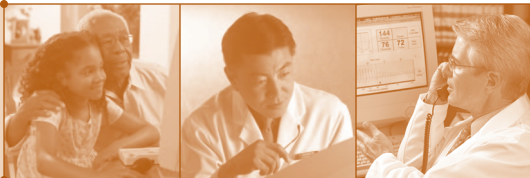




200M Home for Windows

USER'S
GUIDE



DYNAPULSE 200M >>>>

TO Professional DP-200M USERS:

For your reference, this User's guide describes the hardware and software functions and features of DP-200M/Home with RS232 communication.

USB DP-200M users shall follow the Quick Guide instructions to install USB drivers and software, and use USB connection instead.

USB DP-200M is powered via USB, NO Battery is required.

USB DP-200M supports only Windows 98SE, 2000, Vista and Win-7. Please skip the descriptions of RS232, battery & Win-95/98 in this manual.

To help your patients tracking their blood pressures at home, you are welcome to distribute this material to them for hypertension education.

DynaPulse USB 200M/Home BP monitoring & recording system is available. For more information, please visit DynaPulse website at www.dynapulse.com

PULSEMETRIC[®] INC
INNOVATIONS FOR A HEALTHIER WORLD.™

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POTENTIAL FOR RADIO AND TELEVISION INTERFERENCE

This equipment generates and uses radio frequency energy and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference with radio and television reception. It has been tested, together with a certified Class B computing device Personal Computer, in accordance with the specifications of Subpart 15 of FCC Rules, which are designed to provide reasonable protection against interference in a residential installation. Operation with non-certified computers is likely to result in interference with radio and television reception. Note that this equipment may be compatible and can be used with Class A computers. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference with radio and television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference as outlined in the User's Manual for the host computer, with the following measures: 1) reorient the receiving antenna; 2) relocate the unit with respect to the receiver; or 3) move the unit away from the receiver.

If necessary, the user should consult the dealer or an experienced radio/television technician for additional suggestions. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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Introduction

Thank you for purchasing the DynaPulse. To use this system correctly and safely, read this manual carefully before operating the DynaPulse. Retain this manual together with the DynaPulse for future reference.

NO MEDICATION CHANGES SHOULD BE MADE BASED ON INFORMATION PROVIDED BY THE DYNAPULSE SYSTEM WITHOUT FIRST CONSULTING A PHYSICIAN.

The DynaPulse non-invasive blood pressure system is based on a unique *oscillometric* technique, known as Pulse Dynamics. This technology allows clinically accurate measurements to be obtained quickly and easily.

Indicator Used in this Manual



Used to call your attention to an important feature of the system, or system software.

This manual is a guide to installing and using the DynaPulse blood pressure recording system. Pulse Metric recommends that all users read this manual *before* they begin using the DynaPulse.

Blood Pressure Defined

Blood pressure is defined as the force generated by the blood as it flows through the arteries. The heart pumps the blood through the arteries, which act as "pipes" to carry the blood away from the heart. This pumping action causes the blood pressure to rise and fall. When the heart is contracting (pumping), the blood pressure rises, and when the heart is relaxing (not pumping), the blood pressure falls. The highest blood pressure achieved in a single cycle of contraction and relaxation of the heart is *systolic pressure*. The lowest pressure during a single cycle is *diastolic pressure*. Blood pressure is usually recorded in units of millimeters of mercury (mmHg), and read with the systolic pressure first. For example, "120 over 80" indicates a systolic blood pressure of 120 mmHg and a diastolic pressure of 80 mmHg. Since blood pressure is so strongly related to the heart, blood pressure is used as a general index of cardiovascular performance.

How Is Blood Pressure Measured?

There are many methods for measuring blood pressure. The most accurate method requires the surgical insertion of a catheter into the patient's artery. The catheter is equipped with a pressure sensor, which measures the patient's blood pressure directly. These measurements are considered the "gold standard" for blood pressure measurements. However, most patients do not want blood pressure measurement to be a surgical procedure! Therefore, indirect methods were devised to allow safe, quick blood pressure measurements. *The goal of every indirect method is to achieve measurements that agree with catheter-based measurements.*

The most common method for obtaining blood pressure is the **auscultatory** method. In this technique, a cuff is wrapped around the patient's arm, and the physician (or nurse) inflates the cuff, then places a stethoscope over the arm as the cuff deflates. The physician is listening for certain characteristic sounds (known as Korotkoff sounds) to determine systolic and diastolic pressure. The sounds are created by blood flow in the artery. This method is very reliable, but extensive training is required to ensure accuracy. In addition, differences in hearing ability may cause variability between measurements taken by different people on the same patient, *even if they were taken at the same time!* This method has also encountered difficulty when patient conditions, such as hypotension (i.e. low blood pressure), mute or damp the Korotkoff sounds. These difficulties prompted the development of the **oscillometric** technique, which does not rely on a microphone. The technique requires a cuff and a pressure sensor. Instead of listening for characteristic sounds, oscillometric devices examine the *pressures* generated by the cuff and the arterial pulsation to estimate blood pressure. The estimations are based on large amounts of data, and are usually accurate, *but they are still estimations.*

Pulse Dynamics, the patented DynaPulse technology, also measures the pressures generated by the cuff and the arterial pulsation. However, it is the only oscillometric method to measure blood pressure *based on physical phenomena*, much like the auscultatory method. Instead of estimating blood pressure, Pulse Dynamics uses pattern recognition to determine systolic, diastolic, and mean arterial pressure from the Pulse Dynamic pressure waveform. This pattern recognition technique is possible due to the effect that blood flow has on the measured pressures. *Pulse Dynamics agrees extremely well with catheter-based "goldstandard" measurements.*

What Is Mean Arterial Blood Pressure?

Mean arterial pressure is the average pressure in the artery over time. High pressures cause the artery to bulge, like a balloon when it is inflated. At very low pressures, the artery actually bends inward slightly. The forces generated by the velocity (speed) of the blood flow pull the arterial walls inward at these low pressures.

Mean arterial pressure corresponds to the state when the arterial wall is not distended inwardly or outwardly. The forces due to blood pressure are in balance with the forces caused by the arterial wall and the blood flow. By determining mean arterial pressure, we actually determine the pressure required to balance the arterial wall forces. Mean arterial pressure is often used in clinical studies, but no standards have been published regarding its role in the diagnosis of hypertension.

Facts About Hypertension

Hypertension is described as a persistently elevated blood pressure that exceeds predetermined thresholds. The Sixth Report of the Joint National Committee on Detection, Evaluation, and Treatment of Hypertension estimates that 50 million Americans have blood pressures that consistently equal or exceed 140/90 mmHg, and are therefore at increased risk for developing cardiovascular diseases such as coronary heart disease and peripheral vascular disease.

"A blood pressure may vary with the time of day, or whether one stands, sits or lies down. Thus, for any individual, there are variations in blood pressure from one time to the next. As a general rule, the upper limit for systolic blood pressure is 140 mmHg, and the upper limit for diastolic blood pressure is 90 mmHg. Younger people have lower blood pressure than this, elderly people typically have higher pressures. The '140 over 90 mmHg rule' is only a rough estimate."

*Dr. J. Howard Pratt, M.D. ,
Hypertension Research Center, Indiana University School of Medicine,
Indianapolis, Indiana.*

Symptoms of hypertension

Headaches, dizziness, and other easily detectable symptoms have no proven correlation with hypertension. As a result, diagnosing the disease in the absence of blood pressure data is difficult.

Hypertension as a risk factor for cardiovascular disease

Hypertension increases the risk for developing many cardiovascular diseases, including atherosclerosis and left ventricular hypertrophy. Other risk factors for cardiovascular disease include: smoking, diabetes mellitus, lack of exercise, and excessive alcohol intake.

Hypertension management

Mild cases of hypertension can be treated effectively by non-drug therapies. Non-drug therapies usually consists of lifestyle changes aimed at weight reduction, sodium intake reduction, reduction of alcohol consumption, and increased cardiovascular fitness. Over a long period of time, these lifestyle changes can be effective as a method of therapy.

Many cases, however, require intervention with drug therapies. There are many different methods to reduce blood pressure with drugs. It is common for a physician to prescribe several different medications, each of which acts in its own way. A type of drug that works well for one patient often doesn't work for another. Therefore, it is important to follow the treatment plan laid out by the physician.

The DynaPulse Blood Pressure System

The DynaPulse unit is a data acquisition and communication device. It senses the pressure caused by the application of the cuff and the arterial pulsation, digitizes the pressure data, and sends it to your personal computer. The DynaPulse is linked to the computer and its software by the communications cable. **All of the data is stored, displayed, and analyzed on your computer.**

Tips for an Accurate Blood Pressure Measurement

Unlike body temperature, a person's blood pressure is not constant, and often varies from measurement to measurement. The following suggestions will improve the quality of blood pressure measurements.

- Patients should rest and relax for at least 5 minutes before their blood pressure is measured.
- Save blood pressure data for future reference. Readings should be taken before the patient has eaten.
- Take two or three measurements each time and record the results. **DO NOT RELY ON A SINGLE MEASUREMENT.**
- When taking repeated measurements, deflate the cuff and elevate the arm. Allow 1-3 minutes between measurements to ensure normal circulation is restored. Make sure that the cuff is not wrapped around the arm too tightly. The cuff should be snug around the arm when there is no air in the cuff.

- Repeated deep breaths, coughing, sneezing, and talking may affect the reading. The patient should relax and remain motionless during each blood pressure measurement.
- A rolled-up sleeve may constrict blood flow through the arm. Putting all or part of the cuff on top of a sleeve may affect the reading's accuracy as well.
- Blood pressure may be higher after exercise, when under emotional or physical stress, after drinking coffee or tea, or after eating. In general, any circumstance leading to an increase in heart rate tends to cause blood pressure to rise.
- The cuff must be the correct size for the patient's arm. Refer to the Appendix for guidelines on determining correct cuff size.

System Requirements

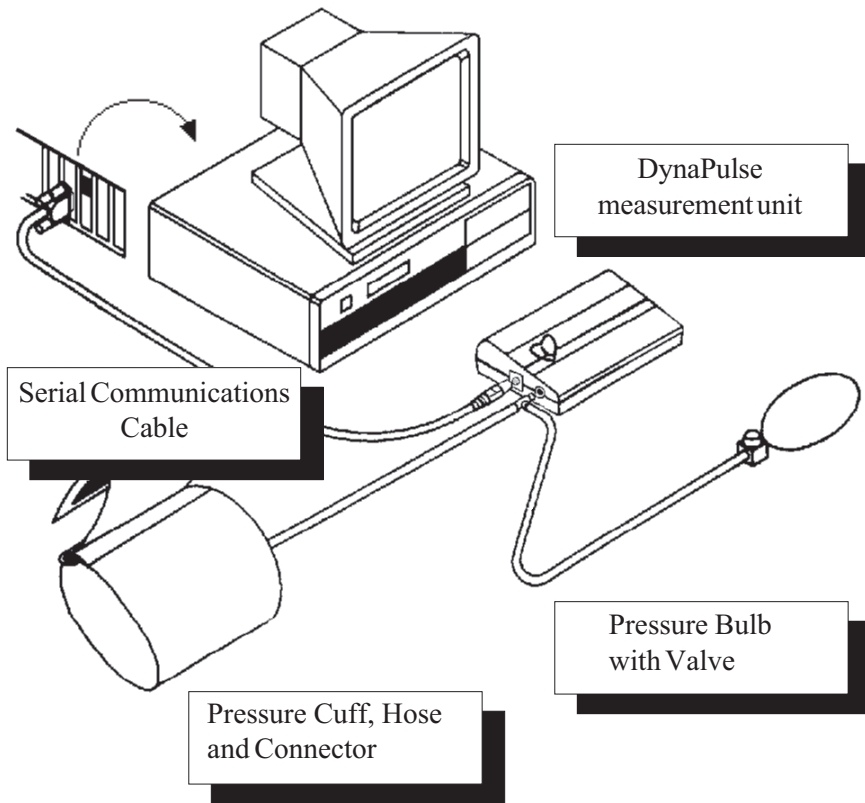
To operate the DynaPulse, you will need the following equipment:

- 80386 or higher IBM, or IBM compatible computer with 2 Mb of RAM, a hard disk drive, and a CD-ROM/floppy disk drive.
- Windows 3.x running in standard or enhanced mode, or Windows 95/98, NT, 2000 or XP.
- An RS-232 serial communications port, independent of ports incorporated by other serial devices, like mouse pointers or serial printers (see Appendix).
- The DynaPulse software.

The DynaPulse manual pump system is comprised of the following:

1. The DynaPulse unit
2. Standard adult blood pressure cuff
3. Air hose with pressure bulb and connector
4. Communication cable
5. DynaPulse software
6. This User's Guide

Equipment Layout



Installing the Batteries

Open the battery cover by pressing slightly downward while sliding the cover in the direction shown on the cover. Install four (4) AAA batteries in the direction indicated on the inside of the battery case.

Connecting the DynaPulse to the Computer

Connect the RS-232 cable from your computer's serial communications port (hereafter referred to as the COM port) to the DynaPulse unit. If your COM port uses a 25 pin connector, use a 9 to 25 standard pin adaptor. Do not connect the DynaPulse unit to any other port. Only COM ports adhering to RS-232 standards can be used.

Backing Up the System CD/Diskettes

It is strongly recommended that you make a backup CD/diskette of the DynaPulse system CD/diskette and use the backup to install the program. Please refer to the Windows *User Guide* for instructions on copying CDs/diskettes.

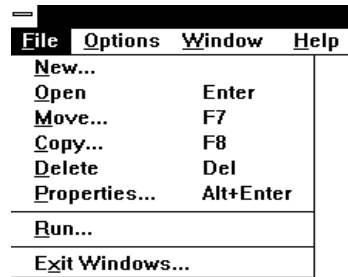
Installing the Software

CD Installation

Put your DynaPulse CD in drive D. The Installation program should automatically start shortly after the CD-ROM drive is closed. If not, from the Program Manager in Windows (or from the Start menu in Windows 95/98, NT, 2000 or XP), select the Run...option. In the Run dialog box, enter

D:setup

then click OK. If the drive letter is different than the one shown in this example, enter the correct drive letter.



File	Options	Window	Help
<u>N</u> ew...			
<u>O</u> pen		Enter	
<u>M</u> ove...		F7	
<u>C</u> opy...		F8	
<u>D</u> elete		Del	
<u>P</u> roperties...		Alt+Enter	
<hr/>			
<u>R</u> un...			
<hr/>			
<u>E</u> xit Windows...			

3.5" Floppy Disk Installation

Put your DynaPulse backup diskette in drive A. From the Program Manager in Windows (or from the Start menu in Windows 95/98, NT, 2000 or XP), select the Run...option. In the Run dialog box, enter

A:setup

then click OK. If the drive letter is different than the one shown in this example, enter the correct drive letter.

If you have a previous version of DynaPulse installed on your hard disk and want to maintain the same measurement files created with that version, enter the drive and directory path where the original program files are stored when the installation utility asks for the installation path. **Do not delete the previous files.**

The Main Menu

File Edit User Measure Trend Record Options Window Help

File

- Save Ctrl+S
- Print
- Print Page
- Quit Ctrl+Q

Edit

- Undo
- Cut
- Copy
- Paste
- Clear

User

- Add...
- Edit...
- Find...
- Select Ctrl+U
- Sort ▶
- Clear
- Delete...

Measure

- Start Ctrl+M
- High Range ▶
- Low Range ▶
- Cuff Size ▶
- Air Release ▶

Store measurement and personal information to disk.
Print the currently selected display.
Print the screen.
Exit the program.

Cancel the previous edit operation.
Cut selected text from the Record Table or Personal Info display.
Place selected item onto the Windows Clipboard.
Paste text from the Windows Clipboard at the selected insertion point.
Erase selected text.

Add a user to the User List.
Change the user's name and/or data storage location.
Find a user by ID.
Select a user.
Sort User List by I.D. number or user name.
Close the current user and resets to Guest.
Remove a user from the User List.

Begin a measurement using current settings.
Select the High (systolic) measurement limit.
Select the Low (diastolic) measurement limit.
Select the cuff setting for the user.
Select the Air Release index value for the user.

File Edit User Measure Trend Record Options Window Help

Trend
Retrieve the measurement Waveform Display

Record
Display or edit personal medical information.
Display blood pressure measurements in tabular form.

Options
Select the communications port to be used by the DynaPulse.
Find the communications port used by the DynaPulse.
Reset the unit due to environmental changes.
Displays the Trend window.
Display the Tool window.

Window
Overlap all open displays.
Tile all open displays.
Arrange displayed icons.
Close all measurement windows.
List all open displays.

Help
On-Line help.
Medical information.
Version information.

Menu Item: Retrieve

Menu Item: Personal Info

Menu Item: Record Table

Menu Item: Com Port

Menu Item: Com Check

Menu Item: Zero Reset

Menu Item: Show Trend Window

Menu Item: Show Tool Window

Menu Item: Cascade Shift+F5

Menu Item: Tile Shift+F4

Menu Item: Arrange Icons

Menu Item: Close All

Menu Item: 1 User (patient) List

Menu Item: Basic Usage

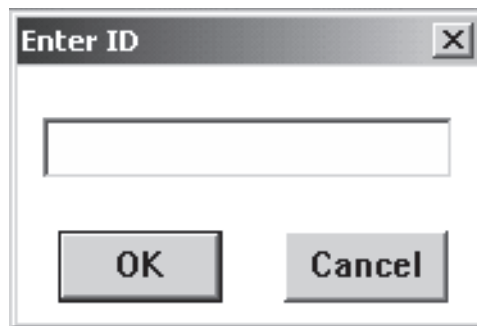
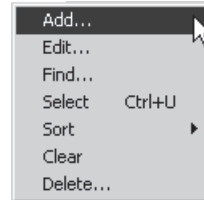
Menu Item: Medical Facts

Menu Item: About DynaPulse F1

Adding a New User

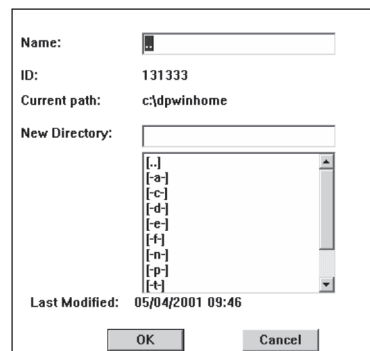
From the User menu, select Add...

The "Enter ID" dialog box will open. Enter a unique, easy to remember ID for the user. The ID cannot contain spaces or punctuation, and cannot exceed 9 characters. Click OK.



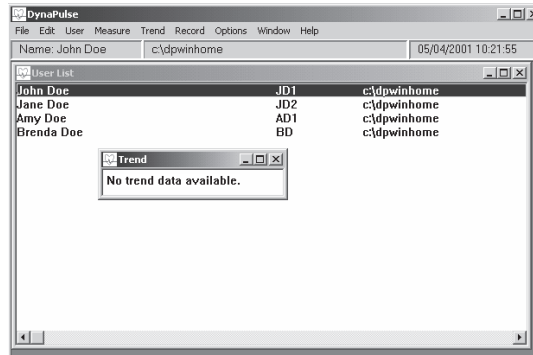
The user "Name" box will appear. Enter the user name. You may enter up to 28 characters, including spaces.

To change the default data folder (shown as "Current path:") type in the new folder name in the "New Directory" field. Select the drive and Click OK.



Selecting a User

When you open the program the "User List" screen will appear. Double click on the name that you wish to use.



If you have taken measurements then . . .

The selected user's "Trend" screen will appear, and you are given the opportunity to recall measurements, and print the "Trend Display" (see *Trend Display*). The Status Bar displays the name and data directory of the selected user.

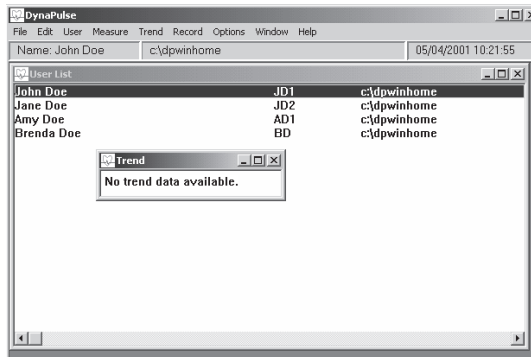
If you have not taken any measurements then "No trend data available" will be displayed. Go to MEASURE option and select start.

The User List

The User List displays the name, data directory, date and time in the Status Bar. Users are listed by name, ID and data directory of each user.



The default user is "Guest". Measurement information cannot be saved for the GUEST user. A user from the User List must be selected before taking a measurement to allow full use of program functions. To clear the current user and return to Guest, choose CLEAR for the USER option.



Editing A User's Settings

First, select a user to edit. Then choose EDIT from the User List. The name and data storage folder may be changed.

The User ID may not be changed.

Name:

ID: 131333

Current path: c:\dpwinhome

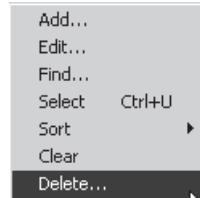
New Directory:

Last Modified: 05/04/2001 09:46

OK Cancel

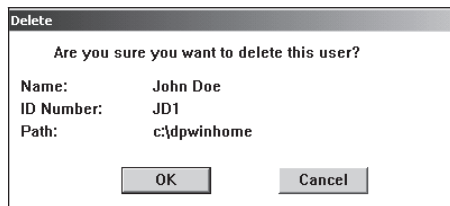
Deleting A User

Users may only be deleted from the User List by selecting DELETE from the User options.



The DynaPulse is an FDA-registered device and generates clinical data. While the program will delete a user from the User List, the program will not delete the measurement data produced by the user.

From the USER List highlight the user name, select DELETE from the USER options. Click OK to confirm the deletion from the Confirmation Screen.

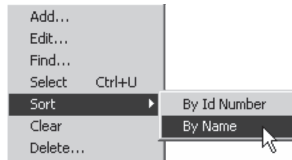


Sorting the User List

The User List can be sorted by either user name or user ID.

To sort the User List by ID, select USER from the Main Menu. Select SORT and choose the BY ID NUMBER option. The User List will be sorted with the lowest number first.

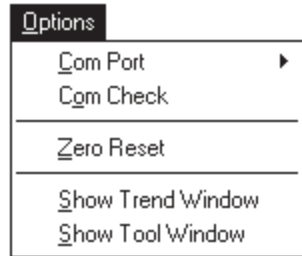
To sort the User List by the User Name, select USER from the Main Menu. Select SORT and choose the BY NAME option. The User List will be sorted alphabetically.



Performing A Zero Reset

After you have entered your user ID and name, you're ready to take a measurement. Before taking your first measurement, it is recommended that you first perform a Zero Reset.

Large changes in atmospheric pressure may affect blood pressure readings. The Zero Reset will compensate for these variations. Select ZERO RESET from the OPTIONS menu.

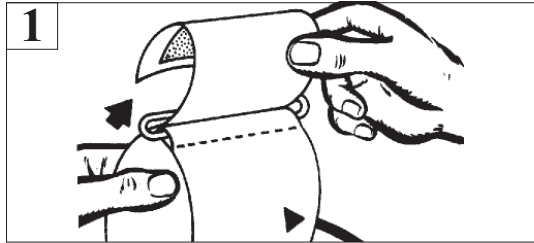


Follow the on-screen prompts to complete the calibration.

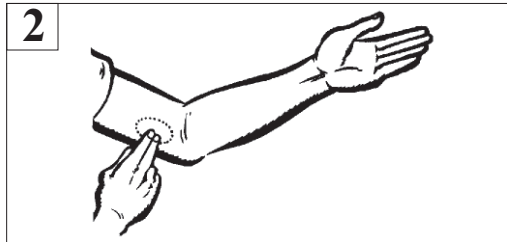


NOTE: Do not reset the DynaPulse before each measurement. Reset the DynaPulse only if a large change in temperature or humidity is noticed.

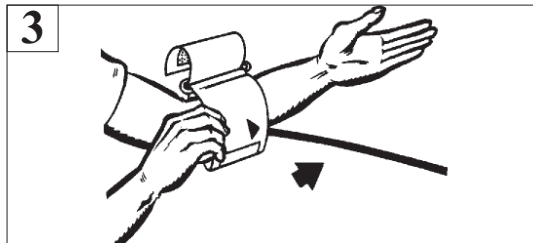
Putting On And Using The Cuff



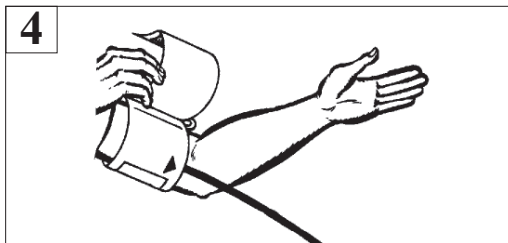
Loop the cuff with the Velcro interlock on the inside. If the cuff does not fit, switch to a different cuff size. See *Selecting the Correct Cuff*.



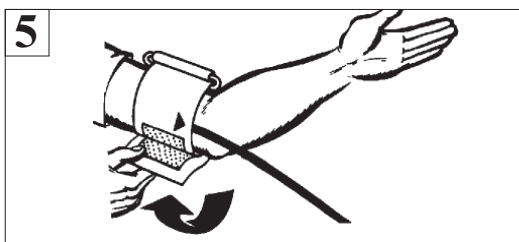
Locate the brachial artery on the left arm. It is located on the inner side of the upper part of the arm.



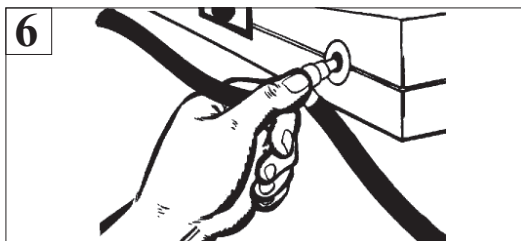
Place the cuff on the left arm with the metal bar on the inner side of the arm (the brachial artery side), and the rubber tubing toward the hand.



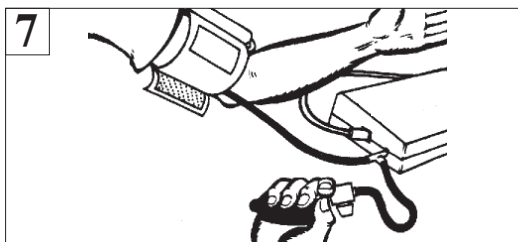
Pull the end of the cuff through the metal loop so that it fits on the upper arm.



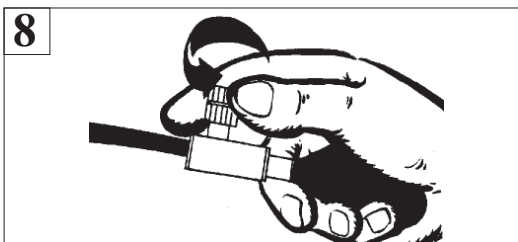
Fold the end of the cuff so that it fastens onto the Velcro panel. **Don't put the cuff on too tightly.**



Plug the tube connector into the DynaPulse unit. Close the release valve on the pressure bulb. (Turn the knob clockwise completely.)



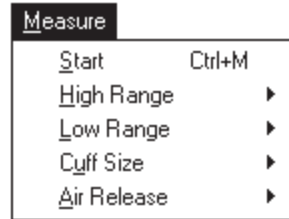
The arm should rest on a table surface. Do not let the cuff rest on any other surface. When the program asks you to start pumping, squeeze the pressure bulb to pump up the cuff.



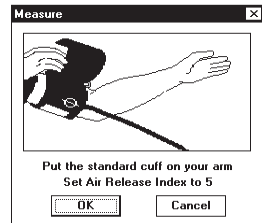
When the program has completed its measurement, release the remaining air pressure in the cuff by slowly turning the valve counterclockwise.

Taking A Blood Pressure Measurement

Select the START option from the MEASURE menu.

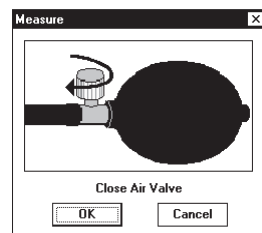


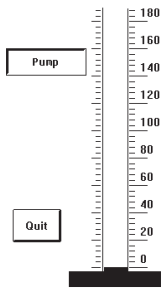
Put the cuff on the arm and press ENTER, or click OK. For further information regarding correct cuff placement, see *Using The Cuff*. Adjust the Air Release Index (the knob on the unit) to the appropriate value.



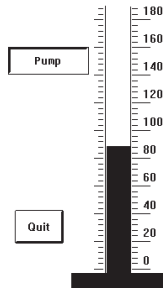
In this example, a blood pressure reading is taken using the default ranges.

Close the release valve of the pressure bulb by turning the valve knob clockwise. After the valve is shut tightly, press the ENTER key or click OK.

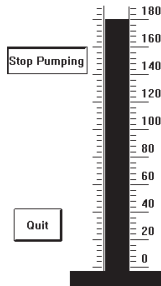




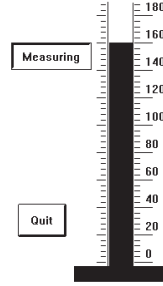
Begin pumping. Don't pump too fast. Click Quit or press ESC to abort.



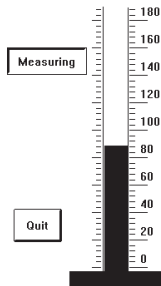
You will see the indicator rise as the pressure increases.



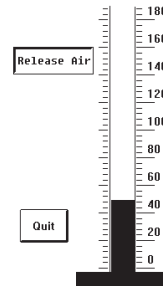
Stop pumping only when the program tells you to.



The measurement will start at the selected upper limit setting.

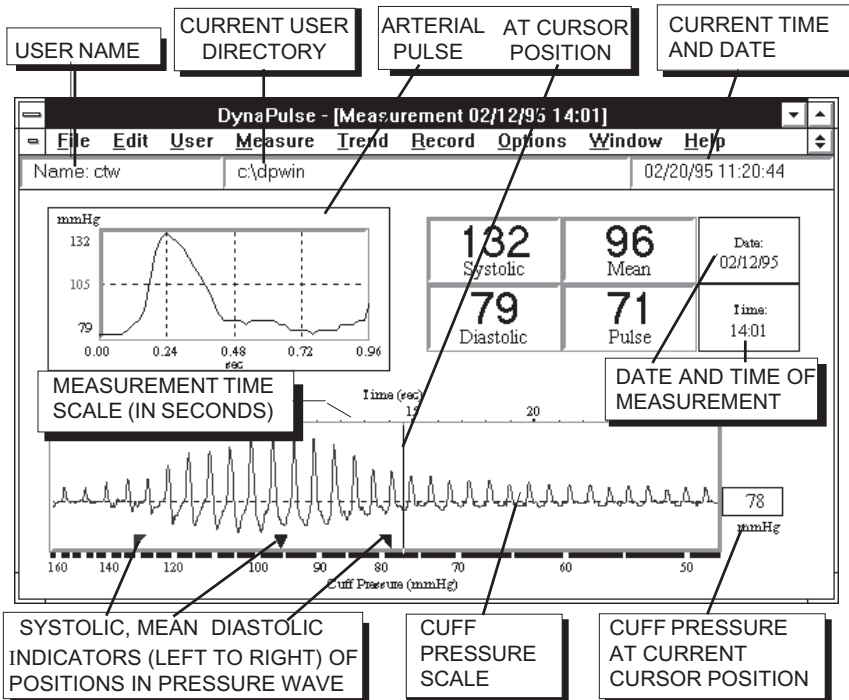


The patient should relax while the measurement is being made.



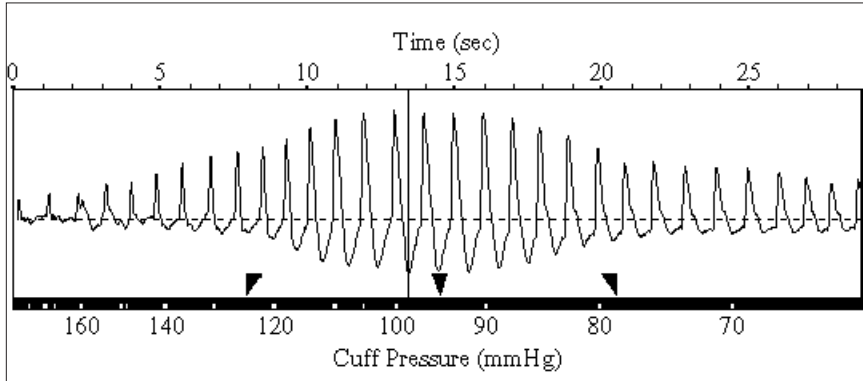
At the end, release the rest of the air from the cuff.

The Measurement Display



NOTE: The measurement display is intended for use as an analytical tool. Any diagnosis must be performed by a qualified medical practitioner.

Looking At The Measurement Display



The application of an occlusive cuff around the artery during blood pressure measurements results in a pressure waveform (shown above).

The sample waveform above is representative of a high quality measurement. The three triangles below the waveform mark the actual points where blood pressures were determined. At these points the cuff pressure was equal to (from left to right) systolic, mean arterial, and diastolic blood pressures. The Pulse Dynamic algorithm used by the DynaPulse products uses pattern recognition to determine blood pressures.

For convenience, the blood pressures are displayed on the top right hand corner of the screen, along with heart rate.

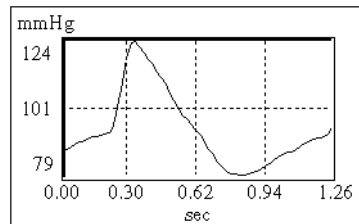
132 Systolic	96 Mean	Date: 02/12/95
79 Diastolic	71 Pulse	Time: 14:01

When first looking at the waveform, one may immediately notice two striking features: the pressure oscillations (the peaks and valleys), and the increasing then decreasing height of the oscillations with time.

Each pressure oscillation is caused by a heartbeat. The peak of each oscillation is systolic pressure and the lowest point (or nadir) of each oscillation is diastolic pressure.

The varying height of each oscillation is caused by the interaction between the occlusive cuff and the blood flow in the brachial artery.

The systolic and diastolic pressures generated by each heartbeat can be seen more clearly on the arterial pulse display. The oscillation marked by the cursor is displayed on the graph, with the peaks and troughs normalized to systolic and diastolic pressure. By scaling the pressure in this way, the height changes caused by the cuff are minimized, and individual heartbeats can be compared for abnormalities. Using the arrows moves the cursor across the waveform. The arterial pulse display changes automatically, to correspond to the currently selected oscillation.



Estimated Measurements

The DynaPulse has the capability to estimate one measurement parameter (such as systolic), provided that it has measured the other two. An estimated measurement can be distinguished from other measurements by the presence of a highlighted background.

151 Systolic	105 Mean
82 Diastolic	80 Pulse

Estimated measurements occur when either the High or Low Range is not set correctly. Upon receiving an estimated measurement, the user should readjust the ranges.

If systolic blood pressure (SBP) was estimated, the High Range should be set to a value greater than the estimated SBP.

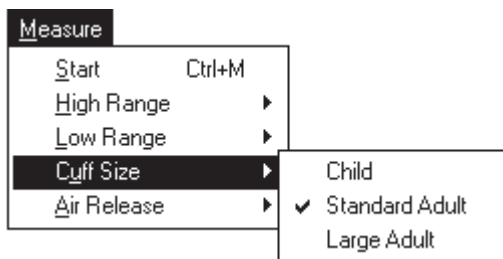
If diastolic blood pressure (DBP) was estimated, the Low Range should be set to a value less than the estimated DBP.

Adjusting Measurement Settings

When taking the first set of measurements for a new user, you should adjust the cuff size and Air Release index for the user. This may require a few test measurements. Once these parameters have been set, however, they will be saved along with the user's data and will not need to be adjusted.

Adjusting the Cuff Size

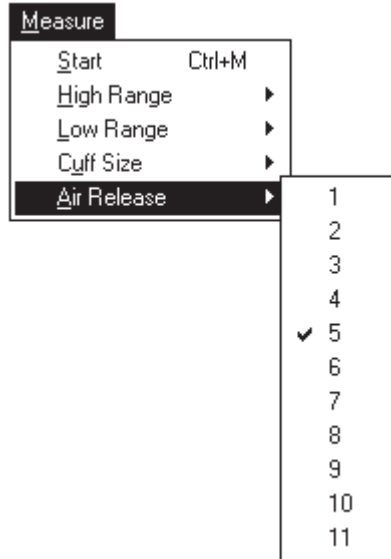
This setting should be adjusted only if you need to use a small or oversize cuff. For guidelines on determining cuff size, see *Selecting the Correct Cuff* in the Appendix. If switching to a different size cuff, choose CUFF SIZE from the MEASURE menu, and select the appropriate cuff. The Air Release index will automatically change to the default setting for the new cuff size. Test measurements should be taken to adjust the index (see *Adjusting the Air Release*), if necessary.



Adjusting the Air Release

The total measurement time should be 25-35 seconds. Measurement time is displayed above the arterial waveform (in seconds). If the total measurement time is outside this range, the Air Release index needs to be adjusted.

Adjust the Air Release index by choosing AIR RELEASE from the MEASURE menu. Decrease the value of the setting to take a slower measurement, or increase the value to speed up the measurement.



Retake the measurement. The software will prompt you to set the Air Release (the knob on the unit) to the new value. Adjust the index and take a test measurement.

Repeat the process until you get a measurement time within 25-35 seconds. The index setting will be saved for the user.



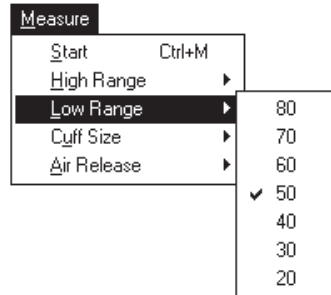
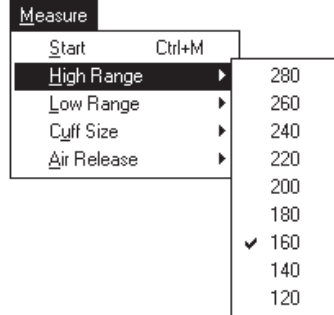
To best determine user settings, the measurement time requirement of 25-35 seconds is used. Once these settings are determined, however, factors such as cuff placement and user position may cause future measurements to be outside this window. However, further adjustment of the Air Release is not required unless the measurement time is outside the range of 15-45 seconds.

Adjusting the High and Low Range Settings

The HIGH and LOW RANGE features enable the user to set HIGH and LOW blood pressure limits. The default settings are 160 (systolic) and 50 (diastolic) mmHg.

The HIGH RANGE varies from 100 to 280 mmHg in 20 mmHg increments. Change the setting by dragging the highlight bar to the desired range. Any HIGH RANGE selection over 200 mmHg will cause the program to confirm the selection.

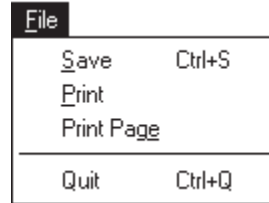
The LOW RANGE varies from 20 to 80 mmHg, in 10 mmHg increments. Change the setting by dragging the highlight bar to the desired range.



In most cases, the program will inform the user when readjustment of either range is necessary (refer to the *Appendix*).

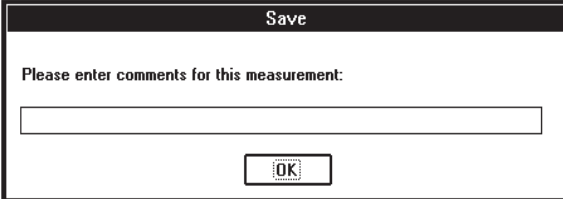
Saving User Data

Select FILE from the Main Menu, then select SAVE. The current measurement or personal information will be saved in the user's data directory. If you try to produce another blood pressure measurement without saving the current measurement or personal information, you will be asked if you want to save the current data. If you do not save the measurement or personal information, it will be discarded.



Information cannot be saved by selecting a user name after a measurement has been taken. A user must be selected before taking a measurement.

A comment line is provided in order to add a one line statement about the current measurement (i.e. "measurement taken after eating"). The comment is stored along with the measurement data. If no comment is needed, simply press the ENTER key.



Save

Please enter comments for this measurement:

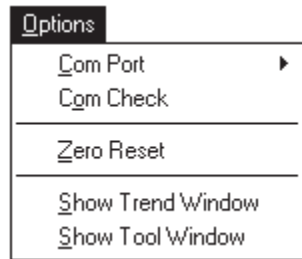
OK

The Trend Display

The Trend Display is another informative feature of the DynaPulse system. With it, you can track an unlimited amount of measurement data (the actual limit is determined by the size of your hard disk storage) for each user.

A user's Trend is displayed when the user is selected, provided that at least one measurement has been saved for the user.

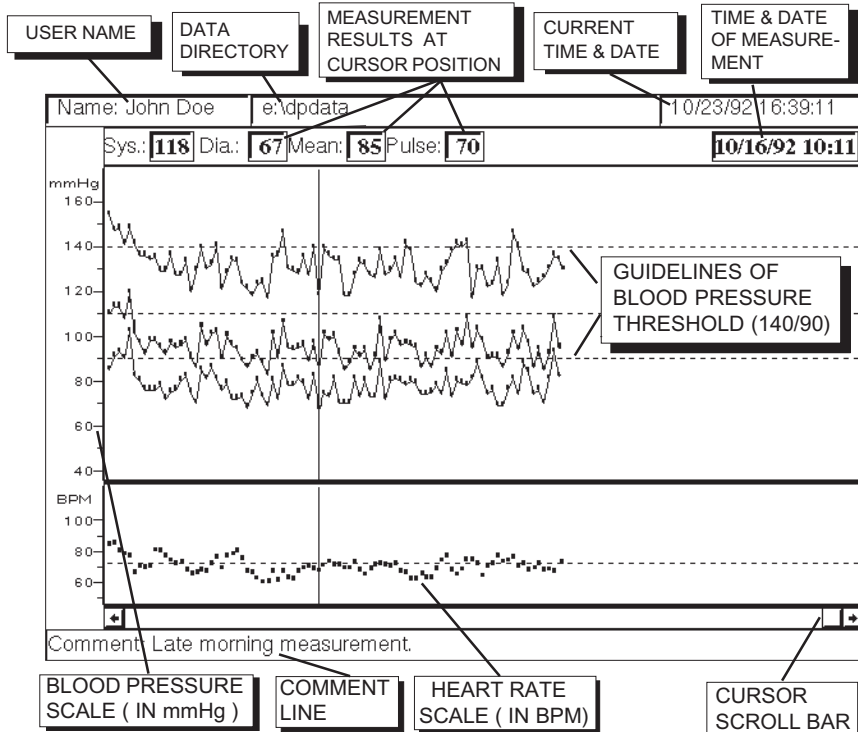
Choosing SHOW TREND WINDOW from the OPTIONS menu will display the Trend. Systolic, mean arterial, and diastolic measurements are displayed as line charts, and heart rate is presented as a scatter chart.



The Trend is divided into two scales for clarity. The top scale is in millimeters of mercury (mmHg), and is used to determine the blood pressure trends. The lower scale is in beats per minute (BPM) and is used for heart rate trends. The display is organized with the most recent measurement on the extreme right.

Use the arrows, or point-and-click to examine individual measurements. Measurement results, along with date and time of measurement, and the comment, will be displayed upon examination. Double-click, or choose RETRIEVE from the TREND menu, to examine the Waveform Display for the measurement.

The Trend Display



The Record Table

The Record Table lets you view measurement data in tabular form. When measurement data is saved, the systolic, mean arterial and diastolic pressures along with heart rate are automatically entered into the Record Table. Additionally, any comments will be displayed with the measurement data.

Date	Time	Systolic	Diastolic	Mean	Pulse
10/16/1992	10:11	118	67	85	70
Late morning measurement.					
10/16/1992	09:46	142	97	114	84
Just after exercise program.					
10/15/1992	21:27	115	81	101	73
Measurement taken just before bedtime.					
10/15/1992	18:59	125	56	65	72
Third measurement in series.					
10/15/1992	18:53	126	57	65	73
Second measurement in series.					

You can use the mouse to move the cursor to the comment box of each measurement and edit the comment. **Press the ENTER key to confirm the changes.** Using the EDIT menu, you may cut or copy comments into other Window applications. You may also paste text from another application into a comment line. Consult the *Windows User Guide* for further information.

Choosing the PRINT option from the FILE menu will allow you to print either the entire Record Table, or only the page at the cursor position.

The Personal Information Record

Choose PERSONAL INFO from the RECORD menu. The Personal Information Record may be used to store relevant medical, doctor, hospital and insurance information. Enter the information as needed. Save the information by selecting SAVE from the FILE menu.

Record

**Personal Info
Record Table**

The Personal Information record is not available to Guest users.

Patient Record	Clinic No.	<input type="text"/>
Institution	<input type="text"/>	
Address	<input type="text"/>	Phone <input type="text"/>
Physician	<input type="text"/>	Nurse <input type="text"/>
Patient	<input type="text" value="John Doe"/>	Soc. Sec. No. <input type="text"/>
Address	<input type="text"/>	Phone <input type="text"/>
Employer	<input type="text"/>	
Address	<input type="text"/>	Phone <input type="text"/>
Insurance Co.	<input type="text"/>	
Address	<input type="text"/>	Phone <input type="text"/>
Policy No.	<input type="text"/>	Insured <input type="text"/>
Date of birth	<input type="text"/>	Age <input type="text"/> Sex <input type="text"/>
Weight	<input type="text"/>	Height <input type="text"/> Blood Type <input type="text"/>
Medical history and clinical tests/results		
<input type="text"/>		

Retrieving the Measurement Display

Recalling measurement data from the Trend screen is accomplished quickly by either double-clicking on measurement, or choosing the measurement and pressing the ENTER key. A Measurement Display may also be retrieved by selecting the measurement and choosing RETRIEVE from the TREND menu.



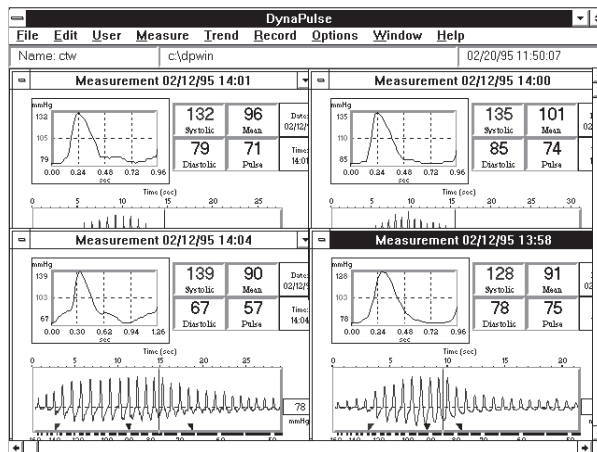
Multiple measurements retrieved from the Trend may be displayed simultaneously.

Display Options: Cascade, Tile, and Close All

One feature of the DynaPulse for Windows is the ability to display multiple measurements on the screen. This feature is useful if you wish to compare data from different measurements.

Features like the CASCADE and TILE options (located under the WINDOWS menu) help organize open windows. Choosing the CASCADE option causes each measurement window to overlap so only title bars are visible. Selecting the TILE option produces a display as seen to the right. Additionally, the WINDOW menu also displays a list of the open measurement displays. Choosing any of the displays from the list will bring that display to the foreground.

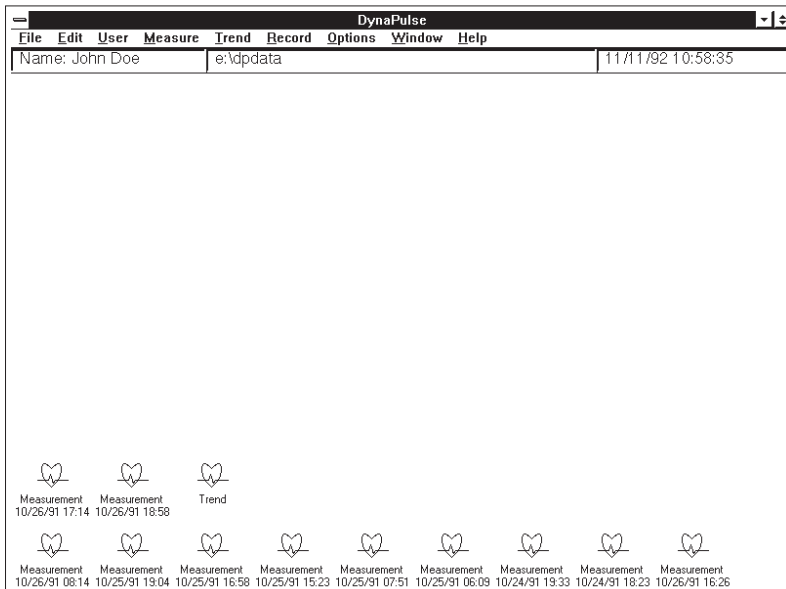
Window		Help
<u>C</u> ascade		Shift+F5
<u>T</u> ile		Shift+F4
<u>A</u> rrange Icons		
<u>C</u> lose All		
1 User List		
2 Trend		
3 Measurement 12/01/92 00:15		
4 Measurement 12/01/92 00:11		
5 Measurement 12/01/92 00:09		
6 Measurement 12/01/92 00:07		
✓ 7 Measurement 12/01/92 00:06		



Display Options: Arrange Icons

You may also "clean up" the display screen and still have several measurements available for your review by using the ARRANGE ICONS option from the WINDOW menu. Any Measurement, Trend, Record Table, or User List may be minimized and arranged by selecting this feature.

Choosing the CLOSE ALL option will clear off all measurement screens and reduce the User List and Trend windows (if open) to icons. The icons will indicate the time and date of the measurement associated with the icon.

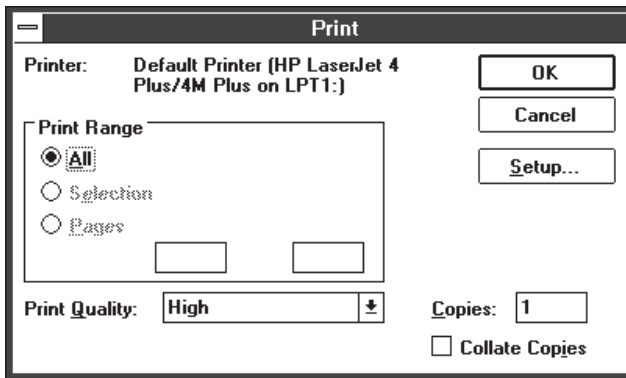


Printing The Displays

The PRINT option is located under the FILE menu.

File	
Save	Ctrl+S
Print	
Print Page	
Quit	Ctrl+Q

Choosing the print option will open a dialog box. Features available are dependent on both the printer and the printer driver selected through the Windows.



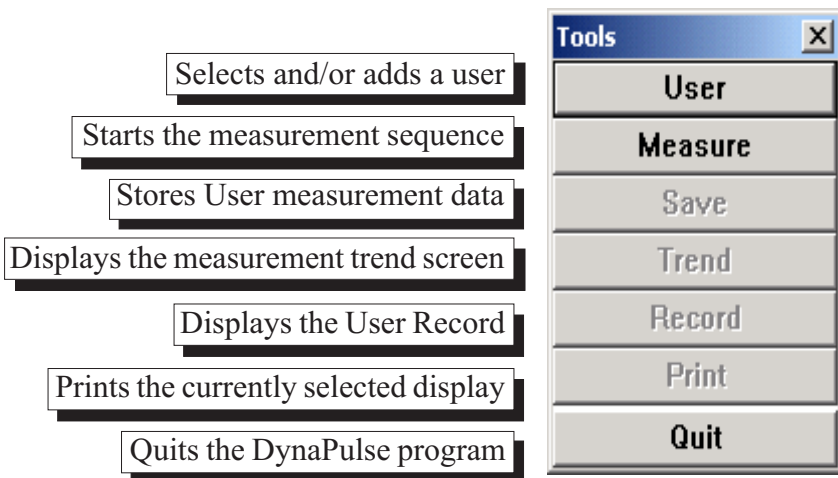
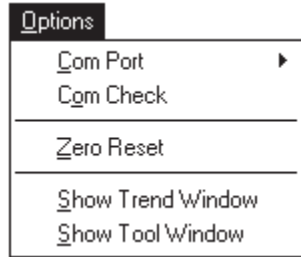
Waveform, Trend, and Record Table displays may be printed out using this control. Only the currently selected display will be printed out. For example, if there are several selections on the screen at the same time, only the highlighted screen will be printed. This is also true for selections arranged using the CASCADE or TILE feature.

NOTE: Print quality is directly related to the printer used and the printer driver selected. The DynaPulse program will print the active window only.

The Tool Window

The SHOW TOOL WINDOW located under the OPTIONS menu is a convenient way to operate the DynaPulse system.

The Tool window contains controls that you use the most. Once selected, the Tool window can remain in the display area for easy access until you close it.



Appendix

Warranty Information

Software Licensing Agreement

COM Port Configuration

Selecting the Correct Cuff

Error Messages

DynaPulse Accuracy

Tips For Accurate Blood Pressure Measurements

Specifications

Warranty Information

Pulse Metric, Inc. warrants that the DynaPulse system unit will be free from defects in workmanship and materials for a period of one year from the date of purchase. This one year warranty extends only to the original purchaser. All other accessories (pressure cuff, RS-232 cable, etc.) will be warranted for 90 days. Pulse Metric, Inc. will repair or replace at its option any defective parts or product when shipped to the initial purchaser. This limited warranty DOES NOT cover damages or losses due to: improper environment, temperature extremes, or other misuse or negligence such as adjustment or repair by personnel not authorized by Pulse Metric, Inc., improper installation, failure to follow the installation instructions, or shipment to or from the distributor or customer. Pulse Metric, Inc.'s liability shall not exceed the price of the defective product itself, which is the basis of the claim. Tampering with the unit voids this warranty. In no event shall Pulse Metric, Inc. be liable for any loss of profits, loss of use of facilities, loss of other equipment, or any incidental or consequential damages, even if Pulse Metric, Inc. has been advised of the possibility of such damages. Some states do not allow the exclusion or limitation of incidental or consequential damages, or allow limitations on how long an implied warranty lasts, so the above limitations or exclusion may not apply to you. This warranty gives you specific legal rights, and you may have other rights which vary from state to state.

Technical Support and Service: Phone: (760) 842-8224
Fax: (760) 758-9425
E-mail: teksupport@dynampulse.com

Technical support representatives are available between 10:00 a.m. and 4:00 p.m. Pacific Standard Time, Monday through Friday, or visit our website, www.dynampulse.com, for technical assistance.

All shipping to Pulse Metric, Inc. must be prepaid and products must be accompanied by a Return Material Authorization (RMA) Number and the original (or a copy) of the dated sales slip as proof of warranty. An RMA Number can be obtained by calling Technical Support at (760) 842-8224. **Packages sent without an RMA Number marked on the outside of the shipping container will be refused.** Please also include a letter with your name, address, telephone number, and brief description of the problem(s).

Software Licensing Agreement

This is a legal Agreement between you and Pulse Metric. Inc. (PMI). By clicking the "accept" button after you see this agreement when you install the software, you are agreeing to be bound by the terms of this agreement. If you do not agree to the terms of this Agreement, immediately remove all traces of the PMI software product from your computer and disk archives and promptly return the disk package and the accompanying items (manuals, DynaPulse unit, and all accessories) to the place you obtained them for a full refund.

LICENSE TERMS

Grant of License. PMI grants you the right to use one copy of the enclosed DynaPulse software program (SOFTWARE) on a single computer at a time. You may not rent or lease the SOFTWARE, but you may transfer the SOFTWARE and accompanying written material provided you do not retain copies and the recipient agrees to the term of this Agreement. You may not reverse engineer, decompile, or disassemble the SOFTWARE. The agreement is effective from the day you open the sealed package until terminated. You may terminate this Agreement by returning to PMI the original disks and any backup copies. If you breach this Agreement, PMI can terminate this license upon written notification to you.

Copyright. The SOFTWARE is owned by PMI and is protected by the United States copyright laws and international treaty provisions. Therefore, you must treat the SOFTWARE like any other copyrighted material except that you may either (a) make one copy of the SOFTWARE solely for backup or archival purposes or (b) transfer the SOFTWARE to a single hard disk provided you keep the original solely for backup purposes. You may not copy the written material accompanying the software.

Controlling Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California.

COM Port Configuration: Windows 95/98

Windows 95/98 is capable of detecting most standard COM ports, therefore we recommend that you use the standard serial ports (COM 1 or COM 2) for your DynaPulse. If the use of COM ports 3 or 4 is necessary, the configuration procedure is provided below. Before attempting to change the hardware settings, we suggest that you run the "Add New Hardware" wizard, using the default option. This allows Windows 95/98 to search your system and ensure that all installed hardware has been properly configured.

To configure Windows 95/98 port settings, perform the following:

1. Click the "Start" button on the desktop. Point to "Settings" and then click on "Control Panel".
2. Double-click on the "System icon, and select "Device Manager".
3. Double-click on the "Ports", then on the port you wish to configure.
4. Click on the "Resources" tab, and confirm that both the Input/Output Range and Interrupt Request (IRQ) values reflect the settings on your COM port hardware. Consult your computer documentation if you are not sure of the hardware settings. If you made any changes, you must restart Windows 95/98 for the changes to take effect.
5. To change the port settings, you must first remove the check mark next to the "Use Automatic Settings" box. The property values must reflect the physical settings of the hardware.



When changing settings, the "Conflicting Device List" does not report conflicts between devices with the same IRQ settings, so be careful!

Selecting the Correct Cuff

The American Heart Association makes the following recommendations with regard to determining the correct cuff size:

- ◆ For adults, the bladder inside the cuff should encircle 80% of the arm.
- ◆ For children less than 13 years of age, the bladder should encircle 100% of the arm.
- ◆ If unable to decide between two cuffs, the larger cuff should be used.
- ◆ If all cuffs are too small, the largest cuff can be wrapped around the forearm, and the radial artery can be used as an alternative measurement site.

Children's/Small Adult Cuff	Standard Adult Cuff	Oversize Adult Cuff
7" to 10.25"	10" to 13.75"	13" to 18.5"

When switching to a different cuff size for a patient, you should change the cuff size setting in the software. Choose CUFF SIZE from the MEASURE menu, and select the appropriate cuff. The Air Release index will automatically change to the default setting for the new cuff size. Take test measurements to adjust the index, if necessary. Both settings will be saved for the user.

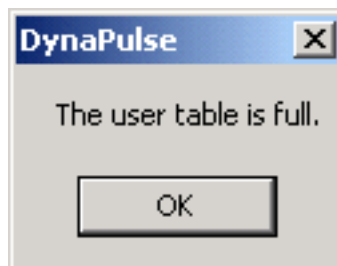
Communication Error

A problem with the DynaPulse or your computer with regards to communication is indicated. The DynaPulse unit could not be started, or the program was not able to keep the communication line open between the DynaPulse unit and your computer. If you have made measurements before, and are now receiving this error, install a fresh set of batteries and try again. If you are using the DynaPulse for the first time, verify that the I/O PORT option is set to the port that the DynaPulse is connected to.



User Table Is Full

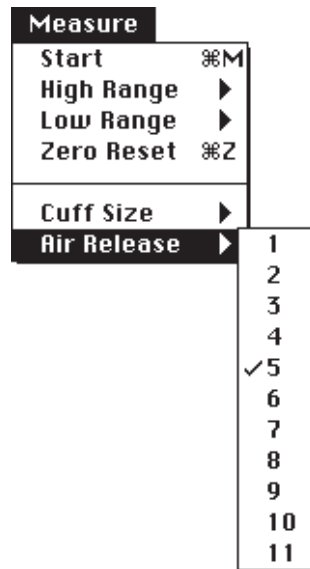
You have reached the user limit of this version of the DynaPulse 200M. You will have to delete a user to add another.



Air Release Too Fast

If you receive this message, check for cuff leaks or hose and connector leaks. If no leaks are found, check the measurement time (the time scale is located above the arterial waveform). The total measurement time should be 25-35 seconds. If the measurement is outside this range, the Air Release index needs adjustment.

Adjust the Air Release index by choosing AIR RELEASE from the MEASURE menu. Decrease the value of the setting to take a slower measurement, and increase the value to speed up the measurement time. Retake the measurement. The software will prompt you to set the Air Release (the knob on the unit) to the new value. Adjust the index until you get a measurement time within 25-35 seconds. The index setting will be saved for the user.



To best determine user settings, the measurement time requirement of 25-35 seconds is used. Once these settings are determined, however, factors such as cuff placement and user position may cause future measurements to be outside this window. However, further adjustment of the Air Release is not required unless the measurement time is outside the range of 15-45 seconds.

Measurement Error. Please Try Again.

The most common reasons for this type of error are excessive cuff movement and/or continuing to pump the air pressure bulb after the DynaPulse program asks you to stop.



◆ The DynaPulse program requires that you pump over the selected "HIGH" range so the DynaPulse system can obtain useful data at the start of the selected High range. For instance, if the High range is set at 160 mmHg., the program will require the user to pump over 160 before told to stop pumping. By slowing down the pumping as you reach the upper limit, you may reduce the possibility of adding erroneous data by accidentally pumping the bulb when the DynaPulse unit is in the process of reading your blood pressure. The unit may interpret the accidental pumping as a heartbeat pressure wave or other anomaly, and may not be able to determine blood pressure correctly.

◆ Excessive arm or cuff movement will also cause the unit to misinterpret your blood pressure. Best results will be obtained if the patient's arm is resting on a table or similar surface, keeping the cuff and hose free from obstructions that might cause the air pressure to change unexpectedly.

High Pressure Range is Set Too Low.

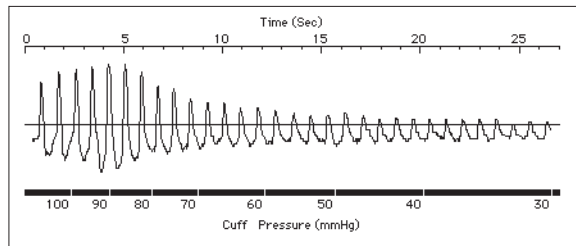
The DynaPulse did not pump to a sufficiently high pressure to measure the systolic pressure.



If the you are asked to increase the HIGH RANGE, choose HIGH RANGE from the MEASURE menu and increase the range by one step (for example 160 to 180).

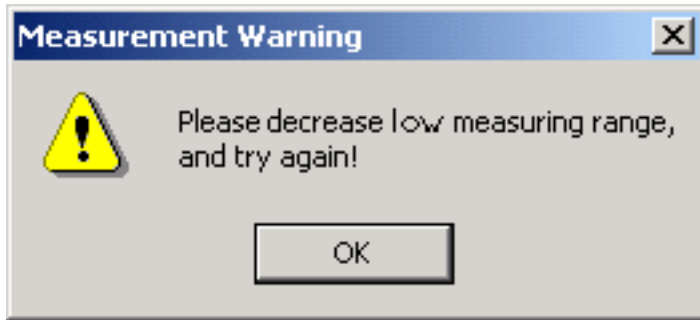
Wait at least one minute, then retry the measurement. Waiting for a minute or so will allow blood flow to recover in the arm before the next measurement attempt.

In this example, the system does not have enough high range information to correctly determine the blood pressure. Increasing the high range will center the waveform, providing a correct blood pressure measurement.



Low Pressure Range is Set Too High.

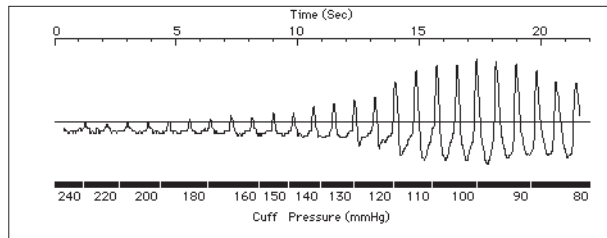
The DynaPulse did not measure to a sufficiently low pressure to measure the diastolic pressure.



If the you are asked to decrease the LOW RANGE, choose LOW RANGE from the MEASURE menu and decrease the range by one step (for example 50 to 40).

Wait at least one minute, then retry the measurement. Waiting for a minute or so will allow blood flow to recover in the arm before the next measurement attempt.

In this example, the system does not have enough low range information to correctly determine the blood pressure. Decreasing the low range will center the waveform, providing a correct blood pressure measurement.



DynaPulse Accuracy

All DynaPulse systems are clinical-grade. The DynaPulse is FDA-registered, and meets or exceeds Association for the Advancement of Medical Instrumentation (AAMI) standards for non-invasive blood pressure monitors. However, like any other device, proper use of the DynaPulse is essential for accurate measurements.

General Tips

The following suggestions will increase the accuracy of blood pressure measurements in general. They do not apply exclusively to the DynaPulse.

- Allow 1-3 minute intervals between measurements
- The user should relax and remain motionless during each blood pressure measurement.
- The cuff must be the right size, and must be applied correctly.
- Blood pressure may be higher due to a number of factors. In general, any circumstance leading to an increase in heart rate tends to cause blood pressure to rise.

Please refer to *Useful Tips...* (in the Introduction) for more details.

Specifications

DYNAPULSE 200M MANUAL PUMP SYSTEM

Measurement accuracy: ± 2 mmHg. or $\pm 2\%$ whichever is greater.

Measurement Range: Blood pressure- 20 to 300 mmHg. Pulse- 30 to 200 bpm.

Deflation method: Air release valve

Inflation method: Manual pump, using rubber bulb

Power Consumption: 60mW when measuring

Operating temperature: 0°C to 45°C (32°F to 113°F)

Power Supply: Four (4) 1.5 VDC AAA batteries

Physical Dimensions: 6.1"(W) x 4.0"(D) x 1.7"(H)

Weight: 8.2 ounces, without batteries

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www.dynapulse.com

