24-Hour Ambulatory Blood Pressure Monitoring and Recording

Hardware Guide

DYNAPULSE 5000A

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Table of Contents

5000A Hardware Guide

I. INTRODUCTION

This User's Guide is divided into two sections: Software Guide and Hardware Guide. Together, they provide technical and operational information, along with procedures for the setup and use of the DynaPulse 5000A (DP5000A) non-invasive 24-hour blood pressure monitoring and recording system.

The DP5000A is intended to be used by operators who are familiar with automated, digital, non-invasive blood pressure monitors. Since the documentation contains important safety and operational information, all operators of the DP5000A system should read both manuals before using the system. Pulse Metric, Inc., recommends that this User's Guide be kept together with the DP5000A system at all times for quick reference.

Interpretation of the blood pressure and heart rate data recorded by the DP5000A system shall be performed by a physician or qualified operator only. No changes in medication should be made without first consulting a physician.

Pulse Metric, Inc. does not claim complete accuracy of the DP5000A under certain conditions such as excessive motion or vibration. Patient conditions such as extreme heart rates, extreme blood pressures, and various arrhythmias may also hinder the readings.

Equipment Overview

Inspection and Preparation

Upon receiving the unit, inspect all equipment and accessories for damage resulting from shipping, such as:

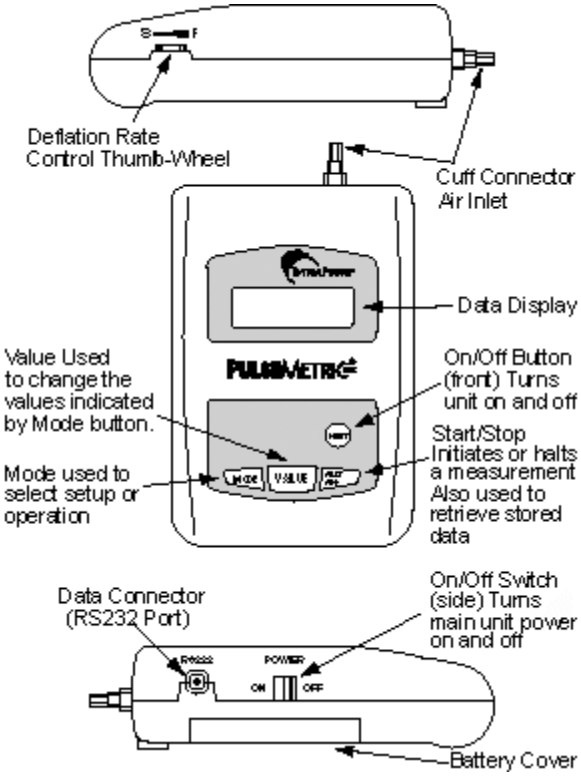
- Leaky cuff connector
- Loosened or broken monitor **On/Off** switch
- Loosened or broken monitor control buttons

Make a note of any tears, dents, or other forms of damage. The cuff, air hose, monitors, and LCD should all be checked. The battery compartment should also be examined. If any damage is found, please contact Pulse Metric Technical Support or its authorized distributor.

DynaPulse 5000A System Contents:

- DynaPulse 5000A monitor
- Storage case
- DP5000A holster
- Three different sized blood pressure cuffs
- Software CD
- USB cable
- Manual
- Cuff support strap

Equipment Layout:



DP5000A Hardware

The DynaPulse 5000A system includes the following accessories in order to perform certain functions and/or applications:

A. The **DP5000A software** program on CD allows the transfer of data from the DP5000A unit to the Physician or Health Care Provider's PC. The software also provides the capability to view, comment, and analyze trend and waveform data, and to enable ambulatory operations.

B. **Storage Case** provides transportation and storage protection.

C. **DP5000A Holster** used in ambulatory applications.

D. **USB Cable** connects monitor to a PC's COM port.

E. **Three Sized Blood Pressure Cuffs.**

F. **Cuff Support Strap** provides additional cuff support during ambulatory operations.

DP5000A Equipment Specifications:

Measurement Method	Pulse Dynamic Oscillometrics	
Measurement Range	Systolic	60–240 mm Hg
	Diastolic	30–200 mm Hg
	Mean	40–240 mm Hg
	Heart Rate	20–200 BPM
Accuracy	Pressure: ± 5 mm Hg vs. auscultatory methods per ANSI/AAMI standards	
Inflation	Micro-rolling pump	
Deflation	Slow air release: Mechanical needle valve	
	Fast air release: Electromagnetic valve	

Default Pressure	160 mm Hg
Ambulatory Mode	5, 10, 15, 20, 30, 60, 120 min.
Measurement Periods	2 different measurement periods per 24-hour period
Automatic Interval Between Measurements	2, 3, 5, 10, 15, 20, 30, 60, 120 min.
Automatic Mode Preset Number of	2, 3, 5, 10, 20, 50, 100 measure-ments per setting Measurements
Measurement Storage	Up to 100 measurements including pressure waveform data
Display	LCD 16 x 60 mm 2 x 16 characters On/Off option (for Auto Mode)
System Power	6V DC with 4 AA standard batteries Low battery warning on LCD
Memory Power	3.6V Lithium battery Low battery warning on LCD
Power Consumption	380–500 mA during pumping 10–15 mA while idle
Patient Safety	2 hardware and 2 software controls
Sound Level During Pumping	40–50 dB (A) at 60 cm (24 in) distance
Operating Temp. Range	5–40°C (41–104°F)
Dimensions	86(W) x 130(L) x 38(H) mm 3.4(W) x 5.1(L) x 1.4(H) in
Weight	10 oz. without batteries, 13 oz. with batteries

DP5000A System Requirements:

A complete DP5000A system requires:

- DP5000A monitor and system accessories
- IBM PC or compatible computer with at least 486x/66 processor, 16 MB of RAM, a hard drive, and a CD-ROM disk drive

II. Getting Started

Battery Installation

To open the main battery compartment, push in and upward to loosen the battery cover, or place a coin or flat object in between the gap of the cover and the housing to lift up the cover. Install four AA batteries according to the directions indicated on the inside of the battery case.

Alkaline batteries are recommended. Four alkaline batteries provide an estimated 150 measurements when using a standard adult size cuff. If a large adult size cuff is used, the results may be closer to 100 measurements.

Pulse Metric, Inc. recommends the installation of fresh batteries prior to each ambulatory monitoring session.

DP5000A Monitor Display and Layout

The DP5000A is a microprocessor-supported automated digital blood pressure device that uses an oscillometric cuff-based technology. The monitor utilizes a pressure transducer and a patented algorithm to measure blood pressure. No microphone is used. The system runs on four 1.5-volt AA batteries. The DP5000A monitor memory can store up to 100 measurements (each measurement includes blood pressure, heart rate, and pulse waveform data). A 3.6-volt lithium battery supports the memory. The unit is equipped with an USB port to communicate with a personal computer. A two-line LCD screen is used to display operational information and instructions.

Measurement Number: Indicates the number of the **next** measurement to be taken. This value will increase after each measurement is stored in the memory.

Measurement Mode: Displays the operational mode: ***M*** (manual), ***AB*** (ambulatory) or ***A*** (auto).

Unit Status: System messages include **Ready, Pumping, Pump Off,** and **Measuring.**

Systolic Upper Limit: Indicates the systolic pump-up pressure used to obtain a measurement. Typically this is approximately 30mmHg above resting Systolic blood pressure.

System Cursor: Used to highlight and/or change a value or mode option.

DP5000A Control Buttons and Switch

There are three control buttons in addition to an **On/Off** button on the front of the unit and an **On/Off** switch on the side of the monitor.

On/Off Switch (side): Connects the battery power to the DP5000A unit when switched on. This switch can be used as an emergency shut off in the event that the unit malfunctions when pumping.

On/Off Button (front): Turns on/off the unit electronically (including LCD and microprocessor). Functions as an emergency shut off button during pumping.

Start/Stop Button: Used to initiate, halt measurement and retrieve a stored measurement from the monitor. Also acts as an emergency button to stop pumping action and release cuff pressure.

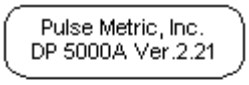
Mode Button: Used to select setup and operation functions.

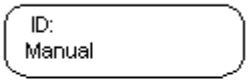
Value Button: Used to advance, select, or set a parameter determined by first using the **Mode** button.

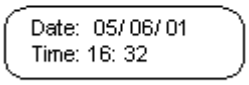
The general procedure in selecting options and changing values is determined by using the **Mode** and **Value** buttons: The **Value** button will perform different functions depending upon what option has been selected using the **Mode** button. Pressing the **Value** button will select between a **Yes/No** or **On/Off** setting, or will increase the value in the option.

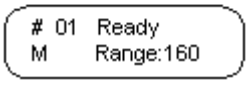
LCD Display: Sequence and General Descriptions

The DP5000A will display the following screens when operating correctly:

1. 

2. 

3. 

4. 

Operating Modes

The DP5000A can operate in either ambulatory or manual patient mode.

M (manual) Mode: For a single measurement, press the **Start/Stop** button. This is the default setting of the unit.

AB (ambulatory) Mode: For 24-hour measurement. A physician or other trained operator using the DP5000A software enables this operational mode.

A (auto) Mode: For automated measurements.

The DP5000A has a power management feature to save battery power. If the unit is inactive for a 3-minute period, the LCD will turn off automatically. During ambulatory operation, the LCD will turn off between measurements.

Each operating mode will be described in detail in the following sections.

Setup Procedure

To activate Setup mode, press the Mode button within 5 sec. of turning on the DP5000A. The LCD will display the Pressure Unit screen.

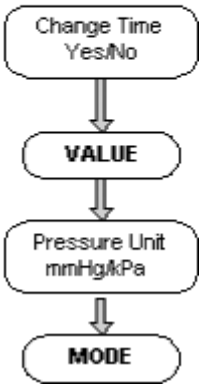
Setting Pressure Unit:

Use the **Mode** button to select pressure unit option. Press **Value** button to place cursor under appropriate pressure unit.

Setting the Date/Time:

Use the **Mode** button to select the **Change Time** option.

Press the **Value** button to change the system cursor to **Yes**.



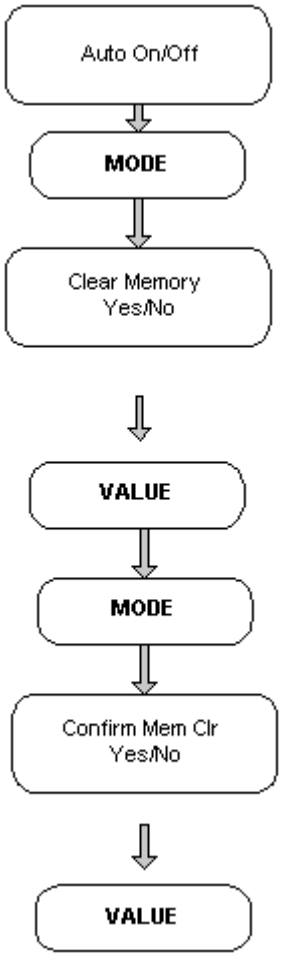
Press **Mode** to enable the setting of the time and date.

Place the system cursor under **mm** (minutes) and press **Value** to set the minutes forward. Start/Stop will move settings backwards. Press **Mode** to move the system cursor to **HH** (hours) and press **Value** to set the hour. Repeat the same sequence to set the **Y** (years), **DD** (days) and **MM** (month).

Press Mode when the system cursor is at **MM** (month) to exit the set **Date/Time** option.

Note: Options for different date displays, e.g., DD.MM.YY, may be available by request.

This Auto setting will be discussed in section V of this manual.



Use **Mode** to select the **Memory Clear** option. The **Memory Clear** option is protected against accidental erasure by requiring the user to confirm their action with an additional **Yes/No** function.

Press the **Value** button to move the system cursor to **Yes**.

Press the **Mode** button to complete the first confirmation sequence.

The second part of the **Memory Clear** option is now initiated. To abort the erasure process, exit by selecting the **No** option with the cursor and pressing **Mode**.

Press **Value** to move the system cursor to **Yes**.

Clear Memory

The DP5000A can store 100 measurements. Transfer any pertinent data first, and then clear the data from memory. Once the memory has been cleared, measurement data **CANNOT** be recovered.

Here is your final chance to abort the memory clear sequence. To complete the **Yes** decision, press the **Mode** button.

-Or-

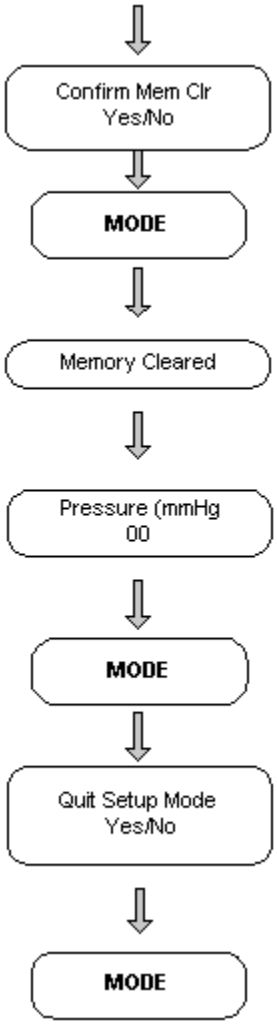
To **exit** at this point, press **Value** to move the cursor to **No**. Then press **Mode**. When **Yes** is selected to delete the memory, press **Mode**.

The DP5000A will delete its stored memory and the display will flash the message **Memory Cleared** for 2 seconds, prior to exiting.

This screen is default for checking the pressure calibration of the DP5000A after the memory clearing option.

Press **Mode,** this will bring you to the Quit Setup Mode screen.

The default is YES. To exit setup if all settings are correct, press **Mode**. Otherwise, go to the next step.



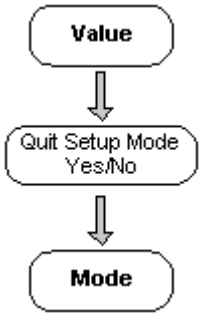
Setup Corrections

If at anytime during Setup you decide to modify a previous setting, the **Quit Setup Mode** option allows another search through the Setup menu.

Use the **Value** button to display Quit Setup Mode

Select **No**.

Press **Mode** to go back through the Setup options again.



Select Measuring Range and Deflation Rate

Use the **Mode** button to move the cursor to the range number and press the **Value** button to select a desired systolic upper limit. Adjust the upper limit from 110 mmHg to 240 mmHg. The default value is set at 160 mmHg.

The deflation rate of the set range can be adjusted manually using the thumb-wheel (on the right side of the unit). To speed up the deflation rate, or decrease bleed time, turn towards ***F***, and towards ***S*** to increase the bleed time. The deflation rate has been preset to deflate from 160 mmHg to 50 mmHg in approximately 30 seconds for a standard adult size cuff. The composition of the arm greatly affects this deflation rate so adjustments will be necessary. Adjustments should be made when applying oversized adult (faster deflation rate needed) or child size cuffs (slower deflation rate needed).

Safety Features and Emergency Procedures

Automatic Cuff Pressure Sensing and Pump/Air Release Control: DP5000A measures the cuff pressure during the pumping process. The system turns off the pump and releases cuff pressure automatically when:

1. Cuff cannot pressurize to 16 mmHg in 12 seconds.
2. Cuff pressure with continuous pumping exceeds 200 mmHg over 30 seconds.
3. Total pumping time exceeds 60 seconds.
4. Cuff pressure remains over 200 mmHg for longer than 20 seconds after pumping ceases.

Independent Real Time Clock (RTC) Pump/Air Release Control: DP5000A uses an independent timer (RTC) to begin a 60-second time-out pump shut off and a cuff pressure release control each time pumping begins. This will prevent any chance of over pressurizing the cuff in case the microprocessor fails during pumping.

Emergency Button: The **Start/Stop Button** on top of the unit will both automatically shut off the pump and release cuff pressure if pressed during pumping sequence.

Emergency Switch: The **On/Off Switch** at the side of the DP5000A unit will turn off the main power supply to the unit, shut off the pump, and release cuff pressure.

The operator should be completely aware of the above safety features and procedures. When the DP5000A is used as an ambulatory device, the technician should instruct the patient on all safety procedures and how to use the emergency controls.

III. Taking a Manual Measurement

Manual Mode: Press the **Mode** button until the **Ready** screen appears on the LCD. To take a test measurement with the current upper systolic limit range, press the **Start/Stop** button to begin the automatic pump. This pressure should be set to 30mmHg above the patient's normal resting systolic blood pressure. Use the **Mode** button to move the cursor under the pressure and change the value using the **Value** button. Then take the measurement.

As the system pumps, the display will show **Pumping** and the current cuff pressure as it increases. Once the cuff pressure exceeds the selected range value, the pumping will stop. The monitor will display **Measuring** as the cuff pressure decreases.

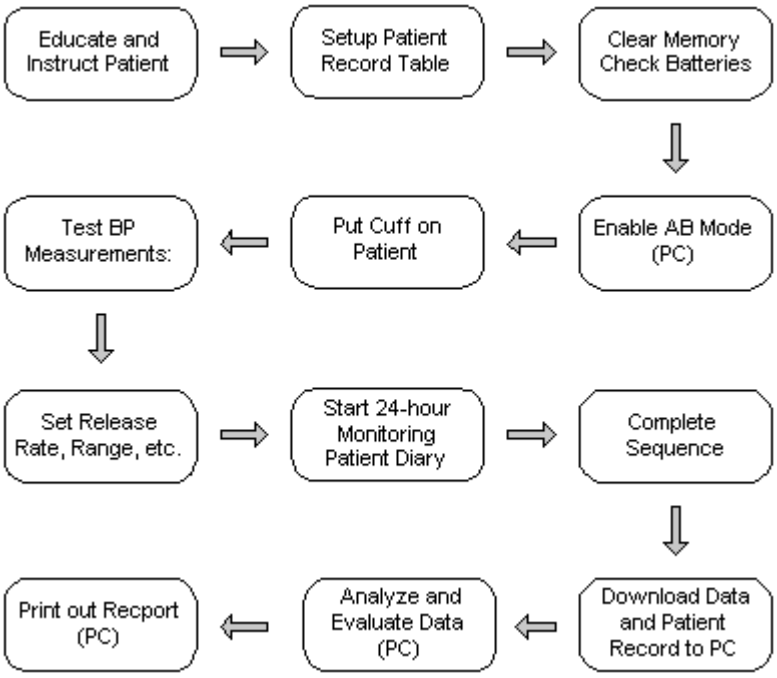
After the measurement is completed, the data will be stored in the memory. The systolic (**S**), diastolic (**D**), mean arterial blood pressure (**M**), and pulse (heart rate) (**P**) will be displayed. The results will be shown for 20 seconds. Use **Mode** to select the **Measure** option to view stored data after the 20-second period. Use **Value** to search through the data. Use **Start/Stop** to view data. A maximum of 100 sets of measurements can be recalled in this manner.

If after 3 minutes there has been no operation, the unit will turn itself off automatically. To turn the unit off manually, press the **On/Off** button.

If a measurement is unsuccessful, an error message will appear. In the ***M*** mode, only the results of a successful measurement will be saved.

IV. Ambulatory (AB) Mode Operations

Ambulatory Operational Flow Diagram:



Patient Education and Instruction

The operator should inform the patient of the diagnostic benefits of ambulatory monitoring, and also instruct the patient on the safety protocols of the DP5000A. The patient should understand the following:

Many outside factors may affect the results of the interval measurements. Minimize arm and body motion during measurements, such as strenuous exercise, driving a car, walking, etc. Avoid unnecessary physical contact while wearing the unit: be careful entering and exiting automobiles, avoid crowded areas, etc.

Note: In the event of measurement failure, the unit will re-attempt the measurement once, one minute after the failure.

Do **NOT** engage in water activities such as swimming or taking a shower while wearing the unit, it is not water-resistant.

The Patient Diary is important. The form, included in the Appendix, may be used to keep track of changes in activities and medication during the 24-hour period. Relevant changes in blood pressure often correlate to outside factors. The diary is designed to ensure complete recording of pertinent events during the 24-hour period.

Guidelines for Accurate and Safe Monitoring

For accurate and safe monitoring, note the following:

Keep the unit away from moisture, heat, and other extreme environmental conditions. Do **NOT** remove the DP5000A unit from the carrying case except in an emergency. Do **NOT** drop the unit.

As an option, the patient may manually activate a measurement to record blood pressure during a specific

activity. Quickly Double-tap the **Start/Stop** button to record any abnormal conditions, events, irregular heartbeats, etc.

Follow the chart as indicated in the Patient Diary (Appendix) to maintain a record of daily activities, and record any changes that may occur.

In the event of a malfunction, such as lack of display of time on the LCD, low battery power, extended pumping, or improper air release rate, the patient should immediately turn off, remove, and return the unit to the clinic or hospital for evaluation.

Prepare Patient Record Table and Monitor

Note: If for any reason the DP5000A goes into sleep mode during the setup procedures, simply press the On/Off button on top of the unit. Then press the Mode button within 5 seconds to enter the Setup Mode once again. Use the Mode button to scroll back to where you were initially. The sleep mode is built into the 5000A to conserve battery life. Because the sleep mode is activated after three minutes of inactivity, you will need to complete each step within that time period.

The monitor and PC should be connected using the RS232 cable. A patient ID must be assigned before initializing the DP5000A to ambulatory mode. In order to accomplish this, go to ***Patient*** and ***Add***, input the patient name and ID. Further patient information may be entered later.

Clear Memory

The memory of the unit must be erased before starting a 24-hour ambulatory sequence. However, it is important to check that all previous data have been transferred to a PC or printed as records **BEFORE** clearing the memory. Also make sure the DP5000A's ID setting is cleared as well; this is done from the PC software. Go to **Data** and choose **Clear Memory**, confirm yes twice.

Initialize AB Mode

After assigning an ID on the PC, go to **Data** and **Enable Amb** to initialize the ambulatory mode. Following the initialization process, the LCD will display the **24-hrs Ambulatory Setup** message followed by the **Date/Time** screen. The DP5000A is now enabled with only this patient's ID. Once the unit has been disconnected from the PC, position the DP5000A monitor and cuff on the patient.

Check Date and Time

Use **Mode** to move through the date and time fields. Use the **Value** key to move forward the underscored date or time field; use **Start/Stop** to move backwards. Use the Mode key to advance the cursor to the next field. When the Mode key is pressed after the cursor is advanced to the last date field, the patient ID number is displayed.

Setup of Ambulatory Parameters

Confirm ID: Make sure the ID listed after setting the time and date matches the patient on the computer. Press the Mode button to continue.

Set Systolic Range/Release Rate: Press the Start button to run a test measurement or press Mode to continue. You should perform a test run to determine the appropriate systolic range and air release rate to ensure accurate measurements throughout the ambulatory session. The

default systolic limit is set to 160 mmHg. **The systolic upper limit should be set to approximately 30 mmHg higher than the patient's resting systolic blood pressure.** This 30 mmHg cushion is advised to allow for variability in the systolic pressure reading over time.

Max/Min Pump Pressure in the following chart lists the maximum and minimum possible pressures (considering reattempt measurements) experienced by the patient at each systolic limit setting. During a measurement, the DP5000A will pump air into the cuff up to this maximum pump pressure before it begins to release air. Generally, the maximum pump pressure experienced will be 15 mmHg higher than the systolic limit (but for a 240 mmHg setting, it will be only 10 mmHg higher). This 15 mmHg cushion is to ensure a smooth measurement. The minimum pump pressure is the point at which the unit stops measuring and deflates the cuff.

Systolic Upper Limit	Max/Min Pump Pressure	BP Measurement Thresholds
120–130	175 / 30	200 / 30
140–160	195 / 35	220 / 25
170	205 / 40	230 / 30
180	215 / 45	240 / 35
190	225 / 50	250 / 40
200	235 / 50	260 / 40
210–240	250 / 55	290 / 45

If an ambulatory measurement is unsuccessful, the DP-5000A will attempt a second measurement (the auto-adjust measurement) after one minute. The unit will automatically raise the systolic limit to ensure a successful measurement

"Start" to Test

During a test measurement, note the air release time. **This time should be 20–30 seconds.** Adjust the dial to a slower (s) release to increase the time, or to a faster (f) release to decrease the time. Press the **Mode** button to continue now.

Day/Night Periods: The monitor will allow the user to specify the start time and measurement interval time for both day and night periods. The user should set the periods to reflect the schedule of the patient.

Press the **Value** button until the desired start time is displayed.

Press the **Value** button to select the **Day Int.** Interval times are 5, 10, 15, 20, 30, 60 and 120 minutes.

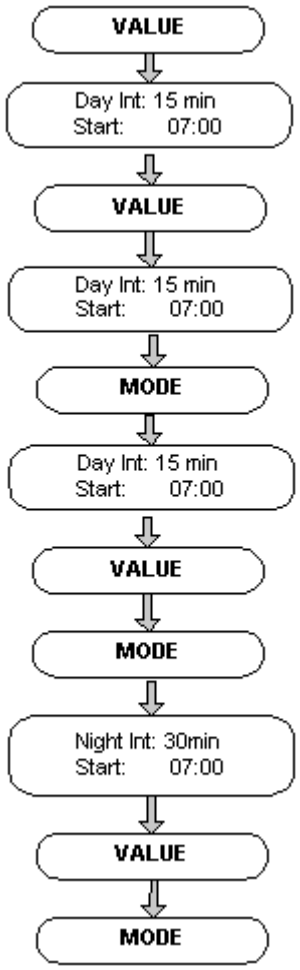
Press **Mode** to set **Day Int Start** time. Time entries are in 24-hour (military) time. 1:00 PM. is 13:00; 2:00 PM. is 14:00, etc. All start times begin at the top of the hour.

Press the **Value** button until the desired start time is displayed.

Press **Mode** to advance to the **Night Int** setup menu.

Press the **Value** button to select the **Night Int.** Interval times are 5, 10, 20, 30, 60, and 120 min.

Press **Mode** to set **Night Int Start.** Midnight is 00:00. 1:00 AM is 01:00, etc.



The test measurements are stored, so you will need to delete these so they are not combined with the ambulatory data. Press **Value** to select Yes; press **Mode** to clear memory.

After clearing the memory, press **Mode** to quit setup. If you need to make any changes to the settings, select no and re-enter setup.

The LCD will now display **24 hrs Ambulatory Press Start key**. Do **NOT** press **Start/Stop** until the cuff and monitor have been correctly positioned.

Position DP5000A Monitor and Cuff

Visible, Over Clothing. Position the monitor onto the patient's dominant-sided hip (i.e. the right hip for right-handed patients, the left hip for left-handed patients). Secure the monitor using the carrying case and shoulder strap included with the system. (A belt clip is also provided.)

Next, position the cuff. First, loop the cuff with the Velcro interlock on the inside. Locate the brachial artery on the inner side of the non-dominant arm. Slide the cuff onto the arm with the metal bar on the inside and the rubber tubing running up toward the patient's shoulder. Pull the end of the cuff through the metal loop until the fit is snug. Fold the end of the cuff so that it fastens onto the Velcro panel. Watch for gathered clothing under the cuff. A finger should barely fit between the cuff and the arm.

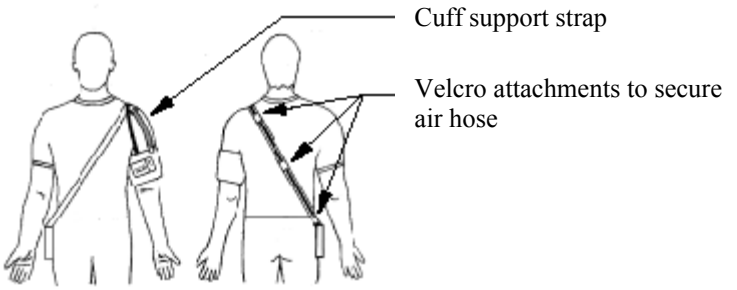


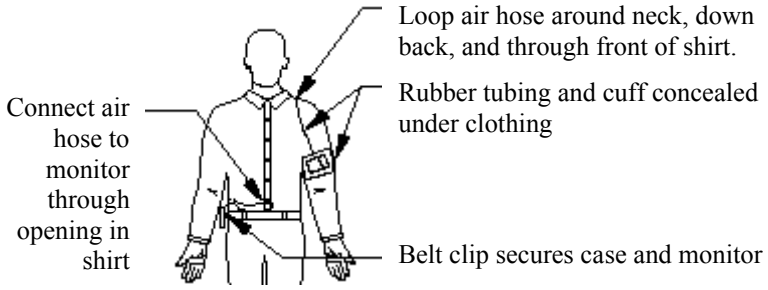
Diagram (for a right-handed patient):

Notes:

1. Connect the cuff to the DP5000A. Secure the air hose to the strap of the carrying case with the Velcro attachments.

2. Attach the cuff support strap to the top of the strap and the top of cuff.

- **Concealed Under Clothing.** Patients may also choose to position the cuff under a loose fitting shirt or blouse, with the air hose concealed beneath the clothing and connected to the monitor along the belt line. In this option, use the belt clip to secure the case and monitor to the belt. (Avoid crimping or obstructions when positioning air hose under clothing.)



Starting the 24-hour Ambulatory Recording Sequence

As soon as the unit has been properly positioned, the patient is ready to begin the 24-hour recording period. The following guidelines may be helpful for a successful monitoring session:

- To ensure the correct settings on the DP5000A for ***AB*** mode, complete all blood pressure measurement tests on the patient and set the proper measurement range.
- Set up all other parameters for 24-hour ambulatory monitoring.
- Then push **Start/Stop** to begin the 24-hour monitoring sequence.
- During a 24-hour ***AB*** monitoring sequence, use emergency buttons and/or switch to stop pumping if necessary.
- Insert any additional measurements when necessary by pressing the **Start/Stop** button twice.

Once the **Start/Stop** button has been pressed, the 24-hour ***AB*** monitoring sequence has begun. Please note that the operator cannot terminate the 24-hour sequence without connecting the unit to the PC and using the **Disable** function.

If the operator decides to modify the setup parameters of the ***AB*** operation, he/she must stop the ***AB*** sequence **within the first 10 minutes of the 24-hour period.** Use the **On/Off** switch on the side of the monitor to turn off the unit. Then, switch the unit back on in order to setup initial parameters. Press the **Mode** button while the LCD displays the **Date and Time** to modify the parameters. The patient cannot view the blood pressure readings during the 24-hour period.

Transfer Data to a PC

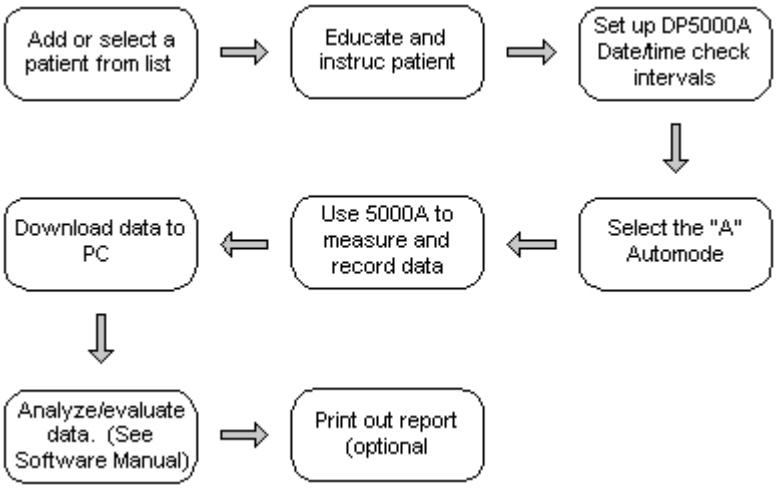
The data stored in the DP5000A can be transferred to a PC by connecting the unit to the computer system. Once the unit has been connected to the computer, run the software program. Go to **Data** and select the **Data Transfer** function, make sure the DP5000A unit is "on" and the USB cable is connected.

Disable Ambulatory Mode

To end the ambulatory mode of the monitor, the user should disable the monitor by using the DP5000A software. To disable the ambulatory mode, the unit must be interfaced with the PC, using the USB cable. The user then initiates the DP5000A software program. Make sure that the patient is selected by highlighting the patient's name. Go to **Data** and **Disable**. The PC will then communicate with the DP5000A.

V. Automatic Measurement Operation

Automatic Operational Diagram



Add Patient or Select from List

Add the patient you are going to measure to the patient list. If the patient is already a part of the list, then select this patient's name from the list. This is only to make sure that when this automated measurement process is completed, the data is transferred to the PC to the correct patient.

Patient Education

The patient should be informed of the procedure, and should be instructed to remain calm and relaxed during the measurement process. The patient should refrain from all unnecessary motion, including talking. It is important that the patient remain as still as possible during the individual measurements for maximum device accuracy and consistency. Otherwise, the patient should perform normal daily activities, with the exception of intense exercise such as running, basketball or lifting weights. Such activities will most likely interfere with the measurements.

Select Measuring Range

At least one test run should be taken to check the measurement parameters. Between test runs, adjust the systolic limit from any value between 120 mmHg and 240 mmHg. The default setting is 160 mmHg, but the value should be adjusted ~30 mmHg above their resting Systolic blood pressure. During the test measurement, observe the air release time. The total air release time should be 20–30 seconds. Adjust the release time by turning the thumb-wheel on the side of the monitor.

Setup, Check Date and Time

Turn the DP5000A off, then on and press Mode within five seconds to display the Date/Time setting on the monitor and check to confirm that they are both correct. Change the date and time if necessary.

Select Mode

The default is preset to the *M* mode.

For Auto-mode press **Mode** until the Auto option is selected.

Press **Value** to enable Auto mode

Select **On**.

Use **Mode** to move the system cursor to the Interval setting.

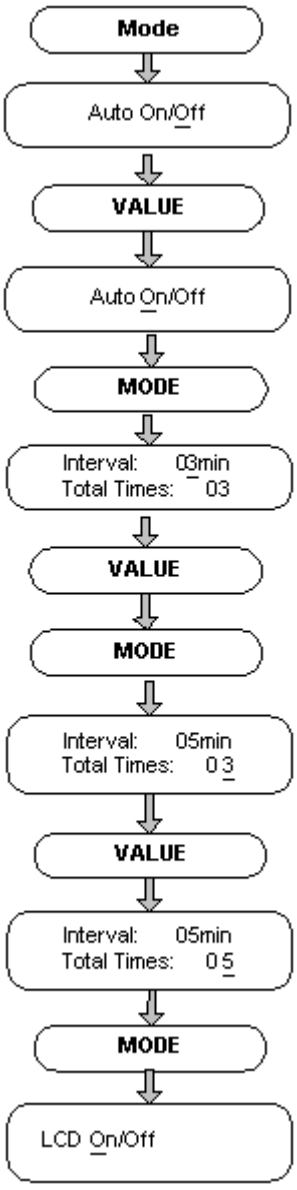
Use **Value** to select the interval between measurements. Values are 2, 3, 5, 10, 15, 20, 30, 60 or 120.

Use **Mode** to move the cursor to Total Times. (i.e., the total number of measurements to be taken.

Use **Value** to select the total times desired. Values are 2, 3, 5, 10, 20, 50, or 100.

Use **Mode** to exit the Auto option.

LCD Display: Use **Value** to display measurements in *A* mode.



If set at Off during measurements, the LCD will turn off within 30 seconds to conserve the battery between measurements.

Clear Memory

Since this device can only store 100 measurements at a time, the memory will need to be transferred and cleared periodically. Again, before clearing the memory, the operator should be certain that the data has been transferred to the PC.

Position Cuff

The cuff must be positioned correctly to obtain accurate measurements. The arrow on the cuff should be placed directly over the brachial artery of the patient. Fasten the Velcro panel so that the cuff fits snug. This instruction is similar to the one found on page 24.

Start Measurement

When the LCD displays Ready, press Start/Stop to begin the measurement sequence. During a measurement, the LCD will display the cuff pressure in mmHg, the Pumping Time, and the Release Time. When complete, results will be displayed on the LCD for 5 seconds.

Automatic Mode: In Auto mode, all necessary setup procedures must be accomplished before measurements may begin. Press Start/Stop to start the preset interval measurement sequence. A measurement may also be taken anytime during the sequence by pushing the Start/Stop button twice. If a measurement fails, the unit will automatically adjust the range and begin measuring again after one minute.

The unit will “sleep” when a sequence has been completed. Or, to turn off the unit manually at any time, press the On/Off button. During an auto mode sequence with the LCD Display option set at off, the unit can be “woken up” by pressing any key.

In the *A* mode, all final measurement data and their associated waveforms will be saved.

Display Measured Data

(Not available in Ambulatory Mode)

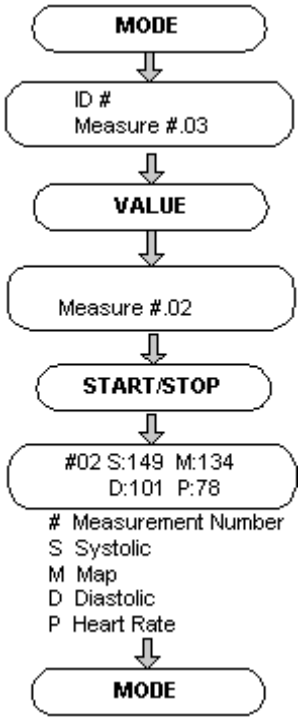
Use **Mode** to switch to the Measure option. Measurements are stored incrementally.

Use **Value** to scroll through stored data and select the desired measurement.

When the desired measurement number appears on the LCD, press the Start/Stop button to display the data.

The DP5000A will display the measurement record selected.

Use **Mode** to return first to the Measure screen, then to the Ready screen.



Transfer Data to a PC

The software must be correctly installed and the monitor must be interfacing correctly with the PC before data can be transferred. The following steps are performed using the DP5000A software.

- Use the cursor keys to select the appropriate patient.
- Go to Data and select “Data Transfer.”
- Double click on the patient and the trend list will come up.
- Select the most recent trend and double click it to bring up the measurement waveforms and trend graph.
- Use the software manual’s guide on Analysis of the patient data.
- At this point, you also have the option of printing any of the measurements and/or the results of the analysis.

VI. Equipment Maintenance

Equipment Care

User should routinely check the DP5000A unit and its accessories for damage. Any defects in the system may cause operational difficulties and/or inaccurate measurements. Problems with the PC may impair communication with the DP5000A functions.

- ***DP5000A Unit****:* The DP5000A monitor is a solid state microprocessor device that may be damaged by excessive heat, moisture, or shock. Excessive dust or accumulated moisture may decrease the effectiveness of the system. Avoid storing the unit near a cold- or heat-generating source such as lamp, heater, oven, etc. To clean the LCD display and the housing of the unit, use a soft, damp cloth to wipe the exterior surfaces clean.
- ***PC****:* Refer to your computer's manual for proper care and maintenance. Please refer to the owner's manual for complete instructions.
- ***Software:*** The system diskette uses magnetic media sensitive to heat and to magnetic fields. Factors that may contribute to floppy diskette damage include dust, moisture, physical alterations, or rough handling. Keep software away from heat and magnetic fields, since information stored on the diskette may be lost if exposed. Once the software is installed on your computer, this will be a backup diskette in the event you may need to re-install the software.

Battery Upkeep

The performance of the DP5000A unit will be hampered if the battery power is low. The system will not operate if the

batteries are incorrectly installed. If the unit is to be stored for a long period of time, remove the batteries to prevent the possibility of leakage.

After each installation of new AA batteries, Pulse Metric, Inc. recommends that the user follow the steps for Setup if the Date/Time display is incorrect. Turn on the unit to display the Date/Time. If either setting needs to be changed, press the Mode button while the LCD displays the Date/Time screen.

Cuff Cleaning and Replacement

To protect and prolong the life of the cuff and carrying case, clean the sleeve and case periodically. To remove small stains or soiled areas, use a damp sponge or cloth. The bladder inside the cuff is made from rubber, which can be damaged by excessive heat, sunlight, and/or sharp objects. In some cuffs, the bladder may be removed in order to wash the cloth cuff cover or the bladder itself. To clean the bladder or cuff, gently hand wash with soap and water.

If desired, you can sterilize the cuff and carrying case only, following the ethylene oxide (EtO) sterilization method using standard clinical procedures.

Storage

Proper storage of the DP5000A unit is vital to preserve the efficiency, accuracy and life expectancy of the system. For best results, store the unit in its original case at room temperature after each use. Keep the unit away from moisture, direct sunlight and magnetic interference. Remember to remove the main batteries before storing for extended periods of time.

VII. Troubleshooting

DP5000A Operations

The following error conditions may occur during operation:

- **DP5000A will not turn on:** Check the hardware such as the **On/Off** switch and main batteries.
- **Low Memory Battery:** If **Low Memory Bat** appears on the LCD, contact Pulse Metric, Inc. or its authorized dealer for battery replacement.
- **Low Main Battery:** If **Low Main Bat** appears on the LCD or the pumping seems weak, replace all of the AA batteries.
- **On/Off button fails:** If the **On/Off** button cannot turn off the LCD display, the CPU microprocessor may be "locked". Use the hardware **On/Off** switch to turn off the unit, then turn it back on for continued operation. The CPU may "lock" if main battery power is too low, or if interference (from outside or within the unit) is present.
- **Preset Date/Time lost:** Changing of batteries, use of the **On/Off** switch, locked CPU, and/or electronic noises and interference may cause the Real Time Clock (RTC) timer to revert to the default date and time. Always check the **Date/Time** display as soon as the unit is turned on. Reset the time and date accordingly.
- **"Unknown" messages or settings:** If during operation the LCD displays unusual messages or settings, it may be an indication that certain memory may have been lost. To reset the unit, turn the unit off and back on again using the On/Off switch on the side.

Memory loss may have been caused by low memory battery and/or electronic interference.

- **Memory loss due to heat:** Memory may be lost under heat conditions that exceed 50°C (122°F). Avoid leaving the unit near heat sources, in cars (especially car trunks), and in direct sunlight. NOTE: The result of memory loss may also cause the DP5000A to reset to the default mode ***M*** (Manual Mode) if it was in ***AB*** (Ambulatory Mode) previously.

Blood Pressure Measurement

Error Messages: All error messages will automatically clear from the display after 20 seconds. To clear the LCD immediately, press the **Mode** button once. Here are the possible error messages you may see:

- **Measure Again:** When the DP5000A cannot properly determine the blood pressure or pulse rate, taking a second measurement may alleviate the error. Common causes for this type of error include excessive arm movement, or a loosened or improperly positioned cuff.
- **Increase Range:** Indicates that the systolic pressure could not be accurately determined. Raise the systolic measurement limit, and try again.
- **Decrease Range:** Indicates that the diastolic pressure could not be accurately determined. Lower the systolic measurement limit, and try again.
- **Release Too Fast:** Indicates that the air pressure flow rate is set too fast. Adjust the airflow rate using the thumbscrew valve located on the right side of the unit.

PC Interface

The DP5000A system is sensitive to PC configuration and operational problems. The presence of such difficulties may cause DP5000A software function to be impaired. Successful data transfer requires proper installation of the DP5000A software. Follow the procedures for correct software installation. Necessary requirements are:

- Correct Com Port configuration in the software setting.
- Correctly assigned ID number for the auto-pump (A) or ambulatory (AB) project. Correct computer assignment of data storage location, floppy diskette and hard drive letters (i.e. a:\, c:\, etc.), and pertinent directory name.
- The DP5000A main batteries are fresh.

If any of the above conditions are not met, data transfer may not occur correctly.

Technical Support

Please contact Pulse Metric, Inc. at (760) 842-8224 during normal business hours 9 a.m. to 3 p.m. (PST), or its authorized distributor, with any questions or concerns regarding the DP5000A system.

VIII. Repair and Services

DP5000A Calibration

Each DP5000A monitor is calibrated at Pulse Metric, Inc. before it is distributed. However, the American Heart Association recommends that automatic blood pressure monitors be checked for proper calibration at least once a year. In addition, memory batteries should also be replaced once every two years. Safety and accuracy considerations require that only Pulse Metric, Inc. or its authorized distributor conduct calibration and battery replacement. Calibration services are free of charge while the unit is under warranty.

DP5000A Hardware Repair

Pulse Metric, Inc. or its authorized service organizations must handle all repairs. Take or ship any repairs to the place of purchase or call Pulse Metric, Inc. to have the repair assessed. When sending the product back for service or repair, the unit must be accompanied by a **Return Material Authorization (RMA) Number. Failure to obtain an RMA number will cause your shipment to be refused.** To obtain an RMA number, call Pulse Metric, Inc. during business hours at (760) 842-8224 or (760) 842-8278. Inquiries may be sent via facsimile to (760) 758-9425, or via e-mail to teksupport@dynapulse.com.

Ship the prepaid package to:

Pulse Metric, Inc. Service Department

2100 Hawley Drive, Vista, CA 92084

Clearly mark the outside of the shipping box with the RMA number. Include a copy of the sales slip as proof of warranty coverage. Please also include your name, address, telephone

number, and description of the problem(s). The product will be returned, postage paid, as soon as it is fully repaired.

DP5000A Software Update Services

Pulse Metric, Inc. will automatically send to every registered owner of the DP5000A any updates in software, user guide information, and warranty/service options within the first year of purchase. To receive the above information, it is important to register your DP5000A by mailing in the warranty card and proof of purchase. Please contact Pulse Metric, Inc. or its authorized distributor about upcoming features and services.

Accessory Replacement

The DP5000A monitor comes complete with a storage case, blood pressure cuff, carrying case, cuff support strap, USB cable, software, and documentation. Please contact Pulse Metric, Inc. or its authorized distributor to replace any of the above or to inquire about available DynaPulse system accessories.

Extended Warranty Services

The DP5000A monitor and software are covered by a one-year warranty. An optional extended warranty may be available for the monitor. Please contact Pulse Metric Sales or its authorized distributor for further information.

IX. Warranty Information

Warranty:

Pulse Metric, Inc., guarantees that the DP5000A monitor and software will be free from defects in workmanship and materials for a period of one year after date of purchase. This one-year warranty extends only to the original purchaser. The purchaser will receive DP5000A software updates free of charge for a period of one year after the date of purchase.

Pulse Metric, Inc. will repair or replace, at its discretion, any defective parts or products resulting from shipment to the initial purchaser. This limited warranty DOES NOT cover damages or losses incurred due to:

- Exposure to an improper environment, temperature extremes, or other misuse or negligence.
- Adjustment or repair by personnel not authorized by Pulse Metric, Inc.
- Improper installation or failure to follow the installation instructions of the monitor or software.
- 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. 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 exclusions may not apply to every purchaser. This warranty gives the purchaser specific legal rights, while those rights may vary from state to state.

X. Appendices

Patient Diary (sample):

To the patient:

The DP5000A portable automatic blood pressure unit you are wearing measures and records your blood pressure and heart rate at predetermined time intervals. Feel free to go about normal daily activities, only remember to keep your arm still during automatic measurement. In order to maximize the information gathered by the monitor, it is necessary to maintain accurate records in the Patient Diary. Specific information that should be recorded includes:

- Start of activities such as exercise, meetings, errands, etc.
- Time when food or beverage (coffee, alcohol, etc.) is consumed.
- Time when medication is taken.
- Symptoms or observations varying from normal.

It is unnecessary to record every time the cuff inflates with an ongoing activity involved. The importance of the diary is to record changes in activity. Record the times whenever you switch environments or activities (for example, office hours to leisure time to exercise). If symptoms occur between intervals, press the **Start/Stop** button twice to insert an additional measurement. The interval sequence will continue undisturbed. Please then make note of the symptom and time of occurrence in the Patient Diary. If at any time you wish to stop a measurement in progress, press the **Start/Stop** button.

Important Notes during ambulatory or automatic mode:

- During the blood pressure measurement process, remain still and keep arm relaxed.
- Do NOT remove the blood pressure unit from the carrying case.
- Do NOT switch off the On/Off switch (on the side of the unit). The switch will turn off all power in the unit and stop the AB sequence. Only use the On/Off switch in emergency cases.
- Do NOT get the unit wet because the unit is not water-resistant.
- Do NOT store the unit in areas of high temperatures (e.g. car, heater, and direct sunlight). It may cause memory loss.

Patient Diary-Record Information

Patient _____ ID_____
Address_____ Phone _____
City_____ State _____Zip_____
Age _____Sex _____Height _____Weight _____
Medication(s)_____
Time Recording Began:_____ Recording Completed: _____
Recording Interval (minutes): Day _____Night_____
Emergency Contacts:
Clinic/Hospital or Physician _____ Phone_____

Time	**Activities/Medication**	**Symptoms/Comments**
6:00		
7:00		
8:00		
9:00		
10:00		
11:00		
12:00		
13:00		
14:00		
15:00		
16:00		
17:00		
18:00		
19:00		
20:00		
21:00		
22:00		
23:00		
24:00		
Until 6:00		

Appendix: Checking Calibration

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.

Appendix: COM Port Configuration: Windows 98SE/ME/2000/NT/XP

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

Appendix: Warranty Information

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

Technical support representatives are available between 10:00 a.m. to 3:00 p.m. Pacific Standard 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 or (760) 842-8278. **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).

Appendix: Company Information

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 Standard Time.

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

Order Lines: Tel (760) 842-8278
E-mail sales@dynapulse.com
Facsimile: (760) 758-9425

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

Technical Support:
Voice: (760) 842-8224
E-Mail: teksupport@dynapulse.com