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## SOFTWARE GUIDE INTRODUCTION

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The DynaPulse 5000A is Pulse Metric's ambulatory version of a non-invasive blood pressure system known as Pulse Dynamics. It is based on a unique *oscillometric* technique that allows you to obtain clinically accurate blood pressure data quickly and easily. The system comes with a hardware monitor and support software. The DynaPulse 5000A Hardware User's Guide describes the hardware monitor and its use. The DynaPulse 5000A Software User's Guide explains how to download data from the hardware monitor and convert the measurements into easy-to-use graphs and reports that allow for simple, yet accurate analysis.

If you are familiar with the standard features of Windows software, you will find the DynaPulse software easy to use. The information required to install and run the software is provided in this manual.

The DynaPulse customer support team is committed to ensuring your continued satisfaction. You are welcome to call us with questions or comments at 760-842-8278.



Indicator Used in this Manual

to call your attention to an important feature

**Note:** The DynaPulse program provides hotkeys to quickly access the main menu items. If an underlined letter is part of the program menu item name, you can activate this item by holding down the <Alt> button on your keyboard and typing the identified letter key.

## **FACTS ABOUT HYPERTENSION**

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Hypertension is elevated blood pressure that persistently exceeds a safety threshold. The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure estimates that the blood pressure of 50 million Americans consistently equals or exceeds 140/90 mmHg. Hypertension increases the risk of developing cardiovascular diseases and stroke, and about three quarters of those who have hypertension are not controlling it well.

## **HOW IS BLOOD PRESSURE MEASURED?**

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There are many ways to measure blood pressure. To achieve the most accurate measurement, a doctor must insert an intra-arterial catheter.

Less invasive indirect methods were devised to allow safe, quick measurements. Still, the accuracy of non-invasive methods is judged against the standard of catheter-based measurements.

The **auscultatory** method is now the most common method used to measure blood pressure. After inflating a cuff around the patient's arm, the health practitioner places a stethoscope against the arm and, as the cuff is deflated, listens for Korotkoff sounds to determine systolic and diastolic pressure.

One benefit of this method is the direct relationship of the technique to the blood flow. Blood pressure variations in the artery create the Korotkoff sounds. Many other techniques obtain blood pressure by mathematical calculations that are not directly observable.

The auscultatory method does have several drawbacks. Extensive training is required to ensure accuracy. The human ear may effectively respond to frequencies between 20 and 20,000 Hz, but the ear hears best between the range of 200 and 4000 Hz. The Korotkoff sounds heard through an acoustic stethoscope range from 18 to 26 Hz at systolic cuff pressures and 40 to 60 Hz at diastolic pressures. These frequencies are not in the range at which humans are most sensitive. Measurements taken by different people on the same patient can vary due to differences in hearing ability, even if the measurements are taken at the same time!

This method also encountered difficulty when patient conditions, such as hypotension, mute or dampen the Korotkoff sounds.

Other automated blood pressure monitors are designed to solve the hearing variability problem by using microphones with sound-based algorithms to estimate systolic and diastolic blood pressure.

Unfortunately, by removing the human element, these devices lose the advantage of professional *validation*. They also have problems estimating blood pressure in patients with muted Korotkoff sounds.

These difficulties prompted the development of the **Oscillometric** technique. Instead of listening for characteristic sounds, the Oscillometric technique uses a cuff and a pressure sensor. These devices estimate blood pressure by examining the pressures generated by the cuff and the arterial pulsation. The estimations are based on large amounts of data and are usually accurate, but they are still estimations. The algorithms are not based on arterial flow or pressure. These devices determine mean arterial pressure, then estimate systolic and diastolic pressures.

### **The Next Step**

What is needed is a technology that combines the best of the auscultatory and oscillometric techniques.

- A technique that, like the auscultatory method, is based on blood flow properties.
- A technique that also offers validation capabilities, like the manual auscultatory method.

- A technique that, like the oscillometric method, works on a broad range of patients, including those whose cardiovascular problems may make their blood pressure difficult to measure.

Above all, the technique must be accurate.

The DynaPulse blood pressure monitor meets all of these criteria. Pulse Dynamics, the patented technology used with the DynaPulse 5000A, 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, each of which is measured independently from the Pulse Dynamic pressure waveform. This pattern recognition technique is possible due to the effect that blood flow has on the measured pressures at the brachial artery. Pulse Dynamics measurements have been found to agree extremely well with catheter-based measurements.

### **Accuracy of the 5000A Systems**

To obtain FDA 510K registration for the DynaPulse, Pulse Metric (PMI) validated Pulse Dynamics accuracy relative to both auscultatory and invasive catheter measurements.

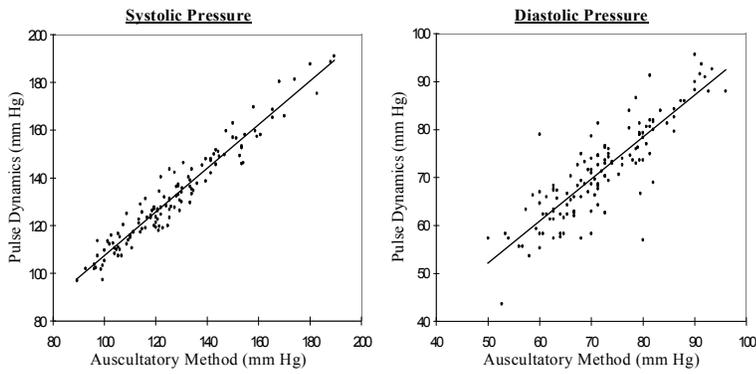
A 132-patient study compared the monitor to the auscultatory method, in accordance with Association for the Advancement of Medical Instrumentation (AAMI) 10-1987 guidelines. The DynaPulse achieved correlations of 0.96 and 0.89 for systolic and diastolic pressures, respectively. When the DynaPulse was compared to invasive, intra-arterial measurements (a 36-subject study), correlations of 0.94, 0.91, and 0.95 were found for systolic, diastolic, and mean arterial pressures, respectively.

Summaries of these two validation studies are presented on the following pages.

### **Interpreting the Results**

In all cases, the graphs compare Pulse Dynamics to either invasive measurements (using a catheter) or auscultatory measurements.

**Pulse Dynamics vs. Auscultatory Method (ANSI/AAMI SP10-1987)**



**Pulse Dynamics vs. Auscultatory Method Summary**

	Systolic	Diastolic
Mean Difference (Ausc. - PD)	-5	1
Standard Deviation	6	5
Standard Error of Estimation	5	5
Correlation Coefficient	0.96	0.89

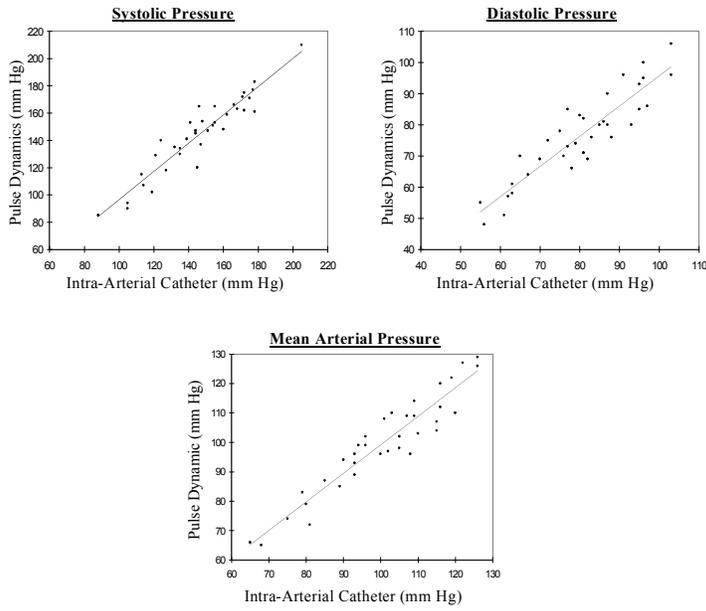
Experimental Conditions:

- |                    |              |                      |   |
|--------------------|--------------|----------------------|---|
| 1. Total Subjects: | 132          | 3. Heart Rate Range: | 45-115 BPM                                      |
| 2. Age Groups:     | (11-24) = 28 | (25-44) = 38         | 4. Data represents a three measurement average. |
|                    | (45-64) = 28 | (65-85) = 38         |   |

The *correlation coefficient* is a measure of comparison. A coefficient of 1 corresponds to a perfect correlation. As a general rule, coefficients

above 0.80 are considered good correlations. The line on each graph has been fitted to the

**Pulse Dynamics vs. Intra-Arterial Catheterization (UCSD Medical Center)**



**Pulse Dynamics vs. Intra-Arterial Catheterization Summary**

	Systolic	Diastolic	Mean Arterial
Mean Difference (Cath. - PD)	-2	-4	-1
Standard Deviation	9	6	5
Standard Error of Estimation	9	6	5
Correlation Coefficient	0.94	0.91	0.95

Experimental Conditions:

- Total Subjects: 36
- Invasive Pressure Site: Descending Thoracic Aorta
- Data represents a three measurement average.

data.

Copies of abstracts and other clinical research information may be obtained by contacting Pulse Metric for a copy of the Pulse Dynamic Clinical Research Guide.

# I. INSTALLATION

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## System Requirements

### Installing the DynaPulse 5000A Software

### Setting Up the DynaPulse 5000A Software

## SYSTEM REQUIREMENTS

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To install the DynaPulse 5000A, you will need the following equipment:

- IBM PC or compatible with at least 486x/66 processor, 32 MB RAM, a hard drive, and a CD ROM drive.
- Windows 98SE/ME/NT/2000/XP
- One USB port

## INSTALLING THE DYNAPULSE 5000A HARDWARE

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See the DynaPulse 5000A Hardware Guide

**IMPORTANT: PROCEDURES ON HOW TO SETUP YOUR COMPUTER FOR USB COMMUNICATION CAN BE FOUND ON PAGE 63 OF THE SOFTWARE GUIDE. THIS MUST BE DONE BEFORE USING YOUR DYNAPULSE.**

## INSTALL THE DYNAPULSE 5000A SOFTWARE

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If you have a previous version of DynaPulse 5000A 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.**

In Windows, click on **Start**, then **Run**, and type in the letter used for your CD ROM drive follow by `: \setup`.

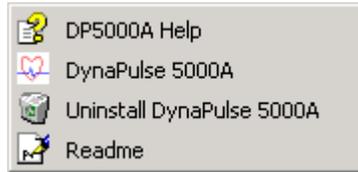
### Start the Software Program

Once the software is installed, you will see the DynaPulse 5000A icon on the desktop. To start the DynaPulse 5000A, double-click on that icon



In addition to the icon on the main window, which you can always use to start the program, the installation program places four function links for the DynaPulse 5000A under

Programs, which you can access via the Windows *Start* button, *Programs, DynaPulse* and click on the DynaPulse 5000A icon.



The first screen will be the Institution Information dialog.



Enter the requested information and click on **OK**. This will take you to the Patient List that displays the patient names and is likely to be empty. The dialog appears automatically only on initial use. If you need to change the information on this dialog, you can access it from the Default menu.

Before you enter any patient information you need to configure the Communication Port for the DynaPulse.

## SETTING UP THE SOFTWARE

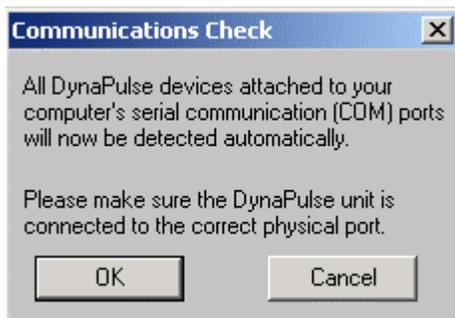
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### Communication Ports

At this time you need to attach your DP5000A monitor, with the 4 AA batteries installed, to your computer.

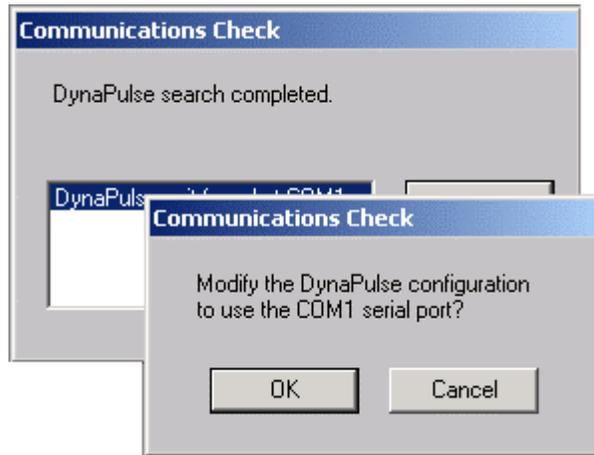
1. Plug the large end of the provided cable into your PC's USB port and the smaller end into the DP5000A monitor.
2. Make sure that the DP5000A monitor is switched ON and in the ready mode and is connected to the computer via the supplied USB cable to an open USB port.

1. From the Port menu, select **Com Check**. This will display the message shown below.



2. Select **OK**.

Com Check will automatically detect and record the communications port used by the DynaPulse 5000A unit and display the message shown below.



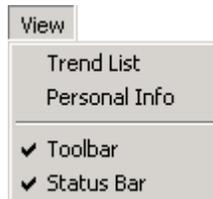
4. Select **OK** to set the Port setting automatically. The Check Box will default to the port where the Com Check program finds the DP5000A.

**Note:** Programs that interface with the computer through a COM port, such as Personal Digital Assistants, will lock out any other devices from using this port. You will need to turn off this feature of the PDA software to communicate with the DP5000A.

The program will return you to the Patient List.

### Activate Toolbar and Status Bar

You can show or hide the toolbar and status bar through the View menu at any time by checking either Toolbar or Status Bar.



The DynaPulse 5000A program has a menu at the top of the screen and a toolbar consisting of clickable shortcut buttons below the menu bar. The menu options found in the File, Window, and Help menus work the same as in other Windows programs. Other menu options are DynaPulse program functions. The content of these menus will change depending on the screen is open when you access the menu. You can select many of the menu options by pressing the <Alt> key and typing the underlined letter in the item name. For example, typing <Alt> and the x key would select the Exit command, quitting the DynaPulse program.

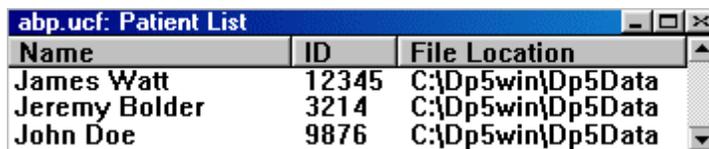


## GETTING STARTED

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### PATIENT LIST

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Name	ID	File Location
James Watt	12345	C:\Dp5win\Dp5Data
Jeremy Bolder	3214	C:\Dp5win\Dp5Data
John Doe	9876	C:\Dp5win\Dp5Data

The Patient List is the first screen to appear when you open the DynaPulse 5000A program. It normally remains open in the background when other screens are open, but you can use the Window menu functions *Tile* (to view the list while other screens are open) or *Arrange Icons* (to reduce it to an icon at the bottom of the screen).

To make changes to the Patient List, highlight the name to be changed, then use the Patient menu options *Edit* and *Delete*, or the Data menu option *Data Transfer*. When a name is highlighted, you can also access the View menu options *Trend List* and *Personal Info*.

If the list is large, you can either scroll the patient list to find a particular patient or use the Find function on the Patient menu to open a dialog where you enter the patient's name to run a search.

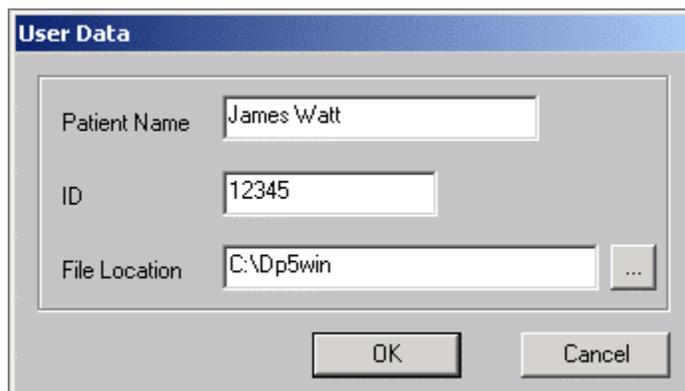
#### Sort: Patient List

In the Patient List, you can sort the patient data in either ascending or descending order by *name*, *ID* or *file location*. For example, clicking on the *ID* column heading will automatically sort the list by ID in numerical order followed by alphabetical order. Clicking the *ID* heading a second time will resort the list in reverse order.

### ADD A NEW PATIENT

---

The best way to get started is to add a new patient (you) and take a few measurements. As you use the DynaPulse 5000A unit repeatedly, you will find that efficient operation quickly becomes second nature.



**User Data**

Patient Name: James Watt

ID: 12345

File Location: C:\Dp5win

OK Cancel

1. Select **Add** from the Patient menu. You will be prompted to enter a name and identification value (ID). Use the Tab button to move between the fields. Using medical record or social security numbers for ID is often helpful.

- File Location displays the default path to the location where the patient's data will be stored. To change the path if it is missing or incorrect, use the button marked with three dots to open the Select a Directory dialog.



To use the Select a Directory dialog, select the drive. Click on the highest-level directory that is in the correct path to display all of the subdirectories, and choose the subdirectory, etc.

Note: Do not store measurement information in the root directory (C:\). Use the default directory (c:\Dp5win\Win32), or an alternative directory such as c:\DpDATA.

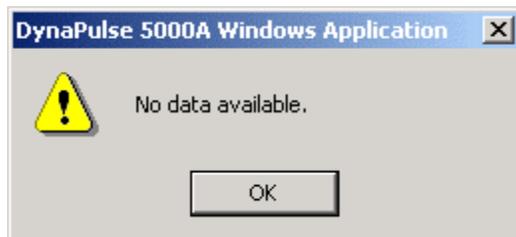
The drive or directory can be on either a hard disk drive (C:) or a CD ROM (Y:). If you will be selecting and sorting the Patient List by last name, type the patient name in a "last name first, first name last" format.

- Select **OK**. Once you have added a patient, the name will appear on a patient list. Below is an example of what you should see after clicking OK. Your patient is now registered.

Page 10 explains the Patient List in more detail. If you

abp.ucf: Patient List		
Name	ID	File Location
James Watt	12345	C:\Dp5win\Dp5Data
John Doe	9876	C:\Dp5win\Dp5Data

double click on the name, a "No data available" box should appear like the one to the right. You are now ready to take measurements and store them in your own patient file.



## TAKING MEASUREMENTS

---

There are two modes for taking measurements with the DynaPulse 5000A: manual and ambulatory. While the DynaPulse 5000A Hardware Guide describes how to use the monitor for both types of measurement, the ambulatory method also requires software setup that is described below.

### **IMPORTANT: Before taking new measurements:**

The DP5000A's internal memory can store up to 100 measurements for a single patient. Before you can use the DP5000A for a different patient or for the same patient taking more than 100 measurements, the data in the DP5000A's memory must be transferred to a host computer so that the DP5000A's memory can be cleared and reused. See pages 13 through 13 for information about the transfer and clear memory functions.

### **Setup for Ambulatory Blood Pressure Recording**

To ensure correct setup and operation of the DP5000A, check the following:

1. Simply plug the small end of the USB cable into the DP-5000A monitor and the larger end into the USB port of your computer.
2. The DP5000A monitor must be switched on and in "Ready" mode.
3. The correct patient name and ID must be highlighted.
4. From the Data menu, select **Enable Amb**.
5. Disconnect the cable from the DP5000A unit to the computer and allow the unit to operate on battery power. See the DynaPulse 5000A Hardware Guide for details.

### **Disable Ambulatory Mode:**

Use this setting for downloading at the end of an ambulatory session or if the ambulatory monitoring needs to be ended prematurely. This does not transfer or clear the data or ID, but the ambulatory mode should be disabled before a data transfer.

To disable ambulatory mode, select **Disable Amb** from the Data menu.

### **Conventional Blood Pressure Recording**

See the DynaPulse 5000A Hardware Guide

### **Guidelines for Blood Pressure Measurement**

#### **Position**

Ambulatory measurement is not intended to imply that the user should be in motion during a reading. Gravity and body position both affect blood pressure. Standard measurement protocols suggest that:

- The patient should be seated comfortably and relaxed for 5-10 minutes before taking measurements. The idea is to get a measurement that is most representative of the patient's "resting" blood pressure. By sitting, the patient is more relaxed, and movement can be kept to a minimum.
- Both legs should be flat on the floor with the legs uncrossed.
- The upper arm should be resting at the level of the heart. Keeping the arm at heart level minimizes the gravitational effect on blood pressure as the blood travels from the heart to the arm.

Measurements may also be taken in the standing position with the arm elevated and rested at heart level.

#### **Use the Correct Blood Pressure Cuff**

Cuffs come in three sizes: Small, standard, and large. Before taking a measurement, determine the correct cuff size for the patient. American Heart Association (AHA) guidelines recommend that the

rubber bladder inside the cuff should encircle 80% of the arm in adults and 100% of the arm in children less than 13 years of age.

### Correct Cuff for Various Arm Circumferences (Measured in Inches at the Bicep)

Small cuff for children and small adults	Standard cuff for adults	Large cuff for adults
7" to 10.5"	10" to 13.75"	13" to 18.5"

If you cannot decide between the cuffs, use the standard cuff.

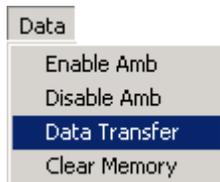
### Transfer Measurement Data to Computer

After taking measurements, the data in the DP5000A's memory must be transferred to a host computer so that the DP5000A's memory can be cleared and reused. Once again:

1. There must be a proper cable connection between DP5000A and the computer USB port.
2. The DP monitor must be on and in "Ready" mode.
3. The correct patient name and ID must be highlighted.

From the Data menu, select **Disable Amb**.

Once the ambulatory mode on the DP-5000A has been disabled, select **Data Transfer** from the Data menu. The Data Transfer command to transfer the measurement data from the DP5000A



device. The session data will be saved as a trend of measurements to the selected patient data file along with the patient ID.

A message will appear briefly during the transfer to display the current status of the transfer. When the transfer is complete, you will be prompted to add a comment.



### Clear Memory

This command, found in the Data menu when the Patient List is displayed, will delete all measurement data stored in the DP5000A device memory. Measurements deleted from the device *cannot* be restored. Data on the computer hard drive is not affected. If you use the Clear Memory function without first transferring the measurements, the data will be lost.

If you transfer data to the host computer without clearing the DP5000A memory, some of the files in the host computer will duplicate the unpurged files in the DP5000A memory. However, the next time you transfer data to the same directory, the system will not allow you to download the duplicate copies.

Clearing memory is necessary to free up space for a new batch of measurements. It is recommended that the device memory be cleared after every data transfer to free up space for the next set of measurements. The only reason the DP5000A does not clear its memory automatically after a download is to allow those who need to do so to download the same data to more than one location.

From the Data menu, select **Clear Memory**. You will be prompted twice to confirm your decision.



**CAUTION:** do not clear the memory until all important data have been transferred. This function also clears the patient ID from the monitor.

## II. BASIC OPERATION

---

### Measurement Result

### Trending and Analysis

### Managing the Displays

## MEASUREMENT RESULT

---

### Blood Pressure

The DynaPulse 5000A can estimate either systolic (SBP) or diastolic (DBP) blood pressure values from accurate measurements of Mean Blood Pressure (MAP) and either SBP or DBP.

The View menu lists the major patient data screens: Trend Graph, Trend List, Measurement List, and Personal Info.

The Personal Info screen is used to note a patient's vital statistics and contact information. The screens listed on the View menu will vary depending



on which window is open when you access the menu. The menu above is accessed from the Trend List.

The toolbar and status bar toggle options are always present in the View menu.

You can also access the Trend List by double clicking on a name displayed on the Patient list. The Trend List displays the measurement trends that a selected patient has recorded and transferred with the DP5000A. For further details on a selected group of measurements when the Trend List is active, the available View menu options include the Trend Graph and the Measurement List.

### View: Measurement List

The Measurement List is a convenient summary displaying for a selected patient the systolic, diastolic, MAP (mean arterial pressure), and HR (heart rate) data as well as any comments appended to the measurements. Unlike the Trend Graph, the Measurement List displays the trend data as a list, rather than a graphical plot.

A screenshot of a software window titled "abp.ucf: Jeremy Bolder ID 3214:2 - Measurement ...". The window contains a table with columns: "Date/Time", "Stat...", "Sys", "Dia", "MAP", "HR", and "Comment". The table has several rows of data, with the row "03/13/01 ... M 96 57 68 49" highlighted in blue.

Date/Time	Stat...	Sys	Dia	MAP	HR	Comment
03/13/01 ...		135	82	99	76	at rest
03/13/01 ...	Err	0	0	0	0	
03/13/01 ...		106	64	78	47	
03/13/01 ...	M	96	57	68	49	
03/13/01 ...		110	56	68	47	
03/13/01 ...		111	56	74	50	
03/13/01 ...		114	64	78	54	
03/13/01 ...		118	64	83	58	
03/13/01 ...		134	74	92	51	

Blood pressures are listed as a systolic (when the heart beats) over diastolic (rest period between beats) reading, for example: 120/80 mmHg. *Mean arterial pressure* is the clinically defined "average" of your blood pressure, taking into consideration both systolic and diastolic pressures.

You can add a comment or mask/unmask any data record in the Measurement List. (You can also mask measurements in the Trend Graph.) Masking a measurement makes that measurement invalid, so it is not counted when analyzing valid data. Masked data are labeled with an "M" under Status, while erroneous data (when the DP5000A could not detect a proper waveform) are labeled with an "Err." Since the erroneous measurements have no valid blood pressure data, the blood pressure and heart rate values display as zeros.

### Sorting the Measurement List

By default, the valid measurements start out listed by when the measurement was taken. You can re-sort the measurements in ascending or descending order by clicking on the column header. The sortable headings in the Measurement List include: *date/time*; *status*, *systolic*, *diastolic*, and *mean arterial pressures*; and *heart rate*. For example, clicking on *MAP* sorts the data in either ascending or descending order according to mean arterial pressure. Clicking on the *Status* heading will move masked and error (Err) measurements to either the top or bottom of the measurement list. Clicking on *Status* after clicking on *MAP* will move the masks and Err measurements to the top or bottom of the list, but the measurements themselves will remain sorted with respect to *MAP*.

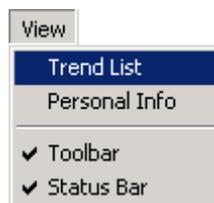
## TRENDING AND ANALYSIS

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Disease management often requires long-term patient monitoring. With hypertension, this often requires blood pressure information to be accumulated and analyzed over the remaining lifetime of a patient. Isolated measurements have a limited benefit, but a series of measurements over time provides a representative average of your patient's blood pressure. Measurements taken during each DP5000A session can be plotted and analyzed to search for trends during the measurement time period.

### View: Trend List

The Trend List lists all measurements taken for a specific patient. You can access the Trend List by double clicking a name on the Patient List or by selecting **Trend List** from the View menu when a patient data screen is open.



A screenshot of a window titled 'abp.ucf: Jeremy Bolder ID 3214 - Trend List'. It features a text input field for 'Comment' and a table with the following data:

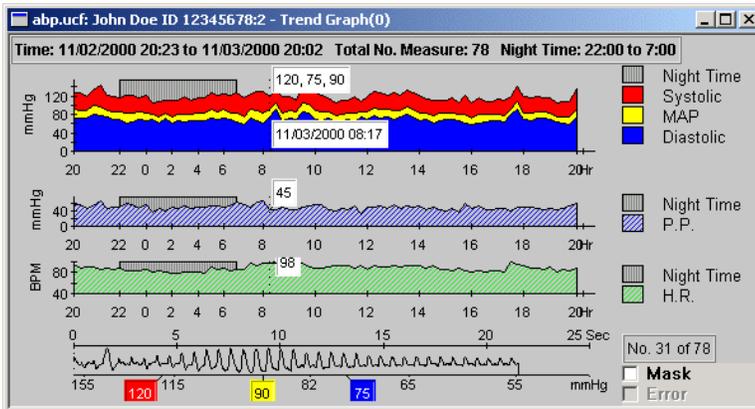
Trend...	No...	Start Date/...	End Date...	Amb	Com
1	36	03/12/01 0...	03/13/01 ...	Y	

The DynaPulse program allows you to sort most listed data by column topic. You can sort data in the Trend List by clicking on a column heading, such as *trend number*, *number of measurements*, *start date/time*, or *end date/time*. As with the Patient List, you can sort data in ascending or descending alphanumeric order in each field. With the date/time columns, they will sort by earliest or latest time.

The comment box allows you to type in messages.

## View: Trend Graph

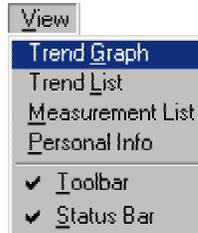
DynaPulse trending allows you to plot a patient's blood pressure information over time in an attractive, graphical format. Line graphs of the blood pressure and pulse measurements show at a glance the patient's response to the treatment regimen. Your DynaPulse 5000A allows you to track a number of patients in this manner.



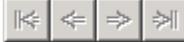
The Trend Graph displays a blood pressure chart (in mmHg vs. time), a pulse pressure chart, a heart rate chart (in BPM, or beats per minute, vs. time) and a waveform of the currently selected measurement. The selected measurement is indicated by a vertical dotted line on the waveform. The value labels show blood pressures, date/time, and heart rate for that reading in white boxes.

By default, systolic values are shown in red, MAP values in yellow, diastolic in blue and HR in green. Night time data is shown as a dark gray region in each chart. (The time period can be adjusted in the analysis setup.)

To access the Trend Graph, double click on a patient name on the Trend List. You can also select the **Trend Graph** feature from the View menu when a trend is selected on the Trend List.



To browse through the data and see corresponding waveforms for any measurement, just click the point you want on BP chart or HR chart.

Use the movement buttons on the toolbar  or the arrow keys on your keyboard, to move the dotted line.

## Plot Style - Line Plot and Area Plot

When the Trend Graph or a linear chart is displayed, the **Style** menu gives options to change the type and format of the displayed chart.



**Area Plot:** By checking this, the DynaPulse software fills the area under the trend curve by its respective color (the systolic trend plot will be colored red, diastolic blue, MAP yellow, and heart rate green). Area plot is the default plot style of all analysis graphs, including the Trend Graph.

**Line Plot:** By checking this, the DynaPulse software plots the chart with measurement points connected by lines (*Note:* when you select one of the plot style options, the other is automatically disabled.)

**Hide MAP:** Selecting the Hide MAP option will hide the MAP values and threshold curve. Deselecting the option will toggle back the MAP values.

**Hide Label:** Selecting the Hide Label option will hide the labels marking the current values in the Trend Graph (this style option is not available with the analysis charts, which do not have labels). Toggle back and forth between hiding and revealing the labels by checking or unchecking this option.

### Masking Problem Data

Using the waveform you can validate each measurement. If you have a measurement that should not be included in the statistical analysis, click on **Mask**, and it will no longer appear on the screen or in the statistics. Clicking on the mask field again will restore the data. A masked measurement will be overlooked during data analysis or printing reports of valid data. Unchecking the box will unmask the measurement. (Measurements can also be masked in the Measurement List.) Erroneous measurements, unlike masked measurements, are automatically labeled and overlooked because the DP5000A device had problems during measurement.

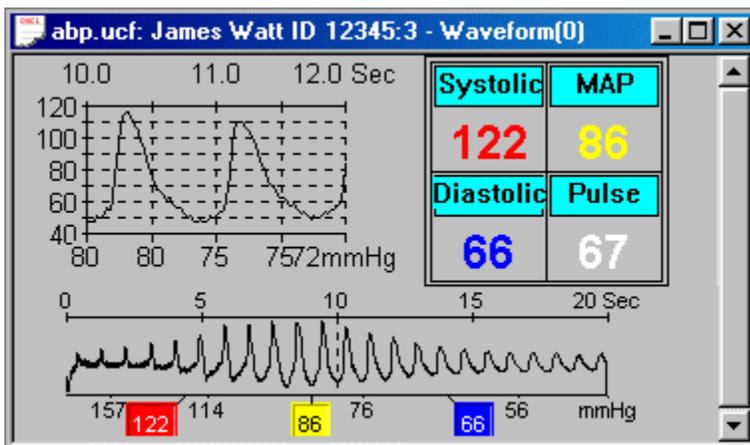
Measurements should not be masked without due cause. Masking decreases the amount of data available for analysis. A pressure waveform does not have to be perfect to yield clinically sound data. To ensure that all the data is evaluated uniformly, we suggest that you create your own criteria for masking a measurement.

To view the waveform in closer detail, use the mouse to double click on an area within the waveform displayed on the Trend Graph. This will change to the waveform screen where you can view the waveform in greater detail.

### Arterial Waveform

The arterial waveform represents the pressure signal produced by the interaction between the restrictive cuff and the pressures generated by the cardiac cycle. A pressure sensor in the DynaPulse unit measures this signal at the brachial artery.

As you view a patient's Trend Graph, you may click on the waveform chart at the bottom of the dialog to enlarge that area of the waveform.



The lower portion of the screen displays entire waveform during the measurement period. The Systolic, Diastolic, MAP (mean arterial pressure), and HR (heart rate, or Pulse) values of this measurement are shown in the upper right table. There are two scales for the arterial waveform. The bottom scale is cuff pressure in mmHg. The upper scale measures time in seconds. The amplitude (height of each individual

spike or pulse) indicates the arterial pressure of a particular pulse relative to the cuff pressure and blood flow.

The current time interval in the upper expanded view is indicated by the vertical dotted line on the lower waveform. To get a clearer view of any portion of the waveform during a two-second interval, click on that point in the lower waveform, and the upper view will expand that area. The upper chart is called the Arterial Pulse Display. It shows a magnified set of heartbeats marked by the cursor in the waveform below. As you move the cursor from one heartbeat to the next, the Arterial Pulse Display changes to show the heartbeat to the right of the cursor position.

Using the arrow keys on the toolbar  or the arrow keys on the keyboard will move the cursor to select a different waveform pulse.

### Understanding the Waveform

Starting from the left, blood flow is restricted by the cuff. As cuff pressure falls, the blood's counter pressure is detected at the edge of the cuff and displayed as a rise in amplitude. As the cuff pressure declines, renewed blood flow allows each pulse to strike the entire width of the cuff, causing the pulse amplitude to increase until it reaches its maximum height on the waveform. Beyond that point the amplitude declines.

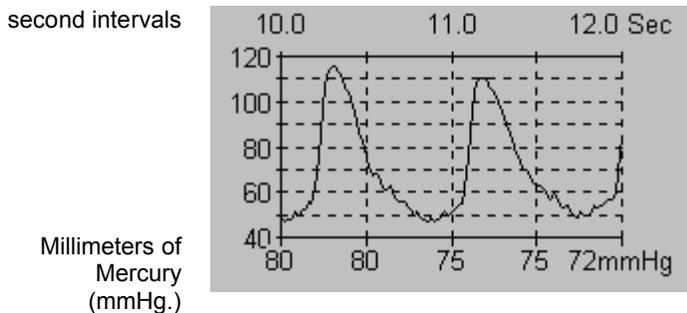
Pressure icons (the three colored boxes located below the pressure waveform) indicate the points where the cuff pressure equaled the patient's systolic, mean, and diastolic blood pressures. The point where blood flow is initially detected is noted by the left-most box and referred to as systolic blood pressure (SPB). The period of maximum amplitude, noted by the middle pointer, is called mean arterial pressure (MAP). The third pointer indicates the diastolic blood pressure (DBP) point.

Note that the systolic and diastolic points can also refer, respectively, to the top and bottom of the wave.

The DynaPulse measurement process relies on pattern recognition to detect changes in the shape of the pressure wave as it moves from systolic to diastolic pressure. It is not dependent on the pulse *amplitude*, or strength.

### The Arterial Pulse Display

The pressure wave shown in the arterial pulse display corresponds to the heartbeat marked by the cursor on the arterial waveform. The pulse wave is displayed in units of mmHg and one-hundredths of a second. You can identify the systolic (SBP) and diastolic (DBP) points of individual heartbeats, as well as specific cardiovascular events such as pressures corresponding to the opening and closing of the aortic valve. This display is often used for educational purposes.



## ACCURACY VALIDATION AND IRREGULAR HEARTBEATS

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The arterial pressure waveform can be used for validating measurement accuracy and detecting irregular heartbeats. Features of the waveform that are used for accuracy validation are:

- Waveform Quality
- Pressure Icon Position

### **Waveform Quality**

Examine the characteristic shape of the arterial waveform.

An ideal waveform has the following characteristics.

- The waveform is 20-30 seconds in length.
- The waveform is symmetrical and has a waxing and waning pattern.
- Pressure limits are set correctly
- No motion artifact is present

Any disruption of the pressure wave caused by irregular heartbeats or by patient movement (arm movement, talking, coughing, etc.) can potentially compromise the accuracy of the measurement. These disruptions in the pressure wave are typically referred to as "artifact."

In a normal waveform display, the heartbeats will occur at regular intervals and will have uniform width and shape. Poor quality measurements often have jagged and unevenly spaced heartbeats.

### **Pressure Icon Position**

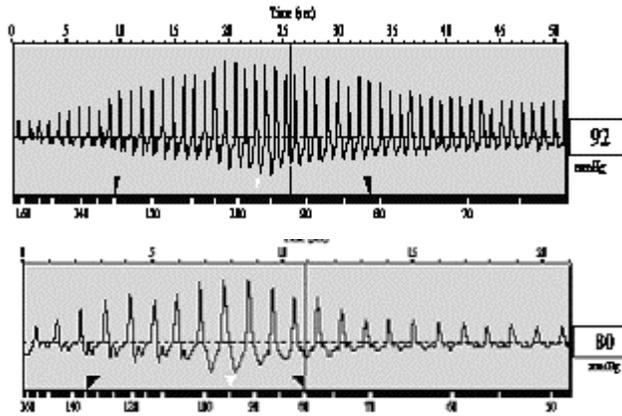
The position of the pressure icons relative to the position of the artifact will indicate whether the measurement has been compromised. If an irregularity in the pulse waveform occurs close to one of the blood pressure icons or if there is significant patient movement at one of the blood pressure indicators, you may have a poor quality measurement.

As you use the DynaPulse, you will notice that individual patients will display characteristic waveform patterns. Some patients will have a shorter, fatter waveform, some a thinner, more elongated waveform. Some waveforms will have a high amplitude, some a low amplitude with differences in the air release time.

Waveform patterns may vary due to various physiological differences, specifically in the composition of the patients' arm. For example, an individual with a muscular arm has little in the way of fat tissue to impede the pressure signal acquired by the DynaPulse. An obese arm has significant amounts of fat tissue, which will tend to damp the pressure signal. These physiological differences will be reflected in the appearance of the pressure waveform.

Let us assume that you keep the air release time within the normal limits of 20-30 seconds, then measurements should be always obtainable; assuming no movement artifacts are introduced. What happens if your measurements are taken with air release times outside this range? Shorter air release times produce individual heartbeats that are spread farther apart. With a longer release time, heartbeats will be close together. This holds true for heart rate as well. With a slow heart rate, the heartbeats will be spread farther apart. With a fast heart rate, the heartbeats will be closer together. With practice, you can become familiar with how a good measurement should appear.

You will discover how the differences in air release rate will cause differences in the appearance of the DynaPulse pressure waveform. The following waveform examples illustrate how pressure waveforms might differ from one patient to the next.



In this example, blood pressure measurements were taken on the same individual. Even with the blood pressures and heart rate being similar, the difference in air release time caused the waveforms to appear quite different.

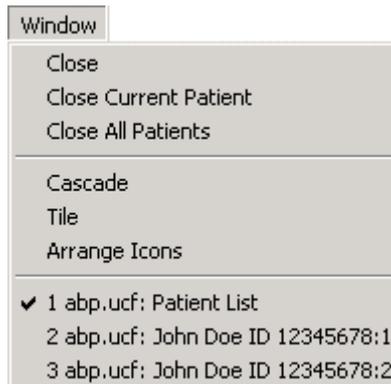
## MANAGING THE DISPLAYS

### Cascade, Tile and Close All Windows

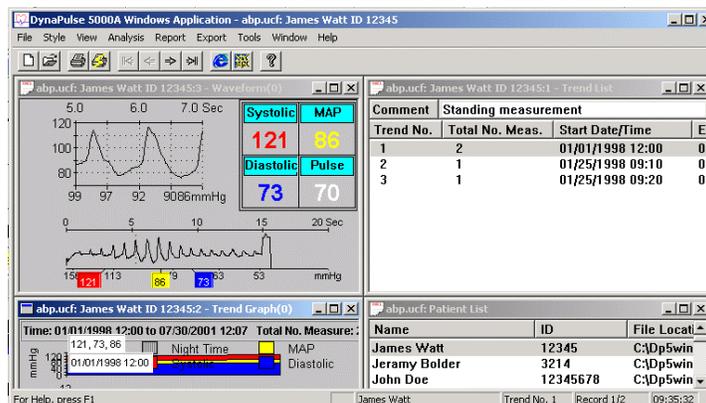
The DynaPulse 5000A allows you to display multiple measurements on the screen. This feature is useful if you wish to compare data from different measurements.

Features like the Cascade and Tile options (accessed from the Window menu) help organize open windows.

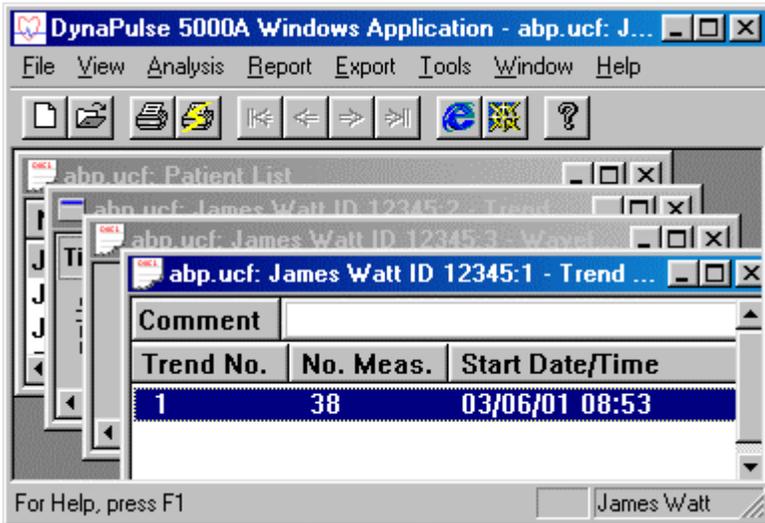
The Window menu also lists the open displays. Choosing any listed display brings that display to the foreground.



Selecting the **Tile** option produces a display as seen below.

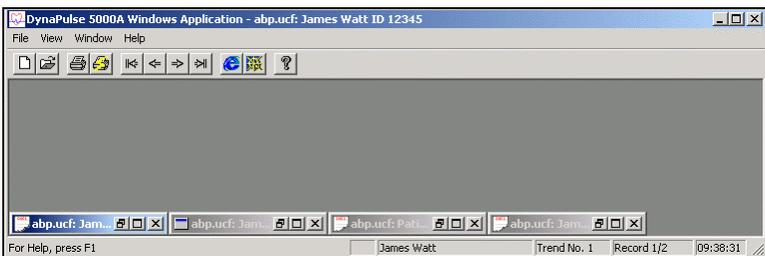


Choosing the **Cascade** option causes each window to overlap so only title bars are visible.



## 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 Patient List may be minimized and arranged by selecting this feature.

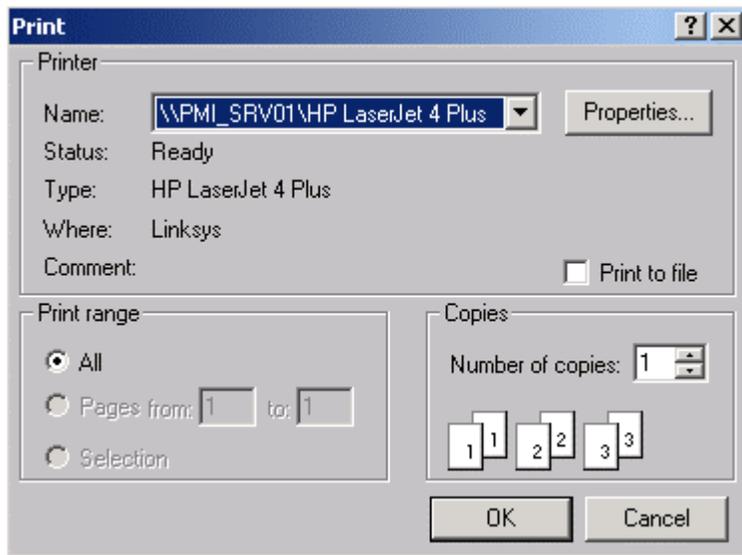


Choosing the **Close All** option will clear off all measurement screens and reduce the Patient List and Trend windows (if open) to icons. The icons will indicate the time and date of the measurement associated with the icon.

## PRINTING

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You can print any displayed graph or report by selecting **P**rint from the **F**ile menu or by using the toolbar print icon.



Use the standard Windows-type Print dialog to select the printer and the number of copies and range of pages. Other print functions are described in the following chapter.

### III. ADVANCED OPERATIONS

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#### Personal Information

#### Statistical Analysis Setup

#### Statistical Analysis Graphic Displays

#### Statistical Analysis Reports

#### Data Export

#### The Tool Window

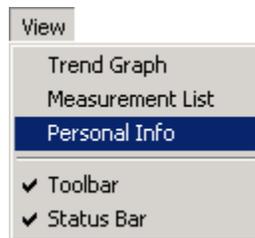
### PERSONAL INFORMATION

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The Personal Info (Patient Record) dialog allows you to create, view or edit personal information for a selected patient. This dialog has sections for entering or viewing such information as physician information, phone numbers, street address, fax numbers, e-mail), medical institution, statistical information (birth date, height, weight, gender) and a brief medical history. Personal information for each patient can be printed in report form.

Use the following procedure to open and use the Personal information dialog for a patient.

1. On the Patient list, click on the patient's name. This will activate the Personal Info option on the View menu.
2. Select **Personal Info** from the View menu. You may be asked to indicate whether you want to use default institution data.



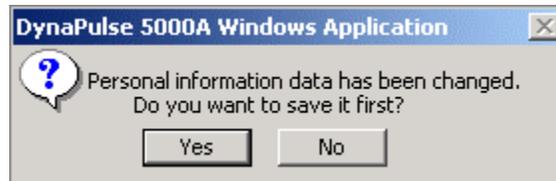
If you click **Yes**, the DP5000A automatically fills in the institution fields with default data.



If you click **No**, the institution fields of the dialog will be empty when it opens.

Patient	
Name	Jeremy Bolder
ID	3214
Street Address 1	Phone
Street Address 2	FAX
City and State	E-Mail
Postal (ZIP) Code	Country
Ethnicity	(unspecified)
Sex	M
Weight	86 kg
Date of Birth	9/25/01 (2002)
Height	176 cm
Cuff Size	Medium
DynaPulse Unit ID	
Medical history and clinical tests/results	
Institution	
Name	Pulse Metric, Inc.
Physician	
Address	11777 Sorrento Valley Rd
Nurse	
City/State/Country	San Diego, Ca 92121
Phone/Fax	

- There is no Save or OK button. Select **Save** from the File menu when you finish. If you forget to do this, you will be prompted to save when you exit the dialog.

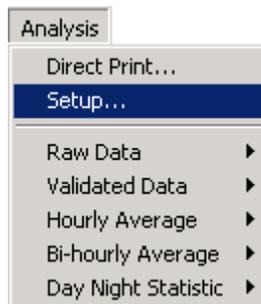


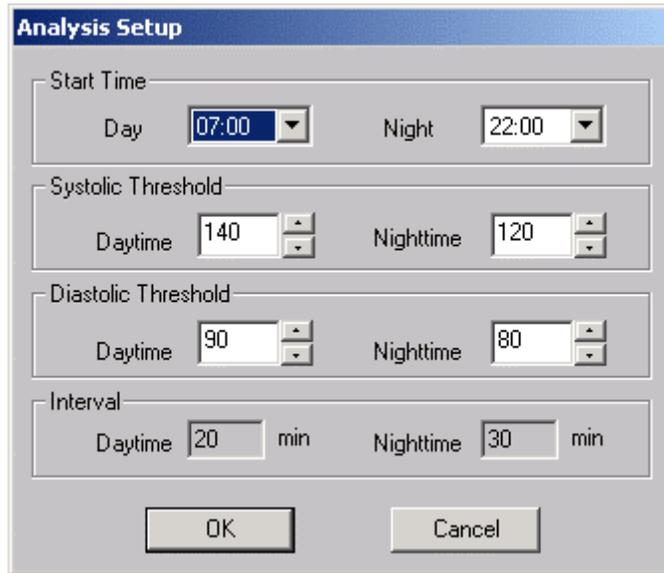
## STATISTICAL ANALYSIS

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### Setup

The Analysis menu is available when you select a patient from the Patient List. The Setup dialog displays the measurement intervals and allows you to reset the day and night start times and the systolic and diastolic thresholds. A single down arrow (Start Time) opens a selection list. A double arrow allows you to Raise or lower the threshold values.





**Start Time:** Ambulatory measurements in a 24-hour period are divided into day and night periods. The selected time indicates the start of the period (the start of the day period will be the end of the night period).

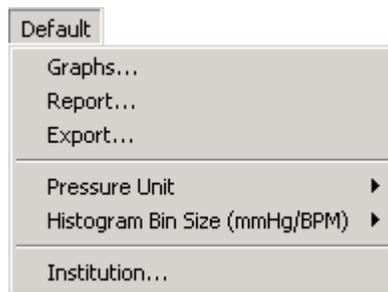
**Systolic and Diastolic Thresholds:** The DynaPulse program will automatically count blood pressure readings higher than the threshold values you specify, and these measurements will be tallied in data reports and charts as percentages of the total number of measurements. Having the thresholds set too low or too high would not be useful in analysis. Both the systolic and diastolic thresholds are set to values suggested by JNC VI<sup>1</sup> guidelines. High blood pressure is defined as pressure in excess of 140/90mmHg, so the default setting for the daytime systolic threshold is 140mmHg, and since blood pressure are normally lower when a person is asleep, the default nighttime systolic threshold is 120mmHg.

**Interval:** The interval between measurements is displayed and cannot be changed from this dialog box. This is set within the DP5000A device itself at the start of each ambulatory session.

## Default Menu Setup

Before using the analysis tools, you should set the defaults for reports, analysis graphs, and printing. Set these values from in the Default menu.

Some of the default options can be changed at any time, but you must be at the patient list window level, and any changes made will not apply until new patient data is opened. While viewing open patient data,

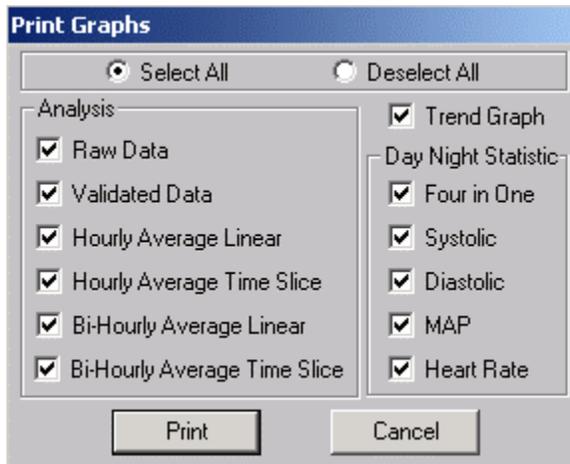


you cannot change default options for Pressure Unit and Histogram Bin Size. In order to change these options, you must close all patient data screens.

<sup>1</sup> Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, November 1997.

## Graphs... (Print Settings)

Selecting Graphs from the Default menu will bring up the Print Graphs window. Use the radio buttons to select or

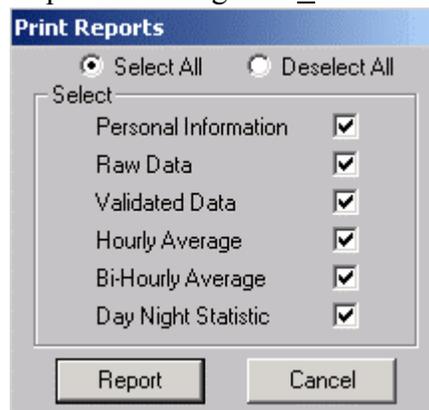


deselect *all* graphs for printing, or use the checkboxes to select or deselect individual graphs to print. Each checkbox corresponds to a chart type located in the Analysis menu. Clicking the **O**k button will not print the graphs, but actually set the default options for future printing, whether by direct print or with the toolbar print buttons (e.g., express print). 

## Default Reports Print Settings

The Default menu has options to change the report printing settings. The Print Reports window lists the different reports that can be printed through the File menu or with the toolbar print buttons.

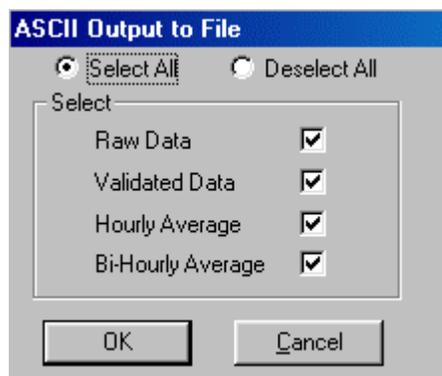
Use the radio buttons to select or deselect *all* reports for printing, and use the checkboxes to select a single report. Clicking the **O**k button will set the default settings and will not actually print reports. These default settings will show up the next time you print



reports and will also determine what will be express printed. 

## Default: Export Settings

Blood pressure data and analysis can be exported into a text (ASCII) file or similar file for use outside of the DynaPulse program. From the Default menu, select **E**xport to bring up the ASCII Output to File dialog.

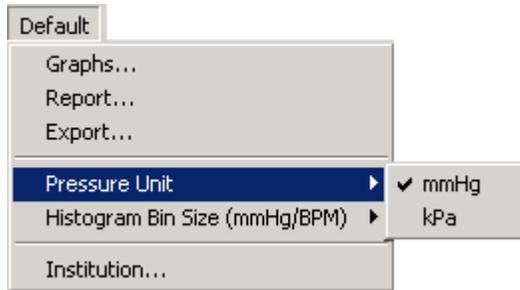


You can select or deselect all via the top two check circles or use the check boxes to select or deselect single options. These default settings will show up the next time you export to a file. They also determine what will be express exported.



### Default: Pressure Unit

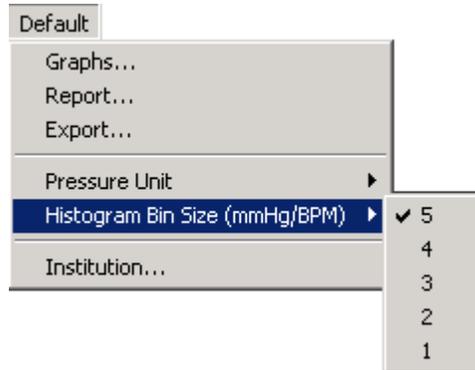
The unit of blood pressure used in all the reports, analyses, and displays can be changed in the Default main menu between



mmHg (millimeters of mercury) or kPa (kilopascals). The mmHg pressure unit is common in North America, while kPa is the metric system equivalent used in China and other countries where the metric system is preferred. You can toggle the DP5000A device itself between displaying pressures in mmHg or kPa, but the DP5000A device does not need to be set in the same pressure unit you select via the DynaPulse software program when transferring data.

### Default: Histogram Bin Size

The Histogram Bin Size selects the bin size number for histograms in the Day Night Statistic analyses. A histogram is a counting chart that displays the number of times a measurement falls



within a certain blood pressure or heart rate range. The results are shown as a frequency (the count) vs. bin size (the measurement range) graph. The bin size in the DynaPulse histograms can range from as small as 1 increment up to as large as 5 increment values. If the pressure unit is chosen as kPa instead of mmHg the bin size must be 1 kPa.

### Default: Institution

The Institution Information dialog opens automatically the first time the DynaPulse program is loaded. You can also select Institution from the Default menu to open the dialog. The information you enter here will become the default institution information that can be imported for each patient to save input time.

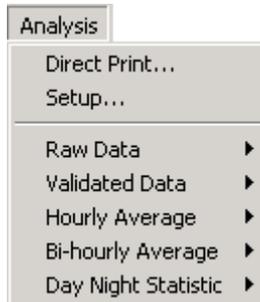
The institution data can be changed at any time for separate patients in each individual's personal information screen.

## Chart Styles

See Plot Style - Line Plot and Area Plot on page 17.

## Statistical Analysis Graphic Displays

The Analysis menu provides a variety of charts and histograms that make the measurements easier to understand. You can use them to compare the analysis data from before and after medication. The following graphic options are available:



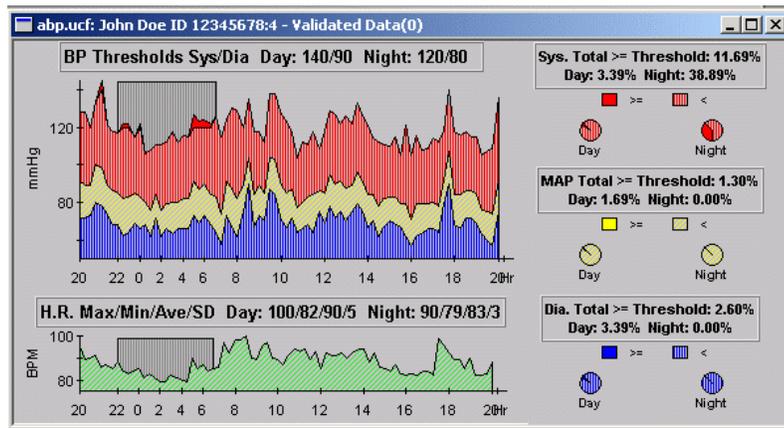
Menu Item	Content	Format Options
Raw Data	Chart of all data over time	Linear only
Validated Data	Chart showing only unmasked measurements	Linear only
Hourly Average	Hourly-averaged data	Linear or time slice
Bi-hourly Average	Data averaged for every two-hour period	Linear or time slice
Day Night Statistic	Histograms of day and night values	Displays for systolic, diastolic, MAP, heart rate, or all of the above

### For all Charts and Histograms

1. By default, systolic values are shown in red, MAP values in yellow, diastolic values in blue and heart rate values in green. Nighttime is shown in gray.
2. The *average value* (Ave) is the arithmetic average of the analyzed measurements.
3. The standard deviation (SD) is a range surrounding the average value within which 67% of the measurements will fall. The larger the SD, the wider the range.

## Analysis: Raw Data vs. Validated Data

Only linear charts are available for the Raw and Validated data displays. The Raw Data display shows all of the blood pressure data, including both masked measurements and validated, or unmasked data. Validated Data excludes the masked and erroneous blood pressure measurements.



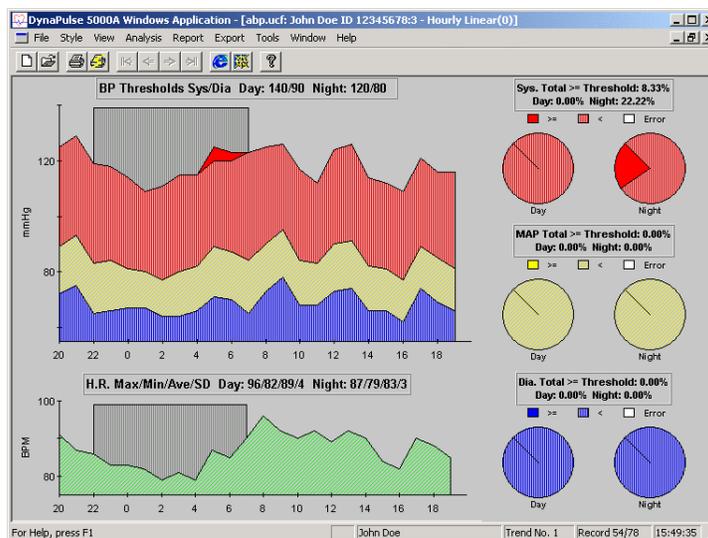
The left part of the chart displays blood pressure (BP) and a heart rate (HR) charts. The BP thresholds are displayed in the upper banner of the BP chart. The maxima, minima, average and SD (standard deviation) heart rates are displayed in the upper banner of the HR chart for both day and night periods.

Charts can be displayed in either area plot style, with values below threshold shaded in; or line plot style, with thresholds shown by dotted line and no shading (see Chart Styles on page 29).

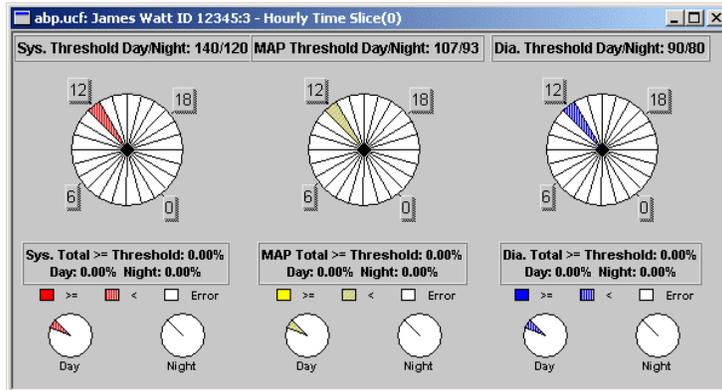
The right part of the chart contains three groups of pie charts analyzing systolic, MAP and diastolic values separately in day and nighttime. Pie charts are drawn as percentage breakdowns of normal, over-threshold, and erroneous data. The upper banners show the percentages of totals, daytime and nighttime values greater than threshold.

## Analysis: Hourly or Bi-hourly Average

The Hourly and Bi-hourly analysis charts have both Linear and Time Slice formats.



Linear



### Time-sliced

Linear charts plot data over time in x-y plots with pie charts also shown to the right. Time-sliced charts display averaged data in pie charts with time periods of one or two hours indicated by slices.

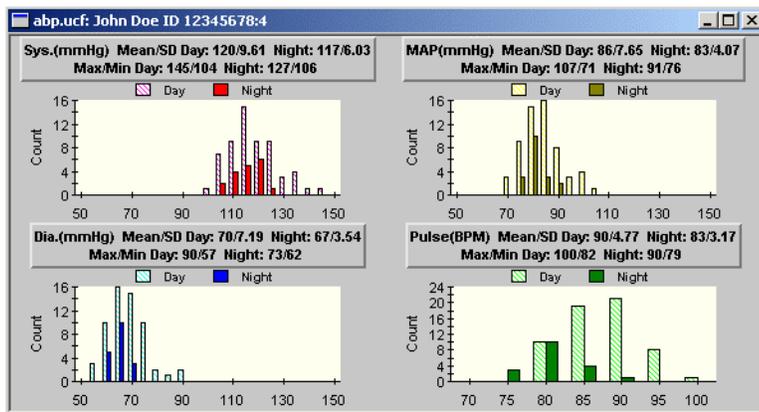
The Hourly Average chart calculates and displays the average of validated data for each one-hour period. The Bi-hourly Average analysis uses two-hour time periods. Linear charts can be displayed in either area plot style, with values below threshold shaded in; or line plot style, with thresholds shown by dotted line and no shading.

**BP:** Blood pressure thresholds are displayed in the upper banner of the BP chart. Set the BP thresholds beforehand, as described above. They are used to flag instances of hypertension or other blood pressure events.

**HR:** Day and night maxima, minima, average and standard deviation values of heart rate are displayed in the upper banner of the HR chart. The right part of the chart contains three groups of pie charts analyzing systolic, MAP and diastolic values separately in day and nighttime. Pie charts are drawn as percentage breakdowns of normal, over-threshold, and erroneous data. The upper banners show the percentages of totals, daytime and nighttime values greater than threshold.

### Analysis: Day Night Day/Night Histogram

The Day Night Statistic option allows you to select Systolic, Diastric, MAP, Heart Rate histograms or All of them for column chart analysis. If you select all, as we have below, and you want to see just one, double click on the one part of the chart and it will enlarge.



A histogram will tally the frequency of day and night pressure readings that exceed your specified threshold levels.

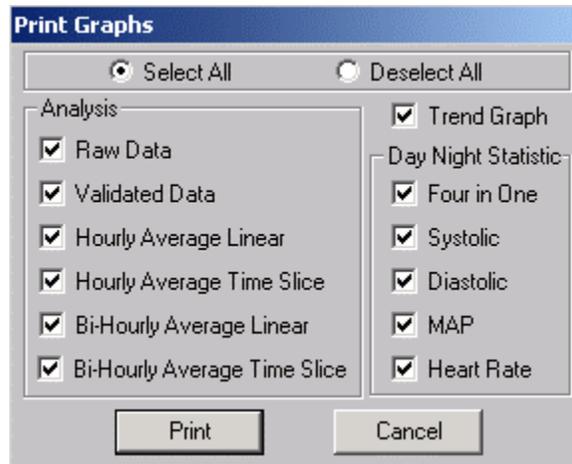
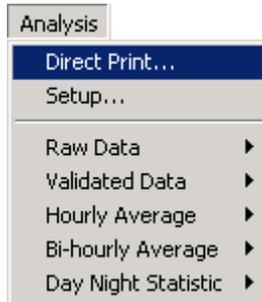
In the upper banners of each histogram, you can see mean, maximum, minimum, and standard deviation (SD) values. By default, data are grouped in five-value intervals. For example, 60 to 64 inclusive is

grouped in 60, and 115 to 119 inclusive are grouped in 115. To change the interval values, select **Histogram Bin Size** on the Default menu.

## Direct Print

Use the express print toolbar button  to export all default data files and print all of the default graphs and reports.

The Direct Print command on the Analysis menu works like the print function on the File menu and toolbar, except that it displays the Print Graphs dialog, which allows you to print selected graphs for a patient without displaying them.



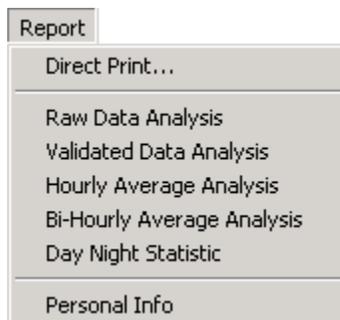
The selections are your previous default print settings, but you may change them here for this printing. Your default selections remain unchanged. You can select all graphs or any combination of the listed options. Click in the check box to toggle the option. Click on the **Print** button to start the print.

## Reports

You can use the Report menu options when you have selected a patient on the patient list.

For printing options, see Printing on page 23.

The following DynaPulse 5000A reports are available:



Menu Item	Content
Raw Data	Chart of all data over time
Validated Data Analysis	Chart showing only unmasked measurements

Hourly Average Analysis	Hourly-averaged data
Bi-hourly Average Analysis	Data averaged for every two-hour period
Day Night Statistic	Day and night values for systolic, diastolic, MAP, and heart rate
Personal Info	Information gathered via the Personal Info dialog

## Report: Day-Night Analysis

The Day Night Statistic report displays error, masked, and validated data with totals. It also reports averages and standard deviations (STD) of the blood pressure and heart rate measurements during daytime, nighttime, and for total

DYNAPULSE 5000A ABP DAY-NIGHT ANALYSIS REPORT 02/15/01 15:51			
INSTITUTION:			
PATIENT NAME:		John Doe	
PATIENT ID:		DOE2001	
ABP Recording Period:		02/13/97 10:18 To 02/14/97 08:32	
Day/Night Start Time:		7:00 / 22:00	
DATA STATUS:			
Category	DAYTIME No. Meas.(%)	NIGHTTIME No. Meas.(%)	SUM No. Meas.(%)
Total	28	9	37
Error	2 [7.14]	0 [0.00]	2 [5.41]
Masked	0 [0.00]	0 [0.00]	0 [0.00]
Validated	26 [92.86]	9 [100.00]	35 [94.59]
	DAYTIME	NIGHTTIME	SUM
AVERAGE & [STD]:			
Systolic (mmHg)	146 [13.00]	141 [12.00]	145 [13.00]
MAP (mmHg)	100 [10.00]	99 [12.00]	99 [10.00]
Diastolic (mmHg)	79 [10.00]	79 [11.00]	79 [10.00]
Heart Rate(BPM)	59 [4.00]	58 [8.00]	59 [5.00]
MAXIMA & [DATE/TIME]:			
Systolic	171 [02/14/97 07:02]	159 [02/13/97 22:02]	171 [02/14/97 07:02]
MAP	120 [02/13/97 10:18]	121 [02/13/97 22:02]	121 [02/13/97 22:02]
	120 [02/13/97 11:46]	-	-
Diastolic	103 [02/13/97 11:46]	100 [02/13/97 22:02]	103 [02/13/97 11:46]
Heart Rate	69 [02/14/97 07:32]	76 [02/13/97 22:02]	76 [02/13/97 22:02]
MINIMA & [DATE/TIME]:			
Systolic	120 [02/13/97 16:16]	123 [02/14/97 03:02]	120 [02/13/97 16:16]
MAP	80 [02/13/97 15:16]	82 [02/14/97 01:02]	80 [02/13/97 15:16]
	80 [02/13/97 16:16]	-	80 [02/13/97 16:16]
Diastolic	60 [02/13/97 15:16]	62 [02/14/97 01:02]	60 [02/13/97 15:16]
Heart Rate	53 [02/13/97 20:16]	52 [02/14/97 03:02]	52 [02/14/97 03:02]
	-	52 [02/14/97 05:02]	52 [02/14/97 05:02]

time, as well as listing the maxima and minima of each value during each time period, listing the time each measurement was taken.

## Report: Raw Data Analysis

Raw Data Analysis reports the percentage breakdown of all raw data. Systolic, diastolic, and MAP pressures are tallied into normal, over-threshold, and invalid (masked and erroneous) measurements according to day, night, and total time. The percentage breakdown can be seen in graphical form in the pie charts of the linear raw data analysis chart.

INSTITUTION: Pulse Metric  
 PATIENT NAME: James Watt  
 PATIENT ID: 12345  
 ABP Recording Period: 01/01/1998 12:00 To 07/30/2001 12:07  
 Day/Night Start Time: 7:00 / 22:00  
 Systolic Threshold (Day/Night): 140 / 120 mmHg  
 Diastolic Threshold (Day/Night): 90 / 80 mmHg  
 MAP Threshold (Day/Night): 107 / 93 mmHg (= 1/3 SYS + 2/3 DIA)

SUMMARY: Percentage Breakdown

	Time	Normal	>= T	Mask+Err
Systolic	Day	100.00	00.00	00.00
	Night	00.00	00.00	00.00
	Total	100.00	00.00	00.00
Diastolic	Day	100.00	00.00	00.00
	Night	00.00	00.00	00.00
	Total	100.00	00.00	00.00
MAP	Day	100.00	00.00	00.00
	Night	00.00	00.00	00.00
	Total	100.00	00.00	00.00

Date/Time	Status	Sys.	Dia.	MAP	HR	Comment
01/01/1998 12:00		121	73	86	70	
07/30/2001 12:07		132	79	98	73	

**Report: Validated Data Analysis**

The Validated Data Analysis report is similar to the raw data report, except that invalid measurements are not reported. Normal and over-threshold systolic, diastolic, and MAP values are shown by day, night, and total time period. A graphical display is also available via the Analysis menu.

## Report: Hourly Average Analysis

DYNAPULSE 5000A ABP HOURLY ANALYSIS REPORT		08/27/2001 14:09		
INSTITUTION:	Pulse Metric			
PATIENT NAME:	James Watt			
PATIENT ID:	12345			
ABP Recording Period:	01/01/1998 12:00 To 07/30/2001 12:07			
Day/Night Start Time:	7:00 / 22:00			
Systolic Threshold (Day/Night):	140 / 120 mmHg			
Diastolic Threshold (Day/Night):	90 / 80 mmHg			
MAP Threshold (Day/Night):	107 / 93 mmHg (= 1/3 SYS + 2/3 DIA)			
SUMMARY: Percentage Breakdown				
	Time	Normal	>= T	Mask+Err
Systolic	Day	06.67	00.00	93.33
	Night	00.00	00.00	100.00
	Total	04.17	00.00	95.83
Diastolic	Day	06.67	00.00	93.33
	Night	00.00	00.00	100.00
	Total	04.17	00.00	95.83
MAP	Day	06.67	00.00	93.33
	Night	00.00	00.00	100.00
	Total	04.17	00.00	95.83
Date/Time	D/N	SYS(>=T)	DIA(>=T)	MAP(>=T) HR
01/01/1998 12:00-13:00	D	126	76	92 71

The Hourly Average Analysis report differs from the raw data report in that the data is first averaged per hour and then analyzed into normal, over-threshold, and masked and erroneous categories according to day, night, and total time.

## Report: Bi-Hourly Average Analysis

The Bi-hourly Average Analysis report is similar to the hourly average analysis, except that the data is averaged for every two hours rather than one.

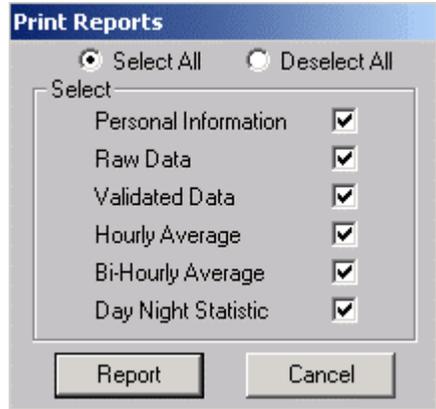
## Report: Personal Info

A detailed two-column personal information report can be printed out to keep in file for each patient. You can fill in basic information about the selected patient in the Personal Information screen.

DYNAPULSE 5000A ABP PERSONAL INFORMATION REPORT		08/27/2001 14:21
PATIENT NAME:	James Watt	
PATIENT ID:	12345	
ADDRESS:	39 Cranberry Street	
CITY/STATE/COUNTRY:	Boston MA	
PHONE/FAX:	234-0987	
DATE OF BIRTH:	01/01/2000	
WEIGHT(lb):	120.00	
HEIGHT(ft in):	5'	
SEX/AGE:	/1	
CUFF SIZE:	M	
<hr/>		
INSTITUTION:	Pulse Metric	
ADDRESS:	123 Washo Street	
CITY/STATE/COUNTRY:	San Diego/CA/USA	
PHONE/FAX:	456-0987	
PHYSICIAN:	Jones	
NURSE:	Mira	
<hr/>		
MEDICAL HISTORY:	Potentially fatal blood pressure variations	

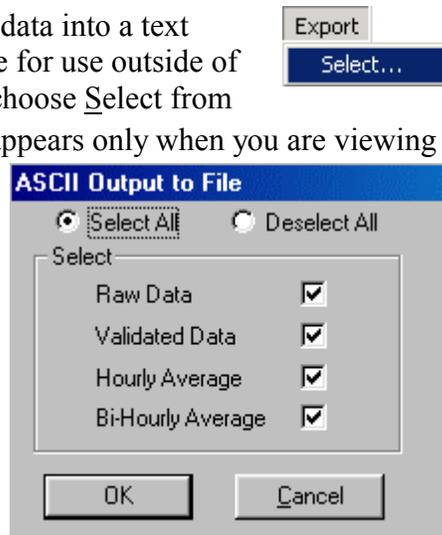
### Direct Print

Use  (the express print toolbar button) to export all of the default data files and print all of the default graphs and reports. Direct Print on the Report menu works like Direct Print on the Analysis menu, except that the print dialog allows you to print selected reports instead of graphs.



## Export Results to a File

To export blood pressure data into a text (ASCII) file or similar file for use outside of the DynaPulse program, choose Select from the Export menu, which appears only when you are viewing a data display. This will bring up the ASCII Output to File dialog. The selections will be your default settings, but you may change it for just this time and output your new selections. Your default selections will remain unchanged.

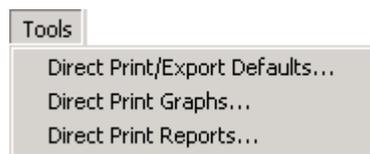


After exporting, a separate dialog box will appear listing the names of the files outputted. These files can be found in the Export subdirectory: for example, if you installed DynaPulse software in the default C:\Dp5win directory, the ASCII files can be found in C:\Dp5win\Export. Text files can be read with any text editor program such as Windows Notepad.

## THE TOOL WINDOW

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The Tools menu appears whenever a patient has been selected on the Patient List. It is a shortcut menu for all the Direct Print options



available in the Analysis and Report menus. As with Direct Print, your default printing selections will remain unchanged after changing printing selections through the Tools functions.

**Direct Print/Export Defaults:** This option allows you to print all analysis graphs and reports and to export data results to ASCII files using to your default settings. The Express Print toolbar button is the shortcut button for this menu item. 

**Direct Print Graphs:** This menu item is the same as the Direct Print in the Analysis menu: it will print all default analysis graphs. You may select new graphs to print for just this time.

**Direct Print Reports:** This menu item is the same as the Direct Print in the Report menu: it will print all default analysis reports. The selected reports are your previous default settings, but again you may change them just for this time and print your new selections.

## IV. OPERATION REFERENCES

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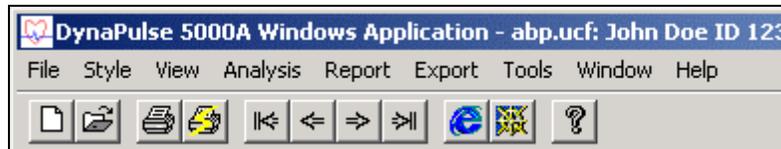
### MENUS FOR THE DYNAPULSE 5000A

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The menu bars and tool bars change as you move from screen to screen. There are at least five variations. The two shown below show all of the 13 menu options listed on the following pages.



Menu and toolbar when Patient List is active



Menu and toolbar when Trend List is active

<div style="border: 1px solid gray; padding: 2px;"> <b>File</b>            Open...      Ctrl+O            Print Setup...            Print Preview            Print...      Ctrl+P            1 abp.ucf            Exit         </div>	Open Patient Lists Print active report window See the document as it will print Set the default printer and active printing List of open files Exit- Exits the DynaPulse program
<div style="border: 1px solid gray; padding: 2px;"> <b>Default</b>            Graphs...            Report...            Export...            Pressure Unit      ▶            Histogram Bin Size (mmHg/BPM)      ▶            Institution...         </div>	Set the data used in reports Set what reports to print Set what data are exported in ASCII Choose mm Hg or kPa MmHg/BMP Edit the institution information
<div style="border: 1px solid gray; padding: 2px;"> <b>Patient</b>            Add...            Edit...            Delete...            Find...            Find Next            Select         </div>	Add new patient to list Edit existing patient information in list Permanently remove a patient's record Search for patient name or ID Show next match to name search Select the highlighted patient name

Style

- Line Plot
- ✓ Area Plot

---

- Hide MAP
- Hide Label

Toggle display mode to show dotted line only or color filled

Toggle display mode to show or hide MAP

Toggle display mode to show or hide label

Data

- Enable Amb
- Disable Amb
- Data Transfer
- Clear Memory

Prepare monitor for ambulatory collection

Disable monitor from ambulatory collection

Transfer collected data from monitor to PC

Clear the memory of the monitor

View

- Trend List
- Personal Info

---

- ✓ Toolbar
- ✓ Status Bar

Patient List display

Display Patient Trend List

View the Personal Info dialog

Turns Toolbar off/on

Turns Status Bar off/on

View

- Trend Graph
- Trend List
- Measurement List
- Personal Info

---

- ✓ Toolbar
- ✓ Status Bar

During graphic display

Display Trend Graph

Display Patient Trend List

Display Measurement List

View the Personal Info dialog

Turns Toolbar off/on

Turns Status Bar off/on

Analysis Report Export

- Direct Print...
- Setup...

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- Raw Data
- Validated Data
- Hourly Average
- Bi-hourly Average
- Day Night Statistic

- Linear

- Linear
- Time Slice

- Systolic
- Diastolic
- MAP
- Heart Rate
- All

Print all reports selected in Default

Set analysis parameters

Display analysis charts using the display method indicated

Report

- Direct Print...

---

- Raw Data Analysis
- Validated Data Analysis
- Hourly Average Analysis
- Bi-Hourly Average Analysis
- Day Night Statistic

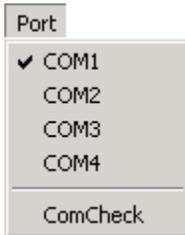
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- Personal Info

Print all selected or default graphs and reports and make default exports

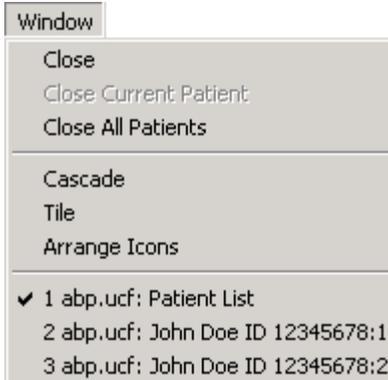
Display tabular column reports

Personal Information Report



Display com port settings

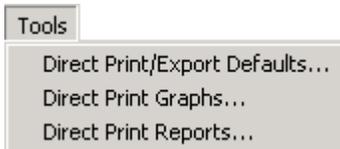
Automatically configure the com port



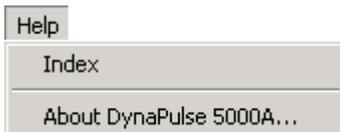
Close the Patient List  
Close a Patient's active windows  
Close all Patient's active windows  
Cascade all open windows  
Tile stack all open windows  
Arrange open dialogs as icons on the bottom of the page  
Displays what windows are open



Export data in ASCII format



Print all reports and exports data  
Print all graphs  
Print all reports



Index of on-line Help topics  
Information about the software

## V. TROUBLESHOOTING

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### ERROR MESSAGES DURING COMMUNICATION:

**“No Data in the unit”**: Indicates that the monitor-PC interface is working, but there are no data in the monitor to transfer.

**“Patient ID Mismatch”**: Indicates that the monitor-PC interface is working, but the ID selected for data transfer does not match the ID chosen when the monitor was enabled for ambulatory operations.

**“Communication Error”**: Indicates a problem with the interface. Possible causes:

- a. *Switched off or inactive DP5000A monitor*: Use the side switch to activate monitor, and push the on/off button on the face of the monitor. Then wait for the monitor to cycle to the “ready measurement” mode.
- b. *Insufficient DP5000A monitor power*: Check batteries, and replace if necessary.
- c. *Faulty USB cable*: Contact Pulse Metric Technical Support or its authorized distributor for replacement information.

When a “communication error” message appears, try to repeat the desired function before assuming there is a problem. The DP5000A has a “sleep” mode that helps to save battery life and just does not “wake-up” fast enough for some processors.



## **VI. APPENDICES**

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### **COM PORT CONFIGURATION: WINDOWS 98/ME/2000/NT/XP**

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For technical problems with the COM port configuration, call Technical Support at (760) 842-8224, or E-mail [teksupport@dynapulse.com](mailto:teksupport@dynapulse.com).

## **CHECKING CALIBRATION**

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To check the calibration of the DynaPulse 5000A unit in reference to a standard sphygmomanometer, you will need to connect a sphygmomanometer (recommend vertical mercury type) T - connector with the DP5000A and the cuff. Wrap the cuff loosely around a bottle that approximates an arm size (non-crushable).

*Before you continue, be aware that you should not open the DP5000A to adjust the calibration of the unit or you will void all warranty. Also, only perform this procedure if you think the DP5000A is off by more than +/- 3mmHg.*

Steps to check calibration:

1. Once sphygmomanometer is connected in line with the DP5000A and cuff, run the DynaPulse software.
2. Go to Measure and set the high range to 220mmHg and leave the low range at default of 50mmHg.
3. Set the top of the speed knob on the DP5000A to S. This is the slowest bleed rate possible.
4. Go to Measure and Start. Select three measurement points such as 200, 160, 80 mmHg to compare the sphygmomanometer with what you see on screen.
5. Once the measurement begins, record the values you get from the sphygmomanometer and the computer screen as the air slowly leaks from the system.

If there is greater than +/- 3 mmHg difference between the values, contact Pulse Metric to schedule a calibration of your DP5000A. Again, do not try to calibrate the DP5000A yourself.

## **DYNAPULSE USB DRIVERS**

Instruction for installing the two DynaPulse USB drivers needed for operation of the DynaPulse Ambulatory Blood Pressure Monitor.

NOTE: Be sure you install the drivers before you connect your DynaPulse Ambulatory Blood Pressure Monitor to your computer.

1. Insert the 'USB drivers' CD into your CD Rom Drive.
2. Next, connect the DynaPulse Ambulatory Blood Pressure Monitor to your computer via the provided USB cable. Please NOTE: the unit must be powered on when making the connection.
3. This will start the 'Found New Hardware Wizard'. Click 'Next >'. Keep the option 'Search for a suitable driver for my device (recommended) selected. Click 'Next >'.  
4. Make sure that the 'Specify Location' option is checked under the 'Optional search locations' then click 'Next >'. When the next window opens, click on the 'Browse' button and navigate to the folder contents found on the CD, which contains the driver belonging to your computer's operating system. If you are using Windows 2000 or Windows XP, you will need to select the folder titled 'Win2K\_XP'. If you are using Windows 98 Second Edition, you will need to select the folder titled 'Win98SE'. When the

appropriate folder is displayed in the 'Look in:' field, click 'Open'. The 'Locate File' window will close. Click 'OK' to close the remaining window. If successful, you should be prompted with the 'Driver Files Search Results' window indicating that the wizard has found a driver to the device. Click the 'Next >' button

5. Finally, you should be presented with a window reading 'Completing the Upgrade Device Driver Wizard'. Click 'Finish'.

6. When this first file installation is complete, another prompt will be given indicating 'New Hardware Found', 'CP210x USB to UART Bridge Controller'. File settings from the previous file installation will carry over and the 'Next >' button needs to be clicked until the final installation screen is displayed, indicating completion of the secondary driver file.

7. The driver files needed to use your DynaPulse Ambulatory Blood Pressure Monitor are now loaded on your computer.

**If the 'Found New Hardware Wizard' does not start when the DynaPulse Ambulatory Monitor is first plugged in to the USB port follow these steps.**

1. From 'Start' open 'Control Panel', then open 'System' or for Windows XP operating systems, open 'Performance and Maintenance' then 'System'. Choose the 'Hardware' tab and then click the 'Device Manager' button.

2. Select the entry 'Other devices', and see if below this heading a listing of 'CP2102 USB to UART Bridge Controller' can be found. If it is, highlight and right click to choose 'Properties'. Then select the 'Driver' tab and choose the 'Update Driver...' button. This will bring up the 'Upgrade Device Driver Wizard'. Choose 'Next >'. Keep the option 'Search for a suitable driver for my device (recommended)' selected. Click 'Next >'.

3. Make sure that the 'Specify Location' option is checked under the 'Optional search locations' then click 'Next >'. When the next window opens, click on the 'Browse' button and navigate to the folder contents found on the CD, which contains the driver belonging to your computer's operating system. If you are using Windows 2000 or Windows XP, you will need to select the folder titled 'Win2K\_XP'. If you are using Windows 98 Second Edition, you will need to select the folder titled 'Win98SE'. When the appropriate folder is displayed in the 'Look in:' field, click 'Open'. The 'Locate File' window will close. Click 'OK' to close the remaining window. If successful, you should be prompted with the 'Driver Files Search Results' window indicating that the wizard has found a driver for the device. Click the 'Next >' button

4. Finally, a window should be displayed reading, 'Completing the Upgrade Device Driver Wizard'. Click 'Finish'. Close the remaining 'Properties' window.

5. The driver files needed to use your DynaPulse Ambulatory Blood Pressure Monitor are now loaded onto your computer.

If the DynaPulse software is unable to detect the DP5000A Ambulatory Blood Pressure Monitor, proceed with the following instruction.

### **Check the Port assignment of the 'CP2102 USB to UART Bridge Controller'.**

1. Check to make sure that there is a new entry under the 'Ports (Com & LPT)' folder found under the 'System' folder in 'Control Panel'. It should read, 'CP210x USB to UART Bridge Controller (Com X)'.
2. You will need to ensure that the COM Port number (X) assigned to the DynaPulse Ambulatory Blood Pressure Monitor is set to a value between 1 and 4. To change this value, right click on the listing 'CP210x USB to UART Bridge Controller (Com X)' found below the sub-heading Ports (COM & LPT) and select 'Properties'. Select the 'Port Settings' tab. Then select the 'Advanced...' button. In the 'COM Port Number:' select any available COM number that is between 1 and 4. Click 'OK' for all open windows in order to complete the settings change. Please NOTE: If one through four is not available, you will need to remove one of the existing devices in order to free up the COM port for the DynaPulse Ambulatory Blood Pressure Monitor.
3. Finally, close all remaining windows pertaining to the control panel and start the DynaPulse 5000A Ambulatory Blood Pressure Monitor software.
4. Click the 'ComCheck' option found under 'Port' option of the taskbar. Please NOTE: the unit must be powered on when running 'ComCheck'. If the DynaPulse 5000A Ambulatory Blood Pressure Monitor is found, the unit can now be used with the connected computer.

### **WARRANTY INFORMATION**

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Pulse Metric, Inc. warrants that the DynaPulse 5000A 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. 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@dynapulse.com](mailto:teksupport@dynapulse.com)

Technical support representatives are available between 10:00 a.m. to 3:00 p.m. Pacific Time, Monday through Friday.

All products returned to Pulse Metric, Inc. 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 may be refused.** Please also include a letter with contact person's name, address, telephone number, return address and brief description of the problem(s).

## **SOFTWARE LICENSING AGREEMENT**

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This is a legal Agreement between you (the end user, being either an individual, or legal entity such as a corporation), and Pulse Metric, Inc. (PMI). By clicking the "**Accept**" button that appears after you see this Agreement when you install your software, you are agreeing to be bound by the terms of this software 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.

### **Part I - 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, recompile, 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.

### **Part II - Copyright**

The SOFTWARE is owned by PMI and is protected by 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.

### **Part III - Controlling Law**

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

## COMPANY INFORMATION

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Pulse Metric, Inc. (PMI) was incorporated in 1990 to develop and market instrumentation and software for the diagnosis and management of hypertension, and to develop technology and instrumentation for arterial pressure and waveform analysis.

PMI's non-invasive blood pressure waveform technology, *Pulse Dynamics*, is patented in the United States and worldwide. Several different DynaPulse products are available including systems for clinical hypertension management, home blood pressure monitoring, and ambulatory monitoring.

If you have any questions or require additional information, you can reach us between 9:00AM and 5:00PM Pacific Time.

Address: Pulse Metric, Inc.  
2100 Hawley Drive  
Vista, CA 92084 U.S.A.

Order Lines: (760) 842-8278  
Internet e-mail [sales@dynapulse.com](mailto:sales@dynapulse.com)

Facsimile: (760) 758-9425

Web Site: <http://www.dynapulse.com>

Technical Support:

Voice: (760) 842-8224

E-Mail: [teksupport@dynapulse.com](mailto:teksupport@dynapulse.com)