power source while being used with patient.
- WARNING:** Fire and explosion hazard. Do not operate the device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment.
- CAUTION:** Read and follow these Instructions For Use or other approved instructions before operating system
- CAUTION:** Use only Nellcor DS-100A PPG sensors specified in this manual. See DS-100A Manual for specific warnings and cautions.
- CAUTION:** The device is not user serviceable. Defective product will be replaced by Vixiar per warranty.
- CAUTION:** This device is not protected against the ingress of liquids and should not be used in the presence of liquids which may enter and potentially damage the device.
- CAUTION:** Results not saved on device or transmitted cannot be recovered. Indicor result readings should be documented in patient chart per institutional guidelines.
- CAUTION:** Do not modify this device.
- CAUTION:** Use only the provided USB Charger described herein and supplied by Vixiar.
- CAUTION:** Use only supplied Lenovo® Tab 4 tablet or tablet approved by Vixiar.
- CAUTION:** Use only the cleaning recommendations contained in this manual.

## Controls, Displays and Connectors

### Indicor™ Handheld

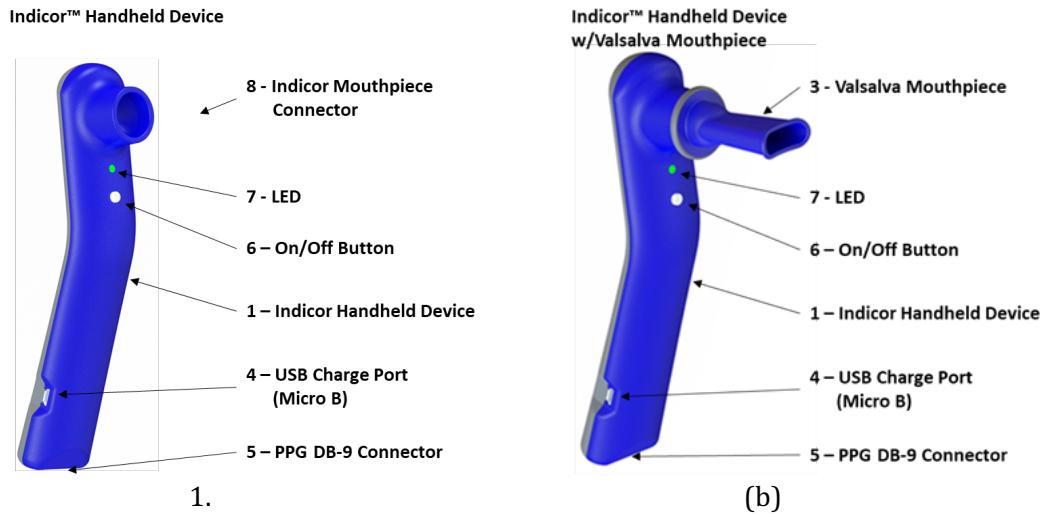


Figure 1. (a) Indicor Handheld and (b) Indicor with Valsalva Mouthpiece.

### Nellcor® DS-100A PPG Sensor



Figure 2. Nellcor® DS-100A PPG Sensor with DB 9 (Blue) Connector.

### Indicor Rolling Stand



Figure. 3. GCX Stand with USB Charger & Tablet Installed, without Bin.

Table 1. Listing of Indicor Components and Accessories

Number	Item	Description
1	Indicor Handheld Device	Handheld device for standardizing Valsalva maneuver
2	Nellcor DS-100A	Reusable finger PPG sensor
3	Indicor Mouthpiece	Single patient disposable mouthpiece with bacterial filter
4	Indicor USB charging port	Charging port on Handheld, micro-B
5	Indicor PPG Connector	DB-9 connector for PPG sensor cable
6	Indicor Power Button	Push button to power on or off
7	Indicor LED display	Color LED display indicating various operating conditions (see LED Indicator Table below)
8	Indicor Mouthpiece Connector	Connection point on Handheld for attaching disposable mouthpiece
9	Indicor Rolling Stand	GCX Rolling Tablet Stand with Handle
10	USB Charger	4-Port USB Charger (AC-DC converter)
11	Tablet	Tablet with Case
12	Bin	Supply Bin (Not Shown)

Table 2. LED Indicators

LED STATUS	DESCRIPTION
*Flashing Red	Handheld charging (will not turn on)
*Solid Red	Handheld fully charged (will not turn on)
*Flashing Blue	Handheld on, broadcasting to tablet Handheld on, searching to connect to paired tablet
*Solid Blue	Handheld on and paired to Tablet
*Solid Green	Handheld on and Tablet on and connected (testing and practice modes)

## Initial Set-Up

### Unpack System

Open and unpack components of Indicor system.

Indicor Device Package Contents:

1. Indicor Handheld: Bluetooth® enabled device for patient Valsalva maneuver
2. Computer Tablet: Lenovo Tab 4 Android tablet containing Indicor Navigator App
3. Finger PPG Sensor: Nellcor® DS-100A adult reusable PPG sensor
4. Indicor Instructions for Use: user instruction manual for system
5. Tablet Protective Case: silicone case

Disposables and Accessories Packaged Separately:

-  Indicor Mouthpiece: single patient disposable for attaching to Indicor handheld packaged
- Indicor Rolling Stand: GCX™ rolling stand with flexible arm, bin and USB charger



Please see separate user instruction manuals for Nellcor™DS-100A and GCX™ Stand included with each accessory package



**CAUTION:** Only use components, accessories and disposables supplied or approved by Vixiar. Use of unapproved parts will impact accuracy of device and operation

#### **Getting Started, First Time Set-Up:**

1. Confirm that all items listed above are available and undamaged. Notify Vixiar if any items are missing or damaged (See Vixiar Contact Information).
2. Complete assembly of the Indicor Rolling Stand (see GCX™ Rolling Stand box for separate directions or Instructions for Use section on Vixiar website, [www.vixiar.com](http://www.vixiar.com)).
3. Open Indicor Handheld Package:
  - a) Remove Handheld, USB Charging Cable.
  - b) Power-on Handheld by pressing and holding button for 1-2 seconds.
  - c) LED will flash Blue if not fully charged.
  - d) If Handheld is not fully charged, plug in the USB Charger on the Rolling Stand and USB Charger to AC wall outlet.
  - e) Handheld will flash Red while charging and transition to solid Red when fully charged.
  - f) Power-off by pressing and holding button for 1-2 seconds.
4. Open Nellcor ™DS-100A PPG Sensor Package
  - a) Read the included Instructions for Use.
  - b) Plug the Blue Connector into the base of the Indicor Handheld .

NOTE: Only the Nellcor™ DS-100A will fit the DB9 connector on the Handheld.

5. Open Tablet Package:
  - a) Remove Tablet, USB Charging Cable, Tablet Instructions.
  - b) Power on Tablet, confirm battery charge state.
  - c) If Tablet is not fully charge, plug in the USB Charger on the Rolling Stand to AC wall outlet and plug in the Tablets USB cable into the Tablet and USB Charger.
6. When fully charged, confirm Tablet settings:
  - a) Launch Tablet settings by clicking on gear icon.
  - b) Select Network WLAN (wireless local area network).
  - c) Enable Bluetooth®
  - d) Select Display – Set Sleep State to 30 minutes.

- e) All other settings are Default.
- f) Press Tablet Back Button (<) to return to the Home Screen.
- g) The Indicor Navigator Application Icon  will be shown here.
- h) Power down the Tablet by pressing the power button.

NOTE: The tablet contains Indicor Navigator application software. This software comes preinstalled and ready for use. Updates to software may be necessary at which time the user should follow directions in the Settings Tab on the Indicor Navigator main screen. User will be notified if update is necessary.

7. Tablet to Handheld Pairing:
  - a) Power on the Tablet by pressing the power button.
  - b) Power on Handheld by pressing and holding button for 1-2 seconds.
  - c) Go to Settings Icon on the Tablet and select Bluetooth®.
  - d) Follow steps for establishing Bluetooth® pairing. The Indicor handheld will broadcast its serial number. This information will be shown under “Available Devices” in the Tablet Bluetooth® screen.
  - e) Select this Handheld serial number by tapping on the number. The LED will turn to Solid Blue while in the pairing process.
  - f) The Handheld will now be shown under “Paired Devices.” When your Tablet is paired, and connected to specific Indicor device, you are ready to proceed to patient testing. Pairing is indicated by a solid blue light on the LED.
  - g) Though additional Handhelds can be paired with a single Tablet, this is not recommended.
  - h) Confirm that the Tablet is still connected to the WLAN – WiFi network.
8. Attach the Tablet to the Rolling Stand
  - a) Remove the Tablet Protective Case from its packaging.
  - b) Insert Tablet into the Protective Case.
  - c) Remove the Tablet Mount Plate from the GCX™ packaging.
  - d) Follow GCX™ mounting instructions to attach the Tablet Mount Plate to the back of the Case of the Tablet.
  - e) Bolt the Tablet Mount Plate to the GCX™ “MOUNT”.
  - f) Place Handheld with connected Nellcor™ DS-100A and Indicor Mouthpieces in rolling Stand Bin as shown.

NOTE: Check that the Handheld and Tablet are charged before bringing to patient area.



**WARNING:** Indicor Handheld should not be used while connected to charger.

### **Starting a New Patient Test:**

NOTE: Always check for Tablet WiFi connection before performing a test if data is to be transmitted electronically (See Getting Started, WiFi set-up above).

**NOTE:** Before commencing test, the following patient data should be collected for input to the Indicor Navigator App: patient ID, height (Ft-In), weight (lbs), systolic blood pressure (mmHg), diastolic blood pressure (mmHg), age & gender.

**1. Patient Positioning & Training:**

- a) For the Clinical Trial, the Patient will be tested in two (2) positions.
  - i. Upright: Patient is seated upright on table or stretcher, inclined approximately 30 degrees from vertical. Position patient's hand with the PPG sensor resting on a table or another surface at the same level as their chest.
  - ii. Supine: Patient supine on cath table with pillow or slight elevation to head. Position patient's hand with the PPG sensor on the cath Table, resting next to patient.
- b) Tap on the Indicor Icon on Tablet Screen to bring up Main Screen (Figure 4).
- c) Position arm of Rolling Stand so that Tablet is approximately 2 feet from the patient either at bedside or in seated position.
- d) Tap on "Training Video" to launch patient instructions, if this is the first time a patient has been tested. The clinician may also choose to train on procedure without video. If instructing patient, the following verbal directions are recommended:
  - "You will perform three sets of ten-second measurements in either a seated or supine position."
  - "You will perform a Valsalava maneuver, forcefully exhaling into the Handheld while watching the virtual pressure gauge on the display screen. You should bear down as if having a bowel movement as you exhale into the device."
  - "The object is to keep the white ball float in the green target zone, as close to the center line as possible for 10 seconds." The actual test will be timed for ten seconds, but the practice screen will allow you to practice keeping the pressure steady, in the green target zone without a timer."
  - "During the actual test, a screen will be shown that captures and analyzes your resting pulse pressure for about 15-20 seconds."
  - "After a stable signal is captured, a grayed-out countdown screen with ball float and target zone appears with the bottom blue bar for 5 second countdown."
  - At the end of this countdown, the screen becomes Colored. Take a normal breath in and then exhale forcefully and hold for 10 seconds. The 10 second clock will countdown once you have entered the Green Zone of the virtual Pressure Gauge."
  - "Your Test Results will be displayed in the next screen where you will be given a 60 second rest period between measurements"
  - "Please keep your arm with the PPG relaxed but avoid movement or talking during the measurements."
- e) Confirm patient understanding.

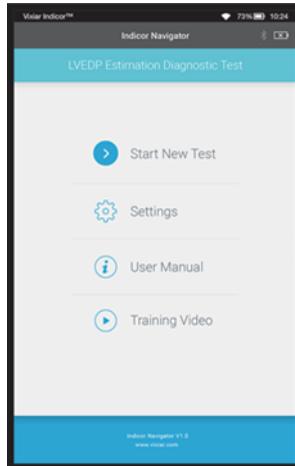


Figure 4. Indicor Navigator App Start-up/Launch Page

2. Prepare the Handheld for patient:
  - a) Attach the PPG blue connector to the bottom of the Handheld.
  - b) Insert a disposable mouthpiece into the top end of the Handheld.
  - c) Place the Handheld with PPG attached in patient's hand and connect the PPG finger clip to the index finger on their opposite hand, wire side up on back of patient's hand (Figure 5).



Figure 5. Correct positioning of the Nellcor™ DS-100A on Patients index finger.

3. Prepare and Run the Indicor Navigator App for the patient test:
  - a) Turn Tablet towards clinician and tap on "Start New Test" on Main Screen
  - b) Clinician should enter previously recorded data on Patient Information Screen (Figure 6). Complete all required fields.



Figure 6. Navigator App, Patient Data Information Entry Screen

- c) Power on Handheld by pressing and holding button for 1-2 seconds. Handheld LED will flash Blue awaiting connection to the Tablet.
- d) Tap on Practice Icon
- e) Tablet and Handheld will now connect via Bluetooth®. Handheld LED will turn Solid Green confirming connection to Tablet. If the Green light does not appear, make sure Handheld power is on indicated by flashing Blue.
- f) Patient should practice the Valsalva maneuver by selecting the 'Target' icon.
- g) Instruct the patient to take a normal inhalation and then exhale forcefully into the Mouthpiece while bearing down.

NOTE: Objective of practicing the Valsalva maneuver is to understand the level of effort to reach and maintain a steady pressure in the target zone, preferably at the center line. When patient can successfully hold the ball float near the center of the target zone (Figure 7), proceed to test.

NOTE: The Practice Mode is not timed and no LVEDP calculation is provided

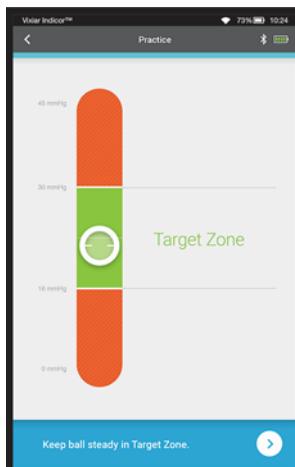


Figure 7. Navigator App, Patient Valsalva Practice Screen

4. Before proceeding, explain to patient that the Indicor Test will begin next. Remind the patient to take normal breaths during the Acquire Baseline Signal period and then exhale forcefully for the Valsalva

at the end of the 5 second countdown. The patient should not take a deep breath before exhaling forcefully.

5. Explain to patient that the Test includes three measurement sequences. At the end of each sequence, the App will display an LVEDP measurement between 5 to 40 mmHg.



**CAUTION:** Patient should keep the arm with the PPG Sensor attached motionless and relaxed. They should also refrain from speaking as movement and speaking will impact the accuracy of the pulse measurement.

6. Tap on Forward Arrow to begin the patient test

- a. App will begin communication with Handheld, acquiring baseline pulse pressure and heart rate data (Figure 8).

NOTE: The App will not begin the testing countdown until an adequate PPG signal is acquired. The App will detect if heart rate is below 40 or over 120 BPM or if arrhythmias are present and not allow test to proceed.

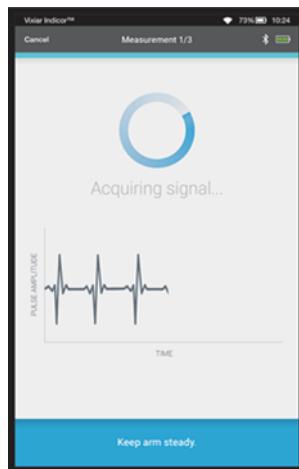


Figure 8. Navigator App, Acquire Stable Pulse Signal Screen

When a stable PPG pulse signal baseline (stable Heart Rate between 40 – 120 BPM and Pulse Response) is acquired, the App will notify the patient - "Test will Begin Shortly", and Screen will change to the Countdown Screen (Figure 9). A 5 second countdown commences on the bottom blue instruction bar, at which time the first of three measurements will be taken.



Figure 9. Navigator App, Test Countdown Screen (showing 3 seconds remaining)

NOTE: Patient should not begin to exhale prior to 0 Seconds as this will cause a Test Fault. After the countdown has reached 0 seconds, the patient has up to 5 seconds to start the test and attain the minimum of 16 mmHg pressure for the Test to continue.

- b. After countdown reaches 0 seconds, Test Screen will become active (changes from Gray to Color) and the patient will perform the Valsalva maneuver by exhaling into the device for 10 seconds, keeping the white ball float steady in the green zone (Figure 10).



Figure 9. Navigator App, Valsalva Measurement Screen (showing 2 seconds remaining)

NOTE: If the patient does not achieve target pressure for the full 10 seconds, a pop-up message will appear providing the option to “End Test” or “Try Again.” In this condition, no LVEDP estimate will be generated. App will return to the Acquire Signal Screen above if “Try Again” is selected (Figure 8).

- c. Within a few seconds after the patient has successfully completed the 10 seconds of the Valsalva maneuver, the App will calculate and display a numeric LVEDP score, Figure 10. The individual test LVEDP data shall be recorded. Tapping on the score will display the patients Pulse and Valsalva Signals.



Figure 10. Navigator App, Valsalva Result Screen (1<sup>st</sup> Measurement) and 60 second rest period has begun.

- d. After 60 seconds of rest, have the patient perform the test again (Step 6a, above).
- e. After completion of the Rest Period, App will return to Acquire Signal screen for tests 2 and 3.
- f. The final test will provide an average LVEDP which should then be logged by the user in the patient chart or applicable record, Figure 11.

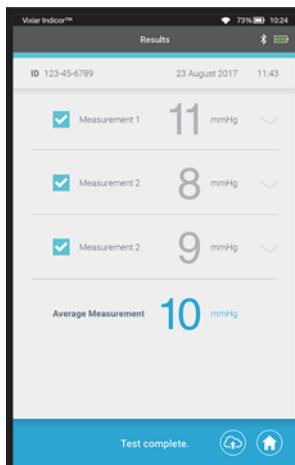


Figure 11. Navigator App, final Valsalva Result Screen (Test Complete) with Cloud icon to save results and Home icon to run a new LVEDP test.

- g. If clinician has selected the option to transmit patient data to cloud, a popup will appear confirming results saved and to return to App Main Page or Patient Information Page to start a new test. (Figure 12).

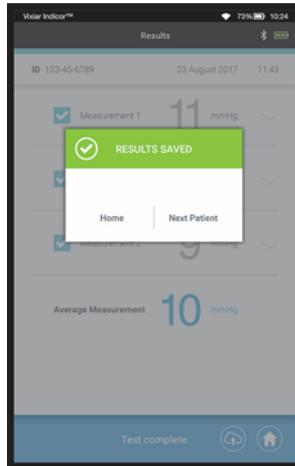


Figure 12. Navigator App, saved results to Cloud, option to return to Home Page or Patient Data Information Entry Screen to begin a new LVEDP test.

NOTE: in clinical studies, the user will be asked to “Keep the Results” and should choose “Yes”.



CAUTION: Data will not be saved if home icon is chosen

#### CLEAN AND DISINFECT

1. Dispose of single patient Mouthpiece per institutional protocol.



**WARNING:** Patient Mouthpieces are single use items. Reuse of mouthpiece could result in cross contamination.

2. Wipe down Indicor Handheld with 70% isopropyl alcohol or Vixiar approved disinfectant wipes between each patient.
3. The DS-100A PPG may be surface-cleaned by wiping it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (~5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur (see Nellcor Instructions for Use).
4. Tablet should be cleaned per hospital protocol.



CAUTION: Use of bleach or non-approved cleaning agents may damage device.



CAUTION: Disposable Mouthpiece comes in contact with patient and shall not be reused to avoid cross-contamination.

#### Biocompatibility:

The patient-contact portion of the Indicor device meets biocompatibility standard ISO 10993-1.

#### Approved Accessories:

Accessory	Manufacturer	Model Number
Indicor Rolling Stand	GCX	PTE-0001-60
Mounting Adapter for Tablet	GCX	TBL-0002-18
Bin	GCX	WM-0001-22
USB Charger	GCX	USB-0001-02
Indicor Display Tablet	Lenovo, Inc.	TB-X304F
Nellcor™ Adult SpO <sub>2</sub> Sensor	Medtronic (Nellcor)	DS-100A

**Troubleshooting:**

Problem/Error Message	Potential Solution(s)*
Handheld will not power-on (no LED visible)	<ul style="list-style-type: none"> <li>-Press power button and <u>hold</u> for longer than 1 second.</li> <li>-Check that Handheld is charged: plug in USB cable to Handheld from charger to charge. LED will flash red if not fully charged.</li> </ul>
Handheld will not pair with Tablet	<ul style="list-style-type: none"> <li>-Check Tablet settings (Bluetooth® should be “On”).</li> <li>-Check paired device list to see if Handheld serial # is listed. If listed, choose “forget device” and start pairing process again.</li> <li>-Handheld must be on with LED flashing blue to pair. LED will turn solid blue when paired with Tablet.</li> </ul>
Handheld will not connect with Tablet	<ul style="list-style-type: none"> <li>-Make sure device is powered on and LED flashing blue.</li> <li>-See above for pairing.</li> <li>-Make sure Navigator app is open and on either the Practice or Test Screen (Tablet and Handheld will not connect on Patient Information screen).</li> </ul>
Navigator App will not progress to Testing Mode from Acquiring Signal	<ul style="list-style-type: none"> <li>-Indicor is programmed to look for a stable PPG signal before launching Test Mode.</li> <li>-Make sure patient is not moving or speaking.</li> <li>-Check that PPG sensor is attached properly to patient finger.</li> <li>-Check that PPG connector is fully inserted into Handheld.</li> <li>-If App continues to fail to progress to Test Mode, the patient may not have a stable enough signal or have a heart that is above 120 or under 40 BPM.</li> </ul>
Error Message: “You must maintain the pressure within the testing range (green target zone) until the test is complete”	<ul style="list-style-type: none"> <li>-Patient did not hold pressure in target green zone (16-30 mmHg) for minimum of 10 seconds.</li> <li>-Ask patient if they are able to attempt again and then restart the Testing Mode by tapping “Try Again” or “End Test” if patient cannot continue. (This error message will display if pressure is out of range or target pressure is held for less than 10 seconds.)</li> </ul>
Error Message: “You have five seconds from when the test starts to hold the pressure in the testing range”	<ul style="list-style-type: none"> <li>-Patient did not achieve Target Zone pressure within 5 seconds after end of countdown.</li> <li>-Remind patient to start Valsalva after countdown when screen turns colored from gray.</li> </ul>

\*If provided solution does not solve issue, contact Vixiar Technical Service

**Vixiar Medical Technical Contact Information:**

Contact: Michael Slavin

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