

CareTaker

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1. Introduction

The CareTaker system tracks blood pressure on the finger by analyzing the amplitudinal and temporal behavior of the component pulses that constitute the peripheral arterial pulse. The primary component pulse originates directly from the left ventricular ejection and its temporal and amplitudinal behavior is shaped mostly by the peripheral arteries of the arm complex because it spends most of travel time there. This is in contrast to the component pulses that arrive subsequently to the primary pulse, which are arterial pulse reflections that originate in the central arteries. By analyzing the behavior of the component pulses, CareTaker effectively makes comparisons between central and peripheral blood pressure. This “intelligent” approach to blood pressure monitoring has advantages and disadvantages.

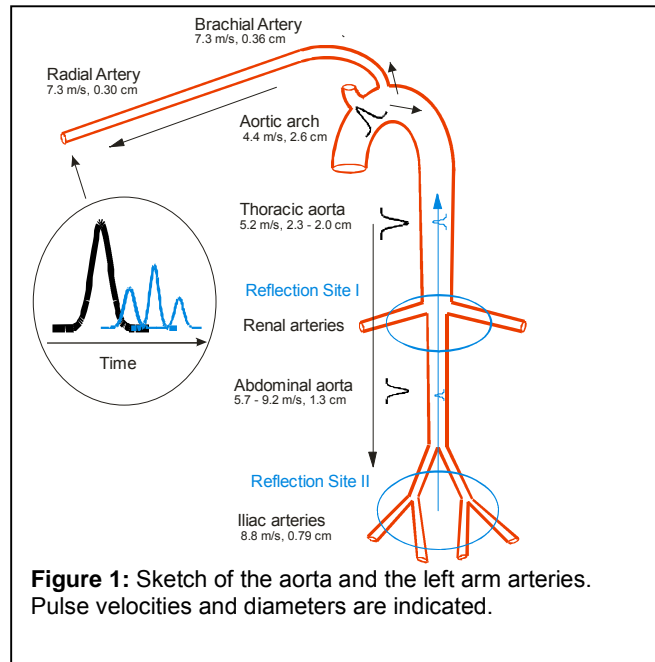
- It does not require the aggressive pressure tracking the devices based on the Penaz principle require. As a result long-term tracking is possible because circulation is not compromised and battery life is significantly improved.
- Frequent re-calibration is not necessary, even after disruption due to motion artifacts, *as long as the equilibrium between central and peripheral blood pressure has not changed* such as due to smooth muscle response of the peripheral arteries. The important implications of this statement are:
 - If a subject is seated or lying down and remains so, a given calibration should be valid throughout. The effect of postural changes (such as leaning forward) on blood pressure can be readily observed. Similarly, the effects of valsalva or cold pressor agents can be readily observed.
 - Comparisons between blood pressures obtained under different postural situations, such as while sitting and standing, will be flawed because peripheral and central pressures temporarily de-couple after the transition and then re-establish themselves in a new equilibrium.
- CareTaker is a passive monitoring system, except during the calibration phase (*if unit is so equipped*). Because of this, as well as the fact that the algorithm has to detect and analyze each heartbeat it is more prone to noise interference than an active system, such as a Penaz principle-based one. Adequate signal fidelity is critical for the system to produce reasonable results. Typically, fidelity problems are due to **A.** inadequate coupling pressure (for weak pulses or poorly perfused or cold fingers coupling pressures of up to 50 mmHg may be necessary), **B.** adequate vibrational isolation of the sensorized finger or **C.** adequate vibrational isolation of the hose between finger sensor and device
- Tracking and quantifying the arterial component pulses is a challenging task and the algorithms that perform this task are still being refined. Even under the best of circumstances there will be occasional intermittent drop-out.

Background

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:

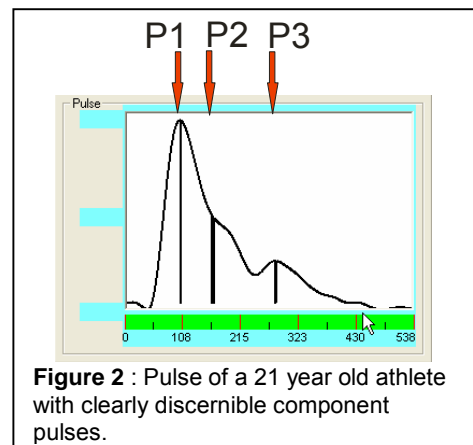
- The primary pulse (P1), which is due to the ejection from the left ventricle.
- The second systolic pulse (P2), which is a reflection of the primary pulse that originates at the junction between thoracic and abdominal aorta where the arterial diameter down-sizes by up to 40%. Since this reflection 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 the left arm. Primary arterial pulses are presented in black while reflected pulses are displayed in blue. **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.



2. Bluetooth installation (Windows XP)

- **First-time installation of the Motorola dongle (skip to 2. if computer is internally Bluetooth-equipped – Widcomm Stack)**
 - i. Follow the instructions for installing the software for the dongle. In the case of the Motorola device, **DO NOT plug in the dongle** until the installation program prompts you to do so.
 - ii. **Be sure that the dongle is compatible with your computer's operating system (XP versus Vista).**
 - iii. Upon successful installation of the Bluetooth software, a blue icon will be visible in the bottom right corner of the Windows XP task bar (**Figure 3**).

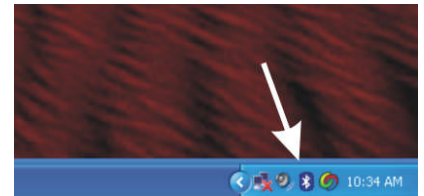


Figure 3

3. Bluetooth communication

- i. Upon double-clicking the Bluetooth icon, a window labeled “My Bluetooth Places” appears (Figure 4).
- ii. Be sure that the CareTaker device is TURNED ON.
- iii. Be sure that the SunTech Medical 247 device is turned on (if this option is available).

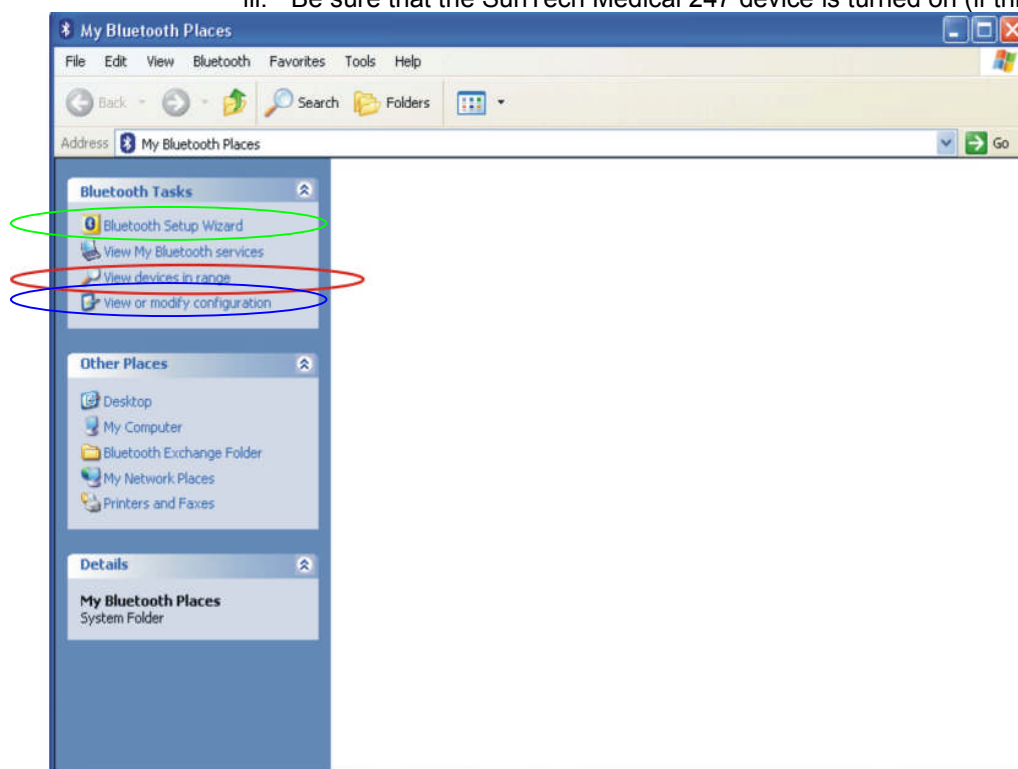


Figure 4: My Bluetooth Places screen

4. Bluetooth Setup Modification (required only if SunTech Medical BP device is to be used)

- i. In the panel “My Bluetooth Places” click on “View or modify configuration” (**Figure 4, blue circle**). The screen shown in Figure 4a opens.
- ii. If two COM ports are NOT LISTED, click on the add COM port to add another COM port
- iii. Click OK.

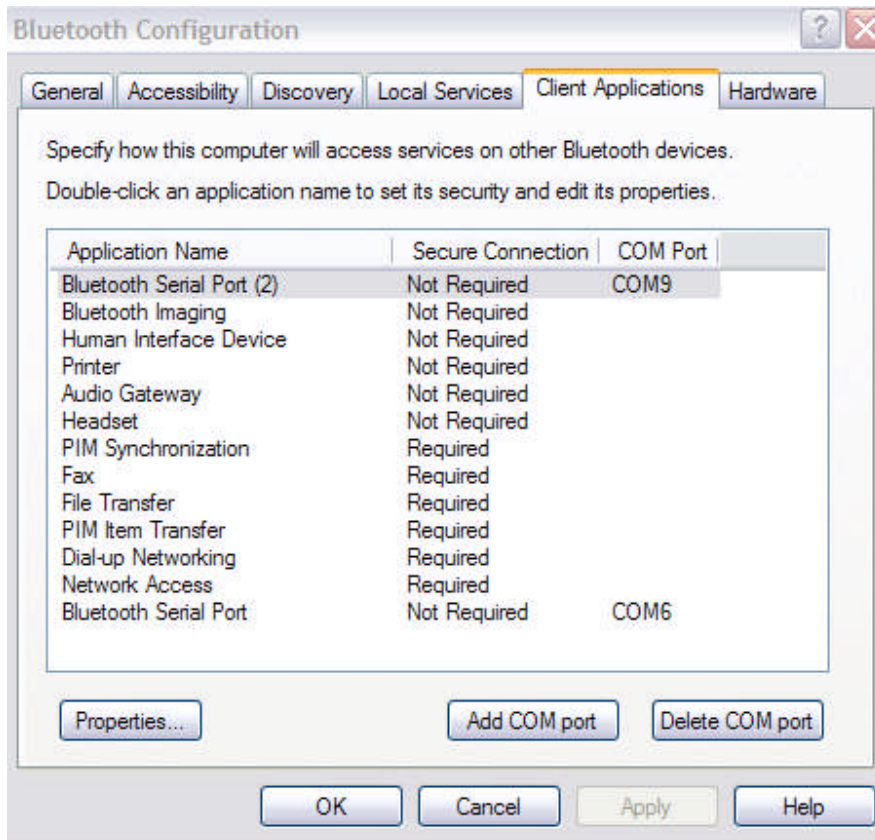


Figure 4a: Bluetooth configuration screen

5. Pairing and Configuration of CareTaker and SunTech Medical BP (247 or Tango)

- i. In the panel “My Bluetooth Places” (**Figure 4**), click on “Bluetooth Setup Wizard”. (green circle)



Figure 5: Bluetooth setup wizard screen

- ii. Select the second option from the top (Figure 5) and click Next.

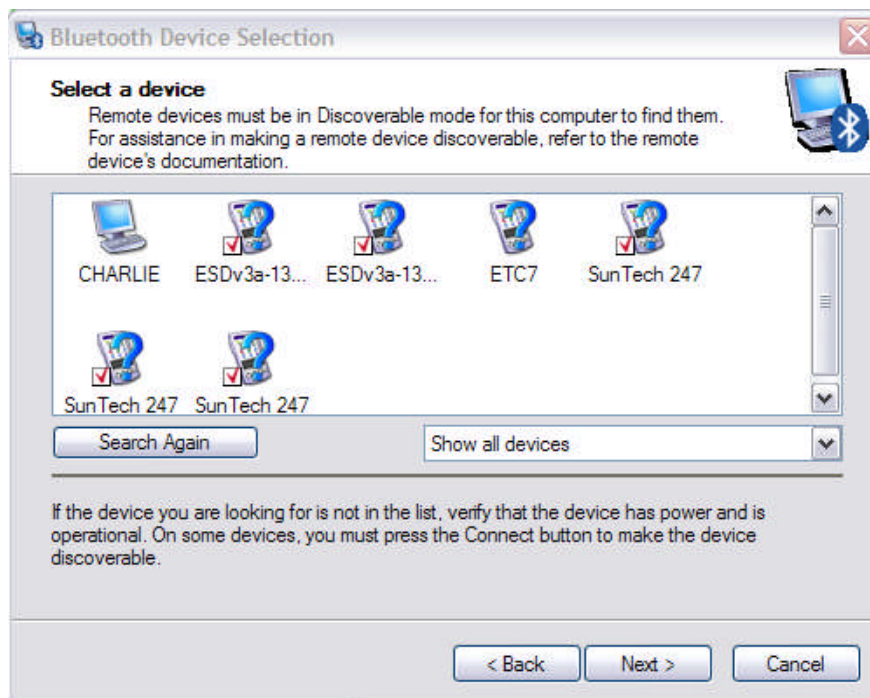


Figure 6: Bluetooth setup wizard screen

- iii. Select the device you want (in this case ETC7, Figure 6) and click Next.

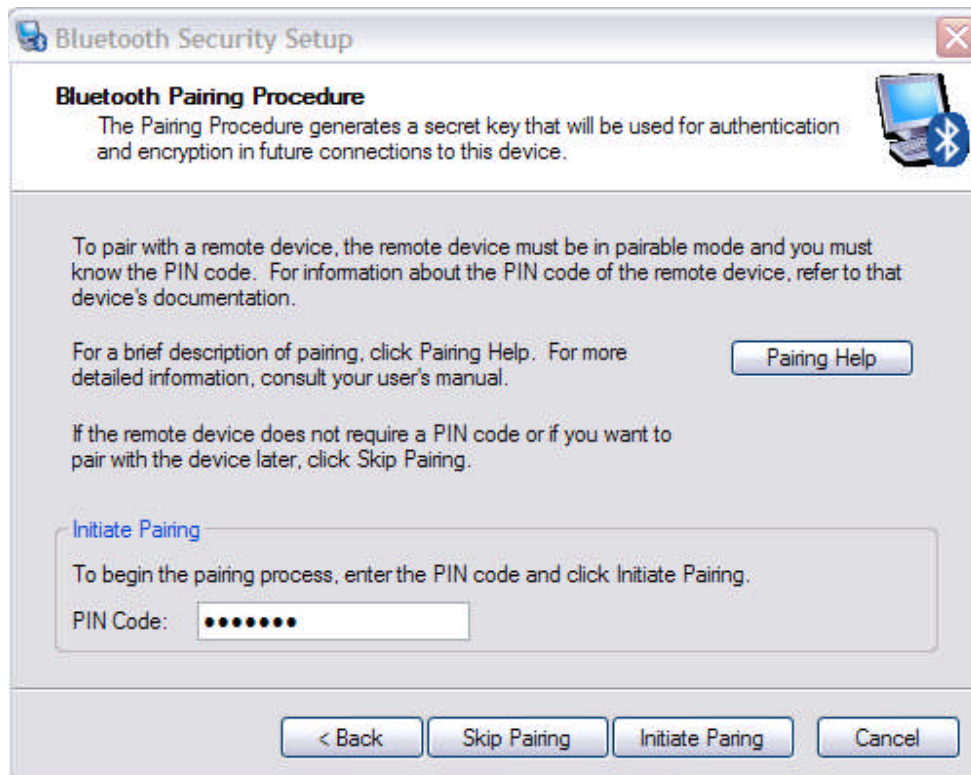


Figure 6a: Bluetooth setup wizard screen

- iv. Enter the code “65536” (the older brace units use “1234” or “default”) and click on Initiate Pairing (Figure 6a)

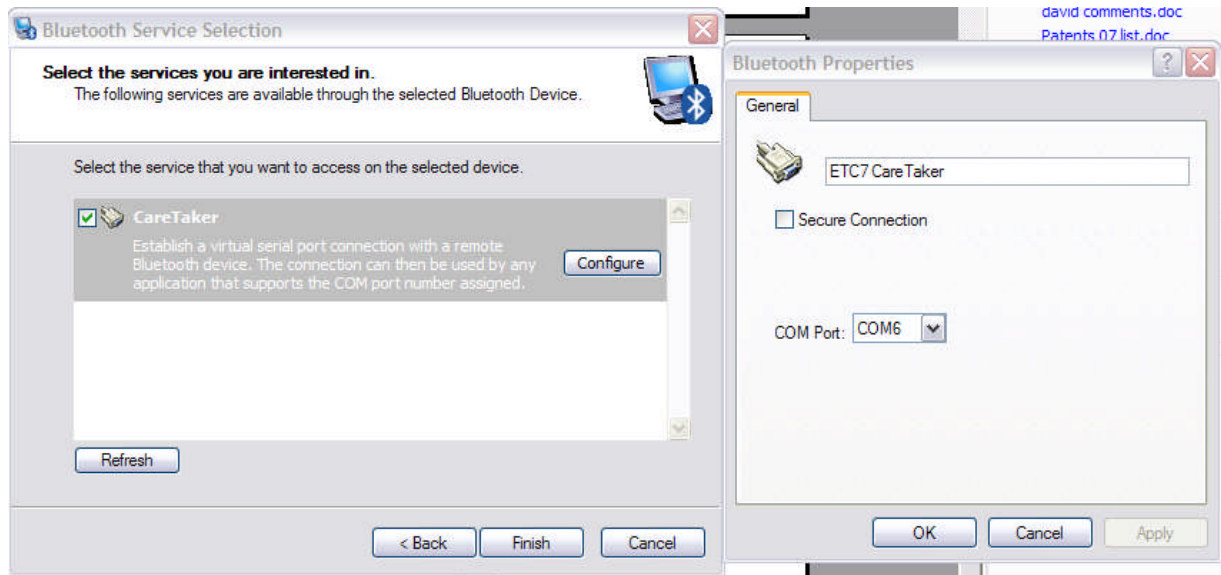


Figure 7 : Bluetooth service selection screen

- v. Select the unit and click on Configure. Select one of the two COM ports available AND MAKE A NOTE OF IT because you will have to select the same COM port in the CareTaker software program.
- vi. If this is the first time, the device will require pairing. Right-click the device icon and a “Bluetooth PIN code request” window appears. Enter “1234” on the PIN code line and click OK (**Figure 6**) .
- vii. Double-click on the device icon. The window changes and a “Generic Serial” icon appears. Right-click the icon and select “Properties”. Make a note of the COM port number, such as COM8 (**Figure 7**). The information can also be obtained by right-clicking the “Generic Serial” icon.
- viii. Click Finish.

Pairing with the 247 with the Bluetooth Setup wizard is identical, including the pass-code “default”. **Be sure to select a different COM port.**

- **Subsequent initiation of Bluetooth communication**

- Insert the dongle into a USB port (Bluetooth-enabled computer users skip this step)
- Double-click the icon, once it has turned blue/white (from blue/red), or right-click and select My Bluetooth Places.
- Double click the device, as in **Figure 7a**.
- Be sure the device is charged and turned on.
- The device icon changes (as in **Figure 7b**) to opposing green arrows to indicated successful connection

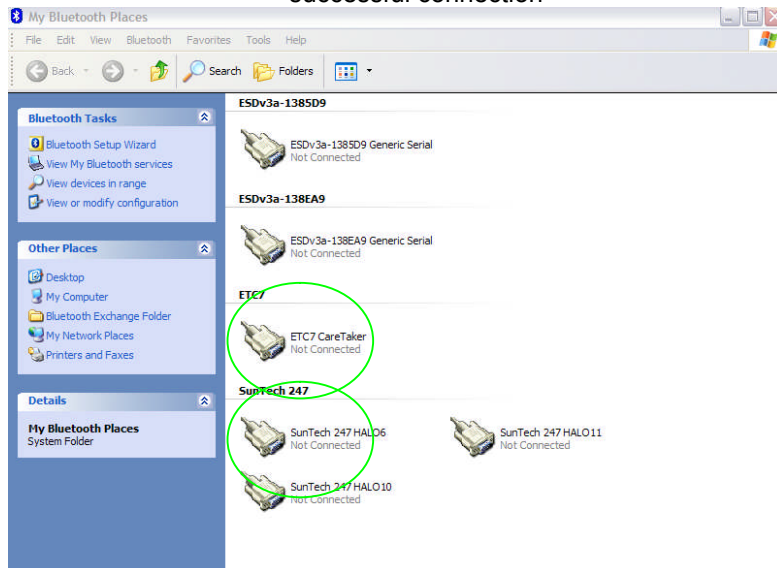


Figure 7a : My Bluetooth Places screen

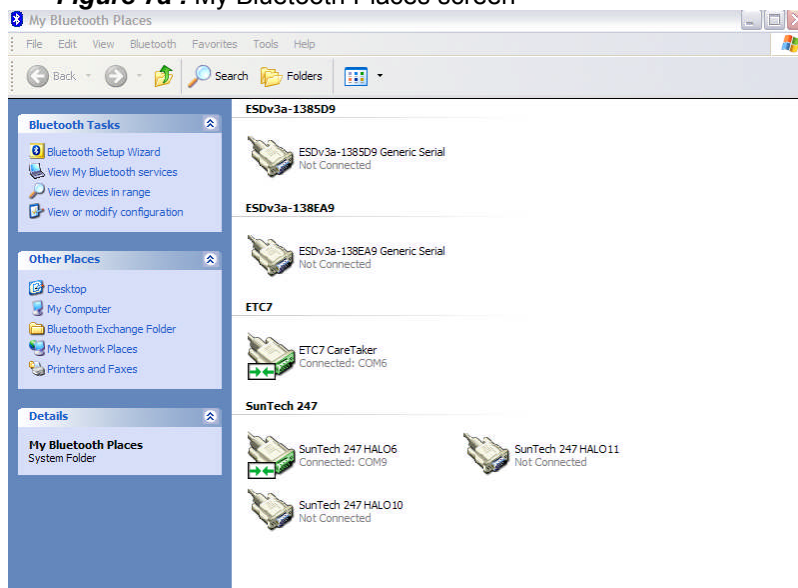


Figure 7b : My Bluetooth Places screen

- Launch the CareTaker program and establish connection as described next.

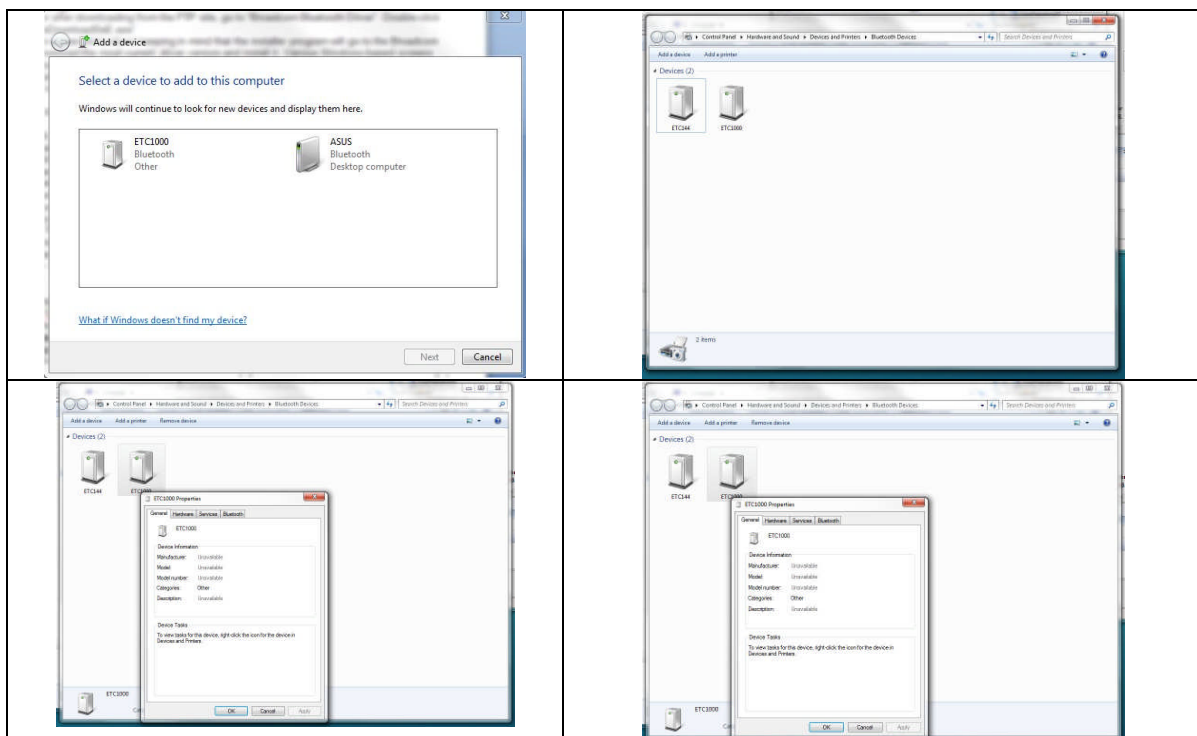
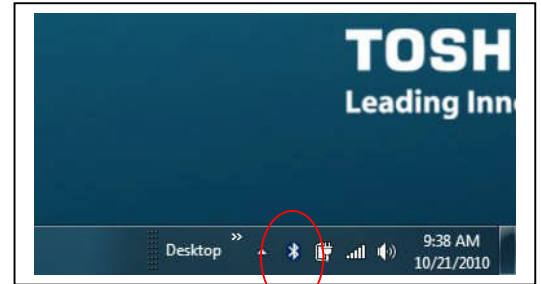
Important Notes

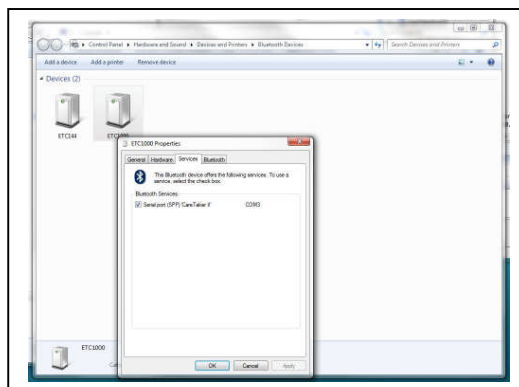
1. **Windows 7 Installation Note:** Right-click on the *setup.exe* file and select “Run as Administrator”!! This is **CRITICAL**, or the program will **CRASH** about 10 seconds after the wireless data stream from the CareTaker device starts. If this was not done, UNINSTALL the CareTaker program (Control Panel etc.) and REINSTALL.
2. We strongly recommend shutting down resource-intensive programs such as Outlook etc. during data collection sessions with the CareTaker. The downloading and virus-checking of e-mails, for example, can cause buffer overruns that can freeze the program.
3. **IT IS IMPERATIVE** that the operating finger cuff pressure be monitored closely in a newly installed system. The system aims to keep the operating pressure in the finger cuff between 40 – 50 mmHg. However, there are differences in the pump efficiencies as a result of which a pump blast of a certain time duration will result in different end pressures.
 - a. If, at the end of a calibration procedure, the finger cuff pressure is significantly higher (55+ mmHg), the “Pump Duration to reach Reference Pressure” parameter needs to be adjusted downward (See page 23)
 - b. If, at the end of a calibration procedure, the finger cuff pressure is lower than 40 mmHg, the “Pump Duration to reach Reference Pressure” parameter needs to be adjusted upward (See page 23).
 - c. If, with Pressure Control on, the pressure barely increases past 40 mmHg as a result of a pump blast, the “Pump Duration to maintain Reference Pressure” parameter needs to be adjusted upward (See page 23).
 - d. If, with Pressure Control on, the pressure increases past 55 mmHg as a result of a pump blast, the “Pump Duration to maintain Reference Pressure” parameter needs to be adjusted downward (See page 23).

6. Bluetooth & CareTaker software installation (Windows 7)

For installation of a Bluetooth dongle supplied by ETC the computer on which the software is to be installed will have to be connected to the internet.

1. Insert the Bluetooth dongle into an available USB port. Because of the small size of the device this can be a challenge.
2. On the CD, or after downloading from the FTP site, go to “Broadcom Bluetooth Driver”. Double-click on “SetupBtwDownloadSeE.exe”.
3. Follow the on-screen instructions keeping in mind that the installer program will go to the Broadcom website to download the most current driver version and install it. Various Windows-based screens will appear along the way to ask for permission to continue the installation.
4. After the installation a Bluetooth icon should be visible in the lower right-hand corner, as shown on the right.
5. Left-click on the icon and select “Show Bluetooth Devices”.
6. At the top left, click on “Add a device”. A search window appears and after a while the CareTaker device should appear in the window.
7. CareTaker devices typically are identified by “ETC####” where the #s are placeholders for an identifying number sequence.
8. **The pairing code is “65536” (white unit) or “default” or “1234” (older black units).**
9. After a new icon has been placed in the “Bluetooth devices”, right-click on the icon and select “Properties”. Then select the tab “Services”. In the window below a serial port designation will appear after a short time. Make a note of the COM port that is listed there, for example COM3. This parameter has to be selected in the CareTaker program to enable the program to communicate with the hardware device.





10. After the completion of the Bluetooth driver installation, continue with the CareTaker installation by going to the “CareTaker” directory on the accompanying CD or the FTP site. **Right-click on the “setup.exe” file and select “Run as Administrator”**.
11. Follow the on-screen instructions.

7. Program launch & COM port setting

- Under *Programs* in the *Start* menu, find the Empirical Technologies Corporation entry.
- Click on the fly-out CareTaker.
- The program’s Graphical User Interface (GUI) loads. (**Figure 8**).
- Click on the menu item “Settings” in the upper left-hand side (**Figure 8, red circle**).
- Click on “COM Port and other Settings”. The “Settings” window appears. (**Figure 9**).
- Click on the radio button(s) corresponding to the CareTaker COM port noted under section 5 and on 247 COM port (if included).
- If the SunTech 247 is included, also check the “Enable Cuff Communication” check mark under “Optional Equipment”.
- Click the exit button (red “X” in upper right-hand corner) to exit the “Settings” window.

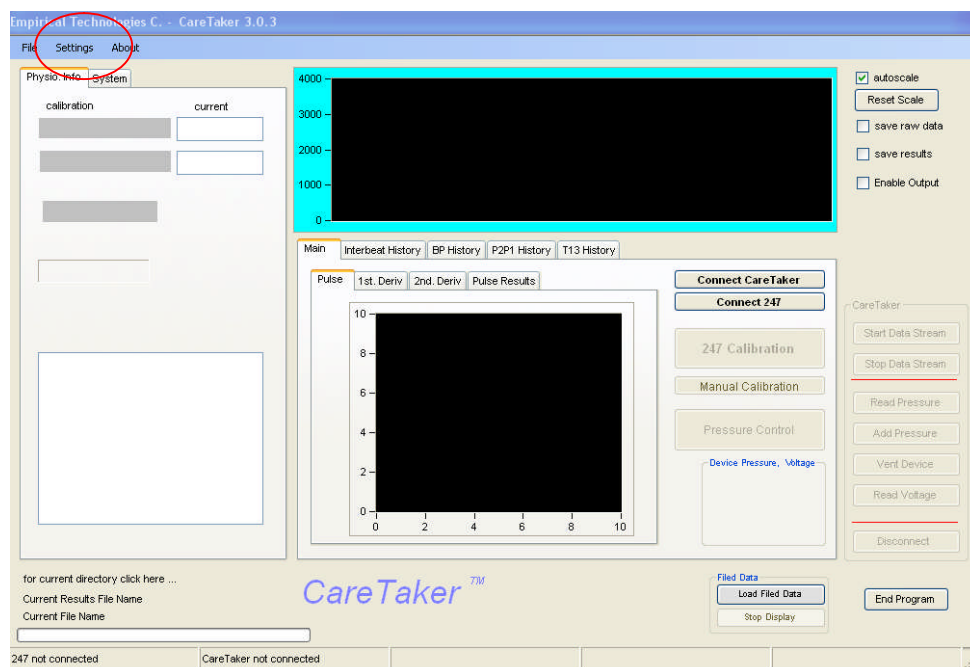


Figure 8: CareTaker GUI

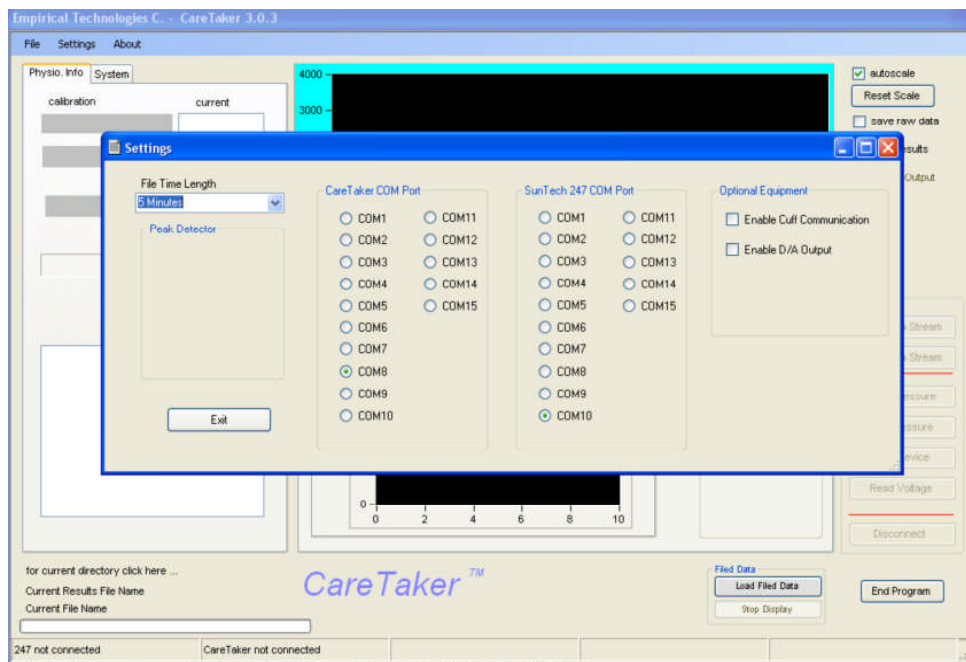
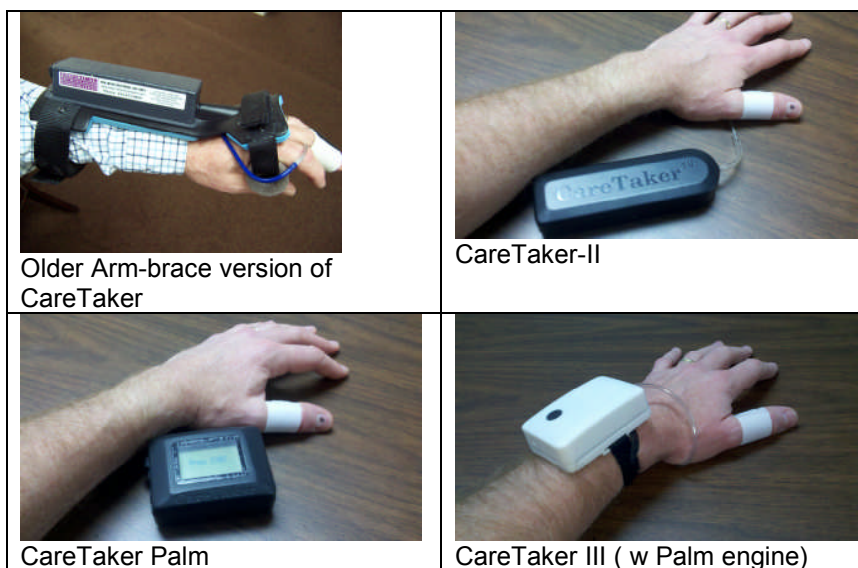


Figure 9: CareTaker GUI with Settings Window

IMPORTANT!!!!

Depending on whether this is an arm-brace unit, a box unit, or a CareTaker Palm unit, **THE CALIBRATION OF THE ONBOARD PRESSURE SENSOR WILL BE DIFFERENT. Please refer to Figure 20 in section 16 (page 22) to select the proper pressure sensor calibration.**



8. Connecting with CareTaker & collecting data

i. Connecting with the CareTaker

- The following assumes that CareTaker has been paired with initially and that the connection with the device's serial port was established through **My Bluetooth Places** as described in section 5b for subsequent sessions (i.e. the Com port icons are featuring opposing green arrows, Figure 7b).
- Click the "Connect w/ CareTaker" button on the right-hand side of the GUI. (**Figure 10, blue circle**). It may take a try or two to connect.

- If a message “CareTaker Connected” appears in the second-to-left corner (**Figure 11, green circle**). (and the buttons under “Device Communications” become enabled) the program has connected with the CareTaker.
- If a message “NOT RESPONDING” appears in the bottom left corner, communication was not established
 - Click the “Connect CareTaker” button on the right-hand side of the GUI again. It can take several attempts to establish communication.
 - Check that the device is on.
 - The device’s battery may be too low. The device’s voltage should be between 3.8 - 4.1 Volts (which is displayed on the GUI, see **Figure 9, blue circle**). Connect the device to its charger.
 - NOTE: CareTaker can be used while the charger is plugged into the unit.
 - Re-check that the CareTaker COM port number matches the one under Bluetooth communication.

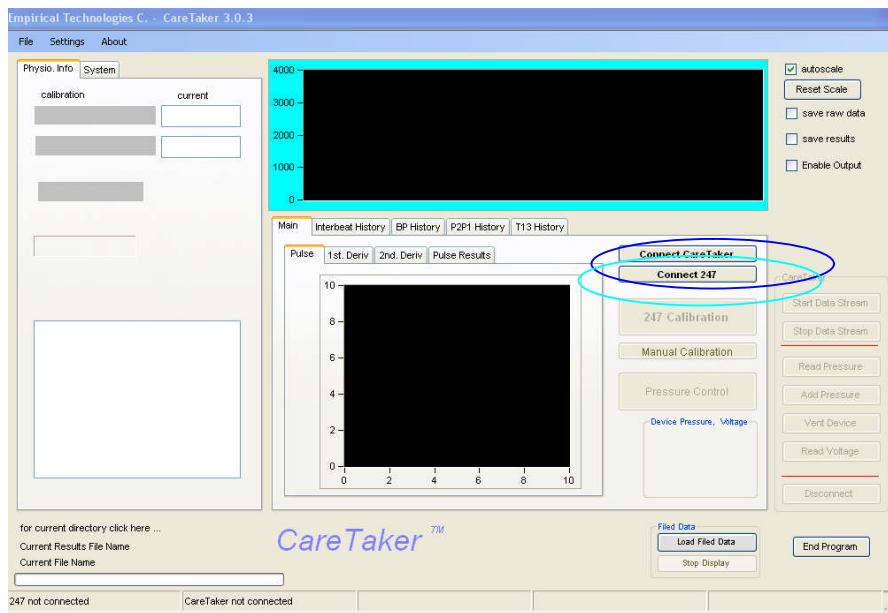


Figure 10: CareTaker GUI w/ both CareTaker & 247 (if included) disconnected

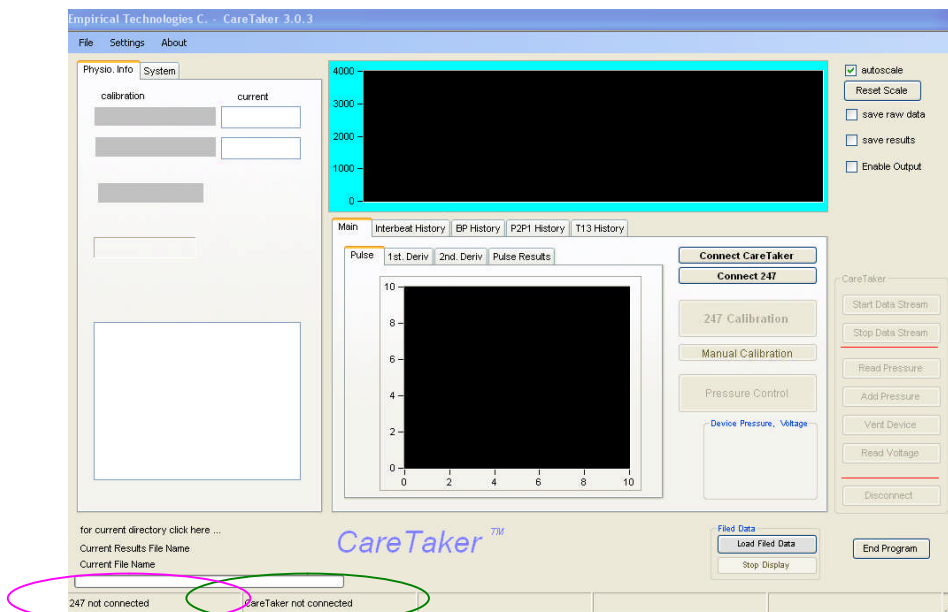


Figure 11: CareTaker GUI w/ both CareTaker & 247 (if included) connected

9. Connecting with the SunTech 247 (if included)

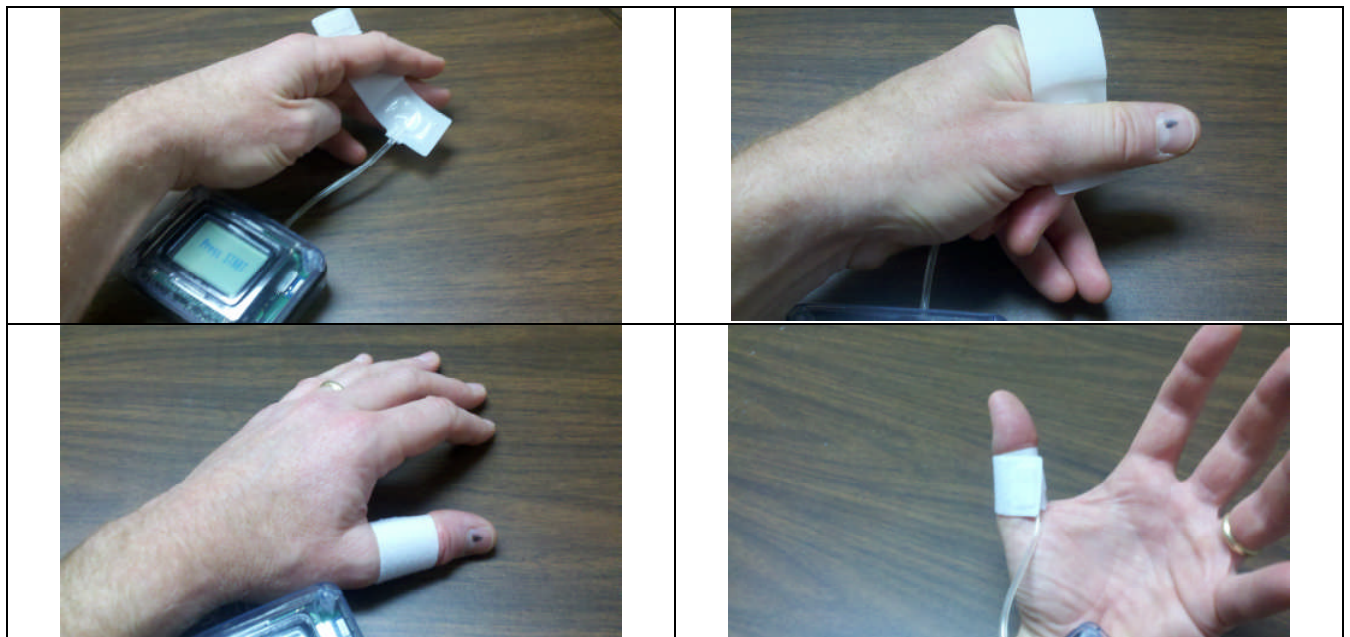
- To enable the “Connect 247” button, click on the Settings menu item, then on “COM port and other Settings”. The Settings window opens (See Figure 9). Check the “Enable Cuff Communication” check mark in the “Optional Equipment” group on the right.
- The following assumes that 247 has been paired with and that the connection with the device’s serial port was established through My Bluetooth Places as described in section 1.
- Click the “Connect w/ 247” button on the right-hand side of the GUI. (**Figure 10, cyan circle**). **It may take a try or two to connect.**
- If a message “SunTech 247 Connected” appears in the bottom left corner (**Figure 11, pink circle**). (and the button “247 Blood Pressure Calibration” becomes enabled) the program has connected with the 247.
- If a message “NOT RESPONDING” appears in the bottom left corner, communication was not established.
 - Click the “Connect 247” button on the right-hand side of the GUI again. It can take several attempts to establish communication.
 - Check that the device is on.
 - The device’s battery may be too low and/or it may not be plugged in. Connect the device to its AC plug.
 - Re-check that the 247 COM port number matches the one under Bluetooth communication.

10. Taking data prior to calibration

Mounting the Finger Cuff

The preferred site for attachment is the metacarpal of the thumb (the section closest to the hand). The thumb is the largest digit and maintains perfusion better than the other digits. An alternative is the proximal phalange of the middle finger (the middle section).

- The sensing pad is positioned on the palm-side of the thumb’s metacarpal.
- Make sure the sensing pad is completely deflated before placing on the fleshy part of the thumb’s metacarpal.
- Do not place the pad on a joint as it will not be able to couple to the digital arteries there.
- The wrap has to be snug. A loosely placed wrap will result in poor signal.



Alternative positioning of the pad on the middle finger



It is important that the sensorized finger NOT TOUCH anything but is preferably suspended.

- Click on the Start Data Stream button (red circle, Figure 12)
- Increase the coupling pressure in the finger cuff to about 50 mmHg by clicking on the Add Pressure button below the Start Data Stream button.
- Observe the coupling pressure readout (blue circle, Figure 12)

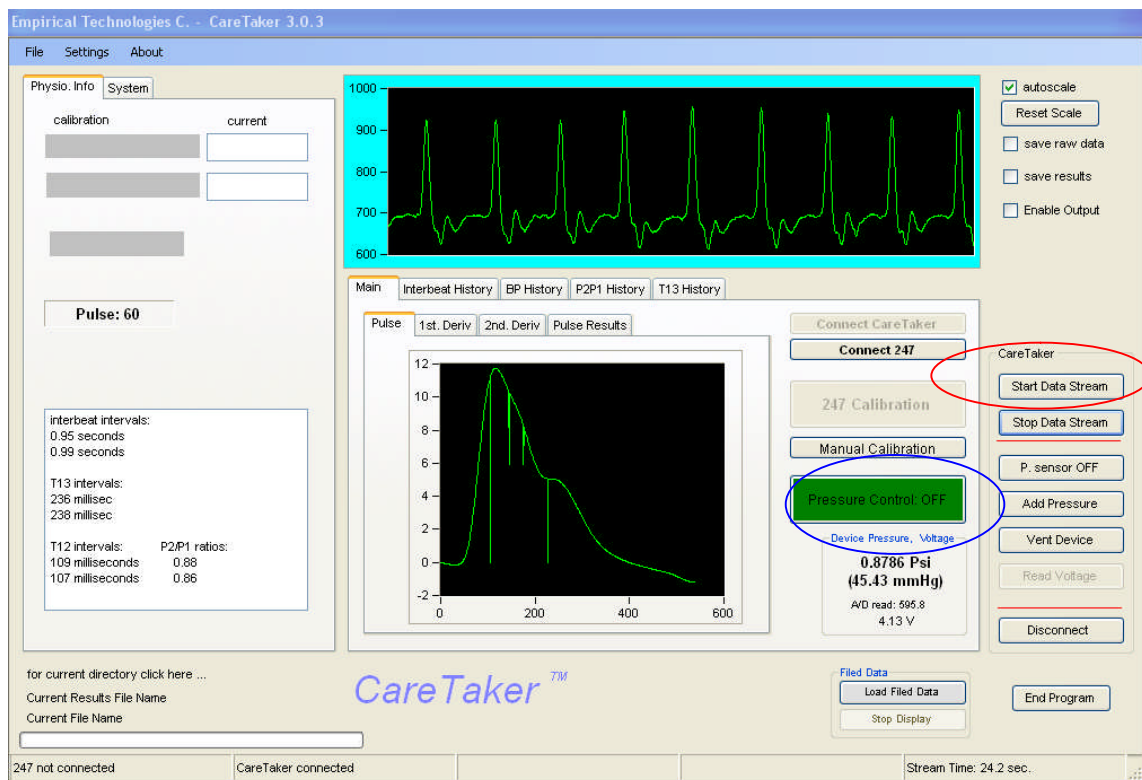


Figure 12: CareTaker GUI w/ data stream

11. 247 BP Calibration (if included)

- Prior to the first time the calibration routine is used please verify that the coupling pressure set point (Pressure Set Point), which is the coupling pressure the CareTaker unit will establish in the finger cuff subsequent to the calibration, is set to 40 mmHg. Please refer to section 15.3, Figure 20.
- The calibration is launched, assuming the 247 is connected as described above, by clicking the 247 Blood Pressure Calibration button whose label changes to BP Calibration running (red circle, Figure 13) while the 247 starts up.
- The current cuff pressure of 247 is now read out continuously on the GUI (blue circle, Figure 13)
- Once the 247 completes its cycle, systole and diastole and MAP are read out (red circle, Figure 14)
- Now the SECOND phase of calibration starts where the PDA algorithm will make the conversion from pulse parameters to blood pressures. It lasts about 15 seconds and it is important to remain still during this period.

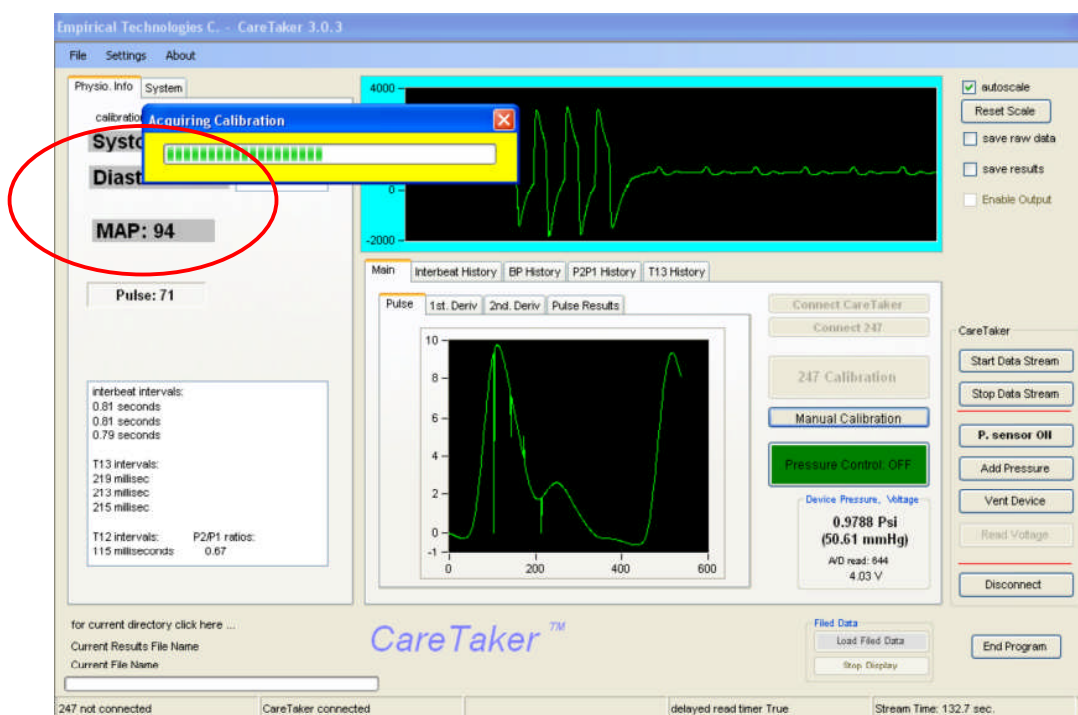


Figure 14: CareTaker GUI during second phase of BP calibration

- Figure 14 shows the GUI during the second calibration phase. A yellow progress bar appears to indicate the duration of this phase.
- The CareTaker vents and then several pump blasts increase the finger cuff pressure into the 40 mmHg range. These pump blasts are visible in the raw data stream in Figure 14.
- IF THE COUPLING PRESSURE IS SIGNIFICANTLY ABOVE 40 mmHg, such as above 60 mmHg or more, THE PUMP BLASTS ARE TOO LONG. The pump duration interval can be changed from the GUI. Please refer to section 2.8.9.
- Once the progress bar vanishes the system will continue to display blood pressure values and graph them (Figure 15). In addition the Pressure Control will enable to maintain the coupling pressure above 40 mmHg by changing from green to red.
- If the end finger cuff pressure is significantly above 55 mmHg, the ***“Pump Duration to reach Reference Pressure” parameter needs to be adjusted downward (See page 23)***

- If the end finger cuff pressure is below 40 mmHg, the **“Pump Duration to reach Reference Pressure”** parameter needs to be adjusted downward (See page 23)

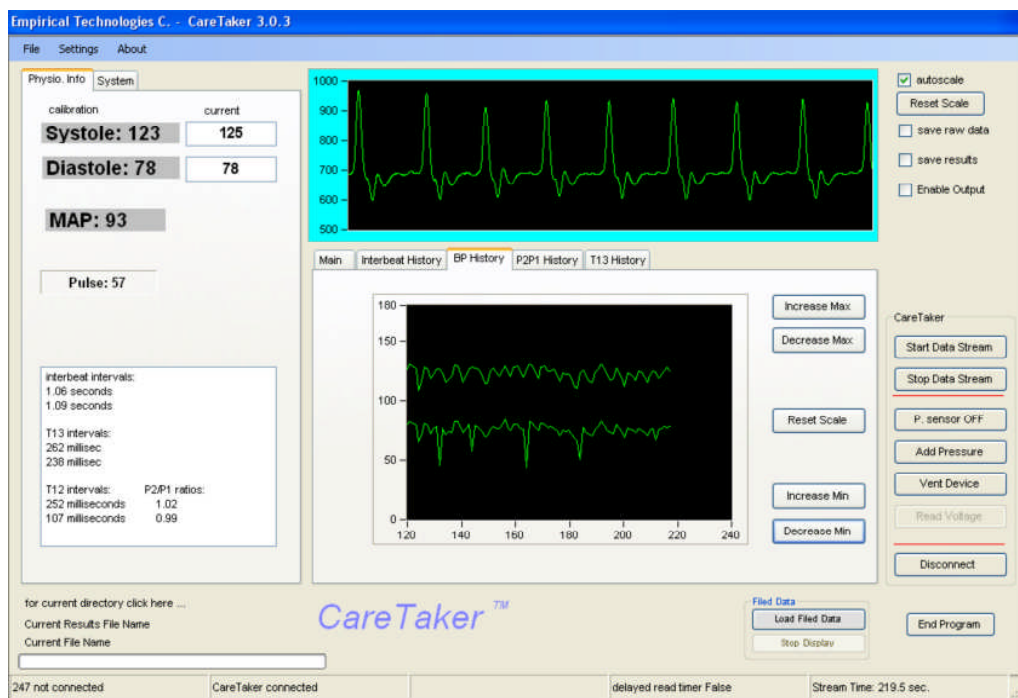


Figure 15: CareTaker GUI in operation. Notice display of BP History tab.

12. Tango BP Calibration (if included)

- The Tango unit does not have an internal Bluetooth device. Instead a 3rd party device is used (such as the Parani SD100). This device has to be plugged into the Tango's serial port and secured. The device will present itself under My Bluetooth Places with an identifier such as "PSD100v1.1.0-06E4E8 Generic Serial".
- The Parani unit also has to be plugged into a wall plug with its separate power module at all times.
- The Tango unit requires two settings in order to assure proper operation, protocol: STANDARD PROTOCOL for communication, and ECG: INTERNAL, for the appropriate ECG trigger. These settings have been made before the unit was shipped. Both items can be set from the front panel Menu button. Please refer to the Tango's manual
- The Tango can only be used if the **ECG leads are connected to the subject** as described in the Tango's manual.

13. Manual BP Calibration

Once a good signal stream has been established, click on Manual Calibration (Figure 16, red circle). A new window (Title: "Please enter BP calibration values ...") will open that provides text boxes for entering systolic and diastolic blood pressure values obtained by external means.

Once the OK button is clicked, the device's valve will open, followed by a sequence of pump bursts to get the coupling pressure of the device to its preset value, usually around 40 mmHg (this is adjustable under Settings – Pressure Settings – Pressure Set Point (lowest drop down menu, see **Figure 20**)).

Then a yellow progress bar (see **Figure 17**) will appear for about 7 seconds. During this time the program calculates the conversion factors between pulse parameters and BP values.

Finally the program's pressure control loop will activate (**Figure 18**, red circle: Pressure Control button turns RED from GREEN). The program will now monitor the coupling pressure every 20 seconds.

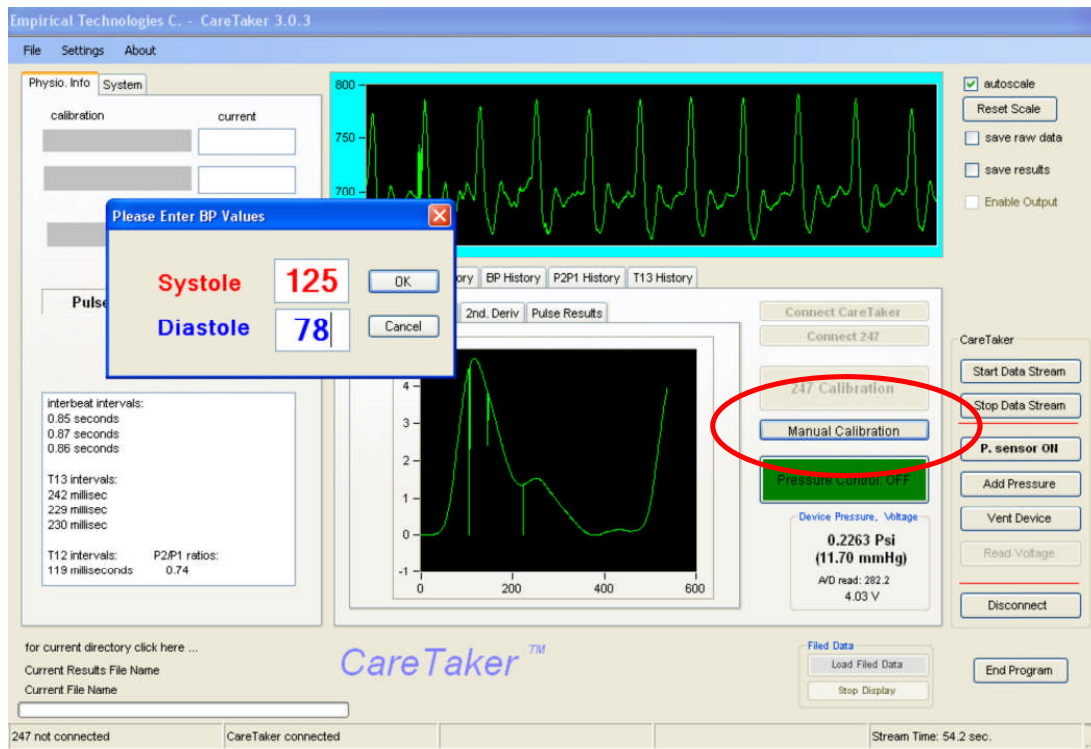


Figure 16: Manual calibration Entry button (red circle) and entry screen.

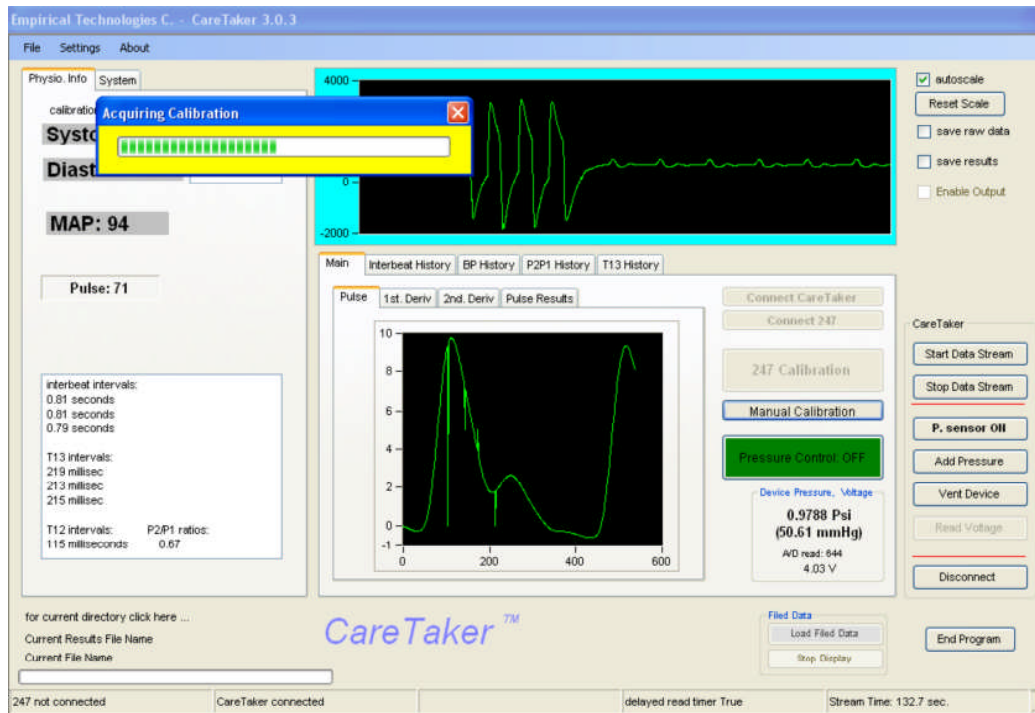


Figure 17: Progress bar appears during calibration

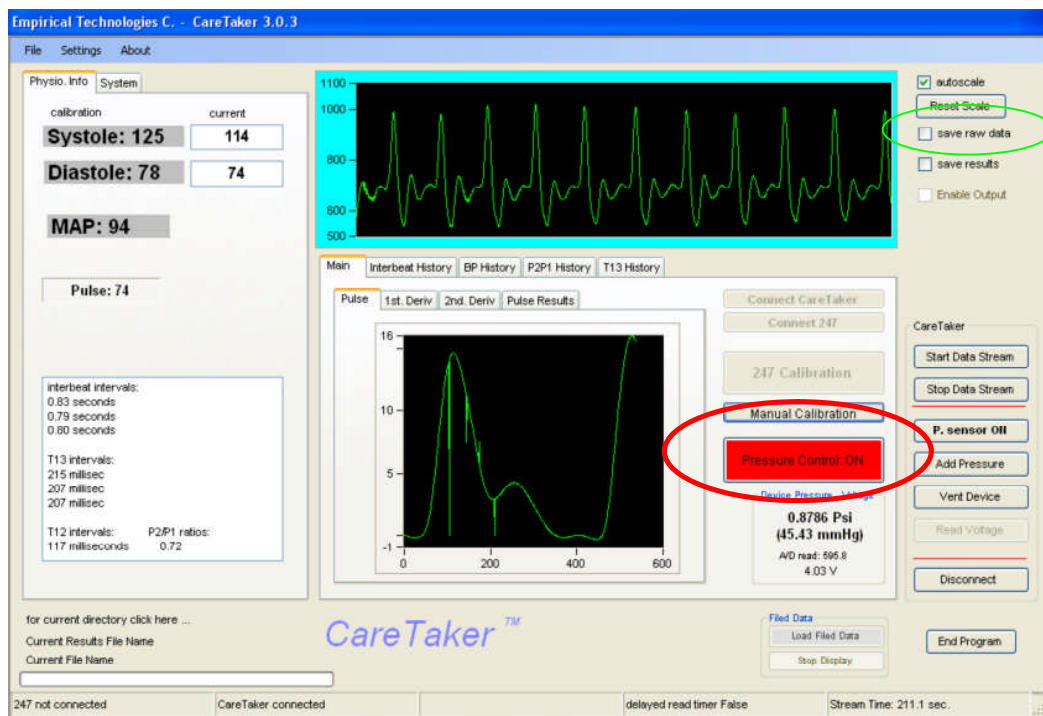


Figure 18: Program switches to Pressure Control: ON (red circle)

14. Continuous (raw) data storage

The program will save the data continuously to the file whose name is displayed under the “Current File Name”. The data is collected and stored at 512 Hz (**500 Hz for the Palm unit**) if the “save raw data” (**Figure 19, red circle**) option is selected.

The file title of the raw data file is “ETC(asc)__(time_date).dat”. The time format can be selected between 12 hour AM/PM format or 24:00 hour format (see Figure 19). This file will have three columns:

- Column 1 is a running index (@ 512 Hz) (**500 Hz for the Palm unit**) that starts when the “save raw data” option is selected.
 - If “save raw data” is selected BEFORE a CareTaker data stream is started, it will start with the start of the CareTaker data stream.
 - If “save raw data” is selected AFTER a CareTaker data stream is started, it will not be synchronized with the CareTaker data stream. In this case it is still possible to synchronize using Column 2.
 - The Column 1 index will also reset every time a new raw data file is opened. The CareTaker program will save raw data continuously, switching from one file to the next after a selectable time interval with no data loss during the switch-over.
- Column 2 is a running index that is transmitted from the CareTaker device. If the “save raw data” is selected AFTER a CareTaker data stream is started, the first recorded value of this counter will indicate how long after the data stream start the file save feature was selected. The index corresponds to 512 Hz (**500 Hz for the Palm unit**). Also, this counter will roll over after it reaches 100,000. The counter in this column can also be used to synchronize with the Results file, which is synchronized to the start of the data stream, not to when the “save results” check mark was selected.
- Column 3 contains the digitized sensor reading values of the analog/digital converter. Since the A/D has 12-bit resolution, the values range between 0 and 4095.

There is a separate file, titled ETC(press) The data stored here is collected every half second (2 Hz). The data file contains the following columns

- The data count (at 2 Hz) corresponding to column 1 of the “ETC(ASC)...” file
- the data count divided by the data collection frequency
- the system time (with millisecond resolution) when this data row was written (large gaps will indicate data lost in transmission)
- the device time (in milliseconds) when the data was collected. Data points should be spaced 500 milliseconds apart. Larger gaps indicate lost data
- the internal device pressure readings, in mmHg, collected at 2 Hz,
- the voltage, and a
- user time mark.
- After a certain selectable time the current file will be closed and a new file opened. The time interval can be changed (click on “File”, then “Settings”, then select from the drop-down menu under “Maximum File Size”). The continuous saving of data can be disabled by de-selecting the “autosave data” check mark in the upper right corner of the GUI.
- Stopping and re-starting the data stream will open a new pair of data file
- The file title is “ETC(asc)__(time_date).dat” for the raw data file.
- The file title is “ETC(press) ...” for the pressure readings etc file.
- If a patient name is entered (see Figure 8, left center of GUI) before the “save raw data” check mark is checked the file title of both described files will incorporate that name.
- It is also possible to select or establish a directory to which the program will save all file output. Click “File” on the top menu and then “Save data to directory...”. At this point the screen shown in **Figure 19** appears.

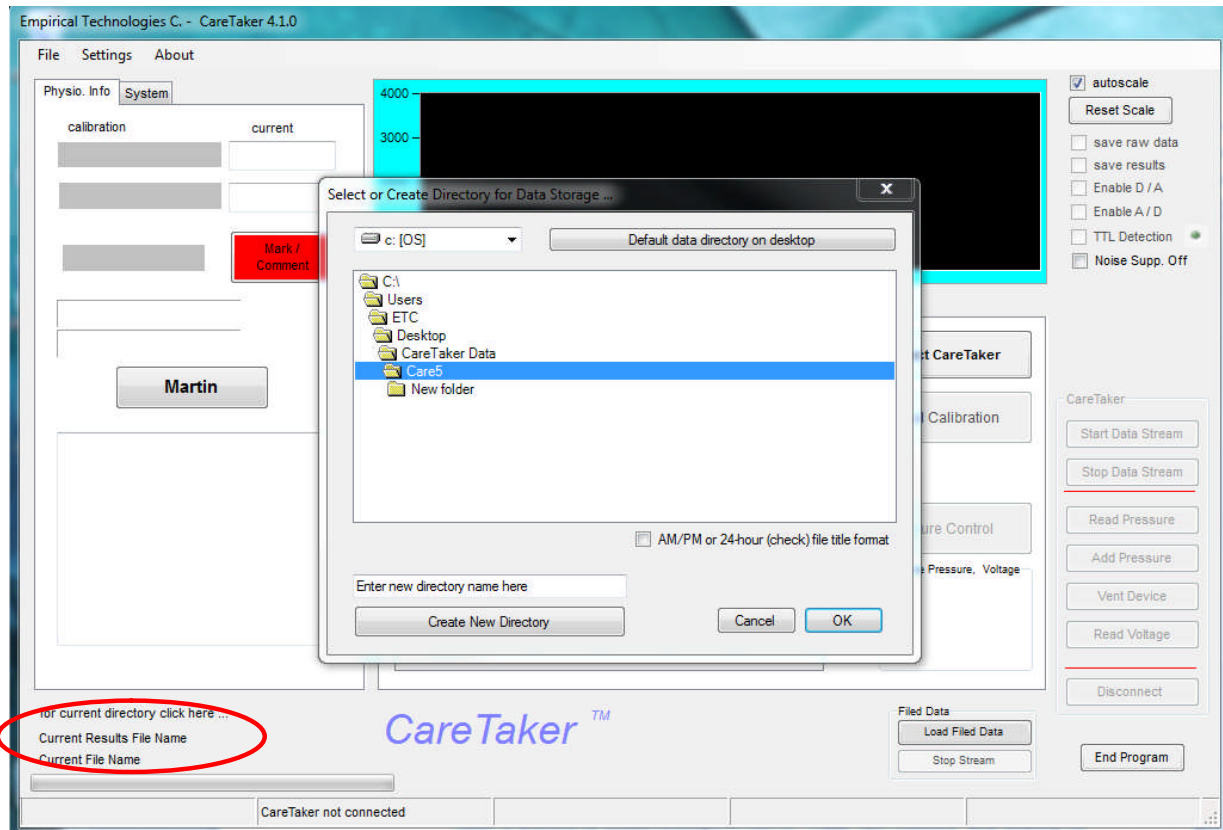


Figure 19:

Select a directory by double-clicking it or click on “Create New Directory” after entering the directory’s name in the appropriate text box.

As a simple default option it is also possible to create a data directory on the Desktop by clicking on the “Default data directory...” button in the upper right of the screen.

To check the status of the current data storage directory, click on “for Current Directory click HERE” (red circle in **Figure 19**). The entire directory path name will appear in the tool-tip of the cursor.

15. Continuous storage of results

The program will save the results continuously to the file whose name is displayed under the “Current Results File Name”. (**Figure 19, below red circle**). This file will save the results of each detected heartbeat per row of the file.

The beginning headings of the file entries are:

Time location of detected heart beat in current data stream (relative to start of data stream in seconds)

Time location of detected heart beat based on computer clock with millisecond resolution

Time location of user-entered Timemark

Device pressure (not blood pressure)

Interbeat interval (present beat to previous beat)

HeartRate (based on 4-interbeat average)

Systolic Pressure,

Diastolic pulse pressure = Pulse systole - Pulse pressure)

The only other user-relevant headings are the entries of the calibration blood pressure values. The file format is ASCII and the file can be important into any graphing or spreadsheet program.

The results file, in contrast to the raw data files, does not “roll over” into a new file unless the “save results” flag is turned off and back on. The program will just keep adding records to the file.

16. Reading the device pressure

- Be sure that the unit is fully vented by clicking on “Vent Device” under “Device Communications” several times. The clicking of the valve should be audible.
- Click on the menu heading “Pressure Settings”, then select “Zero Pressure Sensor”. A message window labeled “Pressure-zero Alert” appears reminding the user to fully vent the device. If the user clicks “OK” the current pressure reading will be zeroed and the offset is stored in the Windows Registry for this and future program runs.
- Click the “Read Pressure” button.
- If the device is NOT streaming data, the results of a single pressure read will be displayed in the “Current Pressure” frame on the left of the GUI.
- If the device is streaming data, continuously updated (every 0.5 seconds) pressure readings will be displayed in the “Current Pressure” display on the left of the GUI.

17. Adjusting the device pressure

- In order to increase the pressure, click on the “Add Pressure” button in the “Device Communication” frame. The device is normally operated between 40-45 mmHg.
- In order to VENT the device, click on the “vent device” button in the “Device Communication” frame. Please note that it **takes about 10 seconds to vent the device**. While the device vents, the “Vent device” button will change color RED and its label will change to “venting”.

i. Adjusting pressure parameters

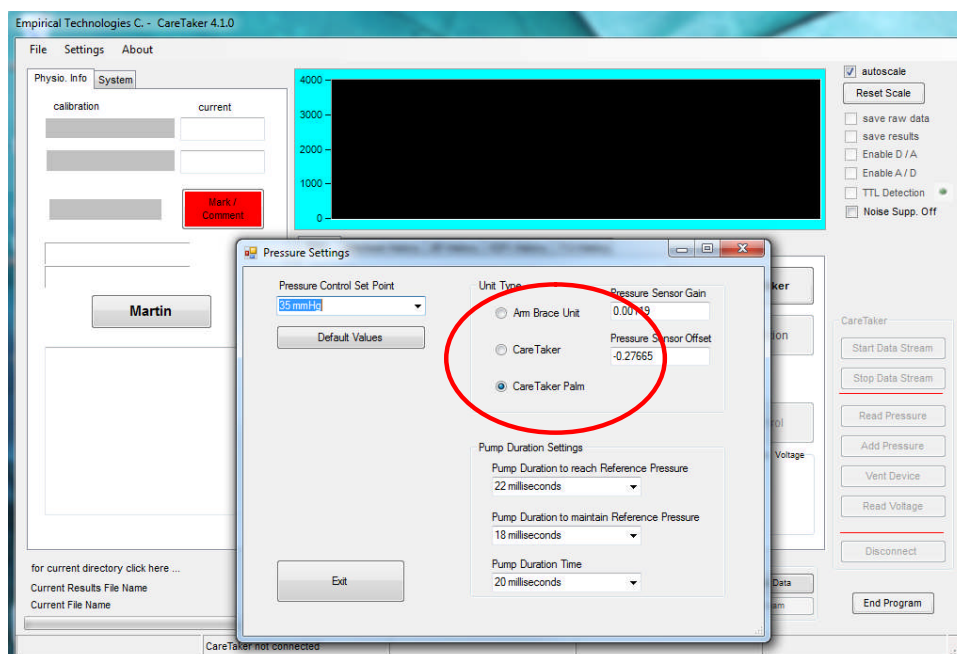


Figure 20 Pressure Control Settings menu

Click on “Settings” in the top menu, then click “Pressure Settings”, whereupon the sub-screen shown in **Figure 20** will open. Choose an appropriate pressure from the top drop-down menu labeled “Maximum Sweep Pressure”. Click OK to exit the panel.

1. **Pump Duration to reach Reference Pressure:** If the finger cuff reference pressure at the end of a calibration cycle exceeds 55 mmHg, adjust this parameter downward. This may require several iterations. If the finger cuff reference pressure at the end of a calibration cycle is below 40 mmHg, adjust this parameter upward, again iteratively, if necessary.
2. **Pump Duration to maintain Reference Pressure:** If, with Pressure Control on, the pressure barely increases past 40 mmHg as a result of a pump blast, this parameter needs to be adjusted upward. If the pressure exceeds 55+ mmHg as a result of a pump blast, this parameter needs to be adjusted downward.
3. **Pump Duration Time:** This parameter controls the duration of the pump when the Add Pressure button (yellow circle) on the main GUI is pressed. If the coupling pressure at the end of the calibration cycle is still above 60 mmHg, change the setting to the next lower value, 70 milliseconds.
4. **Selecting the brace unit versus box unit versus the palm unit pressure sensor calibration:** click on the appropriate radio button (see red circle) and click OK toward lower left of screen.
5. **Pressure Set Point Adjustment:** Refer to the drop-down menu circled in blue. The selected value should be 40 mmHg.
6. **Default Values:** There is now also a default button provided that will re-load reasonable values for the Pump Duration Settings and the Pressure Control Set Point. However, it may still be necessary to perform the adjustments described under points 1 & 2 of this section.

18. Analog Output (if included)

If this option is provided the package includes a digital to analog (D/A) converter module, such as the Measurement Computing device miniLab 1008, which is connected to the computer via USB.

Important: The analogue output is not the continuous sensor signal but the calculated beat-by-beat blood pressure levels. That means that the output will represent voltage plateaus whose height changes from beat to beat, only.

The GUI has an additional check mark (Figure 21, red circle) that, if selected, will enable two D/A channels to output a voltage proportional to systolic and diastolic blood pressure.

The check mark needs to be enabled. This is done, referring to **Figure 23**, by checking the “Enable D/A Output” check mark to the right of the Settings screen, which is reached via Settings (top menu), “COM port and other Settings”. Please refer to section 19(“Enabling analog input or output”).

The following assumes that the driver software for the D/A module has been installed and that the device’s operation has been verified. Please follow the manufacturer’s instructions.

The check mark cannot be modified while a data stream is running.

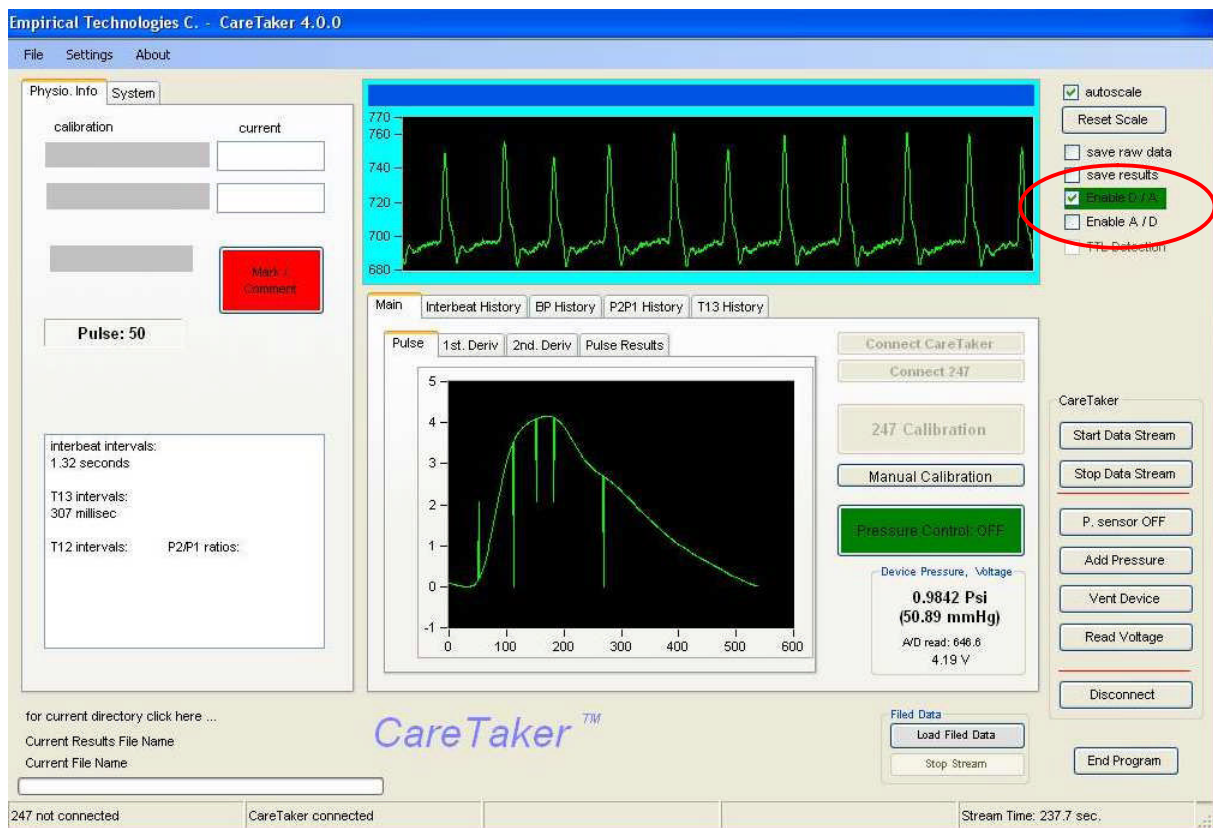


Figure 21 Enabling the D/A output

- It imperative that, using the InstaCal program supplied by Measurement Computing, the manufacturer of the miniLab D/A converter, *the D/A board is in position 0*.
- If, upon selecting “enable output”, an error message is displayed, the D/A converter module has not been properly installed or connected.
- The D/A channels will output non-zero voltages ONLY if either a manual or 247-based calibration has been performed and systolic and diastolic BP values are being displayed (Figure 21, green circle)
- A voltage corresponding to systole is output on D/AOUT 0. To obtain mmHg the voltage is multiplied by 250/5 or 50.

- A voltage corresponding to diastole is output on D/AOUT 1. To obtain mmHg the voltage is multiplied by 150/5 or 30.
- The voltage CHANGE will occur at the position of a detected heart beat. Between heart beats the voltage remains constant.
- A voltage change, signifying a detected pulse, will occur with a 2 SECOND DELAY from when the actual pulse was detected. This is due to the fact that the program analyzes 2-second sections of data every 2 seconds and then sends the beat-by-beat BP values, converted to voltages and spaced correctly in time, to the D/A outputs.
- If an excessive noise condition is determined, in which case the chart display background color changes from turquoise to red, voltages at the D/A outputs are not updated but will remain constant at their last value.

19. Enabling trigger input recording via the analog/digital converter (if included)

If the A/D feature has been enabled (see section 19), selection of the “Enable A/D” check mark will activate the MCC device to acquire data at 512 Hz (this raw data cannot be stored presently). If the “TTL Detection” check mark is selected, the positive transition detector will activate. (See Figure 22, red circle). If transitions are detected the LED next to the checkmark will flash red/green.

The time positions, relative to the beginning of the scan (just as the results file), of the positive transitions will be recorded to file **IF AND ONLY IF** either the “save raw data” or the “save results” check mark **is also selected besides the “TTL Detection” check mark.**

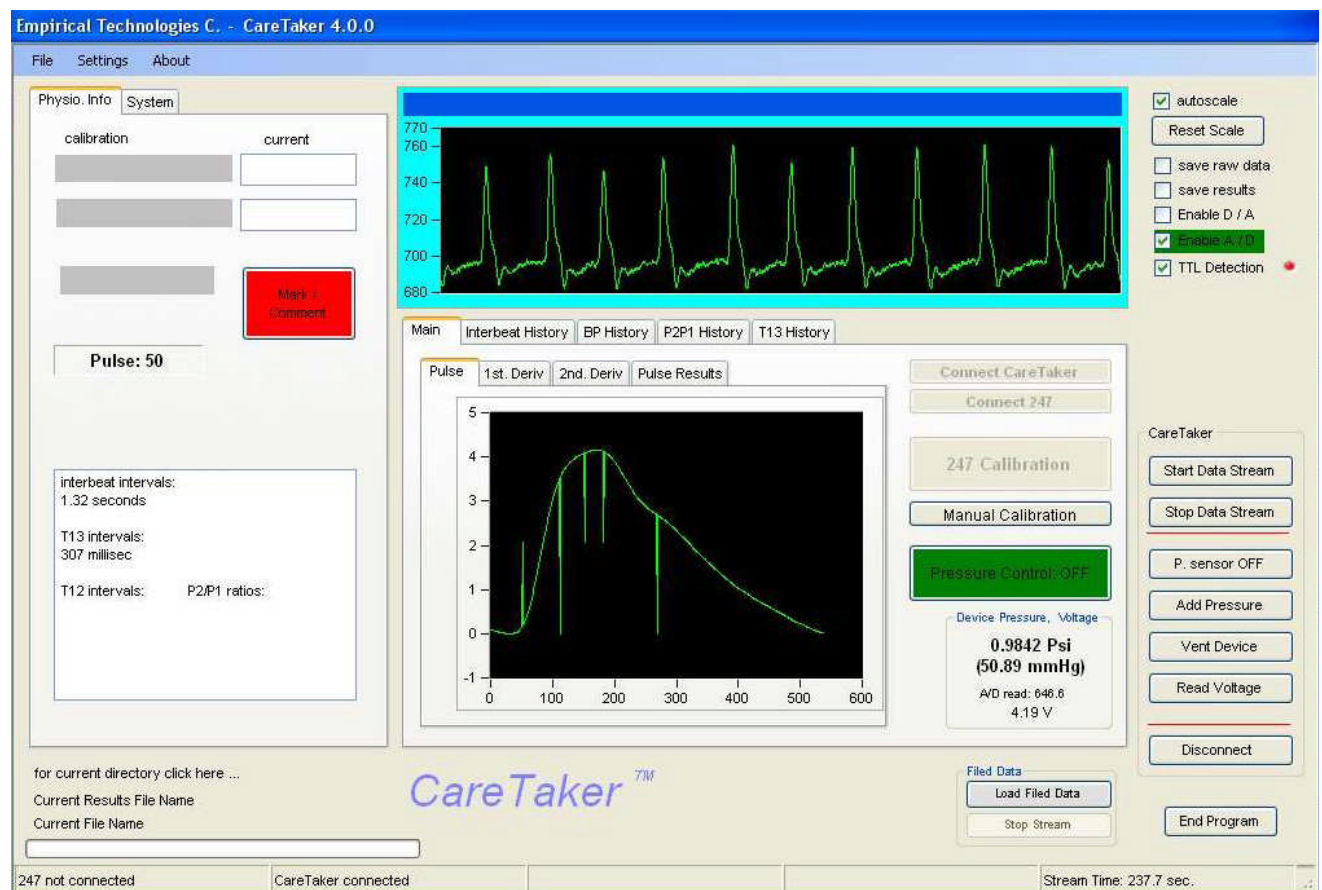


Figure 22 Enabling the A/D input

The time positions of the transitions will be recorded in a file that, depending on whether the raw data or the results file option was chosen first, will have the same date/time sequence in its file name but will also include the string (TRIG). An example would be:

ETC(asc)(TRIG)__(12-04-28 PM_10-8-2009).dat with the corresponding raw data file ETC(asc)__(12-04-28 PM_10-8-2009) or,
ETCResults(TRIG)__(12-45-48 PM_10-8-2009).dat with the corresponding results file ETCResults__(12-45-48 PM_10-8-2009).dat

20. Enabling and testing the analog/digital converter

The Settings panel (see Figure 23) is used to enable and test the analogue/digital conversion board for output or input. **Either input or output can be selected, NOT both.**

Referring to the red circle in Figure 23, selection of either check mark will disable the other check mark and test the board.

1. If the checkmark completes the check, the appropriate device driver has been found. Specifically, the program looks for the "C:\Program Files\Measurement Computing\DAQ\MCCDaq.dll" that signifies that the Measurement Computing drivers have been installed. If a Measurement Computing device (such as the miniLab 1008 via the USB port) has not been installed using the InstaCal program, an error can still occur. Refer to section 24.
2. If an error message occurs the MCC drivers were not installed or the board has not been installed. Refer to section 24.
3. **To test the miniLAB 1008 device:**
 - a. Select the "Enable A/D Input" option – the "Analogue Trigger Input Acquisition" section enables
 - b. Click the "Check A/D Signal Input" (green circle) button. If a signal appears, the board is working and the correct input has been selected.
4. **Setting Trigger levels:** Using either the default TTL checkmark or the adjustable sliders, the high and low trigger levels can be set. The transition detector will only trigger on positive going transitions. Trigger levels are preserved between different program sessions.

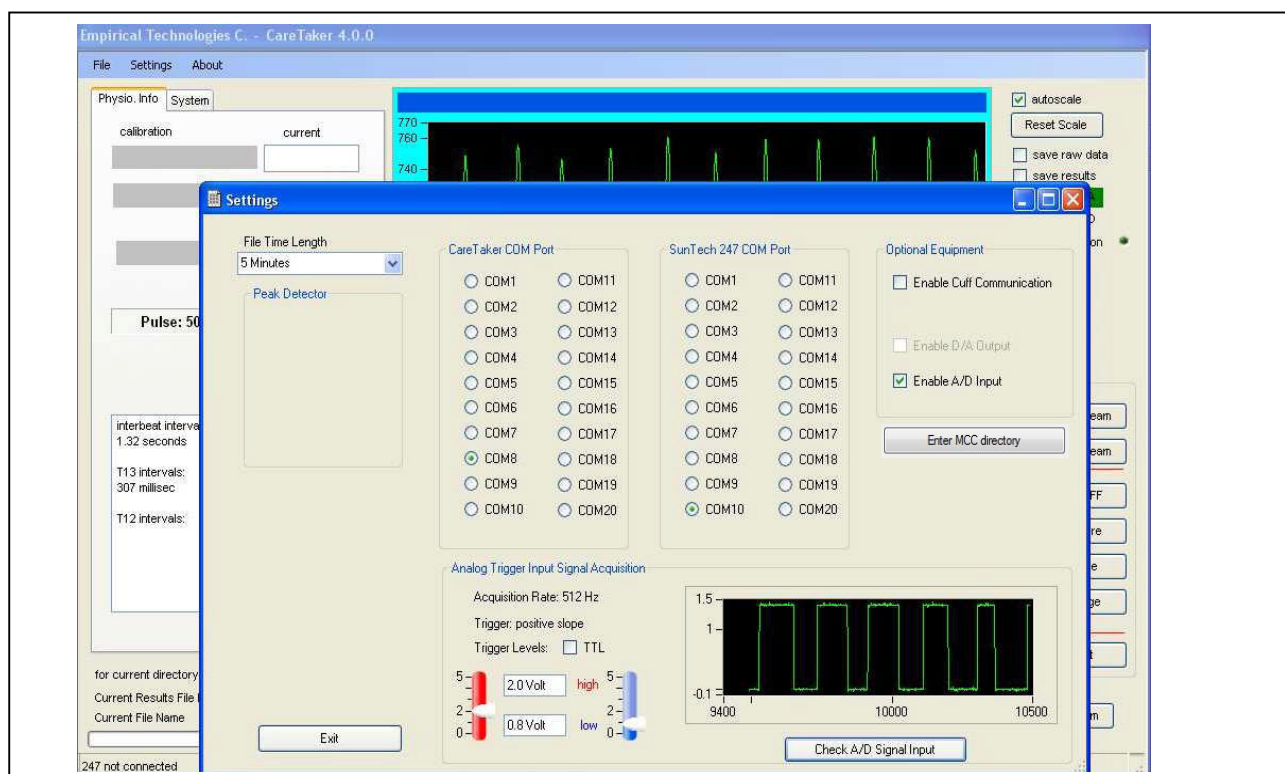


Figure 23 the Settings panel, used for enabling analogue in- and output, and for testing signal acquisition
Important: If the A/D converter is disconnected the CareTaker program, upon re-start, will show an error message:

A/D Error: 1
Invalid Board Number

This indicates that the program could not find the converter. Exit the program, plug the converter into a USB port, and re-launch the program.

Message: “DaqLib.dll not found, please search for file’s directory & click Enter MCC directory”

In this case the program did **not** find the “daqlib.dll” in either of the following directories

C:\Program Files\Measurement Computing\DAQ\
C:\Programs\Measurement Computing\DAQ\
C:\Program Files (86x)\Measurement Computing\DAQ\

Use the Windows search function to search for the “daqlib.dll” file to obtain the directory where it is located. Once you have obtained the directory, click on “Enter MCC directory”, paste in the directory path, and click ok.

21. Making Time Marks & Comments

The capability to make time marks and add comments during a data recording session is available.

- A large red button on the GUI is provided to make the time and to bring up the comment window. Once the red button has been pushed, **subsequently pushing any keyboard key will have the same effect**, until focus is removed from the red button by clicking somewhere else.
- The time of the red button click or key stroke is associated with the comment
- In order to be able to save a mark/comment, EITHER the save raw data or the save results feature has to be turned on.
- Depending on which one is selected (or both) the TIME MARKINGS will be saved in fourth column of the ETC(press)xxx.dat file and/or the second column of the results file (Heading: marker)
- The comments will be saved, under the same time marker, in the XXXX(Log)xx.dat with the same heading as the raw data file or the results file, whichever was enabled first.

22. Summary of CareTaker output files

All files are synched with a “Start Data Stream” – “Stop Data Stream” session. Depending on the selection regarding raw data or results storage, files will be opened at the beginning of the session and closed at the end. Consequently they will all have the same time and date stamp in the later part of their file name.

- ETC(asc)__(time_date).dat for the raw data file. This file will store the raw data, digitized at 512 Hz (**500 Hz for the Palm unit**), from the sensor, in ASCII format. The file is in a three-column format. The first column is a simple data index, referenced to the start of the scan, the second column contains the actual data index transmitted from the sensor unit (and which rolls over at 100,000), and the third column contains the 12-bit A/D reading (i.e. a number between 1 and 4095).
- The file format is “ETC(press)_(time_date).dat for the pressure readings etc file. This file stores time, pressure, battery, and mark information. The file has a five-column format. The first column is time, referenced to the start of the scan, the second column is a counter, the third counter lists the device’s cuff pressure (in mmHg), the fourth column lists the battery voltage, and the fifth column lists the counter value of the time mark, if the user chose to make using the red button on the GUI.
- ETC(Log)_(time_date).dat stores time marks and comments made by the user
- ETCResults_(time_date).dat stores the results of the analysis of the data stream, interbeat interval, systole, diastole, as well as parameters that the algorithm calculates. Please see item 14 for more details. Time positions are stored relative the beginning of the current data scan, not relative to when the “save results” checkmark was selected. Time positions are also time stamped based on the computer’s clock, with millisecond resolution.
- ETC(asc)(TRIG)__(time_date).dat stores the time positions of detected positive-going trigger events relative to the start of the scan.

23. Renaming data files at end of data taking session

All files are synched with a “Start Data Stream” – “Stop Data Stream” session. Depending on the selection regarding raw data or results storage, files will be opened at the beginning of the session and closed at the end. Consequently they will all have the same time and date stamp in the later part of their file name.

If file saving selections were made, at the end of a data collection session, clicking “Stop Data Stream”, will cause the window in Figure 22.1 to appear.

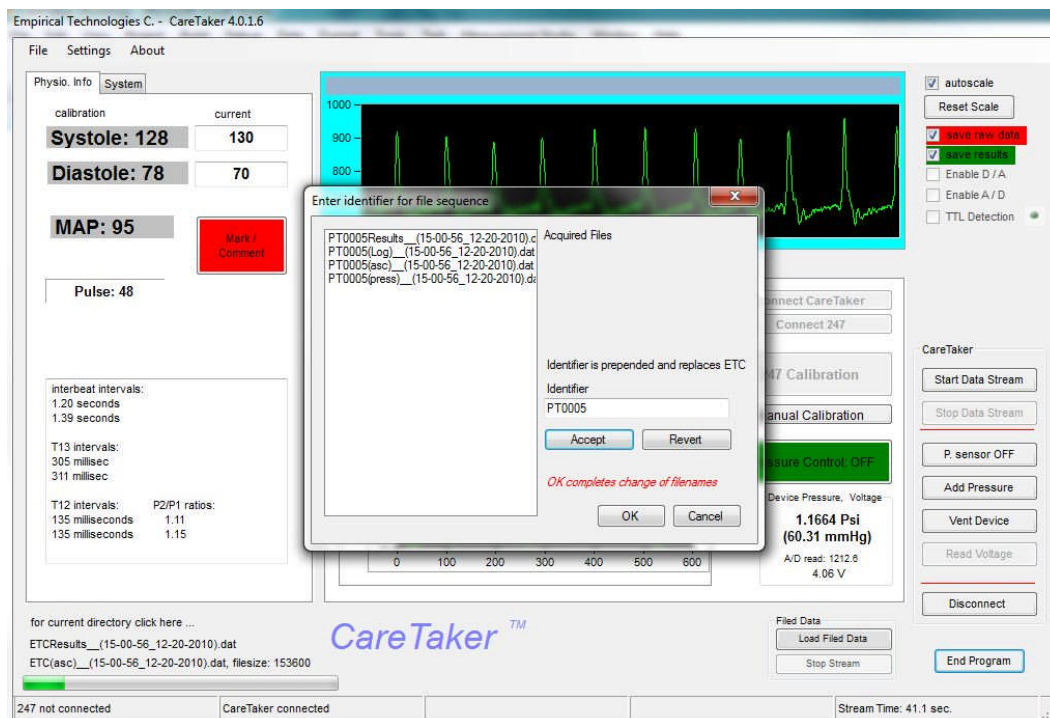


Figure 22.1

This window provides the user with the opportunity to rename the collected data files with an arbitrary prefix, such as “PT0005” as shown in the example. The list on the left presents all of the files that were collected during the latest data collection session.

- The user enters an identifier
- Clicking “Accept” changes the files names in the list BUT DOES NOT RENAME THE FILES yet.
- “Revert” changes the file names back
- Clicking OK finalizes the RENAMING OF THE FILES and closes the window.
- Cancel closes the window without changes to the filenames. Clicking OK without entering an identifier does the same.
- Irrespective of whether the files were or were not renamed, the directory path and the file name list is saved in the associated LOG file.

24. Ending Program Operation

- Click the “Stop Data Stream” button to terminate the data stream
- Click on “End Program” to terminate the program session

It is not recommended to click on “End Program” without terminating the data stream. Doing so can leave the CareTaker unit in a data streaming mode as a result of which the device will be “busy” to subsequent attempts to communicate with it. In this case turn the CareTaker Off and On after removing the cover.

25. Installation of the driver software for Analog Output (Measurement Computing InstaCal)

1. Double-click on the self extracting file "icalsetup.exe". The file is either enclosed on the accompanying CD (MCC driver) or available from the Measurement Computing website link (<http://www.mccdaq.com/software.aspx>, InstaCal).
2. Follow the installation procedure which includes rebooting the computer.
3. After the re-boot, plug the miniLab 1008 into a USB port.
4. Click on Start – All Programs – Measurement Computing – InstaCal
5. After the program launches a second window should open ("Plug and Play Board Detection") that lists the 1008 board – click OK.
6. The board should be in the #0 position. If not, move it into that position.
7. Exit the program by clicking on File – Exit. DO NOT EXIT BY CLICKING ON THE UPPER RIGHT HAND "X" or your settings will be lost!

26. Calibration and Analysis of previously recorded CareTaker raw data files

In order to access the analysis panels click on File - Data Processing. The screen presented in Figure 24 opens.

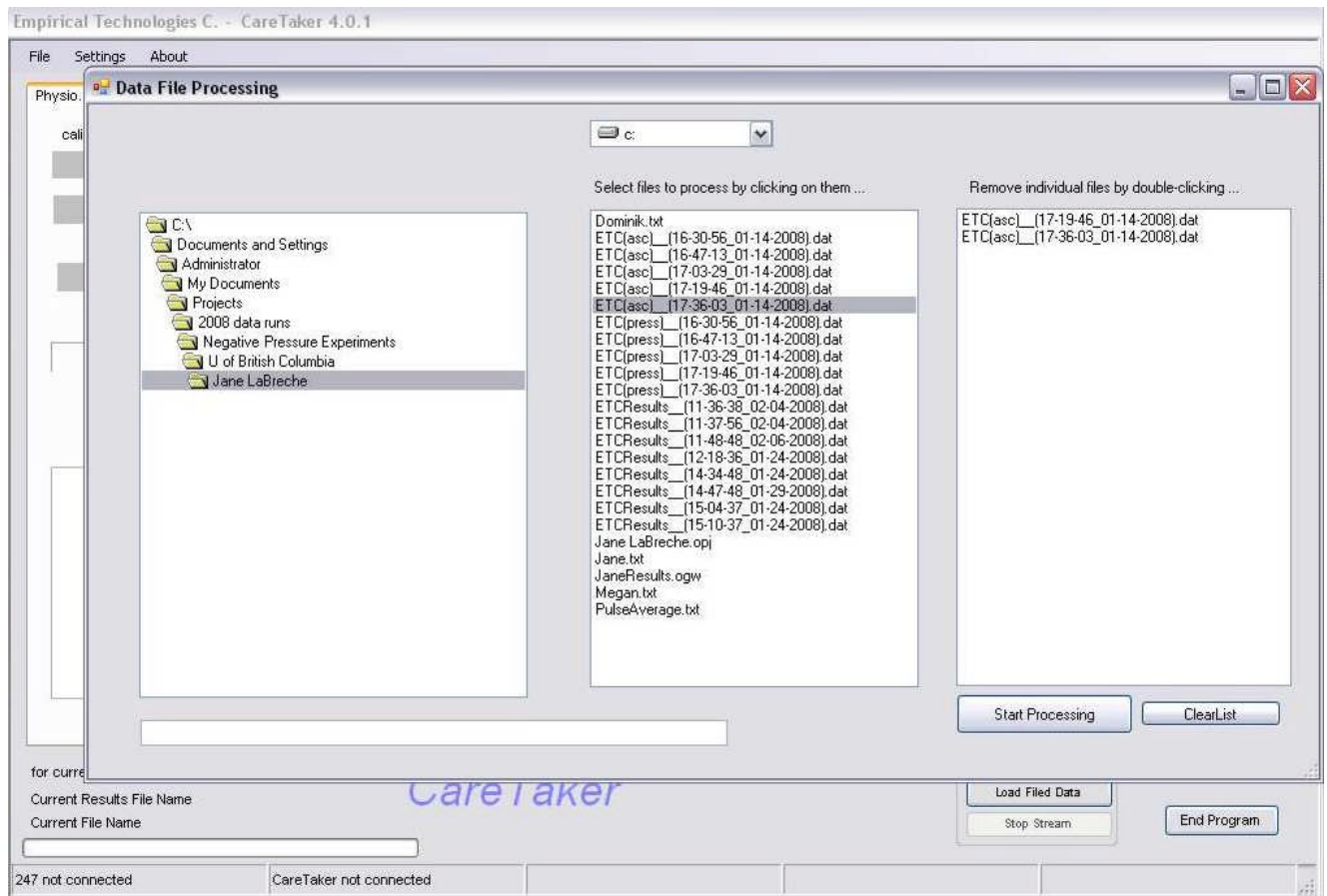


Figure 24 Screen for selecting files for processing.

1. Select the files to analyze by clicking on them, thereby loading them into the list on far right. To remove individual files, double-click them.
2. The files will be analyzed in the order chosen, NOT in the time sequence they were taken.
3. All results will be compiled in a single ETCResults file. *This file will be saved in the same directory that was selected under File – Save Data to...* The filename of this result file is displayed on the main GUI (bottom left corner in Figure 24), next to “Current Results File Name”.
4. Click “Start Processing”. An “Enter Calibration (Y/N)” option appears in regard to calibrating the BP readings:
 - a. OK – the calibration screen opens so that the entire analysis run can be calibrated
 - b. No – the analysis will proceed without calibration and proceed through all selected files. There is no abort option.
 - c. Cancel – return to the file selection screen (Figure 24).

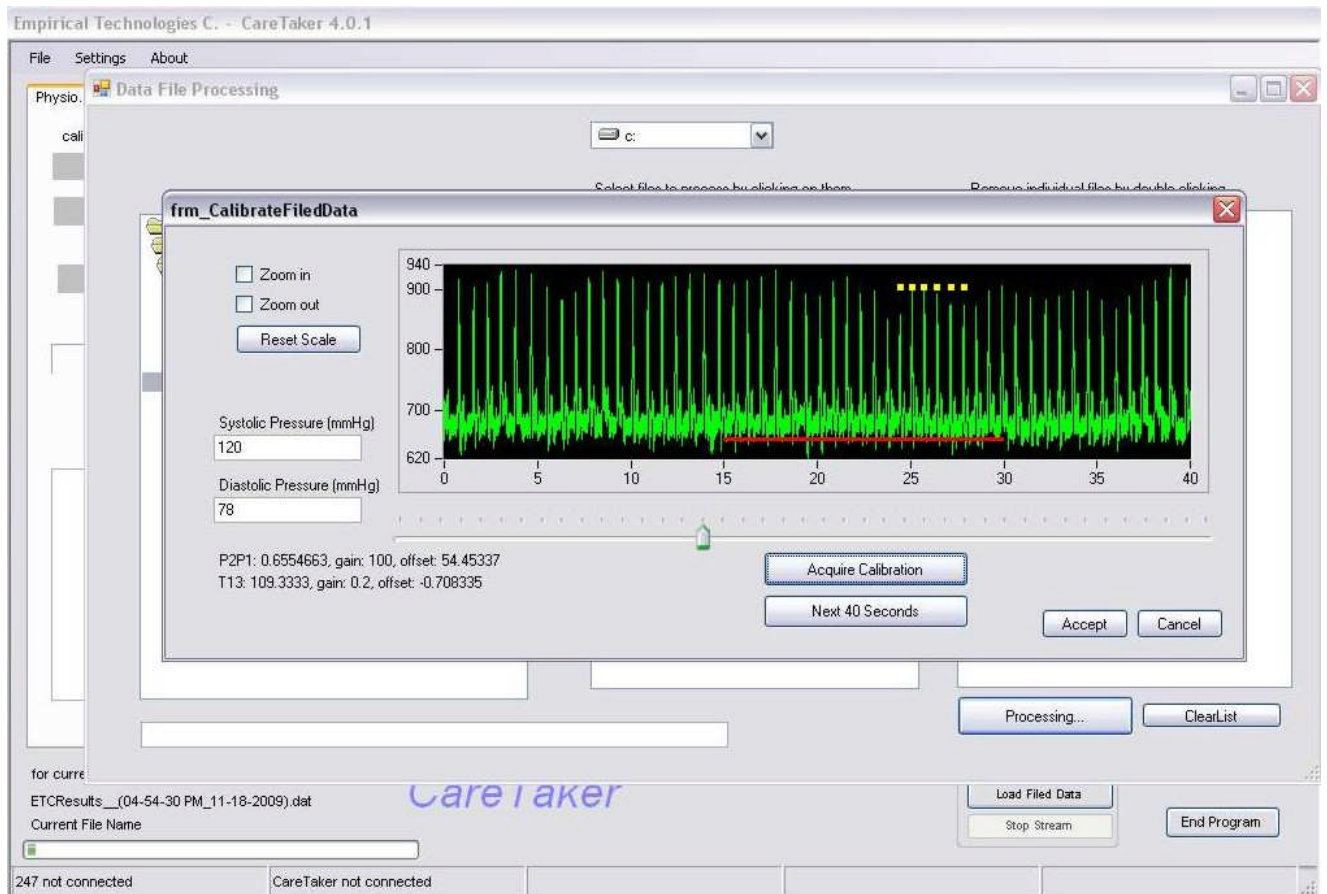


Figure 25: Calibration screen

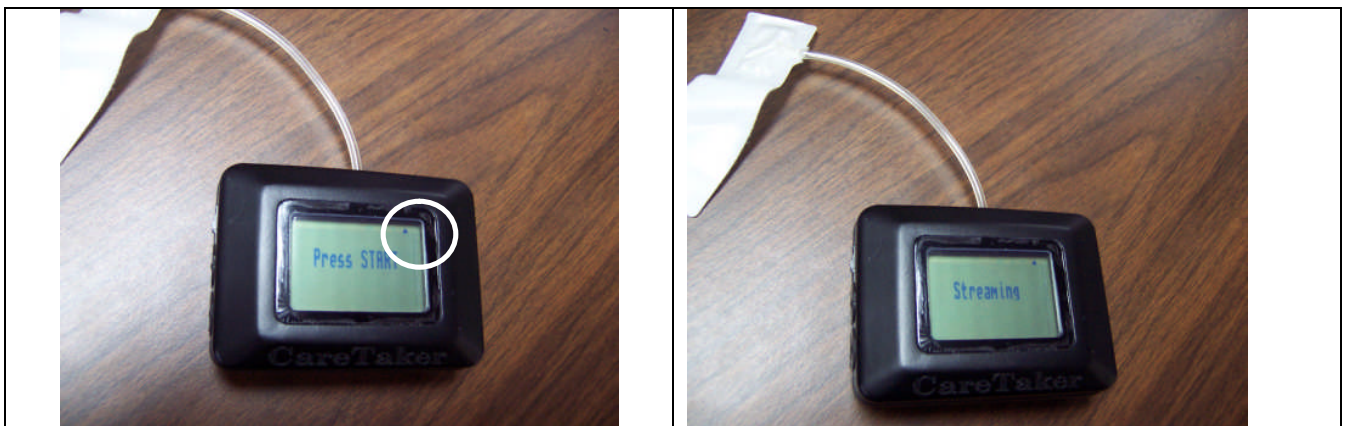
5. If Ok was chosen, the calibration screen opens presenting the first 40 seconds of data from the first file.
6. If the data is not adequate, clicking the "Next 40 Seconds" will load the next data section
7. Data inside the red bar will be analyzed. The bar can be moved using the slider
8. It is also possible to expand the data view by checking "Zoom in" and clicking on the desired region of the data display.
9. Enter BP values in the entry windows. Without an entry the calibration cannot be accepted.
10. Click the "Acquire Calibration" button. The conversion factors appear in the lower left.
11. The heart beat peaks that were used to perform the calculation are marked with yellow squares.
12. The process of selecting different data sections and calculating conversion factors can be repeated.
13. Once the "Accept" button is clicked
 - a. the conversion values as well as the position of peaks are recorded as an entry in the ETCLog file that has the same date/time header as the corresponding ETCResults file.
 - b. The calculation progresses through all selected files. An abort is not available.

27. CareTaker Palm Hardware version

Below are photographs of the CareTaker II (CareTaker Palm) unit.



The unit has two buttons. Use the top one to power the unit on. Powered up, the unit is shown at right above.



After pairing with the computer, the unit's display shows a small triangle (white circle), as shown to the left above.

Upon entering the Start Data Stream mode, the unit locks out all displays and indicates "streaming" (above right).

The second button on the left bottom is used to scroll through the four screens that will be available for display on future upgrades of the unit.

The displays on the unit at this time do not display any meaningful information!!!

The unit is intended only for streaming data to a computer where the GUI-based software will analyze it.

28. CareTaker III Hardware version

Below is a photograph of the CareTaker III. This unit has the same electronics engine as the Palm unit and uses for that reason the same pressure sensor calibration factors as the Palm unit. It has, however, a much smaller and more sensitive sensor for detecting arterial pulsations.



With the unit's current firmware (up to April 2012) press the black button BEFORE clicking the "Connect CareTaker" button on the GUI.

Upcoming firmware changes will eliminate this requirement.