



Caretaker

M E D I C A L

BIOPAC Part # NIBP-A-MRI Caretaker4 User Manual



Caretaker4

Vital Signs Monitor for Continuous Noninvasive Blood Pressure and Vital Signs

This manual is intended to provide information for the proper operation of the Caretaker4 vital signs monitor for measuring Heart Rate and Continuous Non-invasive Blood Pressure (“CNIBP”)

Errors and Omission

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1 Introduction

The Caretaker4 ("CT4") is intended to noninvasively and continuously measure a patient's blood pressure ("BP"), heart rate ("HR"), and respiration rate ("RSP"), which are derived from the pulse pressure waveform using the scientific method of Pulse Decomposition Analysis ("PDA") for use on adult patients at rest.

The Caretaker device is calibrated using a manual method or any AAMI 81060 compliant BP device, or is automatically calibrated using its self-calibration mode. All parameters derived by the Caretaker device are reported to an integrated LCD screen and optionally to a remote data display monitor (RDDS) via standard radio transmission protocols.



The Caretaker4 is a passive blood pressure and vital signs monitoring system, except during the calibration phase. Because the Caretaker device uses an algorithm to detect and analyze each heartbeat, it may be more prone to noise interference than an active system, such as those based on the Penaz measurement method. *Adequate signal quality from the finger cuff is critical for the system to produce reasonable results.* Typically, signal quality problems are due to:

- Inadequate coupling pressure (for weak pulses or poorly perfused or cold fingers coupling pressures of up to 50 mmHg may be necessary)
- Excessive movement of the finger
- Excessive movement of the hose between finger cuff and the CT4, or
- Improper positioning of the finger cuff

CAUTION: The Caretaker device is available only for prescription use under the supervision of trained medical personnel.

2 Indications for Use

The Caretaker4 is intended to noninvasively and continuously measure a patient's blood pressure (BP), heart rate (HR), and respiration rate (RR), which are derived from the pulse pressure waveform using the scientific method of Pulse Decomposition Analysis (PDA) for use on adult patients at rest. The device is intended for use by clinicians or other properly trained medical personnel.

Contra-indications

The Caretaker4's ability to detect Blood Pressure may be limited or difficult in some patients who exhibit extreme or unusual arterial physiology, such as:

- Lack of perfusion of the digital arteries and arterioles in the lower arm and hand, such as may be present in patient with Raynaud's disease
- Tough, Calloused, or Thickened skin and tissue in the phalange area, such as may be present in patients with Scleroderma, Dupuytren's Contracture, or other Rheumatology issues.
- Overly Cold fingers can make it difficult for the Finger Cuff to obtain adequate signal quality to derive an accurate Heart Rate or Blood Pressure reading.

3 Key Features

- Continuous, noninvasive monitoring of “Beat-by-Beat” Blood Pressure (Diastolic, Systolic, Mean Arterial Pressure), Heart Rate and Respiration Rate
- Measurements captured using a single disposable finger cuff inflated to low pressure
- Can be worn for extended periods with no discomfort or loss of circulation in the finger
- Compact wrist-worn device with on-board display
- Automatic and manual calibration modes
- Integrated PDF report generation
- Integrated alarms for all physiological parameters
- Wireless communications using Bluetooth Low Energy technology and an AES 128-Bit encrypted data stream
- Communicates with companion Caretaker Android application
- Compatible with select 3rd party Bluetooth SpO2 and body temperature sensors
- ANSI/AAMI/ISO 81060-2:2013 compliant
- Integration options for Android, Windows and Linux operating environments using Software Development Kits

4 User Responsibilities

The Caretaker4 blood pressure and vital signs monitor will perform in conformance with the description in this Operator's Manual and accompanying documentation when assembled, operated, maintained and repaired in accordance with the instructions provided.

A defective product or accessory shall not be used. Parts that are missing or damaged must be replaced immediately. Caretaker Medical accepts no responsibility for any malfunction of the Caretaker4 that are a result of improper use, unauthorized repair or modification by the end user.

The Caretaker4 provides readings that are to be interpreted by trained medical personal only. Any clinical judgment is the sole responsibility of the end user and should be made in conjunction with all other available clinical indications and data.

As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate heart rate and blood pressure values.

The following considerations must be followed when using the Caretaker Device:

- The Caretaker4 must be calibrated to obtain a baseline Blood Pressure measurement for each patient. Self-Calibration cycles should be spaced at least 10 minutes apart to avoid fatiguing the monitored finger. Self-calibration is not indefinite and the Caretaker4 will periodically re-calibrate itself automatically if in Self-Calibration mode (default = 60 minutes). The Self-Calibration process takes approximately 40-45 seconds. A clinician should be present during the calibration to assess the accuracy of the obtained measurements.
- For additional considerations regarding calibration and re-calibration, as well as the use of manual versus self-calibration, please refer to section 7.8.
- The Caretaker4 is a prescription device, to be prescribed by a physician and operated by qualified clinical personnel only.
- If the accuracy of any reading seems unusual or questionable, the operator shall validate the readings by using an alternate method of measurement.
- The Caretaker4 is intended only as an adjunct in patient health assessment, and therefore other clinical signs and symptoms must be considered by the clinician.
- The accuracy of measurements depends on the proper application of the finger cuff and proper calibration of the device on each patient.
- For best results, the Caretaker4 should be used on patients that are at rest, and the hand using the finger cuff should be still and located at navel height.
- Do not drop the Caretaker4 unit or immerse in liquid.
- For maximum performance ensure that the rechargeable battery is fully charged prior to use.

- Take care when cutting the finger cuff's pneumatic hose to length to avoid injury the patient.
- The Caretaker4 unit is "MR Unsafe." Do not use the Caretaker4 in a Magnetic Resonance Imaging environment.

5 Safety Considerations

5.1 Definition of Terms

- *Warning:* advises against action that could result in personal injury.
- *Caution:* advises against actions that could damage equipment or produce inaccurate data, although personal injury is unlikely.
- *Note:* provides useful information regarding a function or procedure.

5.2 Before Using the Caretaker4

Carefully read this manual and all other accompanying information. If any abnormal situation occurs or if the operator suspects any unusual behavior, do one or more of the following:

- Remove the finger cuff from the patient.
- Remove the wrist worn unit from the patient.
- Clearly mark the device as “Do Not Use” and contact Caretaker Medical customer support.
- Attempt to use the device on a different Android tablet

5.3 Warnings

- Only charge the Caretaker device with the original power supply, using a properly grounded AC receptacle (100V-240V, 50-60Hz)
- Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Strong magnetic fields may cause malfunction or damage to the unit. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Caretaker4, including cables specified by the manufacturer otherwise degradation of the performance of this equipment could result.
- Do not immerse the Caretaker4 in liquid. Follow the cleaning instructions in the Operators Manual. In the case of accidental spills on the unit, remove power and have the unit serviced by qualified personnel.
- Do not use Caretaker4 in the presence of flammable gas or in an oxygen-enriched atmosphere.

- Internal Electrical Shock Hazard – This unit does not contain any user-serviceable parts. Do not remove the instrument covers or enclosures.
- Do not clean the device by submersing it in liquid, or using gasoline, thinner, or highly concentrated alcohol. Do not disinfect by autoclave or gas sterilization.
- Avoid application of the finger cuff on injured skin. Select a clean, healthy finger.
- The device is for attended monitoring only, and must be used under the direct supervision of a qualified health care provider.
- If the accuracy of any measurement is questionable, first check the patient’s vital signs by alternate means then check the device for proper functioning.
- Shock Hazard: do not attempt to plug or unplug the charger with wet hands. Make certain your hands are clean and dry before touching the charging cord.
- The Caretaker4 contains many metal components. Do not use in an Magnetic Resonance Imaging (“MRI”) environment.
- The Caretaker Remote Display Application has the ability to transmit an initial blood pressure calibration value to the Caretaker4 Physiological Monitor. Entering an incorrect value can lead to inaccurate measurements being displayed. Always verify entered values and BP readings prior to beginning a measurement session.

5.4 Cautions

- Federal Law restricts the Caretaker4 to be sold by prescription only.
- Do not crease the finger cuff or damage the cuff’s air bladder.
- Only use original finger cuffs manufactured by Caretaker4 Medical.
- Always use a new finger cuff and wrist strap for each patient and wipe the Caretaker4 unit with a mild antiseptic wipe to minimize infection risk.
- If blood circulation in the patient’s fingers is poor, or if the fingers are unusually cold, the pressure waveform and resulting BP and HR measurements may be inaccurate. It is possible to remedy this by warming the hand/fingers.
- As with all noninvasive blood pressure monitoring methods, motion artifacts and disturbances to the cuff or hose may cause poor signal quality and resulting measurements.
- To avoid interference, do not use Caretaker4 in close proximity to non IEC60601-1 complaint devices. In the event of electromagnetic interference with the BLE data stream to the Caretaker App, the Caretaker4 will continue to operate and device display will continue to function as expected however there may be a potential loss of data updates on the Caretaker App. Should such a condition occur, the numeric displays on the Caretaker App will gray out.
- Do not expose Caretaker4 to dirty or dusty environments.
- Do not drop the device.
- Clean and store the unit after each use. Do not store above +40 °C.

- If you wish to dispose of the Caretaker4 device, protect the environment by returning it to your nearest local electronics recycling facility.
- When using the Caretaker4's Respirator Rate function, the operating range is limited to 6-32 breaths per minute with patient at rest. In addition, respiration readings may not be reliable in the case of apnea or similar conditions.
- To avoid interference, do not use in close proximity to non IEC60601-1 compliant devices. In the event of electromagnetic interference interrupting the data stream, the App will no longer display or store monitored parameters.
- Communications range will be affected by obstacles and other physical objects such as walls or doors in the communications path. For assuring best range it is recommended to use in an open room free of obstructions.
- Bluetooth is a short range, point-to-point communications protocol with CRC error correction, acknowledgments, and re-transmissions in the event of packet failure. Data integrity is maintained with degradation of wireless signal, however the data rate can be effected resulting in slower updates of measurements.
- The Wi-Fi interface is for data forwarding to other patient monitoring systems only; it has not been tested to receive data from connected medical devices.

5.5 Security

- The Caretaker Monitor uses industry standard wireless protocols. Follow your institutional protocols for wireless security. It is highly recommended that for data forwarding applications a minimum of WPA2 wireless encryption on a secure network is used.
- The user has the ability to store patient-identifiable information in the data record retained by the Caretaker Remote Display Application. No patient identifiable information is stored by the Caretaker4. Follow your institutional protocols for handling sensitive information.

6 System Overview

The Caretaker4 system consists of two components:

- The Caretaker4 patient monitor unit that senses the arterial pulsations measured with a finger-worn cuff and analyzes them to obtain vital signs such as blood pressure, heart rate and breathing rate. The unit can be operated in stand-alone mode using its single multi-function button.
- The Caretaker App provides access to all commands and allows for the reconfiguration of the Caretaker4. The Caretaker App stores both vital sign data and real-time pulse waveform data is designed to run on either the supplied Android tablet or on an Android device running Android version 6 or higher.

6.1 Important Items to Remember When Using the Caretaker4:

- Finger cuff placement is critical. Please pay careful attention to the instructions shown below on how to place the cuff on the finger.
- Calibration of continuous blood pressure readings
 - The Caretaker4 requires a starting blood pressure to provide readings and must be calibrated using either Manual or Automatic calibration methods.
 - In Manual calibration mode, the starting blood pressure is obtained using an external device (such as an automatic brachial cuff) and entered into the Manual calibration dialog box in Caretaker App.

CAUTION: When recalibrating in Manual Calibration Mode the previously entered blood pressure values will be re-used automatically!! To recalibrate using the Manual method, it is recommended that the operator obtain new blood pressure readings using an external device (such as an automatic brachial cuff). Stop the current session using the DONE button (bottom of the Caretaker App screen) and start a new Manual calibration session. For details refer to the Manual calibration mode section below.

- In Automatic calibration mode the Caretaker4 device will calibrate itself, as described below. **IMPORTANT ITEMS TO REMEMBER WHEN USING AUTOMATIC CALIBRATION:**
 - Select the correct subject posture using the app (sitting or supine)
 - Keep the hand at navel height during calibration while sitting.
 - If the Automatic calibration fails to obtain a valid reading 2-3 times, it is recommended that Manual Calibration mode is selected and an external device (such as an automatic brachial cuff) is used to obtain the starting calibration pressure. In some situations obtaining a starting

blood pressure may be too challenging for specific physiological reasons (for example cold fingers).

- Blood pressure and vital signs data are only saved on the tablet or device running the Caretaker App. If wireless communication is disrupted between the Caretaker4 and the Caretaker App, the Caretaker4 will continue measuring and displaying vital signs however THE INFORMATION WILL NOT BE SAVED. Once wireless communication is restored, the Caretaker App will continue storing the collected vital signs data.
- Wireless communication disruptions:
 - The system will automatically attempt to recover from brief disruptions.
 - In the event of longer disruptions, the connection WILL NOT RECOVER and the Caretaker4 will need to be reconnected with the Caretaker App.
- **IMPORTANT:** If the Caretaker4 is unable to detect a pulse from the finger cuff for 15 minutes or more, Caretaker device will reset to its starting screen. A Manual or Automatic calibration procedure is then **REQUIRED** to restart vital signs monitoring.

7 Using the Caretaker4

7.1 Caretaker4 Single Button Commands & Display Indicators

Commands	
Single-click	The radio advertises that the device is ready for connection – the Bluetooth symbol in the status bar will turn ORANGE. Once the device connects the Bluetooth symbol in the status bar will turn BLUE.
Double-click	The device starts a self-calibration sequence to find the starting blood pressure for continuous blood pressure measurement operation.
2 second button hold	Stops the current operation and returns the device to starting mode (the Caretaker device will remain connected to the Caretaker App).
6 second button hold	Device will display message: “Push button again to power off”. Upon pushing the button once the device will power off.

7.2 Opening the Caretaker Packaging

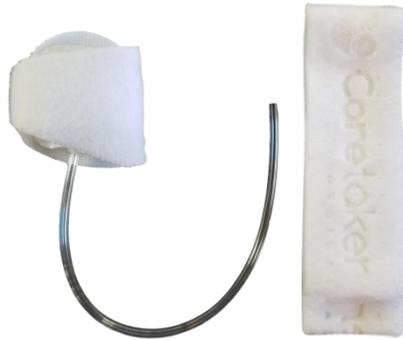
Ensure that the box contains the following items as pictured below:



Caretaker4 Device



AC Power Supply (Caution: Only use the AC-DC adapter and optional country specific blade kits that come with your device)



Biocompatible Finger Cuff & Wrist Strap

The Caretaker4 comes pre-packaged with Single-Patient-Use Finger Cuff and Wrist Straps. Additional Finger Cuffs and Wrist Straps may be purchased from Caretaker Medical or the nearest authorized distributor.

7.3 Preparing the Caretaker4 Unit for Use

- Fully charge the Caretaker4 battery (see recharging instructions below).
- Keep your finger cuffs and wrist straps safely inside their plastic bags until ready for use.

7.4 Connecting the Caretaker4 Device

Ensure the Caretaker4 unit is sufficiently charged to support the time duration needed to measure vital signs information. The battery status is shown in the upper part of the display as a simple bar graph. The bars will change color from Green (fully charged) to Red (critical) as the unit is used. The below example shows the Caretaker4 at about 75% charged:



Caretaker Battery Charge Indicator

Wipe the Caretaker4 unit with an Aseptic wipe to disinfect the unit per your clinical protocol. Disconnect the AC cord first.

7.5 Attaching the Wrist Strap to the Caretaker4

Secure a clean, biocompatible Wrist Strap to the Caretaker4 as shown in the following steps:

1. Insert one end of the wrist strap through one of the loops on the back of the Caretaker 4 device.



Wrist Strap Attachment Step 1

2. Fold the Velcro attachment over and attach to the wrist strap



Wrist Strap Attachment Step 2

3. Slip the end of the wrist strap through the remaining loop on the back of the Caretaker4



Wrist Strap Attachment Step 3

The patient's arm will go through the loop and the "tail" will be wrapped around to secure the device.

7.6 Connecting/Disconnecting the Caretaker4 Finger Cuff

Connect a new Finger Cuff to the Caretaker device by removing the cuff from a sealed package and sliding the plastic hose into the quick-connect on the side of the Caretaker device. **PUSH THE HOSE UNTIL IT STOPS IN THE SEAT OF THE QUICK-CONNECT.** The hose must be free of obstruction or interference during use.



Caretaker Cuff Hose Quick Connect

To disconnect the hose of the finger cuff from the Caretaker device, push on the ring-shaped sleeve that surrounds the hose at the mouth of the quick-connect as show by the red arrow in the image below.



Caretaker Cuff Hose Quick Connect Close-Up

7.7 Placing the Caretaker4 on the Wrist

Insert the patient's hand through the wrist strap loop shown in Section 7.5 as follows:



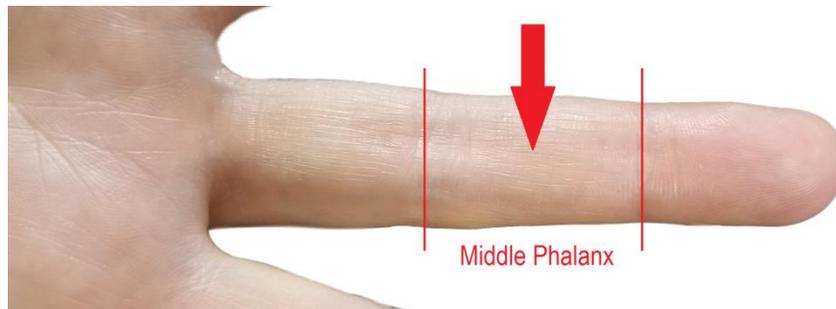
Once the patient's arm has been inserted through the wrist strap loop pull the end of the strap to tighten and secure using the Velcro tab to the wrist strap as follows:



7.8 Attaching the Finger Cuff to the Patient's Finger

Attach the finger cuff to the patient's finger. Loosen the 2 tabs and slide the finger cuff onto the patient's finger with the air-bladder and tube facing as shown in the figures below. Take care to ensure the air bladder is centered as shown in the image below (between the 2nd and 3rd knuckles over the middle phalanx) on the 2nd through the 4th digit (finger) on either hand for best results.

- Make sure the sensing pad is completely deflated before placing on the digit (finger).
- Place the Air Bladder so that it is centered on the between the 2nd and 3rd knuckle over the middle phalanx on the palm-side of the finger as shown below:



Finger Cuff Positioning

- Use the target symbol on the finger cuff to aid with alignment as shown below:



Finger Cuff Target Symbol

- Ensure that the Air Bladder is not located over a finger joint as it will not be able to properly couple to the digital arteries to obtain a pulse signal and may result in abnormal or unusual measurements.



Incorrect!!

The sensing bladder is placed too low on the finger.



Correct!!

The sensing bladder is centered on the middle member of the finger.



Incorrect!!

The sensing bladder is placed too high on the finger.

- Grasp the 2 tabs as shown and pull snug. Secure the large tab first then secure the small tab.



TIPS: The wrap has to be snug. A loosely placed wrap will result in poor signal. Ensure the air hose is in the center of the finger for proper performance. The Caretaker will display error messages if the Finger Cuff is too loose or too tight.

When the Caretaker4 is mounted to the patient's wrist and the finger cuff is properly attached, ensure the patient is sufficiently still and at rest and start the Caretaker4 either through using the button located on the Caretaker4 or using the Caretaker App. As the Caretaker4 measures relative central arterial pressure, ensure that the patient is either Sitting or Supine when the Manual or Automatic calibration is started and that they remain still during measurement and calibration.

The Caretaker4 should be at navel height during Automatic calibration. If the patient is lying down, the arm should be either by the patient's side or on the stomach during automatic calibration.

Refer to the Caretaker App User Guide for operating instructions of your device.

7.9 Removing the Caretaker Device from a Patient

Step 1: Push “Done” on the Caretaker App, or Push and Hold the button on the Caretaker4 for 2 Seconds to deflate the cuff.

Step 2: Detach the finger cuff from the patient's finger and remove the Device from the patient's wrist.

Step 3: Detach the finger cuff hose from the nipple of the Caretaker4 unit. Dispose of the finger cuff and wrist strap after each patient use.

Step 4: Recharge the Caretaker4 and store in a cool dry place until next use.

7.10 Recharging the Caretaker4

To Recharge the Caretaker device, plug the supplied universal charger into a standard electrical outlet and insert the barrel jack into the Caretaker4. The LCD on the Caretaker4 unit will display an icon indicating the battery is charging.

As the battery charge status increases, the bar graph will change from RED to YELLOW to GREEN and the bar graph will become solid indicating that the device is fully charged.

7.11 Cleaning, Storage, And Disposal

The Caretaker4 is a medical device designed for reuse and the finger cuffs and wrist straps are designed for single use. Carefully read the cleaning instructions before using the Caretaker device. After each use, always clean those parts of the device that are in direct contact with the patient's skin.

Finger cuffs are designed for single use only. Please dispose of the Finger Cuff after each use. Finger Cuffs are individually packaged in sealed plastic bags. Finger cuffs can be ordered from Caretaker Medical at www.Caretakermedical.net.

Wrist Straps are designed for single use only. Please dispose of Wrist Straps after each use. Wrist Straps are individually packaged and can be ordered from Caretaker Medical at www.Caretakermedical.net.

The Caretaker4 must be cleaned after each use. DO NOT clean the unit by submersing it into liquid or through the use of autoclave or gas sterilization. DO NOT clean the Caretaker4 using and cleaning solutions that contain a high concentration of alcohol. Always unplug any power cord from the unit before cleaning. Wipe the Caretaker4 with a clean damp cloth using a mild disinfectant or aseptic wipe and allow to air dry.

Store the Caretaker4, the packaged finger cuffs, and wrist straps in a cool, dry, clean place away from direct sunlight. It is recommended that the Caretaker4 be fully charged after each use. Never store the unit while connected to power.

Dispose of Finger Cuffs properly.

Dispose of the Caretaker4 device and your nearest electronics recycling facility or other appropriate method as governed by local regulations.

8 Using the Caretaker App

THE CARETAKER4 ANDROID APP IS PRE-LOADED ON THE TABLET PROVIDED WITH YOUR CARETAKER DEVICE. IF YOU WISH TO INSTALL THE CARETAKER APP ON A DIFFERENT ANDROID DEVICE, PLEASE CONTACT YOUR AUTHORIZED CARETAKER REPRESENTATIVE.

IMPORTANT NOTE BEFORE YOU BEGIN:

The Caretaker4 must be individually calibrated for each patient in order to establish a baseline blood pressure start-point. This calibration procedure can be done in Manual Calibration Mode by entering a starting blood pressure derived from an external blood pressure cuff, or in Self-Calibration Mode where the Caretaker device automatically derives a starting blood pressure using the finger cuff. Please read below for guidance on how to use each calibration method.

8.1 Launching the Caretaker App



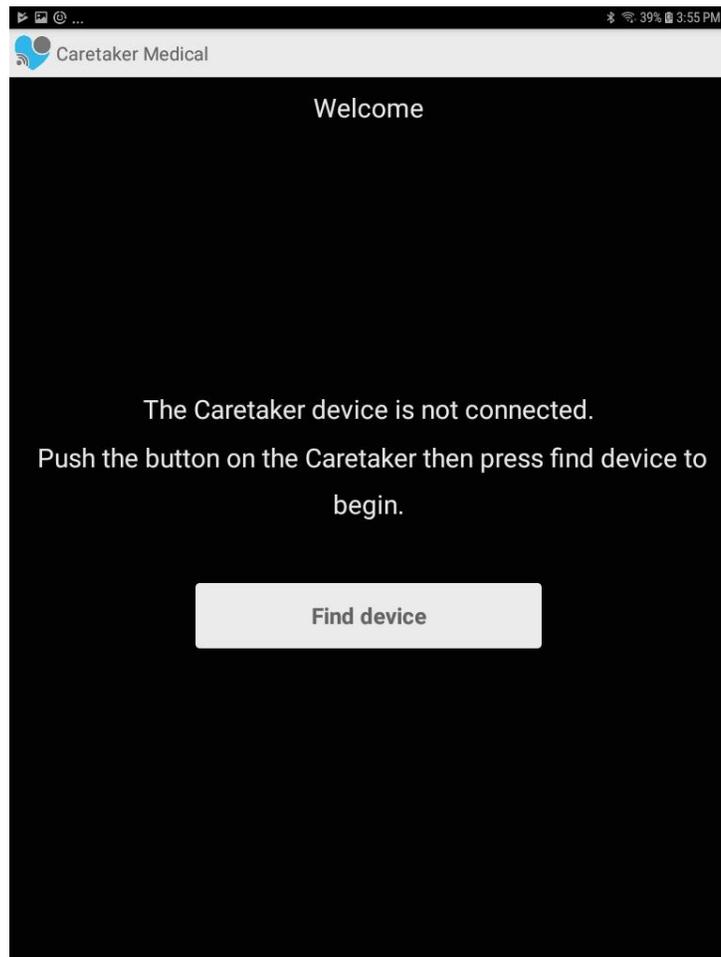
Caretaker Tablet Home Screen

Tap the Caretaker Monitor icon on the desktop to launch the Caretaker App.

Upon launch the Welcome screen shown under the next section (“Connecting with the Caretaker device”) will open.

8.2 Connecting with the Caretaker4

Upon launch of the Caretaker App on your Android tablet or Android device the Welcome Screen is displayed. Click on the find device button in the Caretaker App to start searching for available Caretaker4 devices to connect to.



Caretaker App Welcome Screen

Once you have clicked on the Find Device button, immediately click on the power button on the front of your Caretaker4 device as shown below to start the pairing procedure.



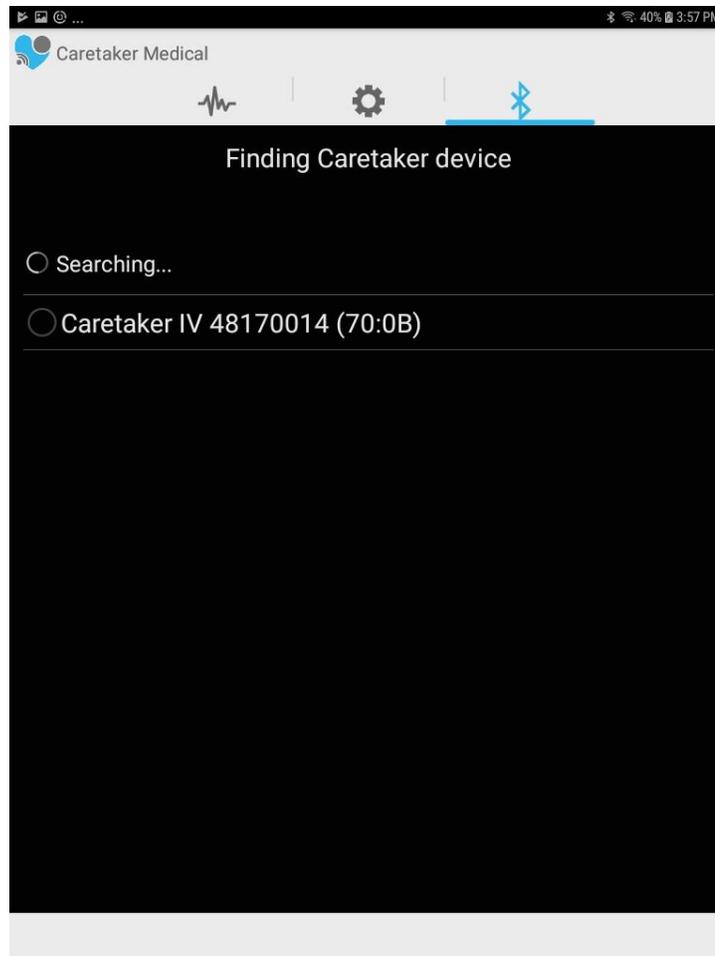
Caretaker4 Power Button

All Caretaker4 devices within range that are currently broadcasting their availability for connection will be displayed including their unique identifier as shown below.



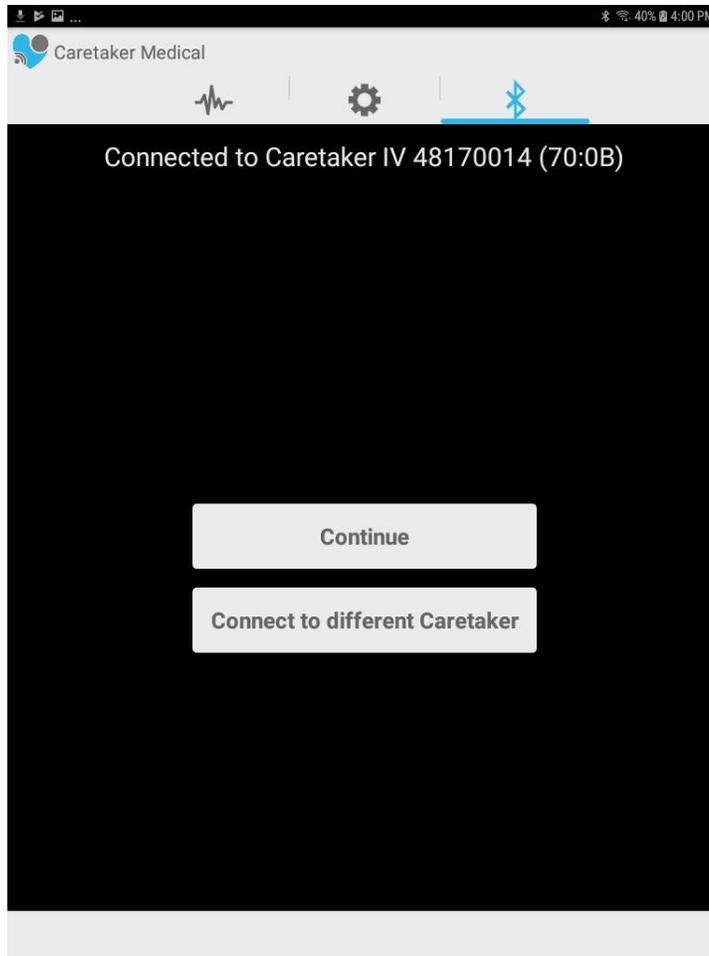
Caretaker4 Unique Identifier

Once the Caretaker app has found available Caretaker4 devices, they will be listed as shown in the following example.



Caretaker App Available Caretaker4 Devices

If there are multiple Caretaker4 devices in range and broadcasting their IDs, tap on the Caretaker4 you wish the Caretaker App to connect to. Use the unique identifier to locate your device in the list of found devices. Once you have successfully connected to the Caretaker App, the following screen will be displayed:

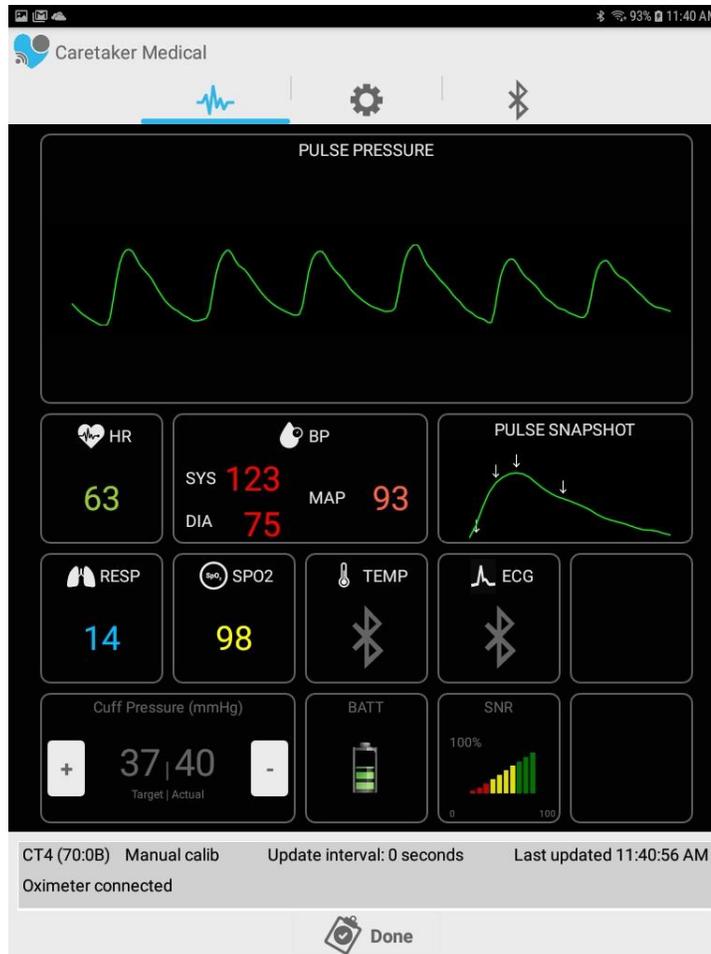


Note that once a device is connected to a tablet, it will not display as available to any other Caretaker Apps running nearby. If you do not see your device listed, check to ensure that your device is set to broadcast its ID and that it is not already connected to another instance of the Caretaker App which can occur if you are running more than one Android based device loaded with the Caretaker App.

If you accidentally connect to the wrong Caretaker4 device, touch the “Connect to different Caretaker” button.

8.3 Monitoring Vital Signs

Touch the “Vitals” tab on the menu bar of the Caretaker App and the display will change to the vital signs monitoring mode. The status bar in the lower part of the display will indicate the current connected device(s) and the calibration status.



Touch the “Start” icon to open the calibration menu. Decide if you will use Manual or Automatic Calibration mode.

8.4 Manual Calibration Mode

Step 1. Using an FDA-cleared blood pressure monitor, measure the patient’s blood pressure. Follow the manufacturer’s directions to obtain an accurate blood pressure measurement from the patient.

Step 2. In the “Manual Calibration” window, touch the default SYS reading until it highlights and opens the numeric keypad.

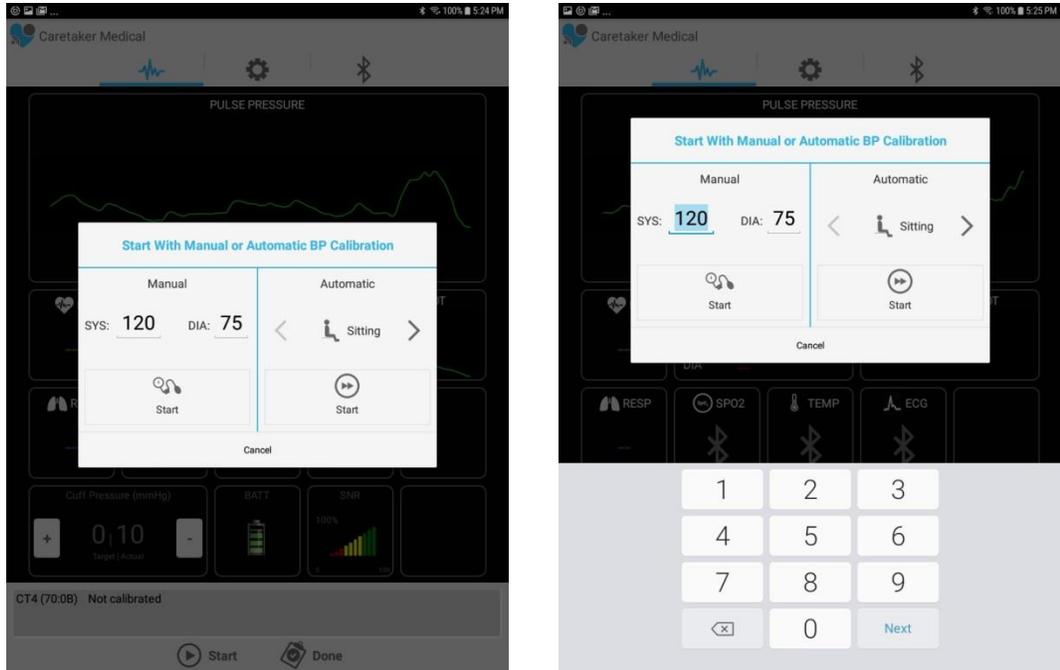
Step 3. Input the accurate blood pressure parameters into the Calibration Fields (below right).

Step 4. Select “Start” on the “Manual” side of the window (see below left) on the Caretaker App.

For the next 20-30 seconds the device will perform a calibration procedure during which **time the patient must remain still**. After that, the Blood Pressure and Heart Rate parameters will display accurate values. Note that in manual calibration

mode, the Caretaker4 will not re-calibrate itself. Follow your standard practice for other manual BP monitors.

CAUTION: To recalibrate using the Manual method, it is recommended that the operator obtain new blood pressure readings using an external device (such as an automatic brachial cuff). Stop the current session using the STOP button (bottom left of the Caretaker App screen) and start a new Manual calibration session (i.e. start with Step 1 above).



Manual Calibration Screen & Numerical Entry Keypad

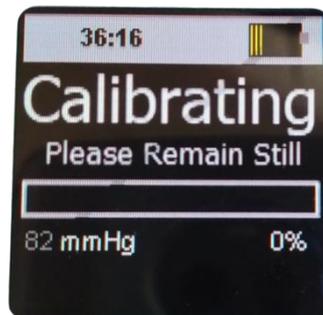
8.5 Automatic Calibration Mode

The results obtained by using the Automatic Calibration mode are influenced by the position of the monitored hand relative to the body as opposed to the Manual Calibration mode which are far less position-dependent. Once Automatic Calibration is complete the patient can re-position as needed.

Before beginning with Automatic Calibration, select the subject's posture. There are two options, which are listed in the right part of the Manual or Automatic BP window (see previous page):

- Sitting (upright posture, monitored hand at navel height)
- Supine (hand approximately at heart height)

Tap the "Start" button in the lower right part of the window. Alternatively, you can double-click the button on the Caretaker4. When you double click the button on the Caretaker4 to initiate the automatic calibration sequence, the device will default to sitting posture unless the Caretaker App was used to perform a previous automatic calibration in which case the last selected posture will be re-used for calibration. The screen on the Caretaker4 device will display the following message during calibration:

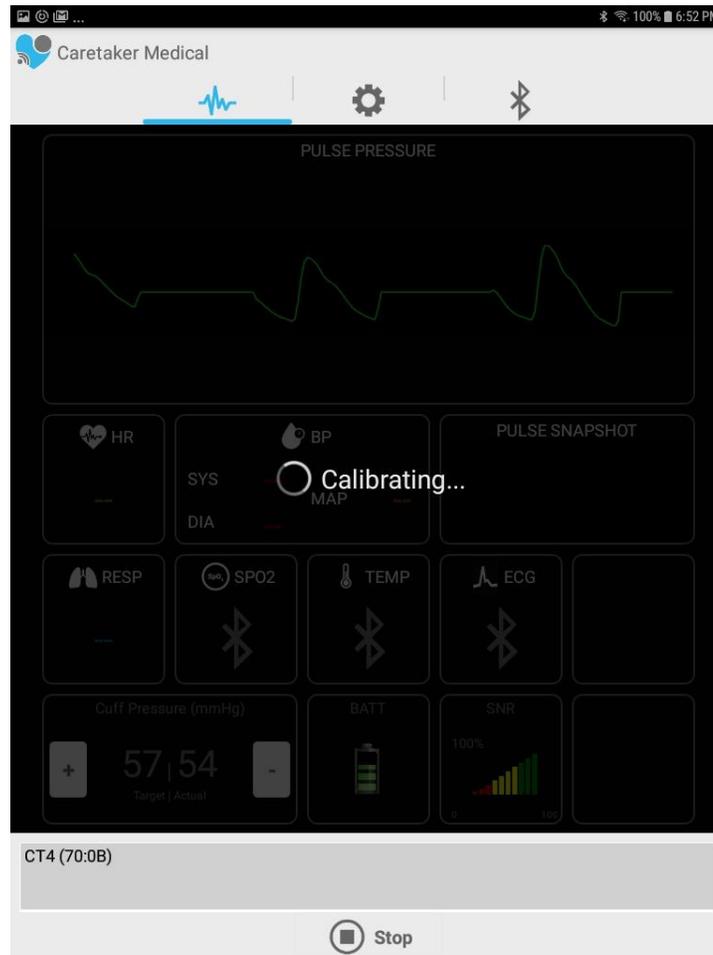


Caretaker4 Calibration Screen

Both the display on the Caretaker4 and the App will indicate "Calibrating" until the process is complete. The Caretaker4 device's display will also indicate the current pressure in the finger cuff for your reference. The calibration sequence will typically take 40-60 seconds.

- Remain still during the procedure.
- While all blood pressure measurements are to some extent position-dependent, the "upright sitting" and "navel height" requirements are particularly important because of the Caretaker4's finger-based measurement,

and significant deviations from the advised positions can produce erroneous readings.



Caretaker App Calibration Screen

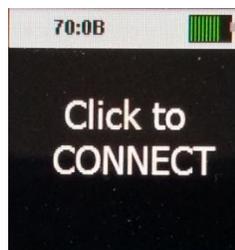
Once a calibration point is obtained via either method, the App's various vital sign displays will start to update. The current update interval timing is displayed in the status bar for your reference and may be changed though the Settings menu discussed later in this document. The displays are:

- PULSE RATE Waveform: (6-second real-time display of arterial pulse rate)
- PULSE PRESSURE Waveform: (6-second real-time display of the arterial pressure pulse)
- PULSE Pressure SNAPSHOT: (captured every 4-5 seconds)
- HR/bpm: Numeric Heart Rate (Beats per Minute)
- BP/mmHg: Systole, Diastole and MAP (mean arterial pressure)
- RESP/pm: Respiration Rate (breaths per minute)

- SPO2%: Blood Oxygen Saturation, NOTE: this will be blank if no SPO2 device is attached.
- TEMP: Reserved for future use
- SQE: Signal to noise estimate of arterial pressure signal. If the number is less than 10%, you may need to re-position the finger cuff.
- CUFF PS: Coupling pressure within finger cuff. Desired value range should typically be 30-50 mmHg.
- TARGET PS: Used to adjust Cuff Pressure. For patients with poor perfusion, consider increasing the target cuff pressure. Note that higher pressures tend to be more uncomfortable.

8.6 Automatic Calibration Using the Caretaker without an Android Device

Step 1. Clicking the Caretaker button will wake the unit, indicated by the click of a valve and the display of the launch screen. The device is ready for use within about 5 seconds and will display the screen shown here.



Step 2. Double-click the Caretaker4 button to initiate the Automatic Calibration sequence, which will proceed as described in section 8.5.

Note: Connection with the Caretaker App can be initiated at any time by single-clicking the Caretaker4 button and following the steps under section 8.2.

8.7 Re-Calibration Considerations

The Caretaker4 supports two calibration modes; Manual Calibration, where externally obtained blood pressure values are entered to provide a baseline for the continuous blood pressure measurement operation, or Automatic Calibration, where the baseline is obtained by the device itself, as described above.

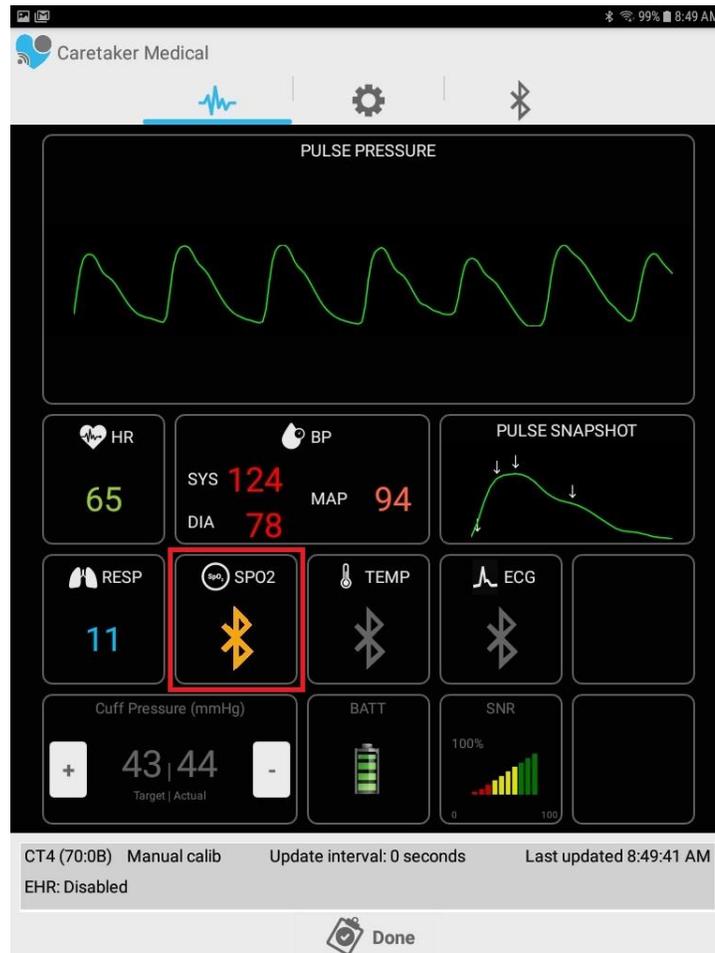
The default for re-calibration in both modes is a recommended time window of 30 minutes; however, this time window can be configured by the clinician depending on specific requirements.

When considering re-calibration, it is important to understand that what drives the requirement is a sustained hemodynamic change that affects the arterial pressure

pulse shape, since pulse analysis is the basis of the Caretaker4's measurement approach. The two principal pulse shape change drivers are significant and sustained changes in heart rate and changes in arterial stiffness. The emphasis here is on sustained changes, which does not include the transient hemodynamic changes associated, for example, with positional changes, i.e. getting up or sitting down. With regard to heart rate, re-calibration is generally recommended for sustained changes in excess of 20 bpm. In regard to arterial stiffness changes, the clinician is advised to consider circumstances. For example, the introduction of vaso-pressors/dilators would likely warrant recalibration.

8.8 Connecting with the Optional Oximeter

To connect to the optional Caretaker Bluetooth SpO₂ monitor with the Caretaker App, press and hold the SpO₂ parameter on the screen until it turns orange as shown in the example below.



Connecting the Pulse Oximeter

Once you have started the search for the SpO₂ monitor, press the power button on the device to turn it on and place it on a finger other than the one being used for the Caretaker4 finger cuff.

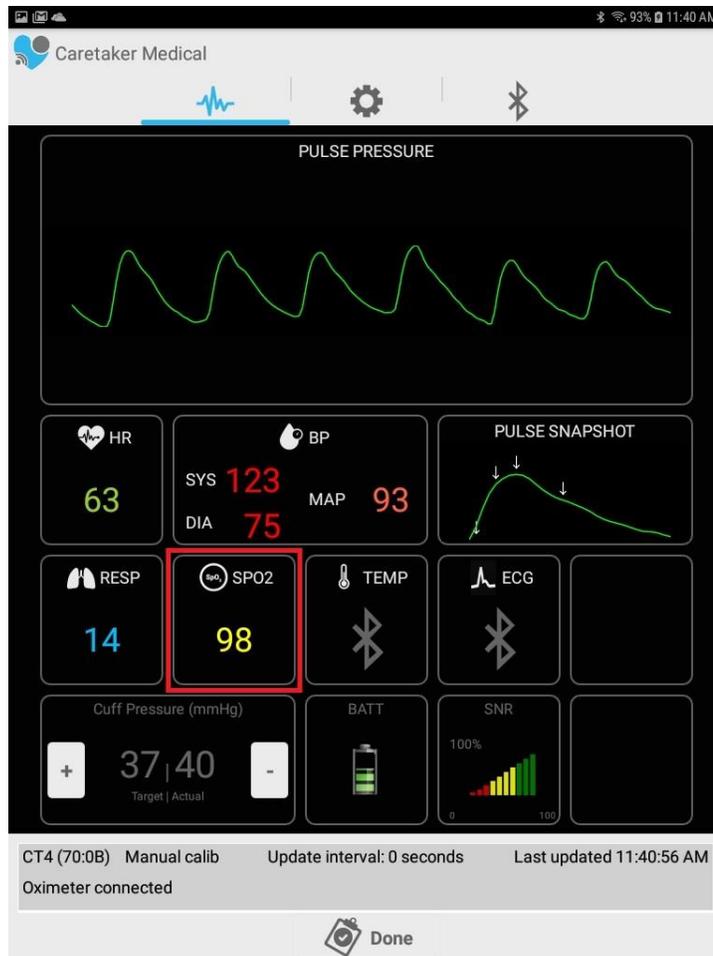


Pulse Oximeter Power Button

Once the SpO₂ monitor is turned on, the Caretaker App will detect it and connect to it. Once a connection is successful, you will see pulse oximetry data appear in the pulse oximetry panel on the Caretaker App.



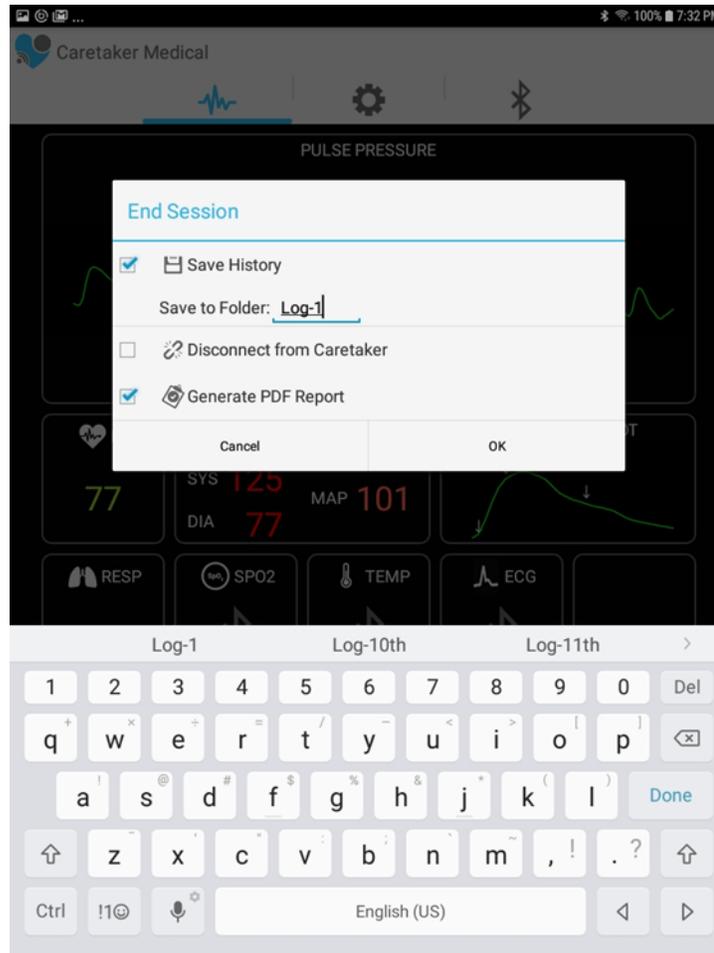
SpO₂ Monitor Turned On



Caretaker App with Pulse Oximetry Data

9 Ending a Session

Touch the “Done” button on the lower menu bar of the Caretaker App and the display will change to the End Session dialog as follows:



From here, you have the option to either save or not save the vital sign history and specify a folder other than the default location.

You can also choose to disconnect (un-pair) the Caretaker4 with the tablet. If you uncheck the box, you can simply start a new session without going through the steps in section 8.2

The Caretaker App can also generate a summary PDF report. If you check the Generate PDF Report checkbox, a report will be saved locally on the tablet. An example of the report is shown on the following page.

Blood Pressure Report

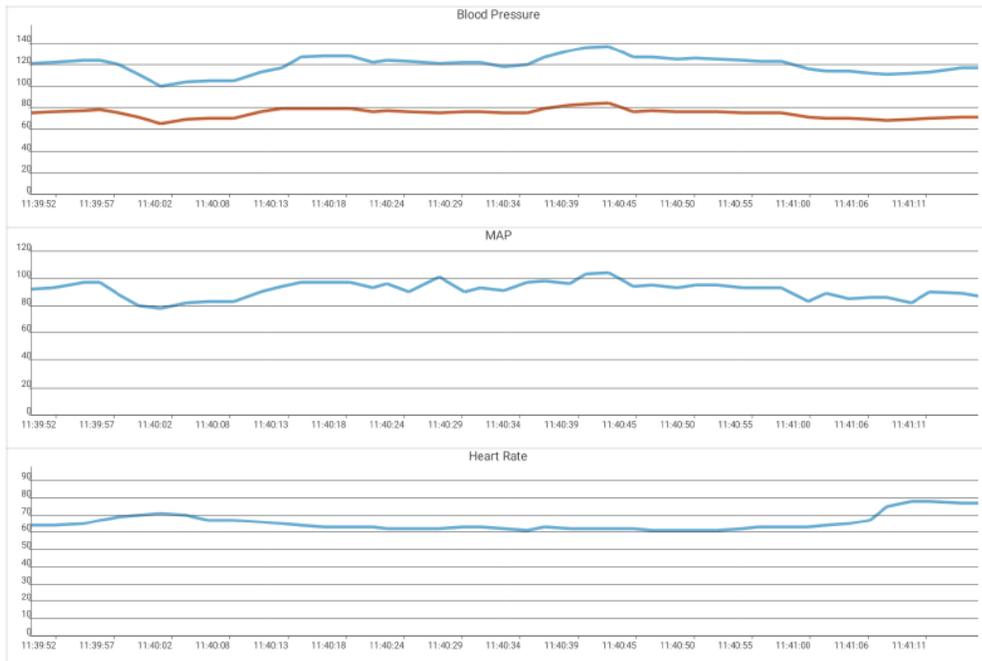


Patient ID:

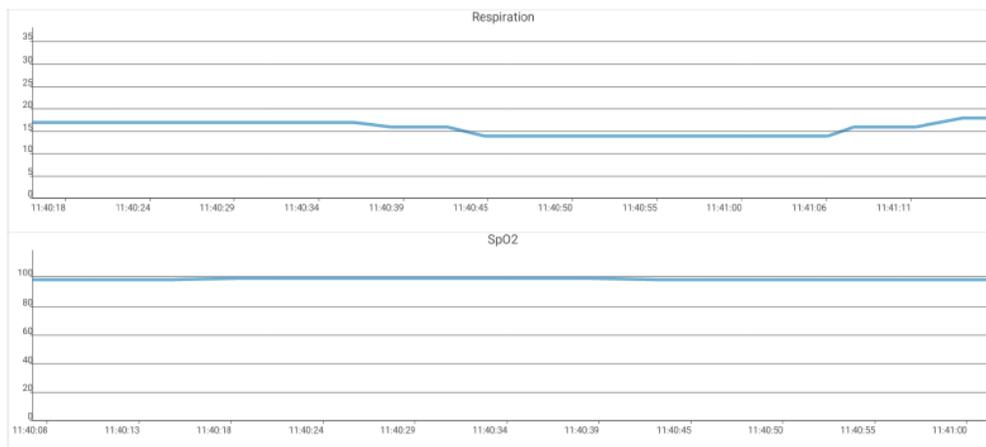
Test Date: 10/15/18
Report Date: 10/15/18

Test Summary Data:

Start: 11:39:50	Stop: 11:41:15	Duration: 00:01:26
-----------------	----------------	--------------------



Caretaker App Blood Pressure & Vital Signs Report Page 1



Caretaker App Blood Pressure & Vital Signs Report Page 2

Blood Pressure Report



Patient ID:

Test Date: 10/15/18

Report Date: 10/15/18

Statistics:

	Maximum	Minimum	Average	Std. Dev.
Systolic	137	100	120	+/- 8
Diastolic	84	65	75	+/- 4.1
Heart Rate	78	61	65	+/- 4.9
Map	104	78	92	+/- 6
Respiration	18	14	16	+/- 1.4
SpO2	99	98	98	+/- 0.5
Temp.	N/A	N/A	N/A	N/A

Caretaker App Blood Pressure & Vital Signs Report Page 3

10 Historical Physiological Data Displays

To view a historical trend graph of each vital sign, touch any of the Numeric Value Boxes (BP, HR, RESP, etc). The length of time represented can be changed through the Settings menu discussed later in this document. To clear the history and start a new historical trend, touch the Trashcan icon in the graph window. When the history is cleared, a log file containing the historical measurements is moved from the Logs folder to the Saved Logs folder (see Appendix).

The Saved Logs folder can contain a number of subfolders numbered sequentially from Log-1 to Log-N; every time the trash can is selected, a new Log-N folder is created and the log files being moved are placed in this folder.

When the log files are moved, the data contained within will not be displayed the next time the historical graph is opened. Note that the data is not deleted by this action and will be maintained within the tablet/phone for viewing at a later date.



Caretaker App BP History Chart



Caretaker App Heart Rate History Chart

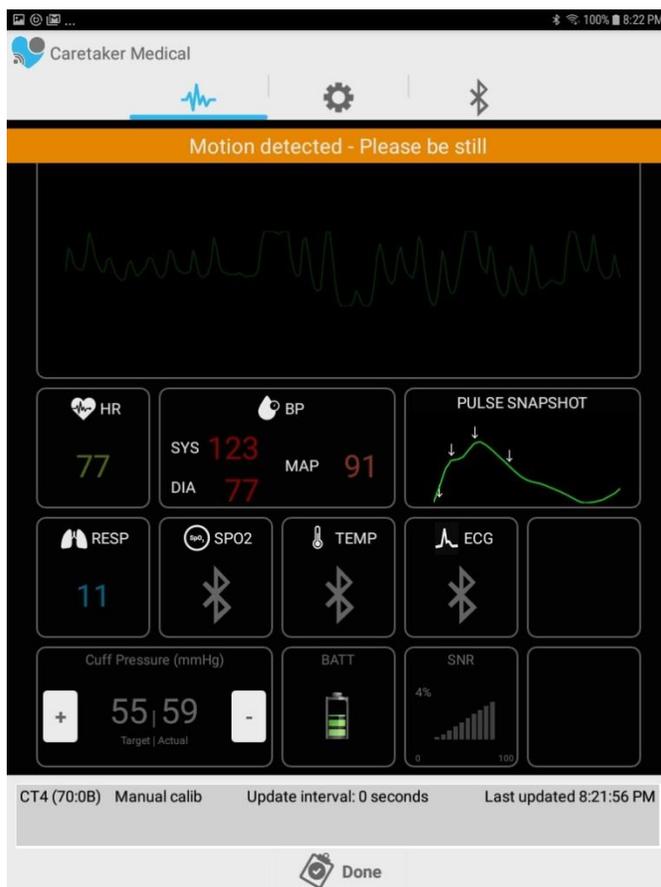


Caretaker App Respiration Rate History Chart

11 Motion artifact-related app responses & messages

As with any blood pressure monitor, it is important that the patient remain relatively still while the device is measuring blood pressure in order to ensure accurate measurements are obtained. The Caretaker4 is tolerant of small motions, but excessive motion will impede the Caretaker4 from displaying accurate vital sign data. In the case where excessive motion is detected, the numerically displayed parameters will dim to a gray color, displaying last good data values measured. If motion disturbance continues, both the display on the Caretaker4 device and the App will change to a warning notice. When motion subsides, the Caretaker4 will automatically resume measurements and the numbers will no longer be dimmed and appear gray in color.

IMPORTANT: if motion related noise occurs continuously for 15 minutes, the Caretaker device will reset to its starting screen. A Manual or Automatic Calibration procedure is required to restart the system.

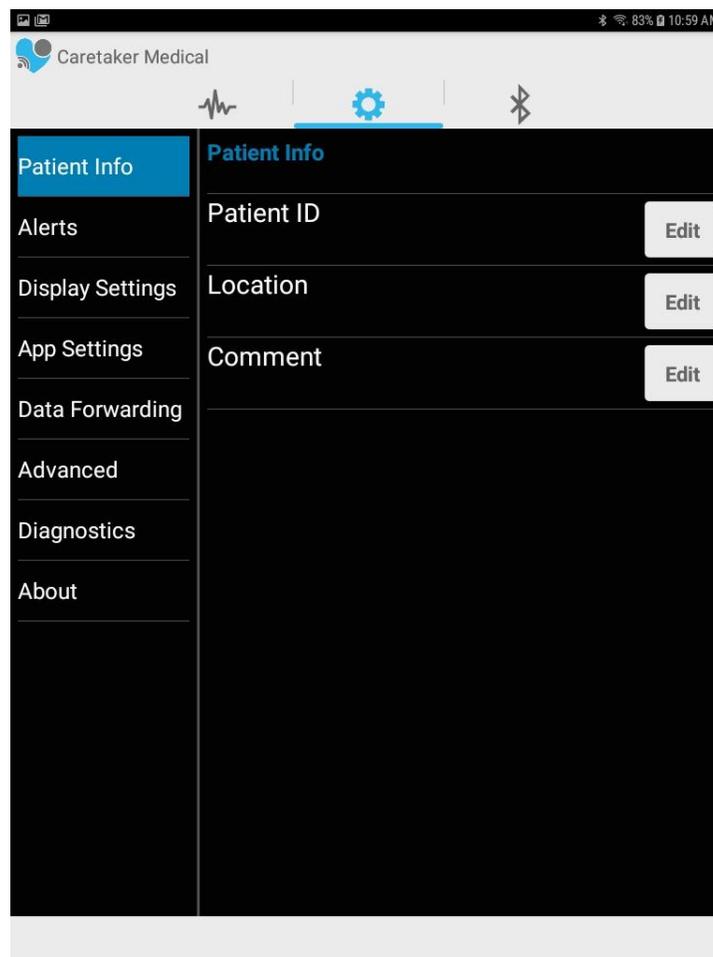


12 Settings

Several features of the Caretaker4 are user-configurable. To access these features, touch the Settings (Sprocket icon) tab on the menu bar.

12.1 Patient info

The Patient Info screen allows users to enter information pertaining to the Patient ID as well as the Location in which the tablet with the Caretaker App and Caretaker4 device are used in a facility or institution. Each parameter can be changed by clicking the Edit button on the right hand side of the screen.



You can add various identifiers and notes by touching the “Edit” boxes and using the keypad input.

Note that if you enter information in the “Location” field, this text will appear in the upper right corner of the display. This can help distinguish between multiple

units if you are using the MultiView app to monitor patients remotely. The location field is also included in HL7 messaging data which is discussed later in this chapter.

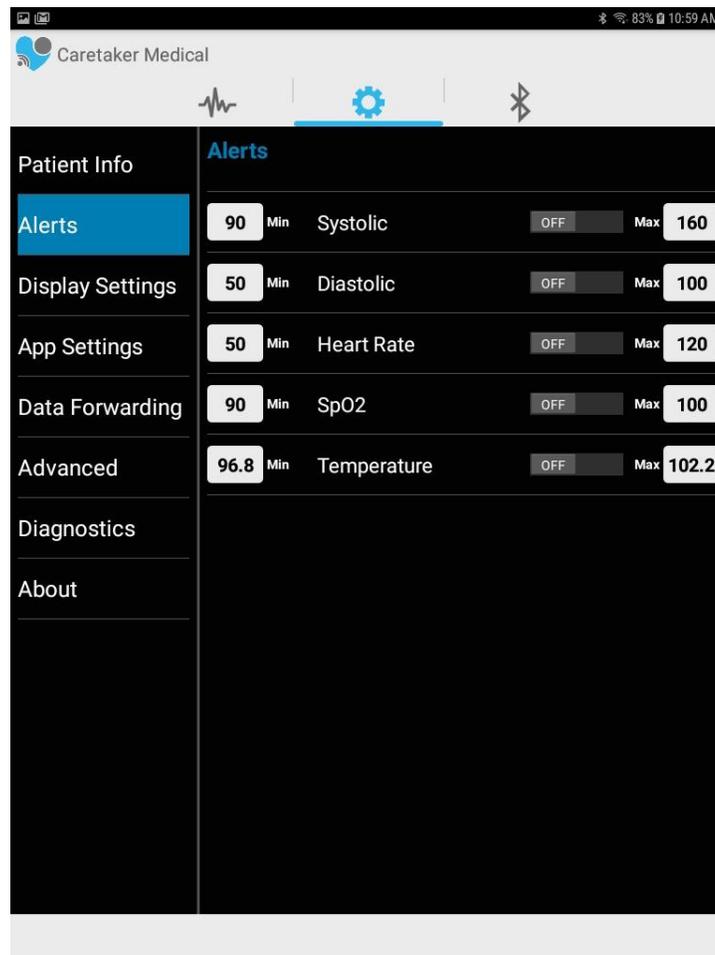


Caretaker App Location Information

12.2 Alerts

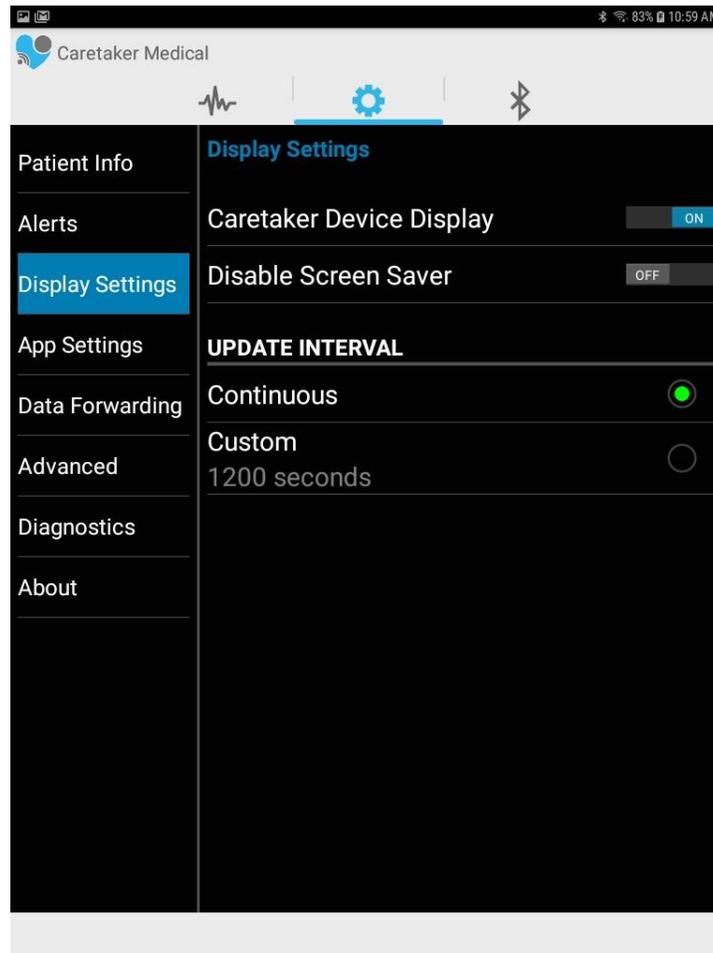
Tapping the “Alerts” field opens the panel for setting alerts for Systolic blood pressure, Diastolic blood pressure, Heart rate, SpO₂ & Temperature

Maximum and minimum values can be set for each of the listed physiological parameters.



12.3 Display Settings

The Display Setting screen in the Caretaker app allows the user to control a number display related parameters for the Caretaker App and the Caretaker4 device.

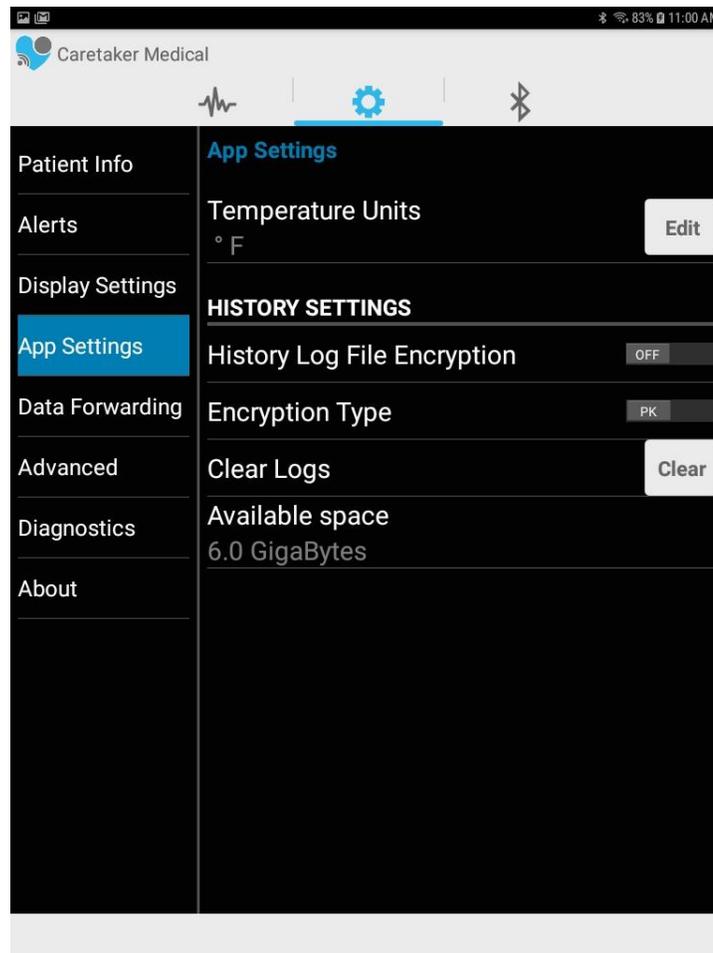


- **Caretaker Device Display** is used to turn the display on the Caretaker4 device on or off while operating. This feature is useful for situations where the brightness of the Caretaker4 display can become disruptive for the patients such as use at night while sleeping. Note: If the Caretaker4 becomes disconnected from the tablet running the Caretaker App, the display will turn back on automatically.
- **Disable Screen Saver** is used to keep the tablet screen on at all times while the Caretaker App is running eliminating the need to “wake” the tablet up from low power mode. Note that this feature decrease the battery life of the tablet due to the fact that the display is on at all times.
- **Update Interval** is used to control the rate at which the BP and vitals data is updated on the Caretaker App from the Caretaker4 device. Options include

either **Continuous** mode (data is updated real time) or **Custom** where an interval in seconds can be set by the user.

12.4 App Settings

The App Settings screen allows the user to configure measurement units, file encryption options and provides the ability to manage data log files. The App Settings screen also provides the user with information on the available storage on the tablet for log files created during each Caretaker4 session.



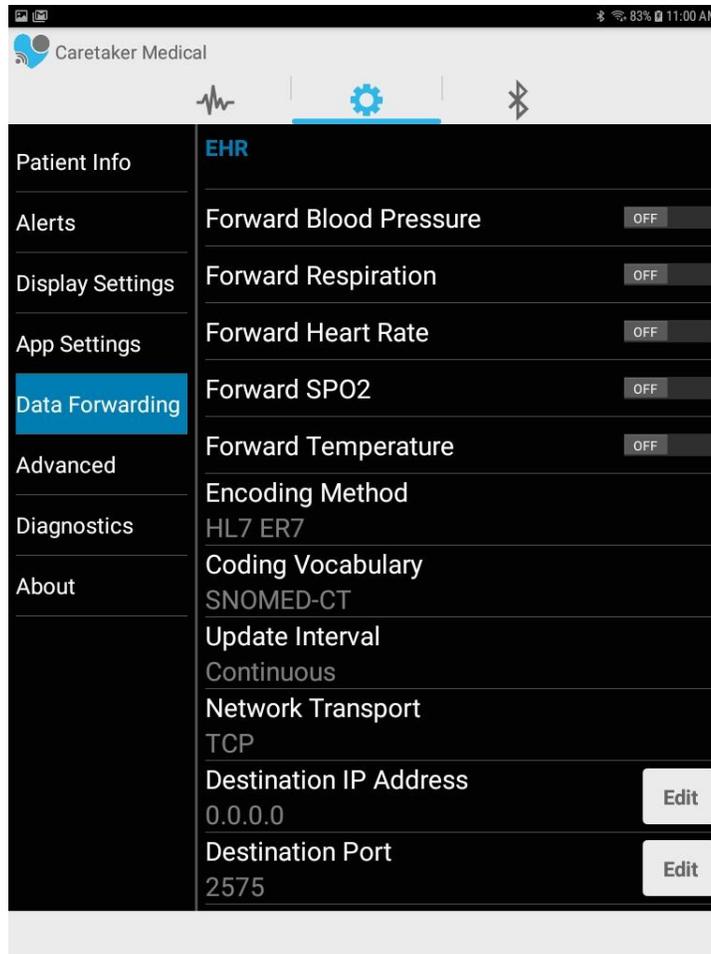
- **Temperature Units** is used to control the units of measure displayed for temperature readings in either Celsius or Fahrenheit
- **History Log File Encryption** is used to control if the log files created after each session that are stored on the tablet are encrypted. Once this feature is enabled, all log files will be encrypted using the password provided when prompted. This password will be required to unencrypt the files when being viewed on a remote computer. If encryption is turned off after a password has

been set, all encrypted files will be deleted from the tablet. **Caution: Caretaker Medical is unable to recover the password if it is forgotten.**

- **Encryption Type** is used to control the type of encryption that is used to encrypt the log files. Options for include Public-Key (PK) and Advanced Encryption Standard (AES).
- **Clear Logs** is used to erase all of the log files generated and stored by the Caretaker App in the Saved Logs folder. **Caution: Once the log files have been deleted, they cannot be recovered.**
- **Available Space** displays the remaining storage space available on the tablet or compatible Android device that the Caretaker App is running on.

12.5 Data Forwarding

The Caretaker App has the capability to send blood pressure and vital signs data to compatible Electronic Medical Record (EMR) and Electronic Health Record (EHR) systems using HL7 communication protocols. The Data Forwarding screen provides the user with the configuration options to utilize the HL7 data forwarding protocol. Supported HL7 formats include SONOMED-CT and LOINC and in both cases, the Caretaker App sends unsolicited Order Results (ORU) messages to the receiving system.



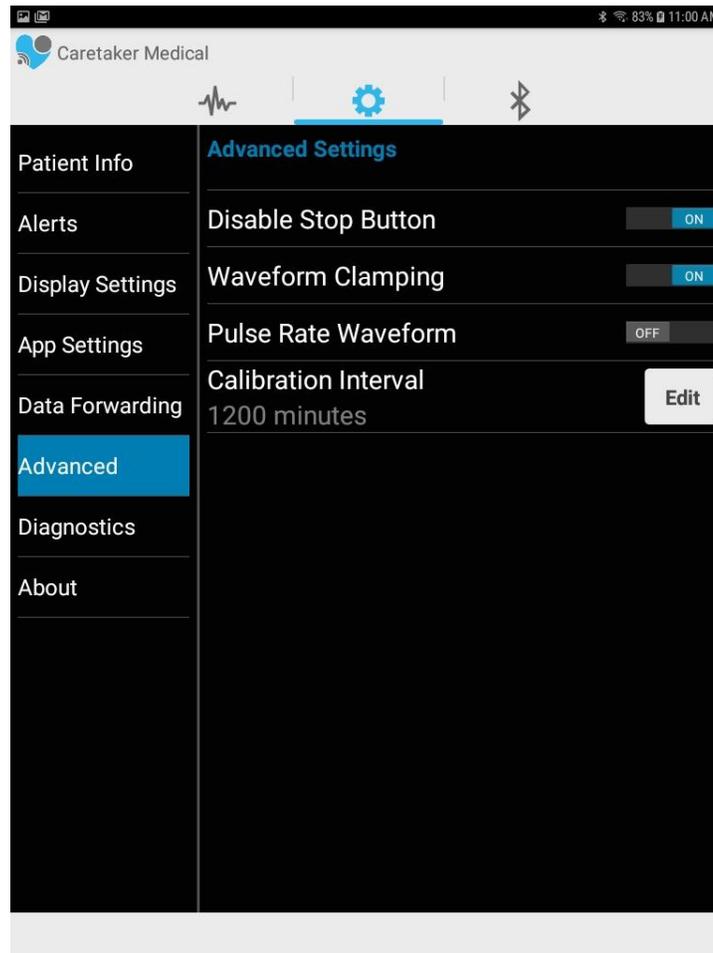
- **Forward Blood Pressure** when enabled will include BP data in the transmitted HL7 message.
- **Forward Respiration** when enabled will include respiration data in the transmitted HL7 message.
- **Forward Heart Rate** when enabled will include heart rate data in the transmitted HL7 message.
- **Forward SPO2** when enabled will include SpO2 data in the transmitted HL7 message.
- **Forward Temperature** when enabled will include temperature data in the transmitted HL7 message.
- **Encoding Method** is a fixed setting. The Caretaker app uses HL7 ER7 format encoding which also referred to as a “pipe delimited” HL7 message.
- **Coding Vocabulary** determines which type of formatted message the Caretaker App will send to the receiving system. Options include:
 - **OBSM174** is a proprietary format used by OBS Medical Visensia software
 - **SNOMED-CT** is a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical reporting

- **LOINC** is a common set of identifiers, names and codes for identifying health measurements and observations.
- **Update Interval** determines the frequency at which HL7 messages with physiological measurements will be sent to the receiving system.
- **Network Transport** can be set as either TCP or UDP.
- **Destination IP Address** defines the IP address of the computer or system on a network that is to receive the HL7 messages.
- **Destination Port** defines the listening port number of the computer or system on a network that is to receive the HL7 messages.

Please consult with your IT department or EMR/EHR system administrator when enabling and using data forwarding at your facility.

12.6 Advanced

The Advanced section in the Caretaker App settings allows users to configure a number of settings that affect the operation of the Caretaker device as well as the data display on the Caretaker App.



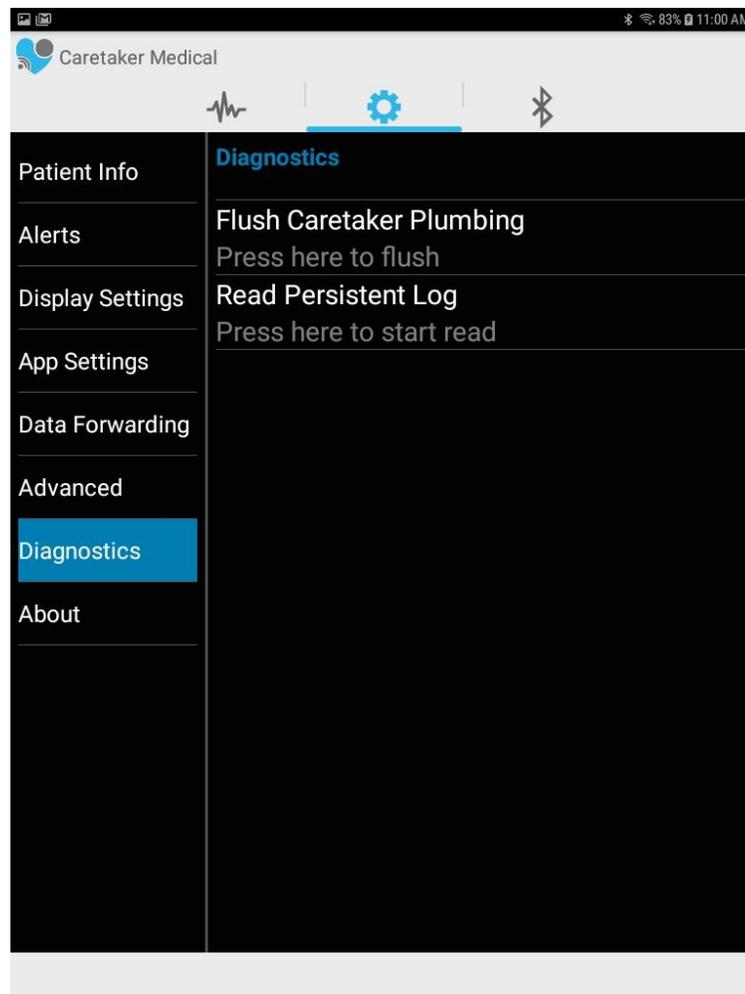
- **Disable Stop Button** is used to disable the stop button functionality on the main button on the Caretaker4 device. During regular operation, if the main button on the Caretaker device is pressed once, the current data collection session will be stop and no further readings will be taken. In situations where an interruption in readings collected by the Caretaker4 would result in the loss of important data, it is recommend that this setting is enable to prevent accidental activations of this feature by patients wearing the Caretaker4 device.
- **Waveform Clamping** controls how the pulse pressure waveform is displayed on the main screen of the Caretaker App. When turned off, the Pulse Pressure waveform will rescale in size in response to noise events.

- **Pulse Rate Waveform** is used to enable or disable the display of the pulse rate waveform on the main screen of the Caretaker App. This is disabled by default.
- **Calibration Interval** is used to determine the time interval between recalibration cycles on the Caretaker4 device when the automatic calibration mode is used.

12.7 Diagnostics

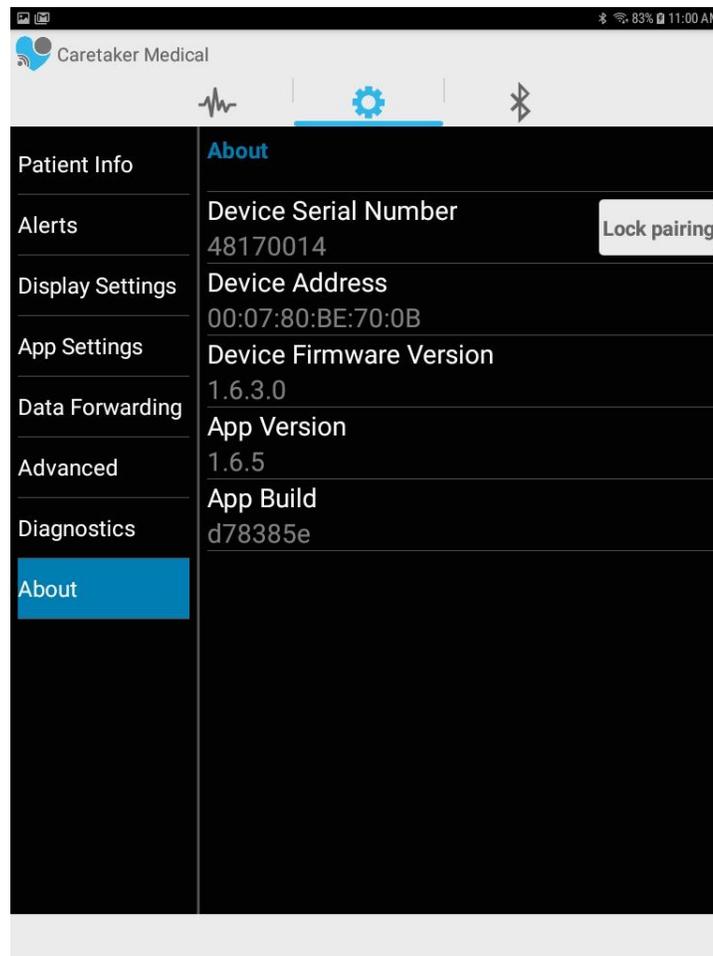
From time to time, the Caretaker4 air plumbing system may need to be flushed of any dust or dirt that may become trapped in the tubing. The **Flush Caretaker Plumbing** setting activates the Caretaker4 pump to force air through the system to clean out any dust or debris that may be present.

If you suspect that your Caretaker4 device is not functioning properly, the **Read Persistent Log** feature (when activated) will collect and transmit diagnostics information about your Caretaker4 device to the Caretaker Medical technical team. Your tablet must be connected to the internet for this feature to be used.



12.8 About

The About screen in the Caretaker App settings provides information about the Caretaker4 device as well as the Caretaker App and also provides the capability to permanently pair a Caretaker4 device to the Caretaker App to help simplify the Caretaker4 device Bluetooth connection process.



Device Serial Number displays the serial number of the Caretaker4 device that is currently connected to the Caretaker App.

Lock Pairing button allows users to permanently pair the currently connected Caretaker4 device to the Caretaker App. This is useful when it is desired to permanently pair a tablet running the Caretaker App with a Caretaker4 device in situations where multiple Caretaker4 devices and tablets running the Caretaker App are being used. **Note:** If the Caretaker4 is turned off or the battery dies, the connection with the tablet will have to be re-established by pressing the main button once after the device is turned back on.

Device Address displays the MAC address of the Caretaker4 device currently connected to the Caretaker App.

Device Firmware Version displays the current version of firmware (software) present in the Caretaker4 device currently connected to the Caretaker App.

App Version displays the current version of the Caretaker App software.

App Build displays the software build information for the Caretaker App software.

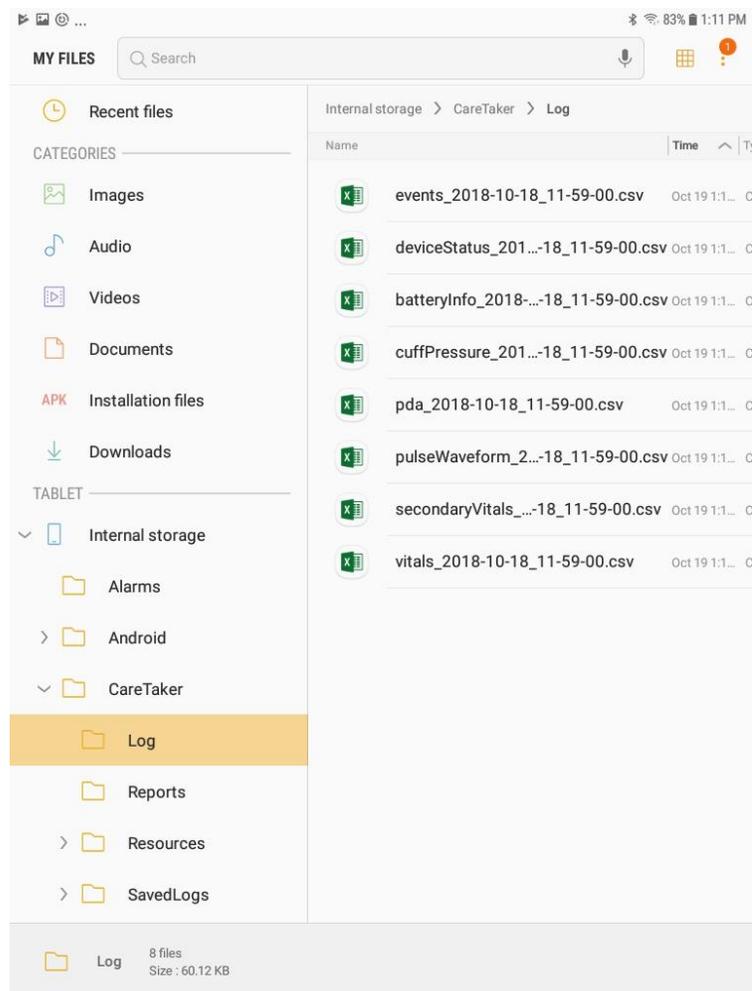
13 Data Saving and File Structure

All logs are contained in the My Files/Caretaker folder on your Android device RUNNING THE CARETAKER APP.

The historical files are saved in .csv format on the device file system. There are multiple historical files located within the folder structure. The files include cuff pressure, vitals, SpO₂.and events. Each file name contains the date/time of when it was created. The cuff pressure file contains current reading of the pressure in the finger cuff each second when the device is connected.

Each pressure reading (mmHg) also contains the timestamp of when it was received by the device and also the internal timestamp of the Caretaker4 millisecond timer.

The vitals historical file contains the time that each measurement was received by the device, the current reading for systolic, diastolic, map, heart rate, respiration rate, SQE, and the internal millisecond timer at which the reading was captured.



14 Warranty & Support

14.1 Warranty

The Caretaker4 is covered by a 1 year warranty against manufacturer defects. Warranty replacements are available from your distributor or by contacting Caretaker Medical directly. Warranty does not cover damage caused by drops, exposure to excessive heat, liquids, or other misuse.

Finger Cuffs and Wrist Straps are covered by a 30 day warranty against manufacturer defects.

14.2 Customer Support and Company Contact Information

Contact your Caretaker distributor for warranty, service, or other questions. If your distributor cannot resolve your issue, please contact Caretaker Medical directly at

www.Caretakermedical.net

or

Caretaker Medical LLC
941 Glenwood Station Ln
Charlottesville, VA 22911 USA
434-978-9000
Email: support@Caretakermedical.net

15 Symbols

On your Caretaker device you will find the following symbols:

	For prescription use only
	Attention, Read accompanying documents
	Indicates compliance to the Medical Device Directive 93/42/ EEC
	Indoor Use Only
	Serial Number
	Date and place of manufacture
	Indicates compliance with FCC standards
	Indicates compliance with safety standards for RF transmission with non-ionizing radiation
	Contains Lithium Ion Battery
	Follow Waste Electrical and Electronic Equipment regulations.
	Type BF part IEC 60601-1 compliant

On the Caretaker Finger Cuff packaging, you will find the following symbols:

	Manufacture Lot Number
	Intended for Single Use Only; Not Reusable
	Expiration Date. Do not use after Expiration Date
	Does not contain latex
	Attention, Read accompanying documents
	Date and place of manufacture

16 Troubleshooting and Maintenance

16.1 Troubleshooting Guide

Symptom	Action
The display does not illuminate on the device when button is tapped.	The battery may be discharged. Charge Battery fully.
The Finger Cuff will not inflate	Ensure battery is fully charged. Ensure finger cuff hose is attached to wrist worn device and no holes or leaks are in the tubing or cuff.
No Vital Sign information is displaying on the display	The battery may be discharged. Charge Battery fully. The unit may be in Sleep Mode. Press the push-button and hold for 1 second to turn on the device. Then double-click the button to start the calibration process.
No Vital Sign Information is displaying on the Caretaker App	The Caretaker app may be off. Turn on the device. The Caretaker App may not be running. Follow your device manufacturer's instructions to launch the App. The Caretaker4 unit may not be paired with the Caretaker App. Navigate to the "Devices" tab of the App and push the button on the Caretaker device. Then tap the radio button that corresponds to your Caretaker device on the Caretaker app screen to connect.
No real-time data displays appear after 8-10 seconds	Re-establish connection. Tap the "Device" tab on the app and single-click the button on the Caretaker device, making sure that the ORANGE Bluetooth icon appears in the message bar of the Caretaker device. Once the Caretaker address appears on "Device" tab listing, tap on it to complete the connection process.
No real-time data displays appear after attempting reconnection	Close the app. To do so, tap the Menu button (usually to the left of the Home button) which will provide a stacked view of the currently loaded apps. Tapping the "x" in the upper right corner of the Caretaker Medical app will close the app. Re-launch the app and go through the connection sequence. Turn the Caretaker device off and on by holding the device's button until the "Push button again to power off" message appears. Click the button to power off, then click it again to power the unit back up.
Obtaining good finger pressure measurement can sometimes be difficult, to ensure a good measurement, consider these conditions:	
Cold Hands/ Fingers inhibit blood flow and	Warm the patient's hands/fingers with a warm

reduces signal quality	towel or water.
Motion inhibits good signal quality and data collection	Ensure the patient is sitting at rest, and not moving during Blood Pressure measurement.
Excessively tough/rough skin can prevent the finger cuff from sensing the pulse pressure	Apply the finger cuff to the supplest digit of the hand, attempting to avoid tough/callused areas.
Blood Pressure readings can vary from beat to beat, depending on patient position, motion, stress, and other factors	Ensure the patient is calm, at rest, and sitting or lying down. Ensure the finger cuff hand is stationary and is located near the torso/heart.

17 Technical Specifications

Specification	Min	Typ.	Max	Units
Dimensions				
Width		58		mm
Length		80		mm
Height		28		mm
Mass		12		g
Operating and Storage Conditions				
Storage Temperature	-20		40	°C
Operating Temperature	0		40	°C
Storage Humidity (Relative, non-condensing)	0		95	%
Operating Humidity (Relative, non-condensing)	5		90	%
Operating/Storage Pressure	70.1		101.3	kPa
Operating/Storage Elevation	0		3000	m
Operating System Pressure	-10		250	mmHg
Medical Parameter Measurement Ranges				
Heart Rate	30		200	bpm
Systolic Blood Pressure	80		250	mmHg
Diastolic Blood Pressure	50		150	mmHg
Respiration Rate	6		32	BPM
Finger Diameters	12		30	mm
Battery Information				
Battery Type	Lithium Polymer (Removable)			
Battery Capacity		2000		mAh
Battery Life	8	12	20	hours
Battery Certifications	UL			
Charger Information				
Charging Source	5V Barrel Jack			
Charging Voltage	5	5	12	V
Charging Current		150	400	mA
Charging Time	5	8	12	hours
Charger Certifications	UL, IEC, EN, RCM, CCC, PSE			
Communications				
Bluetooth Frequency	Low Energy BLE Operating 2400-2483.5MHz ISM Band			
Bluetooth Range	10 Meters LOS from Host/Display			
Security/Encryption	AES 128Bbit Encrypted Data Stream			
Disposable Finger Cuff/Wrist Strap				
Finger Cuff Dimensions	3.8mm x 14.2mm			
Finger Cuff Diameter Range	12mm to 30mm			

Wrist Cuff Dimensions	346mm x 38mm
Cuff Materials	Latex-free Polyurethane
Cuff Infection Controls	Single Use Only, Dispose after each use.

18 Appendices

18.1 Background & Description

The Caretaker system tracks blood pressure by analyzing the amplitudinal and temporal behavior of the component pulses that constitute the peripheral arterial pulse. There are three component pulses of interest:

- The primary pulse (P1), which is due to the ejection from the left ventricle.
- The second systolic pulse (P2), which is a reflection of the primary pulse that originates at the junction between thoracic and abdominal aorta where the arterial diameter down-sizes by up to 40%. Since this reflection site is close to the renal arteries it is sometimes referred to as the renal reflection.
- The tertiary pulse (P3) which is a reflection of the primary pulse that originates at the site where the abdominal aorta bifurcates into the iliac arteries.

Figure 1 displays a sketch of the arteries of the torso as well as well as the left arm. Primary arterial pulses are presented in black while reflected pulses are displayed in blue.

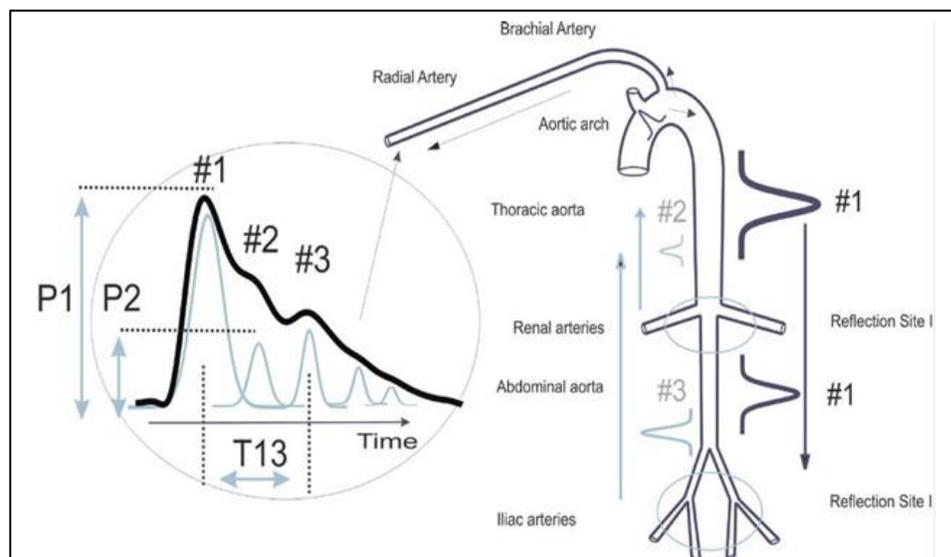
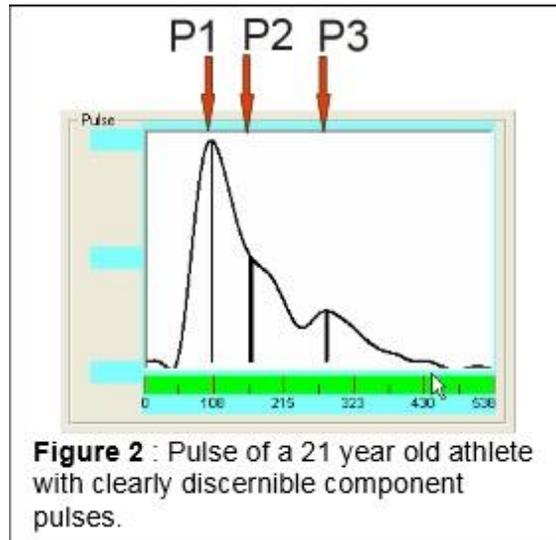


Figure 1: Sketch of the aorta/arm complex arterial system and its effect on the arterial pressure pulse line shape that is observed at the radial/digital artery. Two reflection sites, one at the height of the renal arteries, the other one in the vicinity of the iliac bifurcation, give rise to the reflected pulses (gray) that trail the primary left ventricular ejection (black).

Figure 2 displays an arterial pulse example of a subject with very distinct component pulses. The subject is a 21 year-old tall athlete. Due to his long arterial pathways as well as low arterial pulse propagation velocities due to his exceptional conditioning, the reflected pulses, which cover substantial additional arterial path lengths, arrive delayed and therefore well resolved.



There are two central pulse parameters that Caretaker utilizes for the tracking of blood pressure:

- T13, which is the delay time between the arrival of the P1 pulse and the P3 pulse. Studies support the hypothesis that T13 correlates with arterial pulse pressure. The physiological model is that, since both pulses travel at different pressure amplitudes, they also travel at different pulse propagation velocities. As the differential pressure between them changes, so will their relative arrival time because their individual pulse propagation velocities change, causing them to accelerate or decelerate relative to each other.
- P2/P1, which is the ratio of the amplitude of the P2 pulse to the amplitude of the P1 pulse. Studies support the hypothesis that this ratio correlates with systolic pressure. The physiological model here is that the reflection coefficient of the P2 reflection site is highly pressure dependent. The reason is due to the difference between the Young's modulus of the thoracic aorta (the "softest" artery of the body) and the abdominal aorta. With increasing systolic pressure the thoracic aorta dilates more than abdominal aorta, resulting in an increasing diameter mismatch between the two aortic sections. Decreasing pressure has the opposite effect, as is easily demonstrated by performing the Valsalva maneuver.



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