



Indicor™ Operating Instructions Manual



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CAUTION: Investigational Device. Limited by Federal law to investigational use.

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FCC NOTICE:

The device CYBLE-022001-00, including the antenna 2450AT18B100 from Johanson Technology, complies with Part 15 of the FCC Rules. The device meets the requirements for modular transmitter approval as detailed in FCC public Notice DA00-1407, transmitter 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.



1 Introduction:

The Indicor™ is non-invasive system for estimating cardiac filling pressures by analyzing a patient's pulse response to a controlled Valsalva maneuver. The system includes four main components: 1. A Bluetooth® enabled handheld device (Handheld) for performing a standardized Valsalva maneuver. 2. A finger photoplethysmography (PPG) sensor for capturing the patient's waveform pulse response to the maneuver. 3. The Indicor Navigator App (App) software that resides on an Android®- based tablet and provides the patient with visual guidance and coaching as well as the test procedure and algorithm that calculates and displays the numeric, estimated LVEDP for the clinician. 4. The Valsalva Interface, a custom disposable mouthpiece which the patient exhales into to perform the Valsalva maneuver.

1.1 Intended Use:

The Indicor is intended to analyze the pulse response during a Valsalva maneuver, a forced exhalation against resistance, to estimate cardiac filling pressure. The operators of the device are intended to be physicians, nurses, physician's assistants, medical assistants and other health care professionals in clinical environments.

1.2 Indications for Use:

The Indicor is intended for use by physicians and other clinicians working under the supervision of a physician in non-invasively estimating left ventricular end diastolic pressure (LVEDP) in clinically stable adult patients in a clinically supervised setting. This estimate, when used as an adjunct tool along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the physician 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. The Indicor is not intended to be used as the sole diagnostic tool for estimating LVEDP.

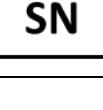
1.3 Contraindications:

Certain patient conditions should be considered as a basis for excluding individual patients for testing based on a possible risk to them of the Valsalva maneuver, such as the following: 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; myocardial infarction within one week of intended Indicor testing; uncontrolled hypertension (systolic BP >160mmHg or diastolic BP> 100mmHg); hypotension (systolic BP <90mmHg); symptomatic bradycardia; known cholesterol emboli; poor LV function with LV thrombus.

1.4 Latex Statement:

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

2. 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 this symbol and in text with a grey background in this 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
	Refer to Operating Instructions Manual
	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

 <p>(01)102222233334(17)091231(10)A1345B(21)1234 Unique Device Identifier DI-Device Identifier PI-Production Identifier Expiration Date Lot Number Manufacture Date</p>	UDI – Unique Device Identifier (Bar Code & Number); Includes both: DI-Device Identifier: Model/Version Number PI-Production Identifier: Serial Number, Lot Number, Expiration, or Manufactured Date
 LOT	Lot Number, for disposable and limited reusable parts. Indicates when built.
	Do not dispose of in trash
 Li-ion	Lithium battery, recycle
 LATEX	No latex used in the product
	Use by date

3. Warnings and Cautions:

- WARNING:** The Indicor captures and presents data on the patient's response to the Valsalva maneuver. When utilized by a trained physician or clinician, this data can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.
- WARNING:** To minimize chances of a misdiagnosis, the clinician should assure that tests are properly administered and interpreted. This includes proper Valsalva technique and accuracy of input data.
- WARNING:** Reuse of Valsalva Interface mouthpieces could result in cross contamination.
- WARNING:** Device must 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.
- WARNING:** Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Indicor System. Otherwise, degradation of the performance of this could result.
- WARNING:** Only use components, accessories and disposables supplied or approved by Vixiar. Use of unapproved parts may impact accuracy of device and operation.
- WARNING:** This device should not be modified.
- CAUTION:** Investigational device. Limited by Federal (or United States) law to investigational use.



- CAUTION:** Read and follow these Instructions for Use or other approved instructions before operating system.
- CAUTION:** Use only Nellcor DS100A or DS100A-1 PPG sensors specified in this manual. See DS100A, DS100A-1 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 or electronic medical record per institutional guidelines.
- CAUTION:** Use only the provided USB chargers described herein and supplied by Vixiar.
- CAUTION:** Use only computer tablets specified and approved by Vixiar.
- CAUTION:** Use only the cleaning and disinfection recommendations contained in this manual.
- CAUTION:** Exposure to Radio Frequency Radiation. This product complies with FCC RF exposure compliance requirements and is only to be used with the antenna and radio module installed on the device. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

4. Controls, Displays and Connectors

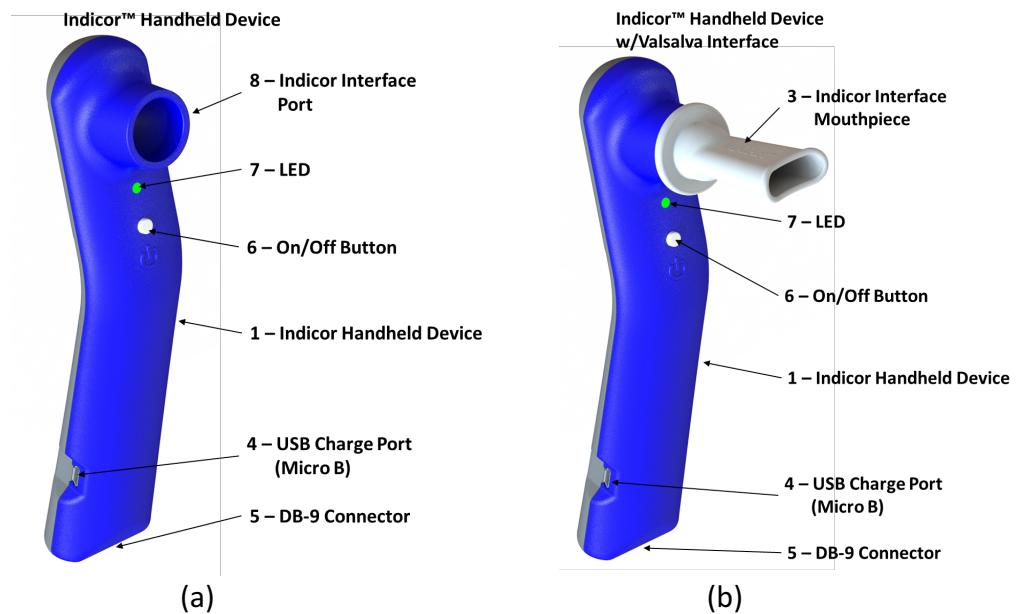


Figure 1. (a) Indicor Handheld and (b) Indicor Handheld with Valsalva Interface Mouthpiece



Figure 2. Nellcor® DS-100A PPG Sensor with DB 9 (Blue) Connector (Medtronic, 710 Medtronic Parkway, Minneapolis, MN 55432-5604).

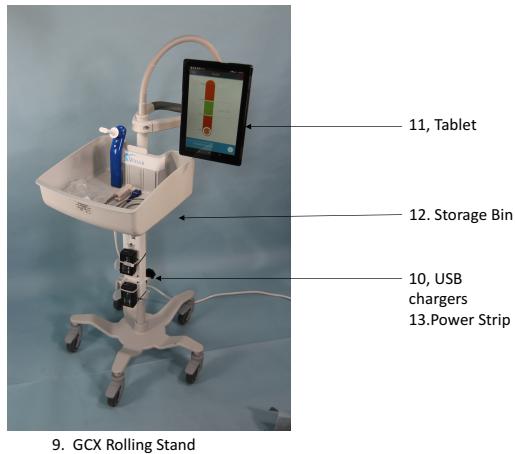


Figure. 3. GCX Rolling Stand (GCX Mounting Solutions, 3875 Cypress Drive, Petaluma, California 94954-5635) with USB Charger & Tablet Installed

4.1 Listing of Indicor Components and Accessories (per Figures 1-3)

Number	Item	Description
1	Indicor Handheld	Handheld component for patient to perform controlled Valsalva maneuver
2	Nellcor DS-100A	Reusable finger PPG sensor (Medtronic, 710 Medtronic Parkway, Minneapolis, MN 55432-5604)
3	Indicor Valsalva Interface	Single patient disposable mouthpiece with membrane
4	USB charging port	Charging port on Handheld, USB micro-B
5	PPG Connector	DB-9 connector on Handheld for PPG sensor cable
6	Power Button	Push button on handheld to power on or off
7	LED display	Color LED display on Handheld indicating various operating conditions (see LED Indicator Table below)
8	Mouthpiece Port	Connection point on Handheld for inserting disposable Valsalva Interface
9	Indicor Rolling Stand: (Accessory)	GCX Rolling Tablet Stand with Handle (GCX Mounting Solutions, 3875 Cypress Drive, Petaluma, California 94954-5635, USA)
10	USB Charger (2)	TRUMPower USB Charger (TRUMPower, 3350 Scott Blvd., Santa Clara, CA 95054, USA)
11	Tablet	Android® computer Tablet
12	Bin (Accessory)	Supply Bin on Rolling Stand
13	AC Power Strip (Accessory)	Tripp-Lite Power Strip on Rolling Stand (TRIPP LITE, 1111 West 35th St., Chicago, Illinois 60609, USA)
Not Shown	VESA Tablet Mount (Accessory)	VESA adapter on Rolling Stand

4.2 LED Indicators:

LED STATUS	DESCRIPTION
Flashing Magenta	<ul style="list-style-type: none"> • Handheld charging



Solid Magenta	<ul style="list-style-type: none">Handheld fully charged
Flashing Blue	<ul style="list-style-type: none">Handheld broadcasting to Tablet for pairingHandheld searching to connect to paired Tablet
Solid Blue	<ul style="list-style-type: none">Handheld paired to Tablet via Bluetooth®. Handheld connected to Tablet
Solid Green	<ul style="list-style-type: none">Handheld and Tablet connected System is ready for use. (practice or testing modes)

5. Initial Set-Up

5.1 Unpack System:

- Open and unpack components of Indicor system.

Indicor Medical Equipment Package Contents:

- 1 Indicor Handheld
- 1 Tablet: Bluetooth® enabled Lenovo Tab 4 Android tablet containing Indicor Navigator App
- 1 Finger PPG Sensor
- 1 Indicor™ Operating Instructions Manual
- 2 Medically certified USB chargers

Disposables and Accessories Packaged Separately:

- 25 Valsalva Interfaces: disposable mouthpieces 
- 1 Rolling Stand with flexible arm and bin
- 1 VESA Mount for attaching Tablet to Rolling Stand



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



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

5.2. Getting Started, First Time Set-Up:

- Confirm that all items listed above are available and undamaged. Notify Vixiar if any items are missing or damaged and do not attempt to use the device.
- Complete assembly of the Indicor Rolling Stand (see GCX™ Rolling Stand box for directions)
- Install Tripp Lite™ power strip with poll mount
- Open Indicor Handheld Package:
 - Remove Handheld, USB Charger.
 - Plug in power strip to AC outlet
 - Plug in USB charger to power strip and to Handheld USB port.

⚠️ WARNING: Use only Vixiar supplied chargers. Substitute chargers may not be medically certified and my damage device.

- d) LED will flash magenta if not fully charged.
 - e) Handheld will transition to solid magenta when fully charged.
5. Open Nellcor DS-100A PPG Sensor package:
- a) Read the included Instructions for Use.
 - b) Plug the blue connector on the PPG sensor into the base of the Indicor Handheld.

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

⚠️ WARNING: Use only the Nellcor DS-100A sensor. Using other sensors may impact the accuracy of the Indicor.

6. Open Tablet Package:
- a) Remove Tablet, & Tablet Instructions.
 - b) Power on Tablet, confirm battery charge status.
 - c) If Tablet is not fully charged, plug in the supplied medically certified USB Charger to AC wall outlet and plug in the Tablets USB cable into the Tablet and USB Charger.

⚠️ WARNING: Use only Vixiar supplied charger. Substitute chargers may not be medically certified and my damage device.

7. When fully charged, confirm Tablet settings:
- a) Select Android™ center icon  to view all Apps.
 - b) Select gear icon to launch tablet Settings, may need to scroll down.
 - c) Select WLAN.
 - d) Select network to identify your WLAN (wireless local area network) and enter credentials.
 - e) Select back button (<) to return to Settings.
 - f) Select Bluetooth®.
 - g) Enable Bluetooth®.
 - h) Select back button (<) to return to settings.
 - i) Select display – Set sleep state to 30 minutes.
 - j) All other settings are default.
 - k) Press Tablet back button (<) three times to return to the home screen.

- l) The Indicor Navigator App icon  will be show on home screen
- m) Power down the Tablet by pressing the power button.

NOTE: Navigator App software resides on the Tablet. 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.



8. Tablet to Handheld Pairing:
 - a) Power on the Tablet by pressing the power button.
 - b) Power on the Handheld by pressing and holding button for 1-2 seconds.
 - c) Go to settings icon on the Tablet and select Bluetooth® (See #6 above).
 - d) Follow steps for establishing Bluetooth® pairing. The Indicor Handheld will broadcast its serial number. This will be shown under “Available Devices” in the Tablet Bluetooth® screen.
 - e) Select this Handheld serial number by tapping on the number. The Indicor LED will turn to solid blue while in the pairing process.
 - f) The Handheld will now be shown under “Paired Devices.” When the 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 per #6 above.
9. Attach the Tablet to the Rolling Stand:
 - a) Remove the Tablet Mount Plate from the GCX packaging.
 - b) Follow GCX mounting instructions to attach the Tablet Mount Plate to the back of the Tablet.
 - c) Bolt the Tablet Mount Plate to the GCX™ “MOUNT”.
10. Place Handheld with connected Nellcor™ DS-100A and Valsalva Interfaces 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 and AC power. The Handheld will not operate while the USB charger is connected.

6. Starting a New Patient Test:

NOTE: Always check for Tablet WiFi connection before performing a test if test results are 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, weight, systolic blood pressure, diastolic blood pressure, age & gender.



WARNING: Entered patient data is used by Navigator App to calculate an estimated LVEDP. Clinician should collect and enter required data accurately.

6.1 Patient Positioning & Training:

- a) The patient should be tested as follows:
 - i. Seated Position: Patient is seated upright on table, hospital bed or chair, approximately 30 degrees from vertical. The patient should **NOT** lean forward.

- ii. Placement of hand with the PPG sensor: Position patient's hand with the PPG sensor on the index finger and the wire side up on back of patient's hand. Hand must be hanging in the air as shown below, either off the arm of a chair or hospital bed.

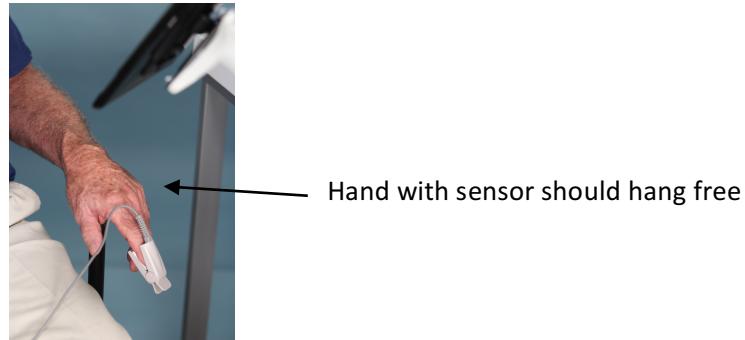


Figure 4: PPG sensor placement

- iii. Tap on the Indicor icon on the Tablet screen to bring up main screen (Figure 5).
- b) Position arm of Rolling Stand so that Tablet is approximately 2 feet from the patient, either at bedside or in seated position.
- c) The clinician should instruct the patient on the Valsalva maneuver. A patient training video is available to play for the patient and the following verbal directions are recommended:
- "You will perform three measurements in a seated position. Each measurement will take approximately one minute and includes a 20 second resting period, a 10 second Valsalva maneuver and a 30 second recovery period."
 - "When instructed, you will perform a Valsalva maneuver by forcefully exhaling into the Handheld while watching the virtual pressure gauge on the Tablet display screen. You should bear down as if having a bowel movement or blowing up a balloon as you exhale into the device. Do not puff your cheeks. The pressure should come from your abdomen rather than upper airway. You'll want to feel the pressure in your chest."
 - "The objective is to keep the white ball float in the green target zone, as close to the center line as possible for the entire 10 seconds. The actual test is 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 your resting pulse pressure. This will be followed by the screen graying out the virtual pressure gauge while a timer on the bottom blue bar counts down 5 seconds until starting the Valsalva maneuver. At the end of this countdown, when the virtual pressure gauge becomes colorful, take a normal breath in and then exhale forcefully into the Valsalva Interface. The testing timer will start after Valsalva pressure reaches the 16 mmHg minimum."
 - "You will be given a 30 second rest period before the next measurement cycle begins."
 - "Keep your arm with the PPG relaxed but avoid all movement or talking during the entire test. Do not put pressure on or tap the PPG"
- d) Confirm that the patient understanding before proceeding to Start New Test.

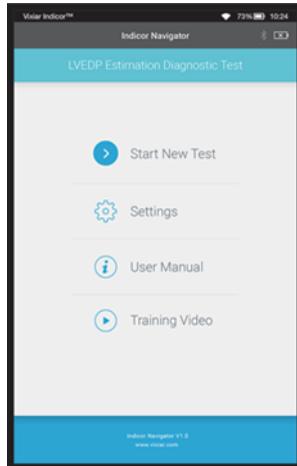


Figure 5. Indicor Navigator App Start-up/Launch Page.

6.2 Prepare the Handheld for the patient. Gloves are recommended for handling the device and disposable:

- a) Attach the PPG blue connector to the bottom of the Handheld.
- b) Insert a Valsalva Interface disposable mouthpiece into the top end of the Handheld.
- c) Place the Handheld with PPG Sensor attached into the patient's hand and connect the PPG sensor to the index finger on their opposite hand, wire side up on back of patient's hand (Figure 6).

**Correct Placement of PPG Sensor
On Index Finger (either hand)**



Figure 6. Correct positioning of the PPG sensor on the patient's index finger.

6.3 Prepare and Run the Indicor Navigator App for the patient test:

- a) Turn on the Tablet and turn towards clinician. Tap on [Start New Test] on Main Screen.
- b) Clinician should enter previously recorded data on the Patient Information screen (Figure 7). Complete all required fields. Confirm input data.

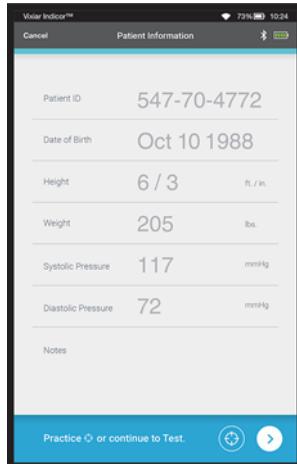


Figure 7. Navigator App, Patient Information screen for data entry.

- 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 LED indicator light.
- f) Patient should practice the Valsalva maneuver. Instruct the patient to take a normal inhalation and then exhale forcefully into the Valsalva Interface while bearing down.

NOTE: The objective of practicing the Valsalva maneuver is for the patient to understand the level of effort to reach and maintain a steady pressure in the target zone, ideally at the center line. When patient can successfully hold the ball float near the center of the target zone (Figure 8) for 10 seconds, allow for 60 seconds rest and proceed to test.

NOTE: The Valsalva Interface has a small intentional leak that is designed to ensure that patient is not generating pressure from the upper airway but rather from the thorax.

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

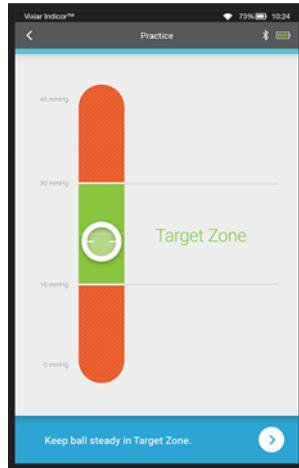


Figure 8. Navigator App, Patient Valsalva Practice Screen.

- 6.4 Before proceeding, explain to patient that the Indicor test will begin next. Remind the patient to take normal breaths during the acquiring baseline signal period, and to begin the forceful exhalation after the end of the 5 second countdown when the screen turns from gray to colored.

Note: The patient should breath normally and **NOT** take a deep breath before exhaling forcefully for the Valsalva maneuver.

- 6.5 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 motionless and relaxed. They should also refrain from all movement and talking. Movement may impact the accuracy of the measurement.

- 6.6 Tap on Forward Arrow (>) to begin the test.

- a) App will begin communication with Handheld, acquiring baseline pulse pressure and heart rate data (Figure 9).

NOTE: The App will not begin the testing countdown until an adequate PPG baseline 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 the test to proceed. The App will also detect if there is not pulse detection, patient movement artifact or radio frequency interference that could impact the measurement, and not allow the measurement to proceed until resolved.



Figure 9. Navigator App, Acquiring Baseline Signal screen.

NOTE: When a stable PPG baseline pulse signal is acquired (with a stable heart rate between 40 – 120 BPM), the App will notify the patient – “Test will Begin Shortly”

- b) Screen will change to the Countdown Screen (Figure 10), where a 5 second countdown commences, after which the first of three measurements will be taken.



Figure 11. Navigator App, Test Countdown Screen (showing 3 seconds remaining).

NOTE: The patient should wait until the screen changes to colored (Figure 12.) After the countdown, has reached 0 seconds and screen changes to colored, the patient has up to 5 seconds to start the test and attain the minimum of 16 mmHg pressure for the test to continue.

- c) After countdown is complete, the Test screen will become active (changes from gray to colored) and the patient will exhale into the device for 10 seconds, keeping the white ball float steady toward the middle of the green zone (Figure 12).



Figure 12. Navigator App, Measurement screen coaching through a controlled Valsalva maneuver (showing 2 seconds remaining).

NOTE: If the patient does not achieve target pressure for the full 10 seconds, a message will appear providing the option to “End Test” or “Try Again.” No LVEDP estimate will be generated. The App will return to the Acquiring Signal screen above if “Try Again” is selected or return to the Patient Information screen if “End Test” is selected and data removed.

- d) 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 13. The individual test LVEDP data shall be recorded.

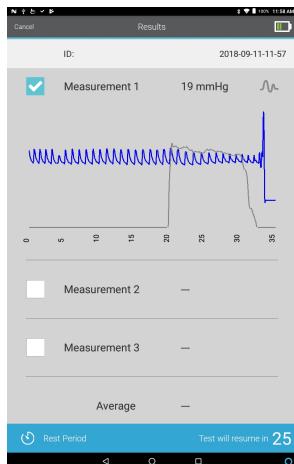


Figure 13. Navigator App, Result screen (1st Measurement) and 30 second rest period has begun.

- e) After completion of the 30 second rest period, the App will return to the Acquiring Baseline Signal screen for measurement 2 and again for measurement 3, (Figures 8-13.)
- f) After the final measurement, each individual LVEDP estimate along with an average LVEDP will be displayed, (Figure 14.) Tapping on the chart icon next to any score will bring up a display of the patients PPG and pressure waveforms for viewing.

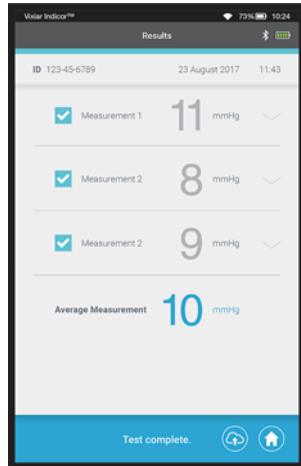


Figure 14. Navigator App, final Results Screen (Test Complete). Results are automatically saved and the home icon will exit to the Home screen to begin a new test.

- g) To exit the current patient test, press the home icon at bottom right of Navigator screen, (Figure 14)

7. Cleaning and Disinfection

Steps:

1. If connected to power source, unplug chargers for Handheld and Table and set aside
2. Perform cleaning and disinfection in a designated area
3. Use Personal Protection when cleaning and disinfecting including gloves, face mask and eye protection
4. Dispose of single patient Valsalva Interface mouthpiece per institutional protocol
5. Surface clean the Indicor Handheld with Caviwipes™ (EPA # 46781-8)
 - a. Dispense 1 Caviwipe towelette
 - b. Clean surface to remove debris
 - c. Discard towelette
6. Low level disinfect the Indicor Handheld with Caviwipes
 - a. Dispense 1 Caviwipe towelette
 - b. Disinfect pre-cleaned Handheld by wiping surfaces
 - c. Keep wet for at least 2 minutes (See Caviwipe Label for hold times)
 - d. Discard towelette
7. Surface clean the DS-100A PPG according to the Nellcor Instructions for Use. The DS100A may be cleaned by wiping with Vixiar approved 70% isopropyl alcohol or 70-30 wipes between each patient
 - a. 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.
8. Surface clean the Tablet
Using Caviwipes or cleaning agent approved by Vixiar, wipe down all surfaces of the Tablet.

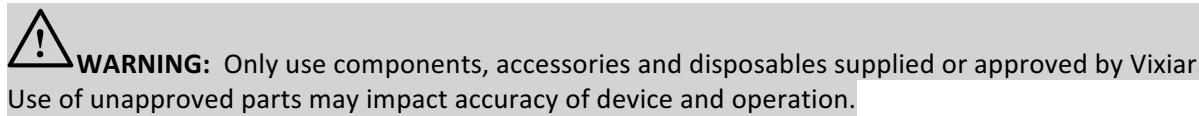


WARNING : The Valsalva Interface comes into contact with the patient and is a single patient item. It should not be reprocessed and should be disposed of between patients to avoid contamination.

8. Biocompatibility:

The patient-contact portion of the Indicor Handheld and Valsalva Interface disposable meets biocompatibility standard ISO 10993-1 for short duration contact.

9. Approved Accessories:



Accessory	Manufacturer	Model Number
DS100-A, Nellcor™ Adult SpO ₂ Sensor	Medtronic, Inc.	DS100A/DS100A-1
Indicor Rolling Stand	GCX Corporation	PTE-0001-60
Bin	GCX Corporation	WM-0001-22
USB Chargers -Handheld -Tablet	TRUMPower, Inc.	TMW12-5-UUB
Indicor Display Tablet	Lenovo, Inc.	TB-X304F
Tablet Case w/VESA Mount	Armor-X, Inc.	PXT-LN23

10. Troubleshooting:

Problem/Error Message	Potential Solution(s)*
Handheld will not power-on (no LED visible)	<u>User should:</u> 1. Press power button and hold for longer than 1 second 2. Check that Handheld is charged: plug in USB cable to Handheld and charger to AC power. LED will flash magenta if not fully charged. When fully charged, LED will stop flashing and show solid magenta.
Handheld will not pair with Tablet	<u>User should:</u> 1. Check Tablet settings (Bluetooth® should be “On”) 2. Check paired device list to see if Handheld serial # is listed. (e.g., VIX000000) If listed, choose “forget device” and start pairing process again 3. Handheld must be on with LED flashing blue to pair. LED will turn solid blue when paired with Tablet.
Handheld will not connect with Tablet <u>Error message:</u> LOST CONNECTION. “The tablet and handheld are not connected. Make sure power is on and the device is in range of the tablet.”	<u>User should:</u> 1. Make sure device is powered on and LED is flashing blue 2. Check for pairing (see above) 3. Make sure Navigator App is open and on either the Practice or Test Screen. The Tablet and Handheld <u>will not</u> connect on Patient Information screen. 4. Select “End Test or Try Again” (All data is lost if End Test is selected)
Navigator App will not progress to Testing Mode from Acquiring Signal Baseline:	The Navigator App is programmed to look for a stable PPG signal before launching Test Mode. The software will not allow the test to proceed if following conditions are detected: 1. The patient’s heart rate is out of range (HR must be between 40 and 120)

Problem/Error Message	Potential Solution(s)*
<u>Error message:</u> "Detecting HR out of range. Do you wish to try again?"	<u>User should:</u> 1.Select "End Test or Try Again" (All data is lost if End Test is selected)
Navigator App will not progress to testing mode from Acquiring Signal Baseline: <u>Error message:</u> "Not detecting a pulse signal. Ensure the sensor is completely on and has good contact with the finger."	The Navigator App is programmed to look for a stable PPG signal before launching test mode. The software will not allow the test to proceed if following conditions are detected: 1. The PPG sensor is not fully on the patient finger 2. The PPG sensor is not properly attached to the DB9 connector of the Handheld <u>The user should:</u> 1. Check the placement of the PPG sensor on the patient's finger 2. Check the connection between the Handheld and PPG sensor 3. Select "End Test or Try Again." (All data is lost if End Test is selected)
Navigator App will not progress to testing mode from Acquiring Signal Baseline <u>Error message:</u> "Detecting movement and/or pressure on the sensor. Ensure the patient is still with the finger sensor hanging free."	The Navigator App is programmed to detect movement or pressure on the PPG Sensor that can affect the measurement. <u>The user should:</u> 1. Remind the patient not to move 2. Remind the patient not apply pressure to the PPG sensor 3. Select "End Test or Try Again." (All data is lost if End Test is selected)
Navigator App will not progress to Testing Mode from Acquiring Signal Baseline: <u>Error message:</u> "Detecting signal interference"	The Navigator App is programmed to detect RF signal interference that can affect the measurement. The Indicor is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Indicor system. Otherwise, degradation of the performance of this equipment could result. <u>User should:</u> 1. Follow above minimum distance recommendations for equipment emitting radio frequency interference 2. Select "End Test or Try Again." (All data is lost if End Test is selected)
Navigator App displays one of the following error messages during the patient Valsalva effort: <u>Error message:</u> "You have 5 seconds to achieve target pressure." <u>Error message:</u> "You must maintain a pressure within the testing range until the test is complete."	The Navigator App is programmed to fault a user effort if they do not achieve 16 mmHg of pressure within 5 seconds or if they do not maintain pressure in the target zone (between 16 mmHg and 30 mmHg) for 10 seconds. <u>User should:</u> 1. Ask the patient if they are able to attempt again 2. Remind them that they have 5 seconds to reach 16mmHg 3. Remind them that they must hold pressure in the target zone for 10 seconds 4. Select "End Test or Try Again." (All data is lost if End Test is selected)

11. Specifications

Indicor

Handheld photoplethysmography diagnostic device

Tests

Estimation of left ventricular end diastolic pressure (LVEDP)



<u>Sensor Types</u>	-Integrated pressure sensor (MPXV4006) in Handheld -Nellcor DS-100 PPG Reusable Finger Sensor
<u>Power Equipment</u>	-None, Internal Battery operated, charged from USB port -AC/DC Charger to 5VDC, 2.4A, 12W Input (Indicor will not operate with charger plugged into AC power)
<u>Pressure Range</u>	0-45 mmHg
<u>Predictive Norms</u>	None, heart rate must be in normal range (40 to 120 bpm)
<u>Interpretation</u>	Pulse amplitude ratio response to a controlled Valsalva maneuver.
<u>Reports</u>	-3 patient measurements -Estimated LVEDP (mmHg) -Graphical display of PPG and pressure waveforms
<u>Measured Parameters</u>	-Pulse amplitude -Heart rate -Expiratory pressure
<u>Input Parameters</u>	-Age -Weight -Height -Systolic and diastolic blood pressure
<u>Quality Checks</u>	-Visual coaching for Valsalva patients -RF noise filter -PPG motion artifact filter -Minimum and maximum heart rate filter
<u>Connectivity</u>	Bluetooth Low Energy (BLE) v4.0 to Tablet
<u>Storage and Environment</u>	-Temperatures between -20 °C (-4 °F) and 20 °C (122 °F) -Relative humidity between 15 and 90% (non-condensing) -Atmospheric Pressure of 70 kPa (10.1 PSI) to 106 kPa (15.3 PSI)
<u>Operation Environment</u>	-Temperatures between 10 °C (50 °F) and 40 °C (104 °F), -Relative humidity between 5% and 90% (non-condensing), -Atmospheric pressure of 70 kPa (10.1 PSI) to 106 kPa (15.3 PSI).
<u>Mode of Operation</u>	Continuous



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