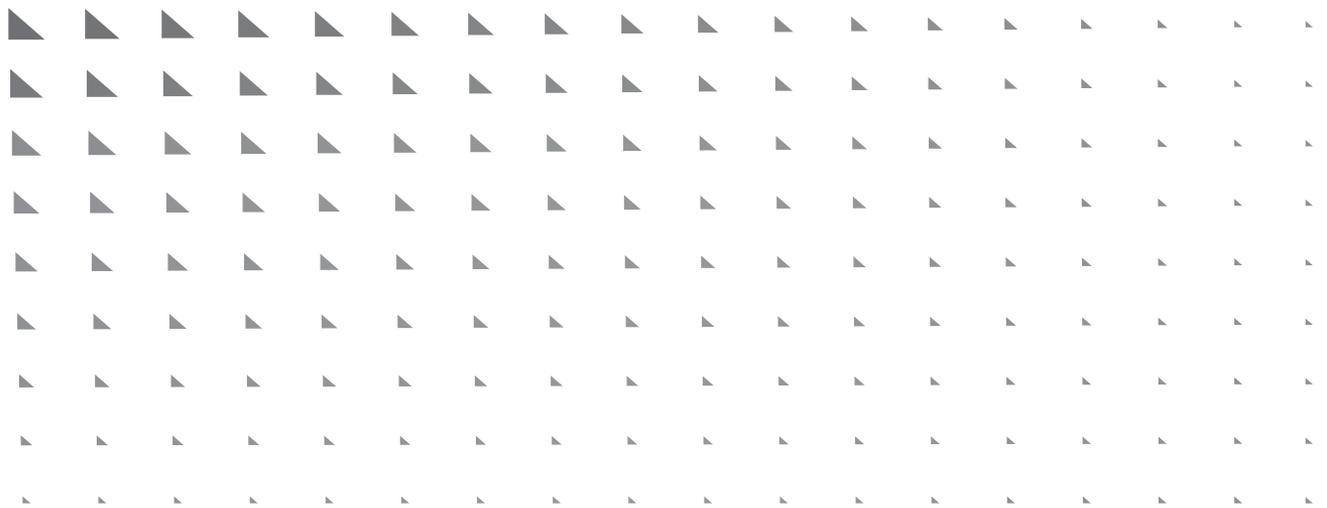


CONNECT **PULSE**

Health Care Provider User Manual



User Guide Copyright

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Legal Notice

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

CONNEQT is a registered trademark of CONNEQT, Inc.

Medical Device

- The CONNEQT PRO App is intended as an accessory to the CONNEQT PULSE. Any insights or advice that is displayed by the app must be assessed by healthcare providers using their medical judgment and in the context of other relevant clinical information about the patient.
- CONNEQT PULSE complies 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.cardiex.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	2
Legal Notice	2
Medical Device	2
Personal Data	2
CONNEQT PULSE	5
CONNEQT PRO App	5
Overview	5
Indications for Use	5
WARNINGS	6
PRECAUTIONS	6
Box Contents	7
Model Number	7
Minimum Requirements for CONNEQT PRO App	8
Important Notice	8
Internet Access	8
Bluetooth Communication	8
CONNEQT PRO App - Latest Version	8
Understanding the CONNEQT PULSE	9
Understanding the CONNEQT PRO App	10
Using the CONNEQT PULSE	11
Connecting the Cuff to the Monitor	11
Apply the Cuff	11
Positioning Before and During the Reading	11
Button Functionality	12
Taking a Reading - App Not Paired	13
Language Selection	14
Using PULSE With CONNEQT PRO App	15
Installing the CONNEQT PRO App	15
Pairing PULSE With a Tablet Device	15
Taking a Reading - App Paired	16
Viewing Results	18
Understanding the Measurements	19
Getting More Insights About Your Patient's Blood Pressure	19
Getting More Insights About the Rest of Your Patient's Measurements	20
Troubleshooting	22
Cleaning and Maintenance	24

Cleaning CONNEQT PULSE	24
Battery Handling and Usage	24
Service and Maintenance	25
Factory Resetting PULSE	26
Specifications	27
Document Release Overview	29
Warranty	29
Explanation of Symbols	30
Performance Compliance Information	31
Other Performance Standards and Compliances	31
Electromagnetic Compatibility Information	31

CONNEQT PULSE CONNEQT PRO App

Overview

CONNEQT PULSE provides brachial blood pressure, central blood pressure, and several other parameters related to central blood pressure. Results of the PULSE readings will be displayed on the device. Once connected to the CONNEQT PRO App, you will be able to upload the patient's readings to their patient record.

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 patient's 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 inflatable 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, prior to inflation.

CONNEQT PRO App

The CONNEQT PRO App is an optional accessory for the CONNEQT PULSE device. The CONNEQT PRO App receives, stores, displays and transmits patient data.

The CONNEQT PRO 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.
- Do not service or perform maintenance while the device 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.
- Take care to inspect the cuff and remove any visible dirt or contamination between patient uses to reduce risk of infection.
- Use of the monitor adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- The device is not intended to be exposed to the Electromagnetic Interference (EMI) environment, please do not use the device within the following environments: Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors.
- Do not drop the 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 the device.
- Do not use any other type of charging cable as it may damage the device.
- Do not use the device while charging. The PULSE will not take a reading while charging.
- Do not use the device on people with allergies to plastic or rubber.
- Take care to avoid injury when using the device in the following situations:
 - Application of the cuff over a wound or inflamed skin.
 - Application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present.
 - Application of the cuff on the arm on the side of a mastectomy or lymph node clearance.
 - Application of the cuff on arm of a patient with reduced blood circulation.
 - Simultaneous use of the device with other monitoring medical equipment on the same limb.
- Please always allow the patient to relax at least 1 to 1.5 minutes between readings to allow the blood circulation in the patient's arm to recover. Prolonged over-inflation (cuff pressure exceeding 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 the 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”. 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.
- 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, ensure that the proper device procedures have been followed. The technical alarm is preset in the factory and cannot be adjusted or inactivated. 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, or 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.
- Take care when using the device on patients having 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 than 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)) before use on a patient.
- The cuff connector is a small part and is removable. As there is risk of swallowing, keep the device away from children.

The essential performance of this medical device is determined by:

- a. Limits of the error of the cuff pressure indication
- b. Reproducibility of the blood pressure determination
- c. Alarms

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 PRO App

Important Notice

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

Internet Access

Access to the Internet is required to:

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

Bluetooth Communication

An Android¹ tablet 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.

Android¹ 8 (or higher) is required to install and run the CONNEQT PRO App.

For any tablet device, Bluetooth² LE (Bluetooth Low Energy) (version 5.0 and above) compatibility is required to communicate with the CONNEQT PULSE.

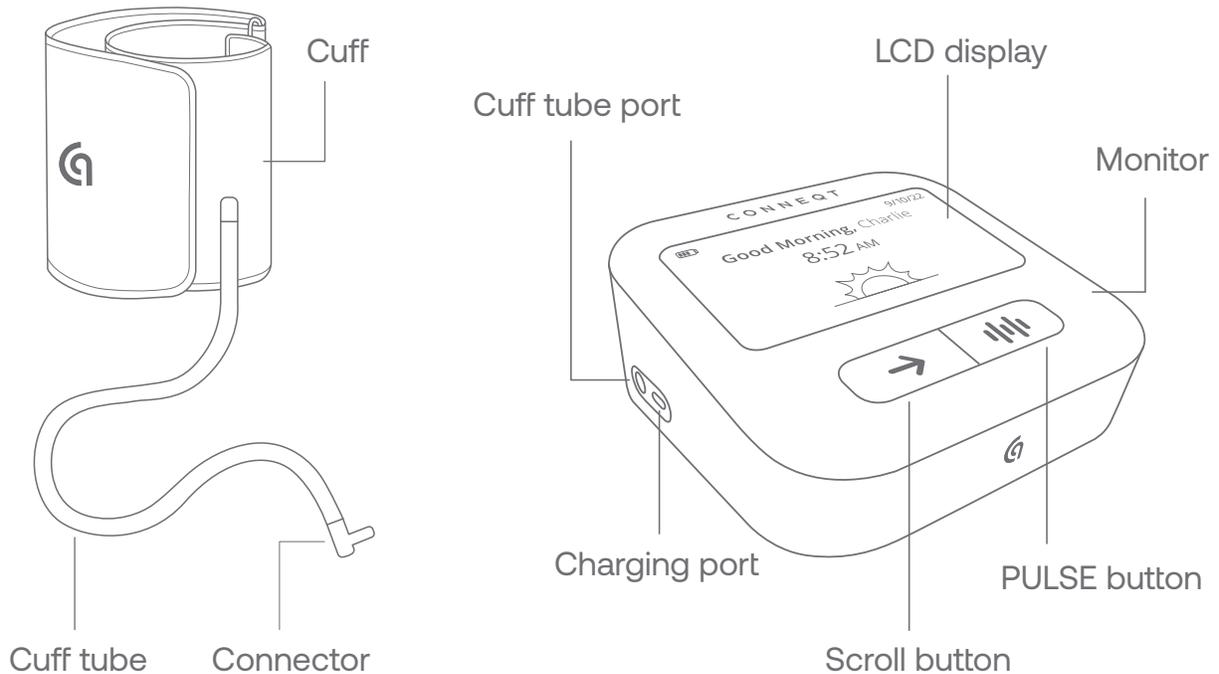
CONNEQT PRO App - Latest Version

The CONNEQT PRO 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 www.conneqthealth.com.

Understanding the CONNEQT PULSE

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

To turn on the PULSE device for the first time. Press the PULSE button (||||) for 2 seconds.



- 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, Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type.

Understanding the CONNEQT PRO App

The CONNEQT PRO App is a software app not unlike other apps on an Android tablet. It is not included in the package.

The following is required to use the CONNEQT PRO App:

- a tablet with minimum specifications as included on page 8 to install CONNEQT PRO App
- an internet connection (wi-fi or cellular)
- an account with the app store (e.g., Google Play)

If further instructions are needed, refer to your tablet manual or online support on how to download and install an app from the app store.

The CONNEQT PRO App is designed with a user interface to provide you the ability to view multiple measurements in a session and receive the average of the measurements. If unsure, refer to www.conneqthealth.com for additional instructions on how to navigate the user interface of the CONNEQT PRO App.

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

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

Using the CONNEQT PULSE

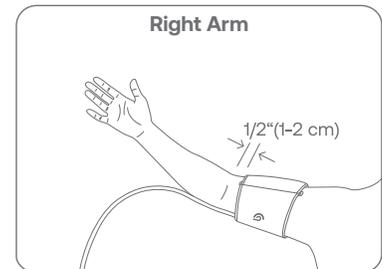
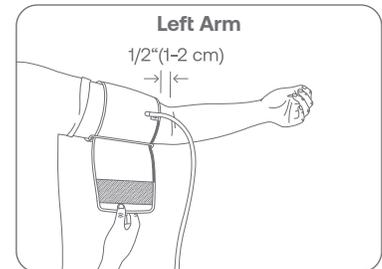
Connecting the Cuff to the Monitor

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 from 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 the body, securing it closed with the Velcro fastener.
4. While seated, place the patient's hand palm-side up in front of their body 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 their middle finger. If the cuff is around the right arm, apply the cuff so that the cuff tube is at the side of their 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 patient's skin. Make sure there is no fabric in between the skin and the cuff.

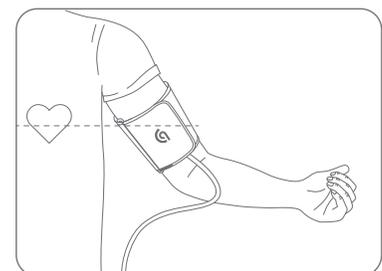


Positioning Before and During the Reading

Sitting During Reading

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

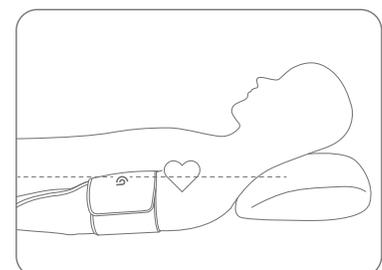
- Take the reading in a calm and quiet environment.
- Seat the patient with their feet flat on the floor without crossing their legs.
- Place their hand palm-side up in front of their body on a flat surface such as a desk or table.
- The middle of the cuff should be vertically positioned at the level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



Lying Down During Reading

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

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



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

- Place the cuff on the same arm for all readings.
- Please always allow the patient to relax at least 1 to 1.5 minutes between readings to allow the blood circulation in the patient's 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
- Turns off the CONNEQT PULSE if pressed when the cuff is disconnected

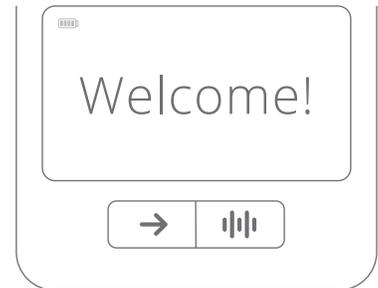
Pressing both buttons at the same time

- View the factory reset confirmation screen by holding for 10 seconds

Taking a Reading - App Not Paired

Pair the device with the CONNEQT PRO App to have full access to all measurements and to upload reading results to the CONNEQT Patient Management Portal (PMP). If the PULSE is not paired with the CONNEQT PRO App then you will receive limited information AND the reading will not be transferred to the Portal.

1. After applying the cuff and ensuring the patient's 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 the patient does not move while the reading is in progress.

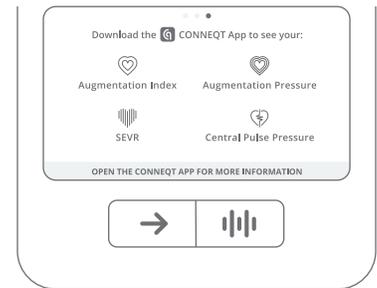
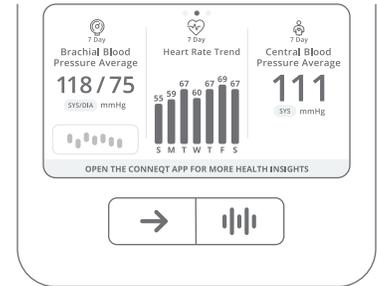
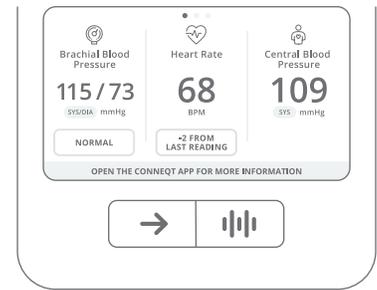


4. When the brachial blood pressure reading is complete, the device will automatically take the central blood pressure reading. Make sure the patient remains still.



Note: During the reading, the PULSE button (||||) can be pressed at any time to cancel the reading.

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 the Measurements'.



Language Selection

English	Chinese
<p>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.</p>	<p>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。</p>



Using the PULSE with CONNEQT PRO App

Installing the CONNEQT PRO App

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

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

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

Pairing PULSE With a Tablet Device

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

Taking a Reading - App Paired

The CONNEQT PULSE device is designed for use in patient clinics through the CONNEQT PRO App. The CONNEQT PRO App is the tool through which the PULSE device can be used with multiple patients in a clinic setting. The CONNEQT Patient Management Portal (PMP) is the web interface for all patient data and administration including the display of central pressure vascular biomarkers and brachial pressures. Prior to using the PULSE device for a patient already registered in the Portal, perform the following steps that will transfer patient information from the Portal to the PULSE device preparing it for use.

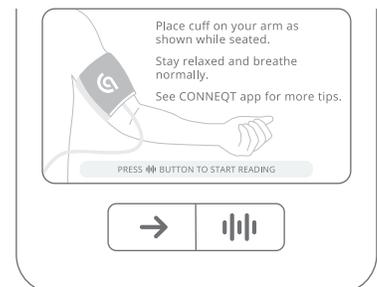
1. Login into the CONNEQT PRO App using the previously authenticated CONNEQT PMP username and password.
-

2. Using the Patient Search dialogue box, enter the patient's name (last name, first name) to be monitored. Once the patient is selected, the CONNEQT PRO App will transmit the information required for assessing central vascular biomarkers (age, sex, height) via Bluetooth to the CONNEQT PULSE.

Note: The PULSE device must be paired and connected to the CONNEQT PRO app, in order to take readings.

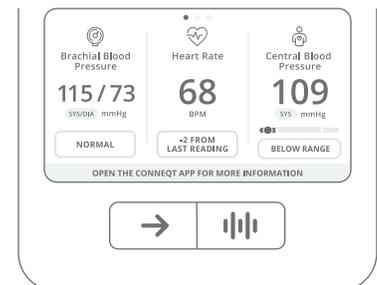
3. Next, using the CONNEQT PRO App to select the number of readings expected to be acquired.
-

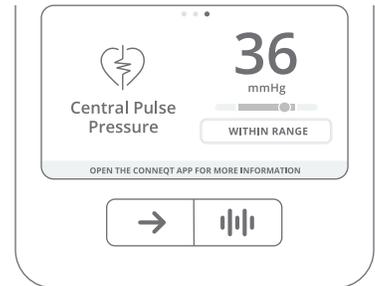
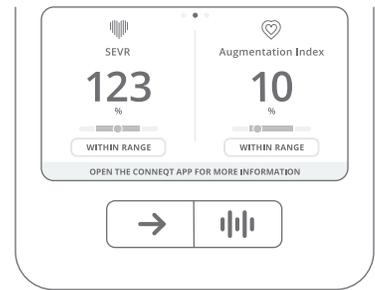
4. Apply the cuff and press the PULSE button (📶) on the CONNEQT PULSE to initiate the reading.



Note: During the reading, the PULSE button (📶) can be pressed at any time to cancel the reading.

5. After the full reading is complete, up to three screens of results will be displayed (the result screens are customizable in the CONNEQT PRO App). Use the scroll button (→) to go through each screen. If a new reading is desired press the PULSE button (📶) on the PULSE device to begin a new reading. To learn more about the measurements, reference 'Understanding the Measurements'.





6. After each reading is complete, the measurement data is transferred to the CONNEQT PRO App via Bluetooth. Make sure the reading has transferred before taking another reading.

7. Once all readings have been taken, press the Upload to Portal button in the CONNEQT PRO App to transfer the results to the Portal. Upon data transfer completion, the CONNEQT PRO App will return to the Patient Search dialogue box screen.

Note: If you have been inactive on the CONNEQT PRO App, you will automatically be logged out.

Viewing Results

After blood pressure measurements are completed, the data will be sent to the CONNEQT PRO App. On the CONNEQT PRO App, the brachial blood pressure (SYS/DIA), central systolic blood pressure and heart rate of each reading will be displayed. To view all metrics for each reading, the readings must first be uploaded to the PMP. Detailed instructions for viewing all metrics will be available with the PMP software.

The screenshot displays the CONNEQT PRO App interface for patient Martin Johnson. At the top, the app name 'CONNEQT' and user initials 'JS' are visible. Below the patient name, personal information is listed: PRN 295832, DOB 02-Jan-1964, Sex Male, Height 172 cm, and Weight 73 kg. The current date and time are 23-Jan-2021 3:02 PM CST. A progress bar shows 'TOTAL READINGS 3/3' with an 'Upload to Portal' button. Three readings are shown: Reading 1 is 'Dropped' (FAILED QC) with Brachial BP 141/90 mmHg, Central SBP 115 mmHg, and Heart Rate 82 bpm; Reading 2 is 'PASSED QC' with Brachial BP 132/86 mmHg, Central SBP 126 mmHg, and Heart Rate 74 bpm; Reading 3 is 'PASSED QC' with Brachial BP 141/90 mmHg, Central SBP 125 mmHg, and Heart Rate 82 bpm. A final instruction box at the bottom says: 'Press the PULSE button (||||) to keep taking readings. Once done, upload results to the Portal.'

Reading	Status	Brachial BP (mmHg)	Central SBP (mmHg)	Heart Rate (bpm)
READING 1	Dropped (FAILED QC)	141/90	115	82
READING 2	PASSED QC	132/86	126	74
READING 3	PASSED QC	141/90	125	82

Understanding Your Measurements

Getting More Insights About Your Patient's 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 blood, and diastolic blood pressure, which is the minimum pressure on the artery during heart filling with 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 nearly 120 million or 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

What is Central Blood Pressure (SYS)?

Central Blood Pressure refers to the systolic pressure in the aorta (the main artery where blood is pumped into directly from the heart). Central 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 21 for more information about the reference ranges.

Getting More Insights About the Rest of Your Measurements

Heart Rate

What is Heart Rate?

Heart rate is the number of heart beats (or contractions) per minute. The 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 heart, brain, and kidney. Elevated Central Pulse Pressure can be used to assess the risk for damage to major organs in your body.

Categories *

- Below Range
- Within Range
- Above Range

Augmentation Pressure (AP)

What is Augmentation Pressure?

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. Several 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

Augmentation Index (AIx)

What is Augmentation Index?

Augmentation Index assesses the increased pressure relative to the Central Pulse Pressure (the 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 an 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 also be used to monitor the long-term stress on the heart and the cardiovascular system, which can contribute to thickening of the heart muscle and/or the development of heart failure.

Categories *

- Below Range
- Within Range
- Above Range

SEVR (Subendocardial Viability Ratio)

What is SEVR?

SEVR (Subendocardial Viability Ratio) 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

*REFERENCE RANGES

The information displayed next to the parameters represents a graphical representation of your numbers in comparison to a cardiovascularly healthy population of approximately 4,000 individuals, between the ages of 18 to 90, who had their central blood pressure (CBP) waveform and its cardiovascular-related features measured. A value in the middle section (labeled as "within range") means that the number falls within the range seen in 90% of this group. Numbers to the right or left represent either "above range" or "below range", each side representing about 5% of the healthy subjects. Whenever the dot is green (whether in the within or outside of range), 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.

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	Make sure the patient does not move and measure 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	
LCD shows “Systolic Pressure Below 60 mmHg or Above 260 mmHg”	Systolic pressure is outside the rated range	Review body posture instructions. Retest when the patient is calm and does not speak or movement during the test. If the reading remains well beyond normal, use your medical judgement to treat the patient.
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

Problem	Possible Cause	Solution
LCD shows “Error Code 011”	Bluetooth error	Ensure your PULSE device is within range of your tablet device and that Bluetooth connectivity is enabled on your tablet device, to enable synchronizing with the CONNEQT PRO 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	
LCD shows “Error Code 103”	Weak or no signal	Make sure the cuff is properly fitted to the patient’s arm. Ensure correct size cuff for patient arm circumference is being used. Review body posture instructions. Retest when the patient is calm and does not speak or move during the test.
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. When the device is used by a single patient, cleaning of the cuff is recommended after every 200 uses. If the cuff becomes dirty, clean it with a moistened cloth. Do not rinse the monitor or cuff with running water.
- In a clinical setting where there are multiple users of the same cuff, it is recommended that the cuff be disinfected after every patient. 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.

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 following 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). Note that the monitor jack size is USB micro-B.
- Charge the battery if the power is at 25% or below.
- 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 only 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.
- ⚠ Change the charging cable if it is faulty or damaged.
- ⚠ Do not use any other type of charging cable as it may harm the monitor.
- ⚠ Do not use the monitor while charging. The PULSE will not take a reading while charging.

- It is recommended to charge the PULSE at a minimum of once every month, even during storage, in order to maintain the battery in a ready state.
- The battery can maintain its 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 device components need to be maintained by the user. Contact Customer Care to obtain the circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist appropriately qualified technical personnel to repair those parts of the equipment designated as repairable.
- The device is expected to operate in conformance with its safety and performance characteristics for a minimum of 10,000 readings or three years of usage. The cuff integrity is expected to be maintained for up to 1,000 open–close cycles.
- Do not use a damaged cuff. To do so will possibly damage the device. Contact Customer Care via email at support@conneqthealth.com



The device, cable, battery, and cuff must be disposed of according to local regulations at the end of their useful lives.

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 PRO 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 PRO App.



Specifications

PULSE

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

Note: One cuff is included in the Box Contents of each CONNEQT PULSE. Please ensure you are using the appropriate cuff size for each patient. Refer to the circumference of the cuff on the purchased package.

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.
- Heart Rate: ± 5 beats/minute.

Tolerance

- Central Blood Pressure: ± 3 mmHg.

Connectivity

- Bluetooth².

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

- Android.

Compatible OS

- Android¹ 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.
- Attention: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Document Release Overview

Date of issue: November 6th, 2024

CONNEQT PULSE Device Health Care Provider (HCP) User Manual 2.0

The screenshots in this manual are used for explanatory purposes. Your 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

 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”



Symbol for “SERIAL NUMBER”

IP21 Symbol for “DUSTPROOF”



Symbol for “MAGNETIC RESONANCE (MR) UNSAFE”

Distributed by ATCOR Medical Inc., a CardieX Company:

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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 device has been evaluated to meet general RF (Radio Frequency) exposure requirement. The device can be used in portable exposure condition without restriction.

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 compliant with the equipment and system requirements for wireless radio frequency data transmissions at the 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 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 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 ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m, 80MHz-2.7GHz 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 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

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

(1) Android is a trademark of Google LLC

(2) The Bluetooth® word is registered trademarks owned by Bluetooth SIG, Inc.