AccuPulse™
Handheld PLUS
NIBP Simulator

Operation Manual

CE

Clinical Dynamics Corporation
www.clinicaldynamics.com

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Phone: 203.269.0090 • Facsimile: 203.269.3402

Warranty Service & Shipping Instructions

Warranty Service

All repairs on products under warranty must be performed or approved in writing by Clinical Dynamics Service personnel. *Unauthorized repairs will void the warranty.*

Assistance

If the product fails to function properly, or if assistance, service or spare parts are required, contact Clinical Dynamics Customer Service at 800 247-6427 or visit our web site, www.clinicaldynamics.com and select the SERVICE Key to fill out a Request for Calibration/Service Form. After this form has been submitted, a Clinical Dynamics' Service Representative will contact you to help solve your problem. Before contacting Clinical Dynamics, please attempt to duplicate the problem and to check all accessories to ensure that they are not the cause of the problem. Prior to calling please be prepared to provide:

1. Product Name, Model Number, Serial Number and Software version.

2. Complete description of the problem including the conditions under which the problem occurred. Ideally, a written problem description would be provided, allowing for more efficient handling of your initial service request and the subsequent diagnosis and remedy of the problem.

3. Your institution's complete name and address. Please also provide a contact name and phone number.

4. A purchase order number if the product needs non-warranty service or you are ordering spare parts.

Returning a Product for Service

Contact Clinical Dynamics Customer Service at 800 247-6427 and provide the information listed above under Assistance. If it is determined that you need to ship the unit back, it is highly recommended that you pack the product in its original shipping carton and packing materials, provided that they are still useable. If the original packaging is not available, select a sturdy corrugated carton large enough to hold whatever items you are returning, *and also to allow 4 to 6 inches of packing material on all sides of the items.* Whether you use the original packaging or an appropriate substitute, please follow these packing instructions:

1. Remove all hoses, cables, power cords and any other accessories from the instrument and, if possible. *Note: if you are using substitute packaging, it is essential that you seal the instrument in a clean, static free plastic bag or in clean bubble wrap in order to prevent packing material from entering the product.*

2. Pack only the accessories you are requested to return; place them in a separate bag.

3. If you are using substitute packaging, create a foundation of 4 to 6 inches of packing material (either bubble wrap or packing "peanuts") at the bottom of the carton.

4. Insert the instrument and the accessory bag into the shipping carton.

5. If you are using substitute packaging, fill the 4 sides and the top of the carton with 4 to 6 inches of packing material (either bubble wrap or packing "peanuts"). Ensure that the instrument and accessory bag are held firmly in place by the packing material.

6. Please place paperwork such as the purchase order, contact info and reasons for return in the top of the carton.

7. Close the carton and securely seal it with tape; since in most cases the carton will have been previously used, it may be necessary to reinforce the original tape on the bottom of the carton.

8. Ship the product via whatever carrier (UPS, FedEx, etc.) is most convenient. However, please be aware that, depending on where you are shipping from, standard UPS ground shipping could take as long as 7 business days. Unless other arrangements are made, Clinical Dynamics will return the repaired product to you via UPS.

9. Shipping insurance is optional. Claims for damage to the product during shipping must be initiated by the shipper.

Customers outside the United States must include a "pro-forma invoice" for customs purposes as part of their shipping documents. It is imperative that the name of the product appears exactly as follows:

AccuPulse Test Equipment

Or

AccuPulse Test Equipment

The use of any other product name could add unnecessary delays when shipping internationally.

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I. Device Power Up

Upon powering up, the **AccuPulse Handheld®** shows a splash-screen indicating the device type, its serial number and the version number (See Fig. 1). In this case, the device type is the **AccuPulse Handheld PLUS®** model, version 1.0, compile 90. The serial number is "**AH09070008**".

Fig. 1

From this screen, the user can see the latest software image that has been loaded into the device. If the user has purchased an upgrade to the software or there is a software fix, either of which has a higher revision number than its version, the **AccuPulse Updater™** allows the user to load a newer image to the device. This software is soon to be available as a web script on the site http://www.clinicaldynamics.com/. Currently, it exists as a standalone program that can be obtained upon request.

Other key information is also displayed at this time; the main information is "SPI: cc (OK)". This information means the SPI bus is OK because the code 0xCC was received. It is a diagnostic check of an internal board, which only sends this data if it is alive. ***If the device powers up with "SPI:xx(BAD)", it will not servo. It may need to be sent back for servicing. This can possibly occur if the device is dropped.***

The version number is:

v.Version.Major.Minor.

The Version Number is the major software release.
The Major version if for customer releases and software *changes*.
The Minor version is for bug fixes and patches (compile number for this model).

Freeze the Splash Screen:

After a few seconds, the splash screen is replaced by the **BP Test** mode screen, which is the main operating mode for the **AccuPulse Handheld®** device. However, if the user encounters a bug, that user will wish to record key information, such as what Model and software version they have. ***Immediately after the ApHandheld splash screen is displayed, the user may press 2 keys simultaneously, then let go of them. This will freeze the splash screen until any new key is pressed.***

II. Device Modes

There are four main modes to the **AccuPulse Handheld PLUS®** product. These are:

- **BP Test:** Tests the accuracy and precision of an attached blood pressure monitor.
  - Motion artifact may be enabled for this mode (through a software upgrade) to simulate operation of the device in harsh environments such as inside a helicopter or ambulance.
  - The **Plus** and model supports 7 Adult and 6 Neonatal presets, giving them functionality compatible with the **AccuPulse®** series of devices.

  - There are several parameter adjustment screens that hang off **BPTest** mode. These Tabs are rotated into use by pressing the **<Menu>** button.
- **Leak Test:** Tests for leaks in the BP Monitor system.
  - The **Plus** model has a built-in pump and supports automated Leak Test and OverP Test (See Below).
- **OverP Test:** Finds the pressure at which the overpressure valve of an NIBP monitor opens.
- **Meter:** Measure pressure in the system in tenths of mmHg
  - Meter has a motion settings tab to control the frequency and amplitude of motion artifact simulation. This is only available as an upgrade option from the **Pro** model.
  - There are several tabs that can hang off this mode which allow the user to
    - Set Language
    - Set Pressure Limits
    - Configure Motion Parameters
    - Set Meter Units (mmHg, kPa, inH20, psi).

Mode Buttons

Pressing any of the front-panel mode buttons **<BP Test>** , **<Leak Test>** , **<OverP Test>** or **<Meter>** causes the **AccuPulse Handheld®** to change to the indicated mode. The exceptions are when there is pressure in the system above a given threshold. Each mode has a trigger pressure past which the user cannot leave the mode. For instance, when in BP Test Mode, the **AccuPulse Handheld®** will servo automatically when Press > 10mmHg. The **AccuPulse Handheld®** will not change modes until the pressure in the system is < 10mmHG for that reason.

All results displayed on various screens are maintained so that a user may run a test in one mode, and come back to a previous mode and see the last data collected in that mode.

Power Control

Power is applied to the **AccuPulse Handheld®** device by plugging the power cord into the back of the unit, then plugging the power supply into an outlet. Battery-powered devices will have a pushbutton on the back panel to override the wall and battery power to shut the device down. Devices that are left plugged in will charge the batteries while powered down. *This feature is under development at the time of writing this document.*

III. Modes Of Operation

The AccuPulse™ Handheld powers up in the BP Test Mode and in the BP Test Screen shown in fig. 2 below.

1) BP Test Mode

The servo actuates in this mode, delivering simulated NIBP cuff pressure pulses. The servo begins actuation when pressure in the system is > 10mmHg. If the user is in a BP Adjustment Tab (accessed through the <Menu> key), the servo will also start up if the system is > 10mmHg. When it starts, the software will change to the BP Test Screen.

Figure 2 shows a typical BP Test Mode Screen with a maximum pressure scale of 200mmHg (left edge of screen). The pressure is at 0 mmHG (upper right corner of screen). There are approximately 27 seconds of pressure data displayed on a given screen (bottom numbers are time: 0-25 Seconds). Finally, the top line of text indicates A(dult) patient type, 80/50 Systolic/Diastolic pressure, 80 Beats Per Minute pulse rate, and 100% amplitude waveform generation.

Three parameters may be adjusted directly in this mode:

- The Up/Down buttons cause the scaling of the pressure to change from 100, 200, 300 mmHg max.
- The Left/Right buttons cause the pressure data to be scrolled 10 seconds at a time from 0 seconds to 120 seconds. *At the present time, the Left/Right buttons are only availible for test review ; they do not scroll while the servo is active.*

- *Motion Artifact: See "Motion Artifact" Section Below. This is a purchased option.*

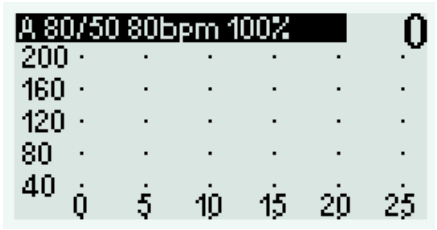


Fig. 2.

BP Test Mode is the primary mode in which the **AccuPulse Handheld®** is used.

Note: all the modes except BP Test are locked out of the servo loop by a solenoid valve so that the servo contributes no pressure leaks to the system.

BP Test Data Engine Selection and Control

The **Plus** model has the ability to utilize Cal Table™ upgrades, or the Generic Test Point Table upgrade. All models come pre-loaded with a Generic Cal Table™. The Generic Cal Table is the only usable Cal Table™ for the base **AccuPulse Handheld™** models. This is the most generic possible set of envelopes. These envelopes are matched to no manufacturer or model in particular. Cal Table™ upgrades may be purchased that conform to a specific Manufacturer's Model.

The Generic Test Point Table upgrade facilitates user-creation of calibration envelopes without much programming or data overhead, typically by dialing up the parameters on the Generic Edit Screen. This allows users to tweak parameters to get the set of numbers they expect so they can use a particular Generic Setting to test a given model of NIBP monitor. Although software may be used to load up a set of Generic Points, these points may be set with the front panel buttons of the AccuPulse™ Handheld as well. Settings are remembered on subsequent power-ups.

CalTables™, while having more degrees of freedom than Generic Test Points, *must* be programmed by remote control commands. If the user wishes to have *named* Generic Test Point entries, the names must be programmed by remote control. Thus, for maximum usability and portability, Generic Test Points should be programmed by remote control. For instance, to clone a set of Generic Test Points, one takes a file and programs it via remote control into each of their units.

These three distinct modes are selected by pressing the <BP Test> button to access the Mode Tab and Cal Table setting tab. Furthermore, based upon upgrades the user has purchased, Motion, and Arrhythmia Tabs may be included as well. For Clinical Dynamics factory use, and possible use to other manufacturers is an Auto Sequence Tab that rotates through all settings in a Cal Table or Generic Cal Table (Generic List Upgrade slated for software version 1.2.7 and beyond) a specified number of times in order to facilitate automated testing. Motion and Arrhythmia tabs are part of this list because they govern overall behavior of waveform generation, regardless of the table that generates the waves.

The tabs here are:

A) Mode Select Tab (Only present if user has purchased Generic Upgrade)

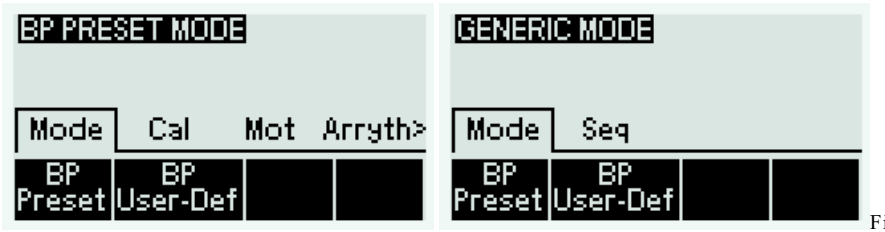


Fig.3

<F1> Selects BP Preset Mode (Cal Table™ or Generic Cal Table™ used to envelope-modulate pressure waves). Two modes are accessed this way.
<F2> Selectd Generic Preset Mode (One of 45 User-Selectable Generic Test Points are used to envelope-modulate pressure waves). One mode is accessed this way.

B) Cal Table Select Tab

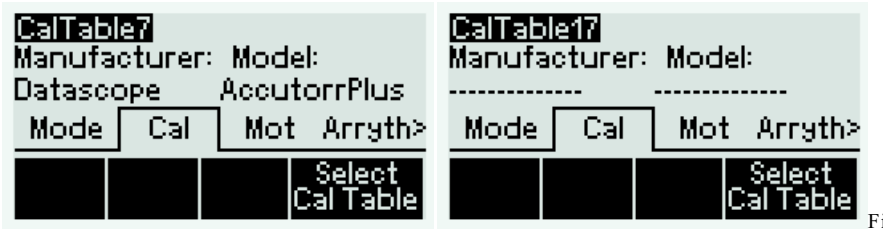
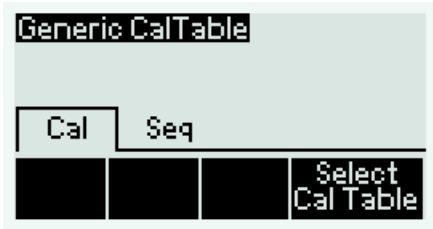


Fig 5

Fig. 5 shows on the left a valid Cal Table™ that has been dialed up with the Up/Down keys. It must be explicitly set using <F4> for it to be used. The right side of Fig. 5 shows a non-programmed Cal Table that has been dialed up. <F4> has no effect, because there is no valid data in this table. Fig 6., below, shows the last Cal Table™, the special Generic CalTable™, that contains no proprietary information and is the standard table in base **Plus** model AccuPulse Handheld™ devices.



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This Cal Table is Cal Table 46, though it shows up as "Generic Cal Table".

C) Motion Artifact Tab

Motion Artifact is only present in if the Motion Artifact Upgrade is purchased. Figure 7 shows this screen. Both step and sine tests may be run from this screen.

- **F1** toggles Step / Sine mode. As of the time of writing of this document, step mode is unimplemented. It is slated for and update of the v.1.2 software.
- **F2** selects Frequency adjust by blinking Freq parameter.
- **F3** selects Amp adjust by blinking Amp parameter.
- **Up / Dwn** keys adjust frequency or amplitude, depending upon which parameter is blinking.

AP_Handheld PLUS® v1.2.7

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  - Set Language
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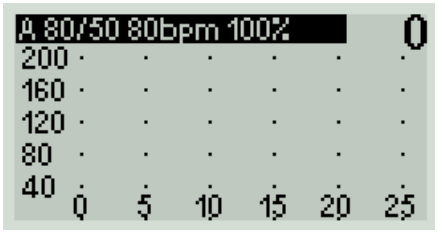

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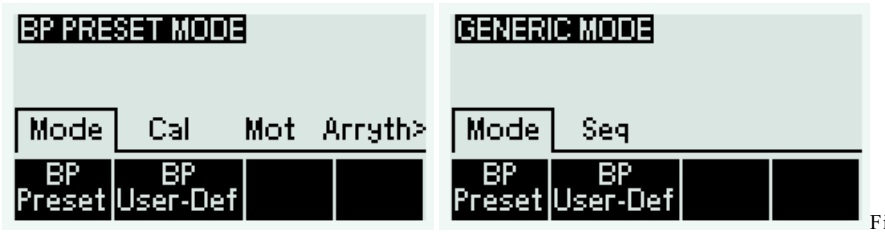

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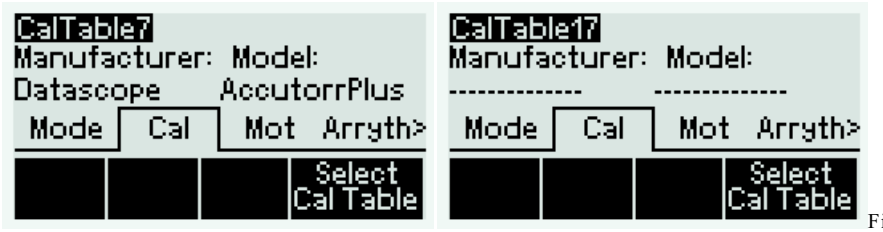

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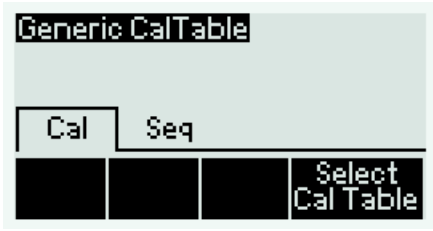

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C) Motion Artifact Tab

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- **F1** toggles Step / Sine mode. As of the time of writing of this document, step mode is unimplemented. It is slated for and update of the v.1.2 software.
- **F2** selects Frequency adjust by blinking Freq parameter.
- **F3** selects Amp adjust by blinking Amp parameter.
- **Up / Dwn** keys adjust frequency or amplitude, depending upon which parameter is blinking.

- **Up / Dwn** keys adjust frequency or amplitude, depending upon which parameter is blinking.
- **F4** turns the test waveform on or off. The **ApHandheld®** will only servo if pressure in the system exceeds a 10mmHg threshold, however.

Fig. 7

After the user sets the amplitude and frequency of the test waveform, the user may toggle this motion off and on while in **BPTest Mode** by pressing **F1**. Figure 32 shows the resulting "**M**" in the upper-right corner of the screen, followed by 5Hz, indicating the motion artifact frequency. Also, there is an 8 to the right of the 5Hz indicating the motion is of amplitude 8 (amplitude is 1..8).

The base **Plus** model has five supporting adjustment tabs accessible from this mode. These tabs allow the user to adjust this mode for different Systolic and Diastolic pressures, different amplitudes, Adult and Neonatal patient types, and to change the simulated Pulse Rate of these simulated Blood Pressure waveforms. ***The support tabs are accessed by pressing the <Menu> button.***

D) Arrhythmia Tab

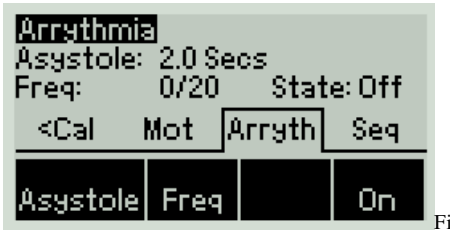

Fig. 8

By pressing <F1> the user may select Asystole so that it may be dialed from 2.0 sec to 8.0 sec in 0.5 sec increments. Pressing <F2> allows the user to select the frequency of activation of this feature from 1 to 19 out of 20 wave generations. Special wave generation is slated for v.1.2.7 and beyond and is not completed as of the writing of this document.

E) Auto Sequencer Tab

This feature is used in conjunction with an NIBP monitor that is set on repeat. As it repeats tests, the AccuPulse Handheld™ repeats the pressure wave for the same preset **RepeatCount** times when it is enabled. Also, if the NIBP monitor reinflates within the timeout period, the AccuPulse Handheld™ repeats this setting, assuming the last test was in error.

If the AccuPulse Handheld™ is in Adult mode, it rotates from the current adult setting DOWN to the first setting, then rolls over to the highest adult setting and finishes at the original setting. The same scheme occurs in Neonatal mode. The reasoning is that many monitors use an adaptive-inflation pattern, repeating the approximate inflation level from test to test. Increasing the BP Test Preset means these monitors will under-inflate, guaranteeing a timeout from test to test, causing many throwaway data sets to be introduced. Rotating downwards minimizes this potentiality to the maximum degree possible, guaranteeing much faster testing rounds than would be possible without this feature.

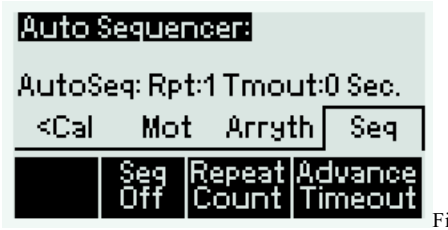

Fig. 9

Mode-Based BP Test Configuration Tabs

The two main modes of BP Test are Cal Table™ based and Generic Test Point based. The Generic Test Point Cal Table is treated the same as a normal Cal Table *except* that the user may purchase trim tabs for the User Test Point Cal Table (not available for normal Cal Tables) so that minor tweaking of the envelopes used for this table is allowed.

Cal Table™ Configuration Menu Tabs

A) BP Adjust Tab – from BP Test Screen, press <Menu>

The right arrow '>' in figure 10 indicates there is another Tab past the end of the screen. The fifth tab in this case is the **Amp** tab shown section d) below. When the user has tabbed past the **Shift** tab, there are now tabs to the left of the leftmost edge of the screen and so the first tab has a left arrow '<', indicating this situation. (See "d) Amp Adjust Tab" for a screenshot of this situation).

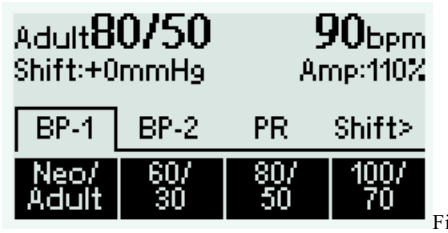

Fig. 10.

Pressing F-Key below the <Neo/Adult> icon of Figure 10 causes the mode to be toggled between Neonatal and Adult Modes. Pressing the remaining three F-Keys chooses one of three BP Presets for this patient type. Figure 3 shows the first BPTest tab for the **Plus** model. Because there are more than 3 presets for the **Plus** model, the **BP** tab of the **Lite** model has been expanded to tabs **BP-1** and **BP-2**.

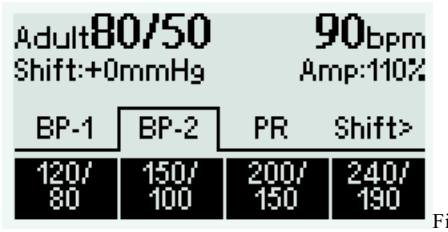

Fig. 11

Figure 11 shows the second BP Test tab for the **Plus** model. The remaining presets may be selected using the second BP Test tab by pressing keys <F1> through <F4>.

B) PR Adjust Tab - – from BP Test Screen

Figure 12 shows the Pulse Rate adjust tab for the **BP Test** Screen.

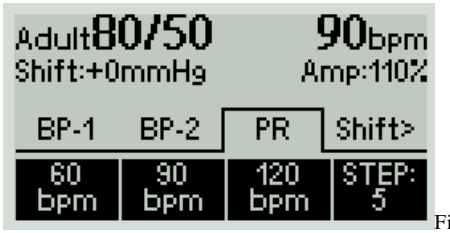

Fig. 12.

From this screen, the user adjusts the simulated pulse rate. Pressing F1-F3 selects the associated Preset (60, 90, or 120 bpm). Pressing F-4 changes the step from 1 to 5 to 10 to 50, and back to 1. Using the Up/Down keys, the bpm is adjusted by the value indicated by the **Step** icon above F-4.

Currently, BPM can range from 15 bpm to 330 bpm.

C) Shift Adjust Tab - – from BP Test Screen

Figure 13 shows the Pressure Shift Tab for the **BP Test** Screen.

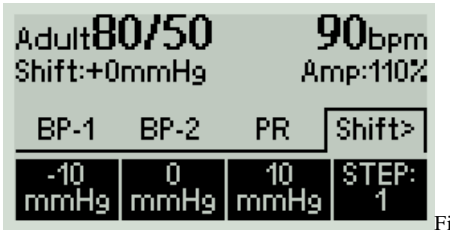

Fig 13.

As for the PR adjust tab, step changes the increment/decrement size. Up and Down keys perform the adjustment. Shift affects both the Systolic and Diastolic settings equally.

D) Amp Adjust Tab - – from BP Test Screen

Figure 14 shows Amplitude adjust tab for the **BP Test** Screen.

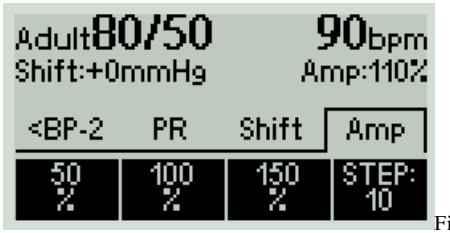

Fig. 14.

In the introductory model, Amp is limited to 100%. In the **Plus** model, amp ranges up to 150%

E) Generic Table Trim Tab - – from BP Test Screen (Generic Cal Table™ only)

Fig. 15

This Tab allows the user to trim the generic Generic Cal Table™ to make it conform better to a specific Manufacturer and Model of automated NIBP tester.

Generic Table Configuration Menu Tabs

A) Generic Adjust Tab – from BP Test Screen, press <Menu>

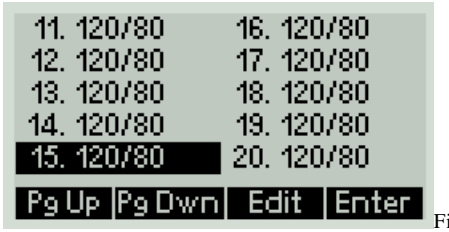

Fig. 16

This screen allows one of 45 User Test Points to be selected. Pressing Edit drops the user into the GENERIC Edit screen (Fig. 17 below). The left screen is the screen to adjust Sys, Dia, PulseRate, Amp, and patient type. Pressing the <Trim> button drops the user into the trim set mode of Fig. 17. The Up/Down arrows are used to perform the actual adjustments.

B) Generic adjust Screens

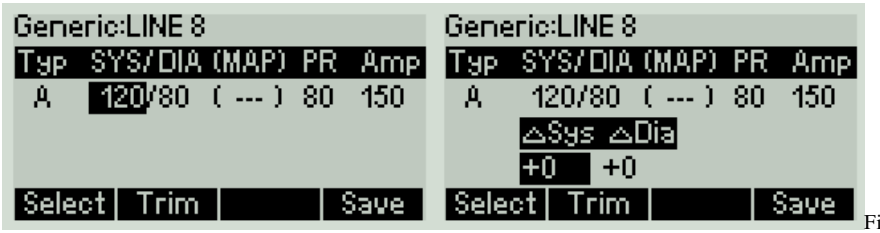

Fig. 17

2) Leak Test Mode

The user may check the leak rate of the **BP Monitor** and cable in this mode. Total leak rate measured is limited to 99mmHg. The measurement takes place over a predetermined period of time. Figure 18 shows the screen for this mode. It is in Auto Inflate mode by default.

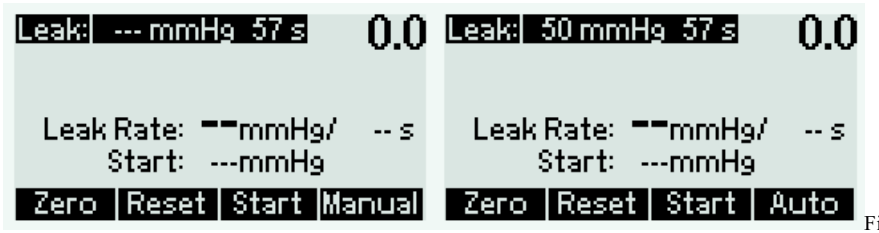

Fig. 18

To obtain manual leak test results, the user may press <F4> to enter manual mode.

The user may zero the pressure sensor by pressing <F1> so that any drift is removed. This also occurs automatically in the **Plus** model every minute. One of three preset pressures and duration may be selected from the Leak Test Configuration Tab. Pressing <Menu> brings the user into and out of the screen of fig. 19. Once a setting is selected from <Set1> through <Set3> buttons, the user may also dial up and down the target pressure from 50 to 300 mmHg and from 20 to 120 seconds in duration. The <Left> and <Right> butons switch from pressure to seconds and the <Up> and <Down> keys allow the user to dial up and down these parameters.

All three presets are remembered upon subsequent power ups. Notice that in manual mode, the target pressure, although it is preset, does not apply. *The pressure at which the user starts a manual Leak Test is the pressure that applies to a manual test.*

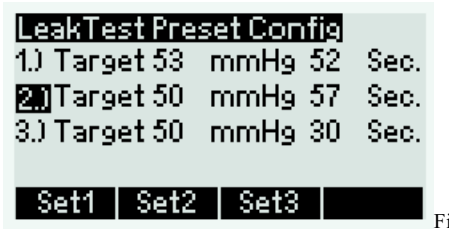

Fig. 19

Auto State

The dump valve is on so that pressure equalizes to zero while the test is idle.

The test commences after the <Start> key is pressed. This causes the pump to turn on, the dump valve to go off so that pressure is retained. Then, the pressure is inflated above the target pressure and then allowed to drift down to the target pressure defined by the selected preset. Once the target pressure has been reached, the test commences, measuring the drop in pressure over the preset number of seconds. ***Provided the user attaches a pressure volume (NIBP cuff or pressure chamber), achieving the target pressure is faster this way and more reliable than doing so manually.*** The test mode is changed to "Complete" and the resulting Leak Rate is displayed.

The <Reset> key stops the test, opening the dump valve.

Note: there should always be a pressure volume in-line with the AccuPulse Handheld™ and device under test. Either an NIBP cuff or a pressure chamber (such as Clinical

Dynamics' 250ml pressure chamber) should be used to perform this test. Changing volumes changes the meaning of the test. Because the total leak rate in (moles of air / minute) cannot be directly measured by this instrument, reasonable efforts should be made to standardize the total volume of air used in the test. Then, a leak rate of x mmHg / minute translates into a real leak rate, calculable in moles / minute. If the cuff hose is used without a pressure chamber, the same number of moles leak rate (with a chamber) per minute is proportional to a leak rate, scaled by:

(Volume Chamber + Volume Hose) / Volume Hose.

This can give leak rates of 50-100 times the leak rate with a chamber. Furthermore, the automated pressure algorithm will not work with arbitrarily small volumes. If the leak rate is desired at this higher precision, it must therefore be performed manually. Even here, the technician is cautioned to use the SAME volume every time; changing from an 8 foot to a 10 foot hose could change the test results by nearly 20 percent.

Manual State

The dump valve is off so that pressure is held while the user inflates the system to his/her desired test pressure.

In manual mode, the requirement for <Start> to trigger a measurement, pressure in the system must be greater than 10mmHg. The test takes place over a preset number of seconds and the result is shown after "Leak Rate:" when it completes and the pressure at the start of the test is shown after "Start:". A running test or a completed test may be reset. However, <Start> must be pressed to restart a test that is stopped while running.

3) Over Pressure Test Mode

This mode is used to determine the pressure at which a Non-Invasive Blood Pressure Monitor throws its safety valve. Damage can be done to the human body if cuff pressure exceeds a certain threshold. Monitors are designed to operate safely by automatically throwing a valve, no matter how high they are commanded to inflate in software.

For this test, the device under test is commanded to inflate and the **AccuPulse Handheld®** graphs the pressure for up to 120 seconds. This is more than sufficient to get a monitor to go into overpressure mode. When the overpressure valve releases, the **AccuPulse Handheld®** reports the maximum pressure achieved to the user on the screen in a window.

Because of the limited space available on the **AccuPulse Handheld®** screen, the result of the test (the maximum pressure achieved) may be toggled on and off by the <Toggle> button so the user may view the pressure waveform. As for BP Test mode, the <Up> and <Down> keys allow the user to change the pressure scale. To run a second test, the user presses <Reset> to clear the old result, then begins the next inflation.

Again, manual and automatic modes are included. Some NIBP monitors have auto-inflate to self-test their Over Pressure valves. Manual mode may be used when this is the case. Figure 20 shows the default (Auto) state for the OverP Test Mode.

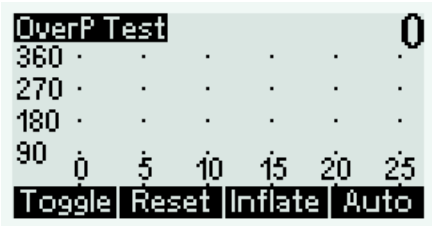

Fig. 20

Figure 21 shows the manual state for the OverP Test Mode screen.

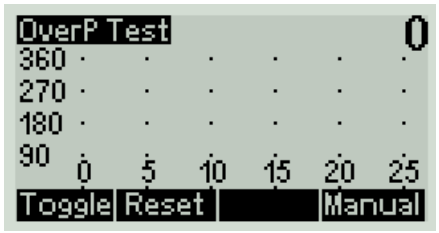

Fig. 21

Pressing the **<F4>** button toggles between these two screens.

Auto Mode

The pump offers much finer control of the target pressure and less bounce in pressure than the hand-inflation bulb does. Pressing inflate closes the dump valve and starts inflation. There are three possible outcomes:

- Timeout – test takes longer than 120 seconds.

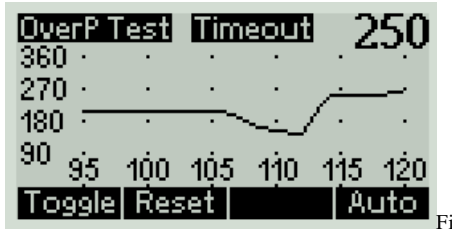

Fig. 22

- Over Pressure – inflation to > 400mmHg occurs.

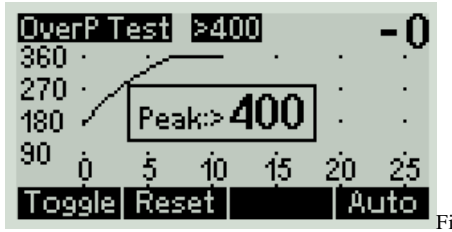

Fig. 23

- Valve Release Pressure Result (left is normal result, right is after pressing <Toggle> button

To turn off the peak display so more information can be seen.

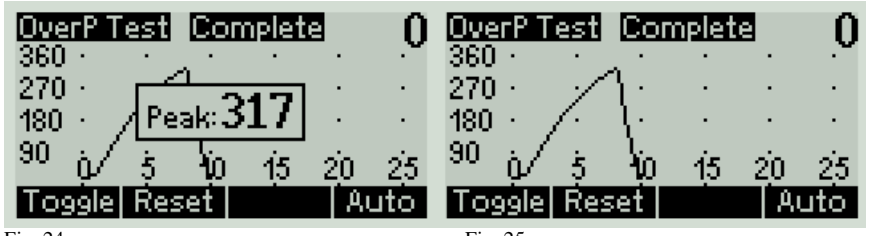

Fig. 24

Fig. 25

Manual Mode

Manual mode operates the same as Auto Mode except it is up to the user with an inflation bulb or an NIBP monitor with an inflate pump to provide the pressure. Instead of starting with the <Start> button, manual leak test starts as soon as the user pumps the pressure to greater than 10mmHg.

4) Meter Mode

This mode allows the user 0.1mmHg precision on the manometer (upper right corner of the display). The user may Zero the pressure sensor with the unit open to the atmosphere to remove any drift. The **Plus** and automatically Zeroes every minute any time pressure in the system is below 10mmHg. A valve vents pressure to the atmosphere so that any pressure in the system is released before the zeroing takes place. During the first 10 minutes after power-up, the zero level drifts, faster in the beginning, more slowly over time. Thus, the automatic zeroing is good if the device is on for several minutes, but the user may wish to manually <Zero> the pressure sensor during the first few minutes of device warm up before capturing data.

Fig 26

This mode is akin to a voltmeter. After <Reset> is pressed, Max. and Min fields track the maximum and minimum the pressure achieves in the system. Avg. is a moving average of the last 8 ¼ second samples (2 seconds).

Meter Mode Menu Tabs

The tabs hanging off the meter mode <Menu> button are one meter-specific tab (Units) and two general configuration tabs. As the general configuration tabs are used infrequently, they are attached to the last mode of the device.

A.) Set Language

Like BP Test Mode, Meter mode also has tabs hanging off it. By pressing <Menu>, one accesses the tabs. Set Language is the first tab in the series. Press **<Menu>** once from Meter Mode to access this tab.

Though <Meter> is not exactly indicative of the fact that adjustments are performed off this screen, it is the *last* screen, and is a logical place for such features to be located.

Fig. 27

If the user dials down using the <Down> arrow to “Espanol”, the language does not change. However, if <Set Lang> is then pressed, the <Set Lang> button becomes <Poner Leng>, or roughly, “Put Language”. The entire device then operates in the language selected. Figure 28 shows the BP Adjust Tab after changing the device language to Spanish:

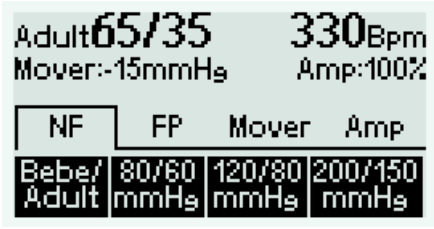

Fig. 28

This is true even upon subsequent power-ups. Hence, the device is inherently international. It may be shipped out of country in English, but a simple quick-start guide readily demonstrates how to change the language to the user’s language.

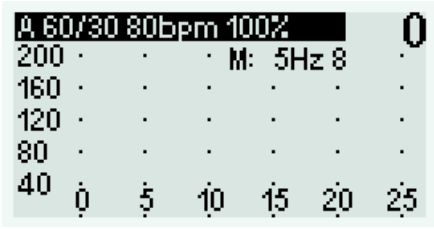

Fig. 29

B) Units

Every country and laboratory setting has a preferred set of pressure units. In the NIBP world, mmHg is the standard. However, the **ApHandheld®** device may be used as a +/- 1mmHg pressure meter in the preferred units for the given situation. This setting is remembered upon subsequent power-ups of the **ApHandheld®** device. The units supported at this time are:

- mmHg
- kpa
- cmH20
- psi

More can easily be added upon request in the future and will be supported through the Web-based software updater utility.

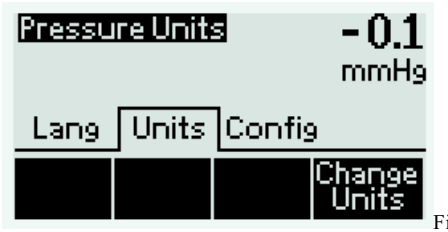

Fig. 30

By pressing **<Change Units>**, the user rotates between the four pressure modes. The precision manometer readout is used so that the user may see the result of the units change in the upper right corner of the device screen.

C) General Config Tab

As of 1.2.7, the only general configuration item is Sound. It is toggled on/off by pressing <F1> in this Tab (See fig. 31).

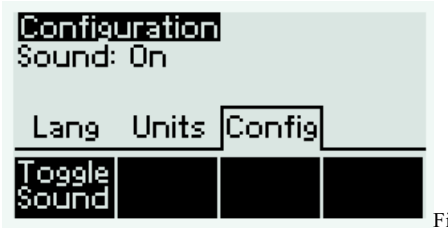

Fig. 31

Other features:

A) Battery

The condition of low battery is shown in figure 32. This is a blinking reverse-video bar that is drawn on the top text line of the display to indicate this condition. This is only the case for devices that have been upgraded with a battery. *This feature is under development as of 1-4-2008, the date this manual was written. It is in test, but not released to the public at this time.*

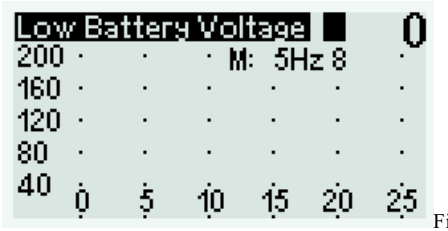

Fig. 32

AccuPulse® Handheld Remote Control Guide v.1.2.7

I. Overview:

The aim of the remote control on the **AccuPulse® Handheld** device is to adhere as closely as possible to the remote control spec of the legacy TruePulse® and AccuPulse® remote control commands. That is, typically, commands and command feedback are accompanied by similar syntax.

There exists in **AccuPulse® Handheld** devices a single-character command set that will likely become obsolete. At the moment, key tools for programming and verifying devices still use these single-char commands. *Thus, they will remain until the tools are changed to use the formal remote control syntax outlined in this document. The single-char commands precede this document.*

The single character and multi-character commands can be separately enabled to keep them from interfering with each other.

II. Terms and Syntax:

The syntax and action of most commands reflects their development with a terminal program (Typically Hyperterm). A packet protocol could have been used, but this approach was not adopted. To support legacy syntax, the terminal interactivity remains. (This is an aid to those debugging code to drive the device.)

<CR> = carriage return = character 13

The remote control syntax is that of an HTML-style tag wrapping each command name and a carriage return:

<COMMAND_NAME> <CR>

In order that differing terminal protocols may be supported, the remote control parser filters, <LF>s (character code 10 decimal) out of the stream. Thus, <CR> works the same as <CR> <LF>, which is sent by many terminal programs and terminal modes.

The prompt returned by the **AccuPulse® Handheld** is:

>

There are, furthermore, several return codes that may precede the prompt. These only apply to multi-char commands that the customers will use. Single character commands (not the subject of this document) may or may not give a response. The responses are:

COMMAND RESPONSES:

- '=' – command executed successfully.
- '#' – data or parameters were out-of-range for the given command.
- '*' – command not usable in the current mode. Set-preset command only operates in **BpTest** mode, for instance. Some commands require a purchased upgrade, etc.
- '?' – COMMAND_NAME is not recognized as a valid command.

- '$' – checksum error in data that was sent.
- '@' – data has overflowed (data was truncated to prevent a memory leak), or bad place in Memory was pointed to.

The software that drives an **AccuPulse® Handheld** must process all these return characters.

III. Using Single and Multi-Char Commands

As noted above, single-character commands are used in the programming and verification tools for the **AccuPulse® Handheld** devices. *These commands are not intended for direct use by customers and will be converted to the formal remote control (multi-char) protocol. When users utilize the updater program, at this time, the device is left in single-char mode, so it is important to distinguish the two modes from each other.*

The original method for starting up remote control is (and what the updater utility uses):

<START_COMMS> <CR>

However, this mixes single-char and multi-char commands. Single-char commands override the multi-character remote control parser, making for some ugly and unexpected results. Thus, if the user types

COMMAND_NAME <CR>

By accident, rather than:

<COMMAND_NAME> <CR>

Then the single-char commands for:

'C', 'O', …

are *all* executed.

The commands outlined in this document are enabled with the following command:

<> <CR>

This starts up **multi-character** commands *without* enabling single character commands.

IV. Argument versus Argument-less commands

Commands that take arguments give their arguments as Carriage-return delimited text:

Sent:
<ARGUMENT_COMMAND> <CR>
ARGUMENT1 <CR>
…
ARGUMENTN <CR>
Received:
= <CR>
>

Sent:
<ARGUMENT_LESS_COMMAND> <CR>

Received:
['=', '#', '*', '$', '@', '?'] <CR>
>

Note: Synch on the '>' character (prompt character) to indicate a command completed. The character and <CR> before the prompt is the command-response status.

V. Using Remote-Control with Hyperterminal

In Hyperterm, set up ASCII with:

<File> ◊ <Properties> ◊ <Settings> ◊ <ASCII Setup>

- Send Line ends with line feeds
- Echo Typed Characters Locally

The speed, stop bits and parity are arbitrary, as the AccuPulse® Handheld uses a virtual comport. In-house, 921600 baud is used, although it may not be necessary.

VI. Commands Supported from version 1.2.5

Note: Customers do not have access to starred (*) commands.

Highest Level Commands – starting remote, identifying devices

A.) Start Remote Control:

Send: <> <CR>

Recv: <USB_MULTICHAR_COMMS_STARTED>
>

B.*) Set Serial Number (This must be set at the factory before shipments take place).

We track devices by their serial number and encrypt data sets and software upgrades using the serial number. For this reason, devices must all have a UNIQUE ID and the <SET_SERIAL>NUM> command is used to set this ID.

Send: <SET_SERIAL_NUM> <CR>
[10-digit serial-number] <CR>

Recv: '=' on success
'#' if number is too short or long or id is already set.
'@' if greater than 200 digits is received.

There is a way to clear the serial number; the user calls <SET_SERIAL_NUMBER> with the serial encrypted (OLD_SERIAL_NUMBER). This is reserved for in-house factory use only. If we have a dead device, we can re-program the serial number and salvage the CPU, for instance. There are few cases where this will be desirable.

C.) Get serial Number

Send: <GET_SERIAL_NUM> <CR>

Recv: On Success:
AH08070006 <CR>
'='
On Failure: (If serial number has not been set.)
'*' <CR>

By CDC convention, AH = AccuPulse® Handheld, 0907 = Sept. 2007 release, and 0006 means device #6. (Handheld software releases began in August 2007.) Overhauls of the software in any major way will cause 0907 to change to the new release month.

D.) Set Device ID

Note: ***This command is given for convenience to the end-user. There exists a utility, distributed for free by FtdiChip.com called*** **MPROG.EXE** ***that allows the USB chip inside the AccuPulse® Handheld device to be programmed with a custom device id. Programmers using FTDI's API may use this to identify devices. This is simpler than opening the port then querying the device. The user does not even have to open the port if it's not the device they are looking for; the ID is exposed through the API.***

This allows users to set their device ID so that a group of them may be controlled remotely. Software configured to control a group of devices can requisition each device for its informal name (or a more formal ID, such as "Factory1", for instance). This way, it does not matter which USB port is used to communicate with a device, even if it is on a Radio-linked USB hub; it just matters that we know which device ID we are talking to. Some users will prefer to ask for the serial number to determine which device is which.

Send: <SET_DEVICE_ID> <CR>

Recv: '=' <CR> - on success
'@' <CR> - on overflow.

E.) Get Device ID

Send: <GET_DEVICE_ID> <CR>

Recv: "Sparky" <CR> – if device id has been set
"*" <CR> – if device id has not been set

NIBP Test Commands – setting and requisitioning BP Parameters

F.) Set BP Preset:

Lite models have presets 1..6, **Plus** and **Pro** have presets 1..13.
For **Lite** models, 1..3 = adult presets 1..3, 4..6 = neo presets 1..3
For **Plus** and **Pro** models, 1..7 = adult presets 1..7, 8..13 = neo presets 1..6.
This selects a preset for the **AccuPulse® Handheld** to simulate with. The pair specifying the preset is:

AdultMode , Preset

Where Adult is: 1=Adult, 0=Neonatal
Preset is: [1..3] for Lite, [1..6] for Neonatal Plus, [1..7] for Adult Plus.

Send: <PRE> <CR>
[0..1],[1..7] <CR>

Recv: '=' – success
'*' – device is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)
'#' – preset out of range.

G.) Set PR

Set PulseRate from 15 to 330 Bpm.

Send: <SET_PR> <CR>
[15..330] <CR>

Recv: '=' – success
'*' – device is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)
'#' – pulse rate is out of range.

H.) Set AMP

Configure the Pulse amplitude from 0 to 100% of normal. In the future, with bigger power supplies, this may be expanded to the legacy **AccuPulse®** range of 0..200%.

Send: <SET_AMP> <CR>
[0..100] <CR>

Recv: '=' – success
'*' – device is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)
'#' – amplitude is out-of-range.

I.) Set SHIFT

Configure the shift of the BP Preset envelope from -100 to +100 mmHg. This is trimmed in from here because there are physical limits (a BP Envelope having a Diastolic pressure of 50 cannot be shifted down greater than 50 mmHg, for instance).

Note that this command returns the greatest shift achievable in the direction requested, performs the change, then returns the actual shift value before the '#' (out-of-range) token is delivered.

Send: <SET_SHFT> <CR>
[0..100] <CR>

Recv: '=' – success
'*' – deVice is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)
32 <CR>
'#' – shift is out-of-range; actual shift performed was 32 mmHg, not the value that was requested.

J.) Get BP Parameters

This command dumps a summary of all the parameters governing a BP Test:

Send: <GET_BP_PARAMS> <CR>

Recv: (On Success)
PRESET_TYPE, BP
PATIENT_TYPE, 1
PRESET, 2
SYS, 100
DIA, 70
PR, 65
SHIFT, 0
AMP, 150
>

'*' – Not in BPTest Screen or Tabs; does not apply.

Calibration Table Commands:

AccuPulse® technology is driven with calibration tables. Typically, there is a table per Manufacturer and Device Type. Cal Tables other than table 46 (see below) are purchased upgrades to the device. There are standalone tools as well that can assist manufacturers in making their own Calibration Tables.

K.) Set Cal Table

Cal Tables have 13 envelopes; 7 adult and 6 neonatal. By setting the Cal Table with this command, all 13 envelopes are associated with all 13 preset buttons of the device. Also, each envelope may be overwritten with the <LOAD_ENVELOPE> command to customize the tables. Typically, this is done at the factory or through an updater program in the field, but users may write their own program to drive these tables.

Currently, 24 Cal Tables are supported in the **AccuPulse®** product line, and the **AccuPulse® Handheld**, due to a larger flash memory, supports up to 45. The user has to purchase (or create their own) additional Cal Tables in order for this command to have a meaningful effect. Cal Table 46 is the default Cal Table and is non-proprietary. It is generic. Every device is set to Cal Table 46 at the factory by default and is shipped with this generic table. ***The generic table matches no device in particular; it is simply a best-fit for all monitors tested by the AccuPulse® Handheld device. No attempts have been made to make it match any manufacturer, nor any particular model of any manufacturer.***

Note: Until all 13 presets of a given Cal Table are set, the user will not be able to select that Cal Table. This is important for those who will make their own Calibration Tables. They need to store all 13 envelopes, even if they have the same data in them, in order for this command to allow them to select their new Cal Table.

Send: <SET_CALTABLE> <CR>
[1..46] <CR>

Recv: '=' – success
'*' – device is in the wrong mode for this command (must be in BP Test Mode or BP Adjust Tabs)
'@' – bad data in this cal table (for tables that were never populated or populated with bad ranges). Users should not rely on this command as a validity check for Cal Tables they write themselves. This command is meant to identify never-before-written tables.
'#' – out of range.

L.) Set Make / Model

This command allows the user to set the name fields of any Cal Table™. The command is used as follows:

Send: <SET_MAKE_MODEL> <CR>
TABLE_NUM<CR>
UP_TO_14_CHARS_MAKE <CR>
UP_TO_14_CHARS_MODEL<CR>
SHORTHAND_MODEL<CR>

Recv: '=' – success
'*' – device is in the wrong mode for this command (must be in BP Test Mode or BP Adjust Tabs)
'@' – names too long
'#' – out of range (table num not 1..45)

M.) Store Envelope

As stated above, each Cal Table™ has 13 presets. Typically, all presets must be defined in order for the AccuPulse® Handheld to behave properly. For this reason, all manufacturer tables come with all 13 presets. The driver program, which loads these tables into the AccuPulse® Handheld, is freeware with open source code that manufacturers may freely copy to expedite their programming efforts. *There is an envelope editor that can be purchased that facilitates dragging, stretching, adding and deleting points from envelopes. This program greatly assists the envelope creation process. It outputs envelope files in a format downloadable by Hyperterminal or the envelope driver program.*

Some of the presets (envelopes) are invalidated by setting their Systolic field to a 0. This is the case where the monitor the table has been made for has no preset of that denomination (Neonatal 35/15 is missing on many monitors) or in the rare case where a best fit has never been found. ***This is important information for the programmer who will use this remote interface or the freeware program:***

- ***Define all 13 envelopes***
- ***Invalidate entries with a 0 in the Systolic field if they have not been created yet.***
- ***Careful: If ALL entries have 0 Systolic, the user will not be allowed to switch to this Cal Table by the <SET_CALTABLE> command.***

This command sets the amplitude envelope for a single preset of one Cal Table™. Envelopes are defined over the 0 to 300 mmHg range of the pressure waveform. The envelope is specified as (Delta Pressure, Amplitude) pairs. Up to 30 pairs may be specified. Delta Pressure entries MUST sum to 300 (table calibration is from 0..300 mmHg). The reason for this is that the legacy SmartArm® and AccuPulse® devices lacked sufficient memory to store all 300 points.

Parameters:

Cal Table	= 1..45 (46 is Special table and is not allowed to be overwritten)
Env Num	= 1..13 (1..7 = adult presets, 7..13 = neonatal presets)
Sys	= 0 (invalidate entry) or 35 .. 275 mmHg
Dia	= 15 .. 250 mmHg
Map	= # between Sys and Dia (arbitrary or typically = Dia + (Sys-Dia)/3).
Pr	= 15 .. 330 bpm
DeltaP	= 1 .. 255 (for legacy compatibility; legacy used one byte to represent this information)
Amp	= 0..32768 (for legacy compatibility; 16 bit word was used, amp of 200% makes effective amplitude nearly 65535 (all 16 bits).

Send: <STORE_ENVELOPE> <CR>
[128-BIT HEXADECIMAL KEY] <CR>
CALTABLE, ENV_NUM <CR>
SYS, DIA, MAP, PR <CR>
DELTAP1 , AMP <CR>
…
DELTAPn , AMP <CR>
0 <CR>

Recv:

'=' - success
'*' – device is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)
'#' – bad parameter
'@' - overflow

N.) Store Utp

This command has no effect if the user has not purchased the User Test Points upgrade. There are 45 User Test Point presets which may be selected by the user. All presets are programmed at the same time (one big data set is sent). Attempts to send less than the entire data set will cause the command to fail with '#' bad parameter / data out-of range token.

The data body of this command consists of 45 text lines (carriage-return delimited) each with the following fields. The fields are separated with commas. The last field is optional (Utp Preset "Name" field)

Parameters:

Adult/Neo	1 = adult, 0 = neo
Systolic	[35..275] mmHg
Diastolic	[15..250] mmHg
Map	Systolic > Map > Diastolic
DeltaSys	[-25..25] mmHg
DeltaDia	[-25..25] mmHg
DeltaMap	[-25..25] mmHg
EnvShift	[-50,50] mmHg
PulseRate	[15..330] bpm
Amp	[0..150] percent of nominal amplitude
SysTrim	[-25..25] mmHg
DiaTrim	[-25..25] mmHg
MapDrim	[-25..25] mmHg
Notes	Up to 20 text characters

Send: <STORE_ENVELOPE> <CR>
[128-BIT HEXADECIMAL KEY] <CR>
1,120,80,97,120,80,97,0,80,100,0,0,0 [,Optional Notes 1]
…
1,120,80,97,120,80,97,0,80,100,0,0,0 [,Optional Notes 45]

Recv:

'=' - success
'*' – device is in the wrong mode for this command (must be in BPTest Mode or BPAdjust Tabs)

'#' – bad parameter
'@' - overflow

O.) Add Feature

Until the web scripts have been updated to support on-line purchases, this is used to activate purchased add-ons. It is also embedded in a standalone utility used at Clinical Dynamics Corporation that will be made available to users.

Each feature must be enabled separately, so that for 2 feature upgrades, users must run this command twice with the 2 keys sent to them following the completion of their transaction.

Send: <FEATURE> <CR>
Encrypted [BIT-FIELD] <CR>

Recv: '=' – success
'#' – encrypted command does not match Encrypted "PLUS", etc.

Virtual Control of Handheld Devices

With the following commands, the user may update screenshots (not quite real-time, but quickly) and push panel buttons to a device in a lab without having to be at the device.

In the future, commands to update just the UI elements that are necessary will be included. At the moment, there IS a streaming manometer (every 250 mSec) from the device that can be used to graph data. Updates to the screen, however, such as button name changes, title label changes, and plots are not sent out the remote interface. This will eliminate the need to grab an entire screenshot to see what the device is doing.

N.) Hex Screenshot:

Upload hex screenshot data. This is more suited to the APH_Booter and AccuPulse® User-Defined Test Points Manager software, as they assemble this data into pictures automatically. These pictures may be printed and saved from the software packages. This command is included in case customers wish to display the pictures of screenshots in *their* software packages.

- Data is in format first byte first, last byte last and is in hexadecimal format.
- Every 8th hexadecimal BYTE is followed by a <CR> for readability when in hyper terminal.
- If a byte is < 16, the number is " n", not "0n".
- A screen is 1024 bytes arranged 128 bytes per row for 8 rows. (8 vertical pixels per byte).

Send: <HEX_SCREENSHOT> <CR>

Recv: 0 0 1 1 1 1 0 0 <CR>
ffab 1 1 1 1baff <CR>
…
0 0 1 1 1 1 0 0 <CR>

O.) Binary Screenshot:

Upload binary screenshot data. This is more suited to the APH_Booter and AccuPulse® User-Defined Test Points Manager software, as it allows for much faster updates than with hex screenshot. This command is included in case customers wish to display the pictures of screenshots in *their* software packages.

- Data is in format first byte first, last byte last and is in ***raw binary*** format.
- A screen is 1024 bytes arranged 128 bytes per row for 8 rows. (8 vertical pixels per byte).

Send: <BIN_SCREENSHOT> <CR>

Recv: 1024 binary bytes

P.) Panel Button

Allows for a virtual-press of a panel-button:

Send: <BUTTON> <CR>
[BP, LEAK, OVERP, METER, F1, F2, F3, F4, UP, DWN, LEFT, RIGHT, MENU] <CR>

Recv: '*' - Bad mode; can't react to button.
'=' – Button processed OK.

Q.) Remove Feature

No one may ever wish to do this, but here it is. The only envisioned reason is a roll back of a feature that positively interferes with the proper functioning of the AccuPulse® Handheld software when enabled.

Send: <FEATURE_OFF> <CR>
SessionId <CR>
Encrypted [BIT-FIELD] <CR>

Recv: EncryptedResultToken <CR>
'=' – success
'#' – encrypted command does not match Encrypt "FEATURE", etc.

The inclusion of a SessionId along with an encrypted result token allows the web script to credit users who have removed a feature if they have a money-back guarantee agreement with the sales department. The user cannot order the feature again and only pretend to remove it by faking the transaction. Also, users may save the SessionId for their records as verification that their account needs to be credited.

Commands for 1.2.8 and beyond (in progress)

R) Store Secure Envelope

The syntax here is the same as for <STORE_ENV> except that the data field is encrypted. The usage is:

Send: <STORE_SEC_ENV> <CR>
[128-BIT HEXADECIMAL KEY] <CR>
CAL_TABLE, ENVELOPE <CR>
[ENCRYPTED HEX DATA – SINGLE TEXT LINE] <CR>

Recv: '=' – success
'#' – Crypto Key, Cal Table, Envelope, or parameter in the encrypted data is out of range.

S) Store Secure Utp

The syntax here is the same as for <STORE_ENV> except that the data field is encrypted. The usage is:

Send: <STORE_SEC_ENV> <CR>
[128-BIT HEXADECIMAL KEY] <CR>
CAL_TABLE, ENVELOPE <CR>
[ENCRYPTED HEX DATA – SINGLE TEXT LINE] <CR>

Recv: '=' – success
'#' – Crypto Key, Cal Table, Envelope, or parameter in the encrypted data is out of range.

T) Verification of data

If the data was sent to the user, it is encrypted, and the 'VERIFY_SEC' verify commands are used.
If the data was created by the user, it is unencrypted, and the 'VERIFY' commands are used.

As with the secure store commands, these commands have the same syntax as <STORE_ENV>, <STORE_UTP>, <STORE_SEC_ENV>, and <STORE_SEC_UTP>.

<VERIFY_ENV>
<VERIFY_UTP>
<VERIFY_SEC_ENV>
<VERIFY_SEC_UTP>

Recv: '=' – success; data in device MATCHES data in command.
'#' – data in device does NOT match data in command