CONNEQT PULSE

# User Manual

# User Guide Copyright

This operation manual is protected by Intellectual Property laws and copyright. Any re-creation, adjustments, representation and/or publication, without CONNEQT INC. prior consent is strictly prohibited. You may only print this manual for your personal use.

# Legal Notice

By using the CONNEQT™ App you expressly agree to the CONNEQT INC. Terms and Conditions of Use available on our website www.conneqthealth.com.

CONNEQT is a pending trademark of Conneqt, Inc.

## Medical Device

- The CONNEQT App is intended as an accessory to the medical device, CONNEQT PULSE. Any insights or advice that is displayed by the app does not replace the need for medical interpretation and/or advice.
- Both CONNEQT PULSE and CONNEQT App comply with applicable medical device regulations and relevant international performance standards and quality standards including: ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes.

## Personal Data

- The company privacy policy can be found at www.conneqthealth.com.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare provider.

# Table of Contents


**User Guide Copyright** ..... **3**

**Legal Notice** ..... **3**

Medical Device ..... 3

Personal Data ..... 3

**CONNEQT PULSE** ..... **6**

**CONNEQT App** ..... **6**

Overview ..... 6

Indications for Use ..... 6

WARNINGS ..... 7

PRECAUTIONS ..... 7

Box Contents ..... 9

Model Number ..... 9

**Minimum Requirements for CONNEQT App** ..... **10**

Important Notice ..... 10

Internet Access ..... 10

Bluetooth Communication ..... 10

CONNEQT App - Latest Version ..... 10

**Understanding the CONNEQT PULSE** ..... **11**

**Understanding the CONNEQT App** ..... **12**

**Using the CONNEQT PULSE** ..... **13**

Connecting the Cuff to the Monitor ..... 13

Apply the Cuff ..... 13

Positioning Before and the During Reading ..... 14

Button Functionality ..... 15

Taking a Reading - App Not Paired ..... 16
Taking a Reading - App Paired ..... 19
Language Selection ..... 22

**Using PULSE With CONNEQT App ..... 23**
Installing the CONNEQT App ..... 23
Pairing PULSE With a Mobile Device ..... 23

**Understanding Your Measurements ..... 24**
Getting More Insights About Your Blood Pressure ..... 24
Getting More Insights About the Rest of Your Measurements ..... 25
Viewing Your Measurements ..... 29

**Troubleshooting ..... 30**
**Cleaning and Maintenance ..... 33**
Cleaning CONNEQT PULSE ..... 33
Battery Handling and Usage ..... 33
Service and Maintenance ..... 35

**Factory Resetting PULSE ..... 36**
**Specifications ..... 37**
**Document Release Overview ..... 40**
**Warranty ..... 40**
**Explanation of Symbols ..... 41**
**Performance Compliance Information ..... 43**
Other Performance Standards and Compliances ..... 43
Electromagnetic Compatibility Information ..... 44

# CONNEQT PULSE
# CONNEQT App

## Overview

CONNEQT PULSE provides brachial blood pressure, central blood pressure, and several other parameters related to central blood pressure. Results of your PULSE readings will be displayed on the device. Once connected to the CONNEQT App you will also have a full history of your results, which you can choose to share with others.

## Indications For Use

CONNEQT PULSE

CONNEQT PULSE is a non-invasive blood pressure measurement system that provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively using a technique in which an inflatable cuff is wrapped around the upper arm. Additionally, the CONNEQT PULSE automatically provides brachial systolic and diastolic blood pressures, and heart rate. It is intended for use in a professional setting or at home. The measurement cuff comes in two sizes: Small measures 8.6”-12.6” (22cm-32cm) in circumference and Large measures 12.6”-16.5” (32cm-42cm) in circumference.

CONNEQT App

The CONNEQT App is intended as an optional accessory to the CONNEQT PULSE device that receives, stores, displays and transmits patient data.

The CONNEQT App provides the functionality to configure the display preferences of the CONNEQT PULSE.

Read all of the information in the User Manual and other provided instructions before operating the unit.

## WARNINGS

- CONNEQT PULSE should not be used for patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patients with arrhythmias.
- The device is designed for use in adults and should not be used in infants or children.
- The device has not been validated in pregnant women and women with pre-eclampsia. Caution should be used in interpretation of measurements in pregnancy and pre-eclampsia. Consult a health care professional if further explanation is needed and if use of the device is recommended.
- Do not service or perform maintenance while the monitor is in use.
- Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.
- Do not plug or unplug the charging cable into the electrical outlet with wet hands.
- If the charging cable is faulty or damaged, please change the cable.
- Do not change the battery. If the battery can no longer be charged, please contact Customer Care via email at support@conneqthealth.com.

## PRECAUTIONS

- This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
- Avoid compression or restriction of the cuff tube during reading, which may cause inflation error, or harmful injury due to continuous cuff pressure.
- Do not share the cuff with any infectious person to avoid cross-infection.
- Use of the monitor adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- The blood pressure monitor is not intended to be exposed to the Electromagnetic Interference (EMI) environment, please do not use the blood pressure monitor within the environment of the following device: Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors.
- Do not drop this device or subject it to strong impact.
- Avoid high temperature and direct sunlight. Do not immerse the device in water as this will result in damage to the device.

- Do not attempt to disassemble this device.
- Do not use any other type of charging cable as it may damage the device.
- Do not use the device while charging.
- If you are allergic to plastic/rubber, do not use this device.
- Do not use this unit in a moving vehicle as this may result in erroneous measurement.
- Too frequent readings may cause injury due to restricted blood flow.
- Consult your physician if you are concerned about the following:
  - The application of the cuff over a wound or inflamed skin.
  - The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present.
  - The application of the cuff on the arm on the side of a mastectomy or lymph node clearance.
  - Simultaneously used with other monitoring medical equipment on the same limb.
  - Blood circulation to the arm where the cuff may be applied.
- Please always relax at least 1 to 1.5 minutes between readings to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than 3 minutes) of the cuff may cause bruising or ecchymoma (swelling due to blood extravasation) of your arm.
- For information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference, please see “Electromagnetic Compatibility Information” on page 44. It is suggested that the blood pressure monitor be kept 10 meters away from other wireless devices, such as WLAN unit, microwave oven, etc. The device should not be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Do not use any other cuff other than that supplied by the manufacturer as this may result in measurement errors.
- Technical alarm description: The display will show “Systolic Pressure Below 60mmHg or Above 260mmHg” or “Diastolic Pressure Below 40mmHg or Above 199mmHg” if the determined blood pressure (systolic or diastolic) is outside the rated range specified in the section “Specifications”. Should this message be displayed, consult a health care professional or ensure that the proper device procedures have been followed. The technical alarm is preset in the factory and cannot be adjusted or inactivated. If blood pressure values continue to be outside the rated range, consult a health care professional.

- Use of charging cables other than those specified or provided by the manufacturer of this equipment could result in improper operation. Do not plug anything other than the supplied charger into the device USB port.
- Motion, trembling, shivering may affect the measurement reading.
- The device may not provide measurements for patients with poor peripheral circulation, low blood pressure, or low body temperature.
- The device will not provide measurements in patients that have an artificial heart and lung where no pulse is present
- Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arteriosclerosis, poor perfusion, diabetes, pre-eclampsia, and renal diseases.
- If you detect a cybersecurity incident (someone other the intended user has been able to electronically obtain or change data on the device), please immediately notify the manufacturer.
- Store the device at room temperature. In the case that the device is stored at its maximum temperature (50˚C (122˚F)) or minimum temperature (-20˚C (-4˚F)) allow for at least 6 hours for the device to return to operating range (10˚C～40˚C (50˚F～104˚F)).

## Box Contents

- 1 Blood Pressure Monitor
- 1 Cuff
- 1 USB Charging Cable
- 1 User Manual
- 1 Quick Start Guide

## Model Number

BPM1AT

# Minimum Requirements for CONNEQT App

## Important Notice

By using your CONNEQT App you expressly agree to the CONNEQT INC. Terms and Conditions of Use available on our website www.conneqthealth.com.

## Internet Access

Access to the Internet is required to:

- Download the CONNEQT App.
- Download the current version of the Terms and Conditions.
- Access current advice on mandatory updates required for the app to perform as intended.

## Bluetooth Communication

An iOS[1] or Android[2] device (with operational Bluetooth Low Energy and Wi-Fi or 3G/4G) is required to:

- Retrieve data from the CONNEQT PULSE;
- Customize the CONNEQT PULSE display; and
- Access additional heart and arterial measurements.

iOS[1] 16 (or higher) or Android[2] 8 (or higher) is required to install and run the CONNEQT App.

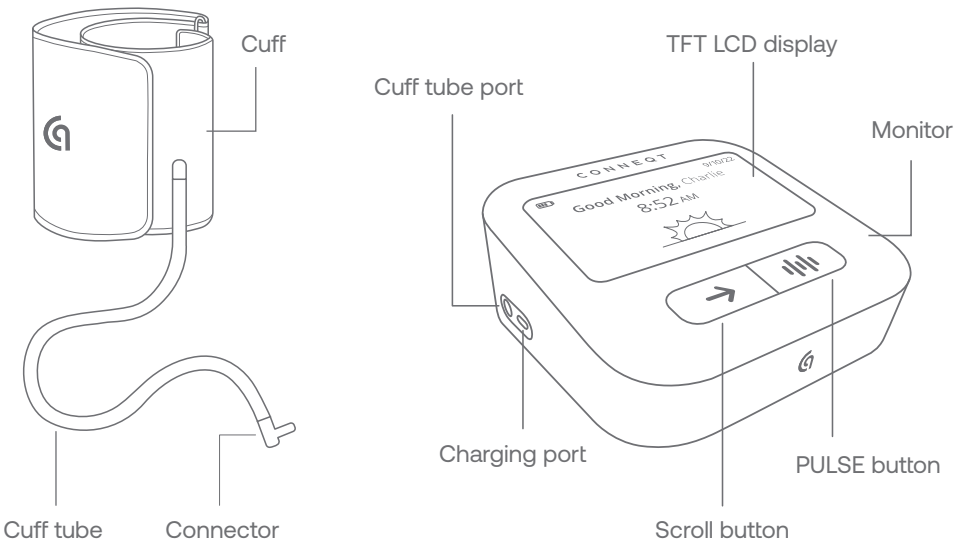
For any device, Bluetooth[3] LE (Bluetooth Low Energy) (version 5.0 and above) compatibility is required to communicate with the CONNEQT PULSE.

## CONNEQT App - Latest Version

The CONNEQT App should be updated as updates become available to access all the latest features. Information on available versions and how to obtain them can be found on the website.

# Understanding the CONNEQT PULSE

CONNEQT PULSE consists of a cuff and a monitor. You can use CONNEQT PULSE alone or with the CONNEQT App.




- Blood pressure measurements determined by this product are equivalent to those obtained by professional healthcare practitioners using the cuff/stethoscope auscultation method within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometer.
- The device was clinically investigated according to the requirements of ISO 81060-2:2018

# Understanding the CONNEQT App

The CONNEQT App is a software app not unlike other apps on a smart phone. It is not included in the package.

The following is required to use the CONNEQT App:

- a smart phone with minimum specifications as included on page 10 to install CONNEQT App
- an internet connection (wi-fi or cellular)
- an account with the app store (e.g., Google Play, App Store)

If further instruction is needed, reference your smart phone manuals or support on how to download and install an app from the app store.

The CONNEQT App is designed to provide a seamless experience on a smart phone. The screen design may be updated from time to time. If unsure, refer to www.conneqthealth.com for additional instructions on how to navigate the user interface of the CONNEQT App.

- Please do not tell strangers your account password.
- Do not leave your connected mobile device unattended when idle.
- Use password for locking the connected mobile device to prevent unauthorized access.
- Use the recommended versions of iOS and Android to ensure the security controls.

Note: The CONNEQT PULSE can be used alone without the CONNEQT App.

# Using the CONNEQT PULSE

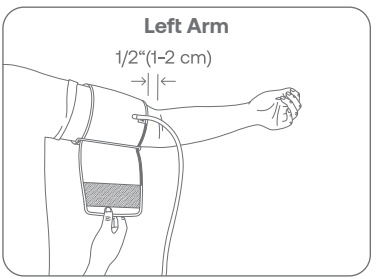
## Connecting the Cuff to the Monitor

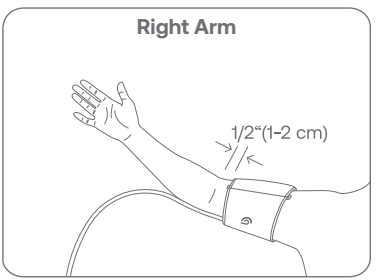
Insert the connector into the cuff tube plug on the side of the monitor. Make sure that the connector is completely inserted to avoid air leakage during blood pressure readings. If the cuff is not connected with the monitor, a message to connect the cuff will be displayed on the monitor.

Avoid compression or restriction of the cuff tube during reading, which may cause inflation error, or harmful injury due to continuous cuff pressure.

## Apply the Cuff

1. Pull the cuff end through the metal loop, positioning it outward (away the the body).
2. Place a bare arm through the cuff and position the cuff 1/2“(1-2 cm) above the elbow joint.
3. Tighten the cuff and close it by pulling it towards your body, securing it closed with the Velcro fastener.
4. While seated, place the hand palm-side up in front on a flat surface such as a desk or table. If the cuff is placed around the left arm, position the cuff tube in the middle of the arm in line with the middle finger. If the cuff is around the right arm, apply the cuff so that the cuff tube is at the side of the elbow.
5. The cuff should fit comfortably, yet snugly around the arm. One finger should be able to be inserted between the arm and the cuff.
6. The cuff should be in contact with the skin. Make sure there is no fabric in between the skin and the cuff.



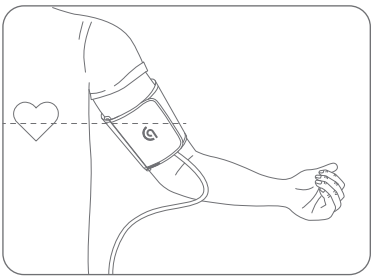



## Positioning Before and During the Reading

### Sitting During Reading

Follow these guidelines in order to receive an accurate reading when sitting.

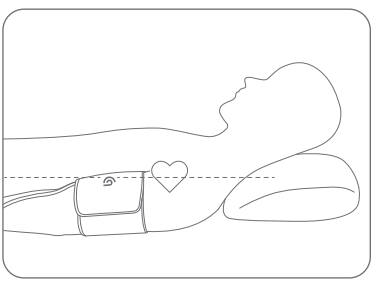
- Take the reading in a calm and quiet environment.
- Sit with feet flat on the floor without crossing the legs.
- Place the hand palm-side up in front on a flat surface such as a desk or table.
- The middle of the cuff should be vertically positioned at the level of your heart.
- Rest for five minutes before taking the reading.
- Do not speak or move during the reading.



### Lying Down During Reading

Follow these guidelines in order to receive an accurate reading when lying down.

- Place the arm straight along your side with the hand palm-side up.
- The cuff should be placed at the same level as the heart.



Note: Blood pressure can be affected by the position of the cuff and your physiologic condition.

- Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Place the cuff on the same arm for all your readings.
- Please always relax at least 1 to 1.5 minutes between readings to allow the blood circulation in your arm to recover.

## Button Functionality

**Scroll button ( → )**

- Scroll through the CONNEQT PULSE
- View download app screen by holding for five seconds
- Tap the button to turn on the CONNEQT PULSE

**PULSE button ( )**

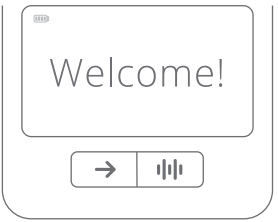
- Initiate a reading
- Cancel a reading while a reading is in progress
- Tap the button to turn on the CONNEQT PULSE
- Perform a software reset by holding for 7.5 seconds

**Pressing both buttons at the same time**

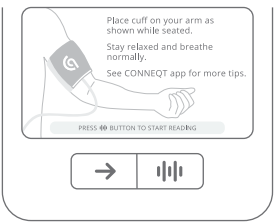
- Perform a factory reset by holding for 10 seconds

## Taking a Reading - App Not Paired

1. After applying the cuff and ensuring the body is in a comfortable position, press the scroll button (→) or PULSE button (⫼) and the monitor will turn on and display a welcome screen.

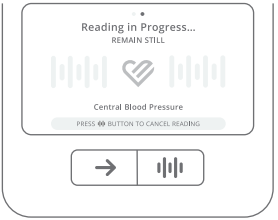



2. Before taking a reading, the following screen will be displayed. Press the PULSE button (⫼) to begin.

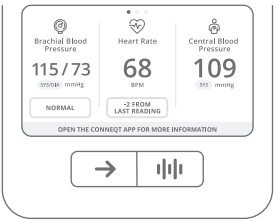


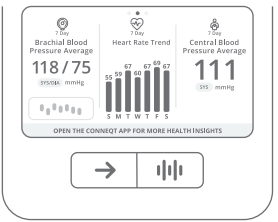

3. The brachial blood pressure reading will begin. Make sure not to move.

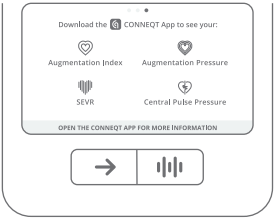
4. When the brachial blood pressure reading is complete, PULSE will automatically take the central blood pressure reading. Please remain still.




5. After the full reading is complete, three panels of results on two screens will be displayed. Use the scroll button (→) to go through each screen. Press the PULSE button ( ) if a new reading is desired. To learn more about the measurements, reference ‘Understanding Your Measurements’ (pg 24).






6. During the reading, the PULSE button ( ) can be pressed at any time to cancel the reading. If the reading is canceled, then no results will be shown.

Important: Please consult a health care professional for interpretation of blood pressure measurements.

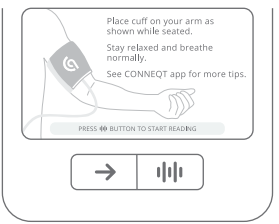
## Taking a Reading - App Paired

The PULSE device and app are intended for use for one person as functions include recording and displays of previous measurements for evaluation of values over time.

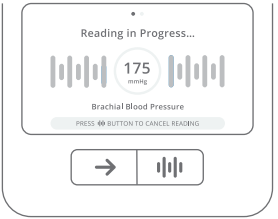
1. After applying the cuff and ensuring a comfortable position, press the scroll button (→) or PULSE button (〰) and the monitor will turn on and display a welcome screen.


---

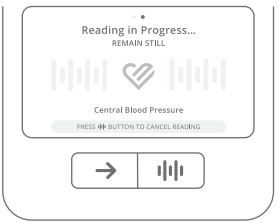
2. Before taking a reading, the following screen will be displayed. Press the PULSE button (〰) to begin.



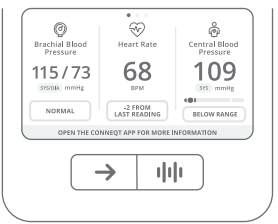
3. The brachial blood pressure reading will begin. Make sure not to move.

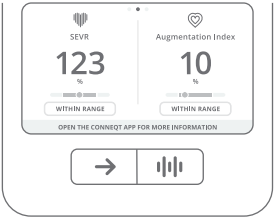


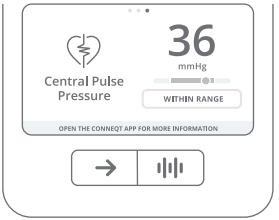

4. When the brachial blood pressure reading is complete, PULSE will automatically take the central blood pressure reading. Please remain still.




5. After the full reading is complete, either three, two or one panels with the results will be displayed. Use the scroll button (→) to go through each screen. Press the PULSE button ( ) if a new reading is desired. The result screens are customizable in the CONNEQT App. To learn more about the measurements, reference 'Understanding Your Measurements' (pg 24).





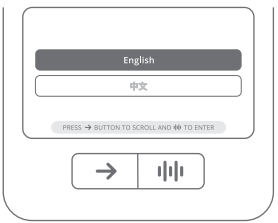




6. During the reading, the PULSE button ( ) can be pressed at any time to cancel the reading. If the reading is canceled, then no results will be shown.

Important: Please consult a health care professional for interpretation of blood pressure measurements.

## Language Selection

| English | Chinese |
|---|---|
| Press the scroll button (→) for 5 seconds to get to the download CONNEQT App screen. While on the download CONNEQT App screen, press the scroll button (→) to move to the Language Selection screen. While on the Language Selection screen, you can press the scroll button (→) to change the default language and then press the PULSE button (⫼) to confirm the selection. | 按住 (→) 键5秒进入CONNEQT App下载界面。当处于下载CONNEQT App 界面时，按 (→) 键进入语言选择界面。 当处于语言选择界面，按 (→) 键更改默认语言然后按 (⫼) 键确认。 |

# Using PULSE With CONNEQT App

## Installing the CONNEQT App

Perform the following steps in the App Store to install the CONNEQT App if not already installed on a mobile device (i.e. smart phone):

1. Search for CONNEQT in the App Store.
2. Tap “Get” on the App Store.
3. Tap “Install” and follow the steps to download.
4. Once installed open the app and follow the steps to pair a mobile device with PULSE.

Perform the following steps in the Play Store to install the CONNEQT App if not already installed on a mobile device:

1. Search for CONNEQT in the Play Store.
2. Tap “Install” and follow the steps to download.
3. Once installed open the app and follow the steps to pair a mobile device with PULSE.

You will be prompted to update your CONNEQT App when a new version is available.

## Pairing PULSE With a Mobile Device

You can access the CONNEQT App by searching in the Apple App Store or the Google Play Store or by scanning the QR code on the PULSE screen. Follow the instructions on the CONNEQT App to complete the pairing. The PULSE device will be in pairing mode until it is paired with a mobile device.

# Understanding Your Measurements

## Getting More Insights About Your Blood Pressure

**Brachial Blood Pressure**

What is Brachial Blood Pressure?
Brachial blood pressure is the pressure or force of blood on the brachial artery in the upper arm. Brachial blood pressure is represented by two numbers: systolic blood pressure, which is the maximum blood pressure on the brachial artery during heart ejection of oxygenated blood period, and diastolic blood pressure, which is the minimum pressure on the artery during heart filling with oxygenated blood.

Why it Matters
High blood pressure can cause major cardiovascular disease if untreated or treated but poorly controlled. The 2017 American Heart Association guidelines for management of high blood pressure noted that, 47% of American adults are hypertensive, yet only 24% have their blood pressure under control. Left untreated, hypertension can damage major organs like the heart, brain and kidneys and can lead to serious cardiovascular diseases such as heart attacks and strokes.

The categories, and their associated colors, shown below are based on the 2017 American Heart Association (AHA) guidelines.

| **Category** | **Systolic** (mmHg) | | **Diastolic** (mmHg) |
|---|---|---|---|
| Normal | less than 120 | and | less than 80 |
| Elevated | 120-129 | and | less than 80 |
| Hypertension Stage 1 | 130-139 | or | 80-89 |
| Hypertension Stage 2 | 140 or higher | or | 90 or higher |

**Central Blood Pressure (SYS)**

What is Central Blood Pressure (SYS)?
Central aortic blood pressure refers to the systolic pressure in the aorta (the main artery where blood is pumped into directly from the heart). Central systolic blood pressure represents the maximum pressure load at the heart in a cardiac cycle. Central systolic blood pressure is the maximum pressure the heart and major organs face and differs from the measured brachial systolic pressure at the arm by up to 40 mmHg.

Why it Matters
Measuring central blood pressure in conjunction with brachial blood pressure gives a more complete picture of arterial health and heart health.

Categories *

- Below Range
- Within Range
- Above Range

See page 28 for more information about the reference ranges.

## Getting More Insights About the Rest of Your Measurements

**Heart Rate**

What is Heart Rate?
Heat rate is the number of heart beats (or contractions) per minute. CONNEQT Pulse offers users an accurate heart rate measurements similar to heart rate measured from an electrocardiogram.

Why it Matters
Monitoring heart rate is an important measure for assessing the cardiovascular system. Heart rate assessments should be similar to the heart rate measured by standard medical electrocardiogram.

**Central Pulse Pressure**

What is Central Pulse Pressure?
Central Pulse Pressure is the difference between central systolic and diastolic pressures.

Why it Matters
The higher the central pulse pressure, the greater the load on the heart and the blood pulse impact on major organs like the brain and kidney. Elevated central aortic pulse pressure can be used to assess the risk for damage to major organs in your body.

Categories *

- Below Range
- Within Range
- Above Range

**AP (Augmentation Pressure)**

What is AP?
Augmentation pressure refers to the increase in central aortic blood pressure after its initial peak in systole. The increase is caused by pressure wave reflection where the pressure reflected back from branching points in the arteries comes back to the heart. An increase in augmentation pressure is due to the reflected pressure returning more rapidly due to hardened (stiffened) arteries. An increased augmentation pressure is indicative of an extra load and strain on the heart.

Why it Matters
Major arteries act as a cushion to absorb continuous heart pumping. As you age, these arteries become stiffer, which instead of absorbing the pressure during systole, the pressure is reflected back thereby increasing blood pressures and negatively impacting important body organs including the heart. A number of diseases can cause your arteries to stiffen early in life. A marker of arterial stiffness, elevated augmentation pressure is associated with the presence of, and risk of developing cardiovascular disease.

Categories *

- Below Range
- Within Range
- Above Range

**AIx (Augmentation Index)**

What is AIx?
Augmentation index assesses the increased pressure relative to the central pulse pressure (difference between systolic and diastolic pressures). Augmentation index is an indirect measure of arterial stiffness. It increases with age and reflects the increased load on the heart due to stiffening arteries.

Why it Matters
Increased pressure on the heart forces it to work harder. The augmentation index provides as assessment of the relative increase in pressure on the heart that may be due to arterial stiffness and can help evaluate the risk for cardiovascular disease. Augmentation index can be used to monitor the long-term stress on the heart and the cardiovascular system, which can contribute to the development of heart failure and/or thickening of the heart muscle.

Categories *

- Below Range
- Within Range
- Above Range

**SEVR (Subendocardial Viability Ratio)**

What is SEVR?
Subendocardial viability ratio [SEVR] is an index of the oxygen supply to the inner heart muscle (endocardium). It is a reflection of the amount of blood that flows to the inner heart muscle.

Why it Matters
Understanding this number is especially important for those with cardiovascular disease who have an increased risk of not having enough oxygenated blood to meet the body's demands. In the presence of heart disease, this measurement can help in assessing risk of problems when the need for increased oxygen supply is high (e.g., exercise) and is particularly important to the heart, brain and kidneys.

Categories *

- Below Range
- Within Range
- Above Range

See CONNEQT App for more insights.

*REFERENCE RANGES

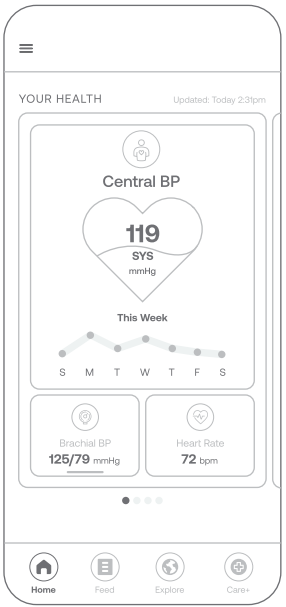
The information displayed next to the parameters are a graphical representation of your numbers in comparison to a cardiovascular healthy population of approximately 4,000, between the ages of 18 to 90, who had their central blood pressure waveform and its cardiovascular related features measured. A value in the middle section (labeled as "average") means that the number was in the range seen in 90% of this group. Numbers to the right or left represent either "above average" or "below average", each side representing about 5% of the healthy subjects. Whenever the dot is green (whether in the average or outside of average), the number is consistent with values that are generally expected for that age, sex, and height. A red dot indicates that the numbers fall in a range that appeared in at most 5% of the healthy people and is potentially not optimal for someone of the same sex and similar age.

The numbers from your central blood pressure measurement are to help you and your health care professional decide on what treatment may work best for you. It is important to measure your blood pressure regularly as sometimes single measurements may not reflect how it is most of the time. If you have any concerns about your blood pressure, please consult your health care professional.

## Viewing Your Measurements

Once you take your blood pressure your measurements will be sent to the CONNEQT App if you have it installed on your device.

On the CONNEQT App, you will be able to see more comprehensive details about your measurements.



# Troubleshooting

| Problem | Possible Cause | Solution |
|---|---|---|
| Low battery | Battery is at 25% or less | Charge the battery |
| Cuff is not connected | The connector is not plugged into the device | Plug in connector |
| LCD shows “Error Code 000” | Pressure system is unstable before measurement | Do not move and try again |
| LCD shows “Error Code 001” | Failure to detect systolic pressure | |
| LCD shows “Error Code 002” | Failure to detect diastolic pressure | |
| LCD shows “Error Code 003” | Pneumatic system blocked during inflation | Apply the cuff correctly, make sure the cuff tube is not twisted or pinched (this causes blockage), and ensure the connector is fully inserted and try again. |
| LCD shows “Error Code 004” | Pneumatic system leakage during inflation | |
| LCD shows “Error Code 005” | Cuff pressure above 300 mmHg | Measure again after five minutes. If the monitor is still abnormal, please contact Customer Care via email at support@conneqthealth.com |
| LCD shows “Error Code 006” | More than 160 seconds with cuff pressure above 15 mmHg | |
| LCD shows “Error Code 007” | Memory accessing error | |

| Problem | Possible Cause | Solution |
|---|---|---|
| LCD shows “Systolic Pressure Below 60 mmHg or Above 260 mmHg” | Systolic pressure is outside the rated range | Review body posture instructions. Retest when calm; avoid speaking or movement during the test. **If the reading remains well beyond normal, you should see a medical specialist ASAP.** |
| LCD shows “Diastolic Pressure Below 40 mmHg or Above 199 mmHg” | Diastolic pressure is outside the rated range | |
| LCD shows “Error Code 010” | Pressure sensor parameter error | Measure again after five minutes. If the monitor is still abnormal, please contact Customer Care via email at support@conneqthealth.com |
| LCD shows “Error Code 011” | Bluetooth error | Ensure your PULSE device is within range of your portable device and that Bluetooth connectivity is enabled in your portable device, to enable synchronizing with the CONNEQT App. If the issue is not resolved, please contact Customer Care via email at support@conneqthealth.com |
| LCD shows “Error Code 101” | CBP Processor is not awake | Please contact Customer Care via email at support@conneqthealth.com |
| LCD shows “Error Code 102” | Communication error between Master Processor and CBP Processor | |

| Problem | Possible Cause | Solution |
|---|---|---|
| LCD shows “Error Code 103” | Weak or no signal | Make sure the cuff is properly fitted to your arm. Also ensure the user is performing a measurement according to section ‘**Positioning Before and During the Reading**’ (pg 14) and try again. |
| LCD shows “Error Code 104” | Artifact/erratic/movement in the signal | |
| LCD shows “Error Code 105” | Heart rate out of range | |
| LCD shows “Error Code 106” | Pulse pressure less than 10mmHg | |
| LCD shows “Error Code 107” | Internal processing error | |
| LCD shows “Error Code 108” | CBP memory access error | Please contact Customer Care via email at support@conneqthealth.com |
| LCD shows “Error Code 111” | CBP POST error | |

# Cleaning and Maintenance

## Cleaning CONNEQT PULSE

- Clean the screen and body of the monitor with a dry, soft cloth or a moistened and well wrung soft cloth using water, diluted disinfectant alcohol, or diluted detergent.
- Keep the cuff clean. Cleaning the cuff after every 200 times of usage is recommended. Wipe the inner side (the side that contacts the skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air dry the cuff.
- It is recommended that if the cuff is used, for example, in a hospital or a clinic, it be disinfected twice a week. Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air dry the cuff.
- If the cuff becomes dirty, clean it with a moistened cloth. Do not rinse the monitor or cuff with running water or submerge them in water.

## Battery Handling and Usage

Do not change the battery. If the battery can no longer be charged, please contact Customer Care.

- When charging is needed, please plug the monitor to its charging cable and connect the charging cable to an electrical outlet.
- The charging cable can connect to the below electrical outlets:
  - USB port on a computer
  - Wall charger with a USB output (not provided in the PULSE box).
- An electrical outlet with an output of DC 5.0V and complies with IEC 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2 is suitable for this monitor such as UES06WNCPU-050100SPA (input: 100-240V, 50/60Hz, 0.2A; output: DC 5.0V, 1.0A). Please note that the monitor jack size is USB micro-B.
- If the power is at 25% or below, please charge the battery.
- When charging the device, the monitor will display different indicators for the charging status. See the table on the following page for details.

| Monitor Status | Status Indicator |
|---|---|
| Charging | Dynamic battery symbol |
| Fully charged | Full battery symbol |
| Low battery | Low battery symbol and reminder “Please charge your device” |

- The battery should be charged when power is less than 25%. Overcharging the battery may reduce its lifetime.

Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.

Do not plug or unplug the charging cable into the electrical outlet with wet hands.

If the charging cable is faulty or damaged, please change the cable.

Do not use any other type of charging cable as it may harm the monitor.

Do not use the monitor while charging.

- It is recommended to charge the PULSE once every month, even during storage, in order to maintain the battery in a ready state.
- The battery can maintain the performance characteristics for a minimum of 300 charge cycles. Battery replacement should only be performed by a qualified PULSE technician. To do otherwise will void your warranty and possibly damage your unit.

## Service and Maintenance

- It is recommended that product performance be checked every 2 years or after each repair. Please contact Customer Care via email at support@conneqthealth.com.
- No monitor component needs to be maintained by the user. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated for repair can be supplied.
- The monitor can maintain the safety and performance characteristics for a minimum of 10,000 readings or three years of usage, and the cuff integrity is maintained after 1,000 open–close cycles of the closure.
- Cuff replacement should only be performed by a qualified PULSE technician. To do otherwise will possibly damage your unit.

The monitor, cable, battery and cuff must be disposed of according to local regulations at the end of their usage.

# Factory Resetting PULSE

Performing a factory reset will delete all of the stored data.

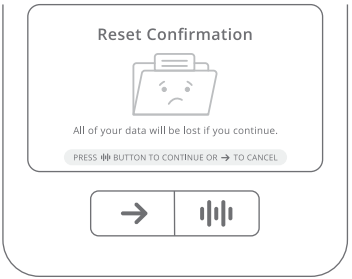
Important:

- Factory resetting PULSE will not remove any data which was previously synced to the CONNEQT App.
- All data that was not synced before resetting PULSE will be lost permanently.

To factory reset PULSE, perform the following steps:

1. Hold both buttons for 10 seconds.
2. Press the PULSE button ( ) to confirm.

Once the factory reset is complete, the PULSE can be reconfigured from the CONNEQT App.



# Specifications

## PULSE

- Length: 4.7in (119mm).
- Width: 4.6in (118mm).
- Height: 2in (51mm).
- Weight: approx. 12.3oz (350g) (excluding cuff).
- Cuff circumference: 8.6”-12.6” (22cm-32cm), 12.6”-16.5” (32cm-42cm) (Optional).

## Measurement Range

- Cuff pressure: 0-300 mmHg.
- Systolic: 60-260 mmHg.
- Diastolic: 40-199 mmHg.
- Pulse rate: 40-180 beats/minute.

## Accuracy

- Brachial Blood Pressure:  ±3 mmHg.

## Connectivity

- Bluetooth[3].

## Storage and Memory

- Extended storage on CONNEQT App.
- 450 readings without CONNEQT App.

## Technology

- Oscillometric method.
- Inflation: automatic inflation.
- Atcor SphygmoCor

## Certifications

- Bluetooth BQB certification.

## Power

- DC:5V ⎓ 1.0A.

## Battery

- 1*3.7V ⎓ Li-ion 2200mAh.

## Metrics

- Brachial Blood Pressure (SYS/DIA).
- Central Blood Pressure (SYS).
- Heart Rate.
- Augmentation Index.
- Augmentation Pressure.
- Central Pulse Pressure
- SEVR (Subendocardial Viability Ratio).

## Battery Life

- More than 150 readings on a full charge.

## Compatible Devices

- iPhone (8 or higher).
- Android.

## Compatible OS

- iOS[1] 16 or higher.
- Android[2] 8 or higher.

## Environmental

- Temperature for operation: 10˚C～40˚C (50˚F～104˚F).
- Humidity for operation: ≤85%RH.
- Temperature for storage and transport: -20˚C～50˚C (-4˚F～122˚F).
- Humidity for storage and transport: ≤85%RH.
- Pressure: 80kPa-105kPa.

Notes:

- These specifications are subject to change; where practicable or necessitated per regulatory guidance, changes will be communicated as appropriate.
- Classification: Internally powered, Type BF applied part, IP21, No AP or APG, Continuous operation.
- All components belonging to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff, Sensor.

# Document Release Overview

Date of issue: TBD

PULSE Device Patient User Manual 1.0

The PULSE display images in this manual are used for explanatory purposes. The actual screens may differ from the screenshots in this manual.

# Warranty

This blood pressure monitor is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the instructions provided. This warranty extends only to the end user. We will, at our option, repair or replace without charge the blood pressure monitor covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

# Explanation of Symbols

Rx Only Symbol for “PRESCRIPTION USE ONLY”

Symbol for ”THE OPERATION GUIDE MUST BE READ”

- The sign background color: blue.
- The sign graphical symbol: white.

Symbol for “CAUTION”

Symbol for “TYPE BF APPLIED PARTS” (The cuff is type BF applied part)

Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”.

Symbol for “MANUFACTURER”

Symbol for “COUNTRY OF MANUFACTURE” and “DATE OF MANUFACTURE”

SN Symbol for “SERIAL NUMBER”

IP21 Symbol for “DUSTPROOF”


Symbol for “MAGNETIC RESONANCE (MR) UNSAFE”

**Distributed by AtCor Medical Inc., a CardieX Company:**
AtCor Medical Inc.
184 Shuman Blvd, Ste 515, Naperville, IL 60563
1-234-CONNEQT
www.conneqthealth.com

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China
Tel: 86-22-87611660

# Performance Compliance Information

This device complies with Part 15 of the FCC Rules. Its 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.

Changes or modifications not expressly approved by CONNEQT INC. would void the user's authority to operate the product.

NOTE: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device has also been tested against this SAR limit.

Hereby, [ANDON HEALTH CO., LTD.] declares that the radio equipment type [BPM1AT] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.conneqthealth.com.

## Other Performance Standards and Compliances

The Blood Pressure Monitor corresponds to the following standards: IEC 60601-1:2005 +A1:2012(E)/EN 60601-1: 2006/A11: 2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment -- Part 1-2: General

requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), IEC80601-2-30:2018/EN IEC80601-2-30:2019 (Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers)EN 1060-1: 1995 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems).

## Electromagnetic Compatibility Information

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types:GFSK, effective radiated power: <4dBm.Maximum output power:0dBm.

### Table 1 - Emission

| Phenomenon | Compliance | Electromagnetic environment |
|---|---|---|
| RF emissions | CISPR 11<br>Group 1, Class B | Home healthcare environment |
| Harmonic distortion | IEC 61000-3-2<br>Class A | Home healthcare environment |
| Voltage fluctuations and flicker | IEC 61000-3-3<br>Compliance | Home healthcare environment |

## Table 2 - Enclosure Port

| **Phenomenon** | **Basic EMC Standard** | **Immunity Test Levels** Home Healthcare Environment |
|---|---|---|
| Electrostatic Discharge | IEC 61000-4-2 | ±8 kV contact<br>±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 10V/m, 80MHz-2.7GHz<br>80% AM at 1kHz |
| Proximity fields from RF wireless communications equipment | IEC 61000-4-3 | Refer to table 3 |
| Rate power frequency magnetic fields | IEC 61000-4-8 | 30A/m<br>50Hz or 60Hz |

## Table 3 – Proximity fields from RF wireless communications equipment

| **Test frequency** (MHz) | **Band** (MHz) | **Immunity Test Levels** Professional Healthcare Environment |
|---|---|---|
| 385 | 380-390 | Pulse modulation 18Hz, 27V/m |
| 450 | 430-470 | FM, ±5kHz deviation, 1kHz sine, 28V/m |
| 710 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 745 | | |
| 780 | | |

| **Test frequency** (MHz) | **Band** (MHz) | **Immunity Test Levels** Professional Healthcare Environment |
|---|---|---|
| 710 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 745 | | |
| 780 | | |
| 810 | 800-960 | Pulse modulation 18Hz, 28V/m |
| 870 | | |
| 930 | | |
| 1720 | 1700-1990 | Pulse modulation 217Hz, 28V/m |
| 1845 | | |
| 1970 | | |
| 2450 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5240 | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| 5500 | | |
| 5785 | | |

## Table 4 – Input a.c. power port

| Phenomenon | Basic EMC Standard | Immunity Test Levels<br>Home Healthcare Environment |
|---|---|---|
| Electrical fast transients/burst | IEC 61000-4-4 | ±2 kV<br>100kHz repetition frequency |
| Surges<br>Line-to-line | IEC 61000-4-5 | ±0.5 kV, ±1 kV |
| Surges<br>Line-to-ground | IEC 61000-4-5 | ±0.5 kV, ±1 kV, ±2 kV |
| Conducted disturbance<br>induced by RF fields | IEC 61000-4-6 | 3V, 0.15MHz-80MHz<br>6V in ISM and amateur radio bands<br>between 0.15MHz and 80MHz<br>80%AM at 1kHz |
| Voltage dips | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚<br>and 315˚ |
| | | 0% $U_T$; 1 cycle and 70% $U_T$; 25/30 cycles<br>Single phase: at 0˚ |
| Voltage interruptions | IEC 61000-4-11 | 0% $U_T$; 250/300 cycles |

(1) iOS is a trademark of Apple Inc.
(2) Android is a trademark of Google LLC
(3) The Bluetooth® word is registered trademarks owned by Bluetooth SIG, Inc.