Code 33351
GIMA HOLTER

Operator’s manual

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Specifications

Method of Measurement:	Oscillometry with step deflation.
Blood Pressure Range:	25-260 mmHg (max inflate 280mmHg)
Heart Rate Range:	40-200 bpm
Accuracy:	±3 mmHg
International Standards:	EN 60601-1, EN 60601-2-30, EN 60601-1-2 (EMC), EN 1060-1, EN 1060-3, "Non-Invasive Sphygmomanometers -General Requirements & Supplementary Requirements For Electro-Mechanical BP Measuring Systems", AAMI SP10 ES1 category C' (battery powered)
Operating Conditions:	10°C (50°F) to 50°C (122°F) 20-95% RH non-condensing
Power:	Two "AA" alkaline batteries or high capacity rechargeable batteries (NiMH)
Calibration:	Minimally, once every year
Safety Systems:	Maximum inflation pressure limited to 300 mmHg; Auto safety release valve for power failure. Maximum BP measurement time limited to less than 180 seconds.
Size:	Approximately 120 x 80 x 32 mm
Weight:	Approximately 350g (including batteries)
Storage Conditions:	-20°c to 70°c, 15%-95% RH non-condensing
Data Connector:	6 pin minidin: 1=PC-TXD (data from PC) 2= N/C 3= Ground 4= PC-RTS 5= PC-RXD (data to PC) 6= PC-DTR Max voltage on any pin = ±15V with respect to ground.

Safety and Effectiveness Considerations

The following safety and effectiveness issues are to be considered prior to the usage of the Ambulatory Blood Pressure Monitor.

This device is defibrillator protected
Note: No precautions specific to the Ambulatory Blood Pressure Monitor are required during defibrillation, and defibrillation discharge has no effect on the BP Monitor.

The monitor is intended for use following consultation and instruction by a physician.

The reliability of the device is dependent upon conformance with the operation and service instructions, as detailed in this manual.

This device has been designed for use on patients with normal sinus rhythms.

The interpretation of blood pressure measurements should only be made by a physician. The accuracy of any blood pressure recording may be affected by the position of the subject, and other factors, his or her physical condition, and use outside the operating instructions detailed in this manual.

Safety and effectiveness in pregnant women and neonates have not been established.

Warnings and Contraindications
Precautions for Use

DO NOT use in the presence of the flammable anesthetics; this could cause an explosion.

DO NOT immerse the monitor in any fluid, place fluids on top, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. If accidental wetting occurs, please return to GIMA S.P.A. (refer to pg. 20 for shipping instructions).

CAUTION: Substitution of a component different from that supplied may result in measurement error. No repair should be undertaken or attempted by anyone not service trained by GIMA S.P.A. or having a thorough understanding of the repair and operation of automated blood pressure equipment.

CAUTION: If cuff fails to deflate within 3 minutes, instruct patient on manual removal of cuff.

CAUTION: Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.

CAUTION: Avoid compression or restriction of pressure tubes.

Principles of Operation

Indications for Use:

The Ambulatory Blood Pressure Monitor is a non-invasive oscillometric blood pressure monitor an associated PC-based computer program (the PGMAPWIN or ACCUWIN Pro program), capable of recording up to 250 measurements. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time.

The system is only for measurement, recording, and display. It makes no diagnoses.

The monitor is worn by the patient, and records the ambulatory blood pressure during normal daily activities. The associated PGMAPWIN PC-based program provides the display and record-keeping functions of the system. After the ambulatory blood pressure (ABP) has been recorded for the desired period of time, the stored readings in the Ambulatory Blood Pressure Monitor are down-loaded into the PGMAPWIN program. PGMAPWIN Pro provides the data in tabular and graphic form, as well as a patient report. A measurement plan can also be constructed with the PGMAPWIN Pro, and up-loaded to the Monitor.

How the Ambulatory Blood Pressure Monitor Takes a Blood Pressure Reading

The Ambulatory Blood Pressure Monitor unit is worn by the patient either in a waist belt or shoulder strap and is connected to a traditional cuff around the non-dominant upper arm. The cuff is inflated automatically at intervals that can be programmed during set-up, using PGMAPWIN Pro. Blood pressure is measured by the oscillometric method, which senses the cessation of pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves also enables heart rate to be measured.
Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers.

The ACCUWIN Pro (PGMAP Win Pro) program

The associated PGMAPWIN Pro PC-based program provides the display and record-keeping functions of the system. After the ambulatory blood pressure (ABP) has been recorded for the desired period of time, the stored readings in the Ambulatory Blood Pressure Monitor are down-loaded into the PGMAPWIN Pro program. The PGMAPWIN Pro program provides the data in tabular and graphic form, as well as a patient report. A measurement plan can also be constructed with the PGMAPWIN program, and then up-loaded into the PG MAP monitor. The PGMAPWIN Pro program can be used on compatible Personal Computers, and is supplied as a compact disk.

The PGMAPWIN Pro program does not diagnose any conditions; it is used to establish the measurement plan (e.g., measurement intervals, times, and numbers of measurements) before the test, and to organize and display the results after the test.

Warnings and Contraindications
Precautions for Use

Precautions:
Ensure pressure compatibility with all patients. If any abnormality occurs in the unit, suspend the operation immediately and disconnect the unit from the patient. This device may not meet performance specifications if unit has been used or stored outside its acceptable environmental conditions (see “Specifications” on page 3). If cuff fails to deflate the patient should be instructed on proper and safe removal of the cuff. Use only the cuffs supplied with this unit, or cuffs approved by GIMA.

Adverse Reactions:
Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff. Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

DO NOT use in the presence of the flammable anesthetics; this could cause an explosion.

DO NOT immerse the monitor in any fluid, place fluids on top, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. If accidental wetting occurs, please return to GIMA (refer to pg 20 for shipping instructions).Refer to page 19 for instructions on maintenance and cleaning.

DO NOT remove unit covers. The monitor does not contain any user serviceable components. Refer to page 19 for service instructions.

DO NOT use the monitor if it has failed its diagnostic self test, or if it displays a greater than zero pressure with no cuff attached. The values displayed by such a unit may be inaccurate.

DO NOT use on neonates or children, and patients known to be readily susceptible to bruising.

DO NOT attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, causing harm to the patient.

CAUTION: Substitution of a component different from that supplied may result in measurement error. No repair should be undertaken or attempted by anyone not service trained by GIMA, or having a thorough understanding of the repair and operation of automated blood pressure equipment.

CAUTION: If cuff fails to deflate within 3 minutes, instruct patient on manual removal of cuff.

CAUTION: Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.

CAUTION: Avoid compression or restriction of pressure tubes.

Un-Pack and Set-Up

STEP 1: Unpacking the Unit
Remove the Ambulatory Blood Pressure Monitor and accessories from retention packaging.
Review page 17 “Product and Accessories” for contents.

PGMAPWIN Pro Hardware Requirements
• IBM compatible PC with hard disk drive
• CD - Rom drive
• VGA or compatible display adapter and monitor
• One available serial port (for GIMA Interface cable no. 91-0056-00)
Software Requirements
• Microsoft Windows® version 3.1 95/98, or Microsoft® NT™ Workstation rev 4.0, service pack 3.

STEP 2: Installing the PGMAPWIN Pro Software
Place the CD-ROM in the CD-ROM compartment located on your computer.
If Auto Play for CDs is enabled, place CD in reader and follow instructions when they appear on the screen, otherwise:

Windows NT
1. Open Windows NT Explorer
2. Click on the root CD -Rom directory
3. Double click file SETUP.EXE
4. Follow the instructions on the screen

Windows 95/98
1. Open Windows Explorer
2. Follow same steps 2-4 above

Windows 3.1
1. From the File Manager
2. Follow same steps 2-4 above

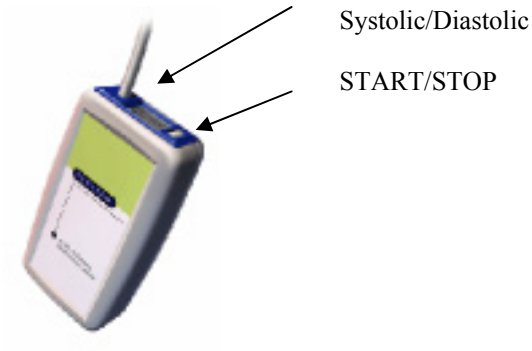
STEP 3: Setting-Up the Ambulatory Blood Pressure Monitor.
A. Install 2 “AA” batteries in the battery bay. (located at the back of the unit).
If rechargeable batteries are used please refer to the manufacturers guidelines to ensure safe use and adequate maintenance. When batteries are properly loaded the unit will display the following:

1. Incrementing dashes for 2 seconds
2. Software version for the unit displayed
3. Battery voltage displayed for 2 seconds
4. Three quick beeps

5. The number of BP readings in memory with flashing printer symbol for 3 seconds
6. Long beep
7. Displays flashing time for 20 seconds

Unit is now ready to upload a “BP Study”.

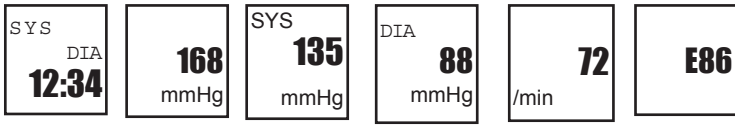
LCD & Keys Diagram of PG MAP (PG MAP)

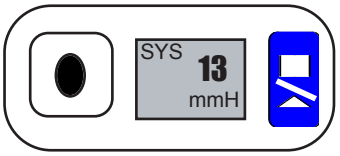


START/STOP Button Functions Explained

ABP Monitor State	Button Action	Button Pressed	Hold Button Down
Off		3 Beeps number of readings displayed printer symbol displayed time flashes	
Time Flashing (normal mode and unit is ready for an action)		Unit goes into “study mode” And takes a reading	At 5 beeps unit turns off
Study Mode		unit takes a reading	At 5 beeps unit turns off
While unit is taking a reading		unit aborts reading (unit displays abort code E86) cuff deflates unit goes back to study mode	

To abort a reading in progress press the start/stop button and cuff will automatically deflate.





Patient Hook-Up and Proper Cuff Replacement

STEP 4: The Hook-Up

Fig. 1

One:
It is important to select the cuff size that is appropriate to the diameter of the patient's upper arm. Use the "range lines" on the inside of the cuff to determine the correct size cuff to use.
Wrap the cuff snugly around the arm as shown in Figure 1. The cuff may be worn over a thin shirt, without compromising accuracy or performance. However, it is advised that the cuff is secured using the cuff anchor.
Ensure the air hose from the monitor to the cuff is not compressed, crimped or damaged.

Please remember that using the wrong size cuff may give false readings.

Fig. 2

Two:
With the patient cable draped over the patient's shoulder, attach an adhesive cuff anchor to the snap on the hose of the cuff bladder as in figure 1 and 2. Do not remove the adhesive backing of the cuff anchor at this time.

Before you proceed to Step 3 you should upload the BP Study (Refer to page 11 and 12). Once all the data is uploaded you may return to this page and complete Step 3.

Fig. 3

Three:
Insert the PG MA Pinto its pouch with the LCD showing through the window. Attach the pouch to either the shoulder strap or the belt, (as shown in fig 3) depending on the patient's preference. Finally, with the patient's arm resting at their side attach the cuff anchor to the top of the patient's arm by removing the adhesive backing. This will keep the cuff in place during the study (Refer to fig 1).

Uploading a BP Measurement Plan to the Ambulatory Blood Pressure Monitor

STEP 5: Connecting the Unit to the Computer

Connect the cable to the monitor at the bottom of the unit as shown in figure 4.

Fig. 4

Connect the PC Interface cable to the 9-pin serial port on back of the computer.

Fig. 5

Before you upload a BP measurement plan to the ABP monitor make sure:

- The PGMAPWIN Pro Software is installed (refer to page 8)
- Batteries are in the unit
- The serial cable is connecting the ABP monitor to the computer.

STEP 6: Creating and Uploading a BP Measurement Plan
ABP measurement plan is created in PGMAPWIN Pro by selecting certain parameters (refer to page 12) for each patient and then uploading it to the ABP monitor.

1. Open PGMAPWIN Pro.
2. A prompt will appear each time you open PGMAPWIN Pro for the user's name. Type in user's name. To change user go to FILE then click on Change User. This feature is available to allow each user to store his or her own configuration such as report and thresholds.
3. Next you must configure the port but only the first time you set-up the ABP monitor.

Configuring the Port

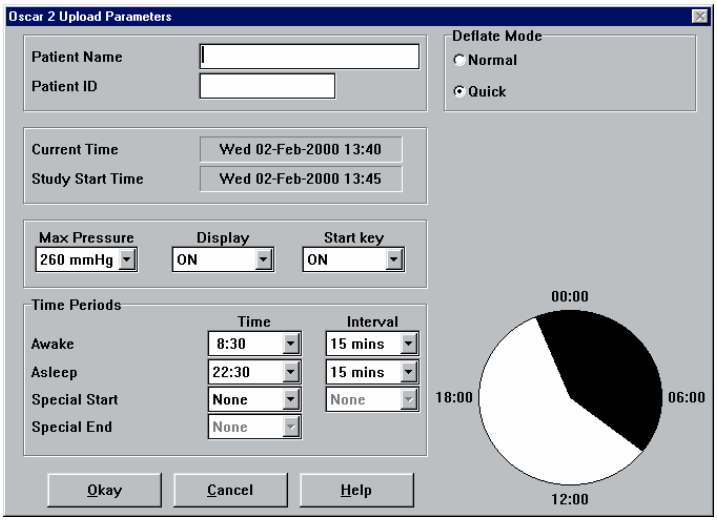
1. Select the DOWNLOAD function from the file menu then select CONFIGURE PORT
2. Select the communications port to which the PC cable is connected.
3 Select PG MAP (OSCAR 2)
4. Select OK when finished

Uploading the Data

1. Click on the UPLOAD icon
2. Follow the pop-up menu.
3. Click on the data fields to enter data.
4. Click OKAY when data entry is complete
5. The dialog box on screen will show the progress as the data is transferred to the unit.

Uploading a BP Measurement Plan to the PG MAP (PG MAP) Unit

Uploading Data - The Parameters



In the Upload parameters menu, shown above, the test parameters will be adjustable in the following ranges:

• Patient name and ID (for reporting and referencing data)
• Max Pressure: 220 to 260 mmHg
• Time Periods: Up to 3, with automatic retry function
• Display: On will allow the patient to view the results
• Duration: 24, 27, 48, and 52 hour study periods
• Time Intervals: 5, 10, 15, 30, 45, 60, and 90 minute intervals
• Deflate Mode: Normal deflate mode is approximately 3 mmHg/sec.
Quick deflate mode is designed to deflate at a faster than normal rate to enhance patient comfort.

8. Click OKAY when data entry is complete
9. The dialog box on screen will show the progress as the data is transferred to the unit.

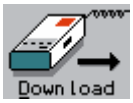
Note: Once the data is uploaded to the unit the first reading will begin in 5 minutes.

Programming the ABP monitor for the Patient's BP Measurement Plan

PGMAPWIN Pro (ACCUWIN) Functions

PGMAPWIN Pro provides functions to download ABP data from the monitor, edit data, and print reports. The most frequently used functions are made available as icons at the top of the main window.

Upload a programmed BP measurement plan to the ABP monitor



Download data from the ABP monitor

Exit the PGMAPWIN Pro Program

Edit the tabular data

Displays the configuration input for the study

Retrieve previously downloaded data

Print a report

Displays statistics for current BP report

In addition to the toolbar buttons, a menu bar at the top of the main window gives access to other functions:

- Copying BP data to other disks or directories
- Deleting BP data
- Selecting and configuring the serial port used to download data
- Selecting and configuring the printer to use for report printouts
- Configuring the PGMAPWIN Pro report
- Setting BP thresholds and patient's sleep times
- Uploading to the ABP monitor

Refer to the PGMAPWIN Pro manual for more detailed information.

Programming the ABP Monitor for the Patient's BP Measurement Plan

A BP measurement Help Guide

1. Patients should be informed about the goal and expected results of the study.

2. Patients should avoid excess movement during measurements. They should hold their arm loose, slightly away from the chest.

3. The cuff should be wrapped snuggly around the arm above the elbow. The patient may wear a thin shirt under the cuff without influencing the accuracy or performance of the device. However, it is recommended to directly apply the cuff to the arm and secure it with the cuff anchor (see page 10).

4. Patients may start extra blood pressure measurements with the START/STOP button. PATIENT CAN ABORT A READING AT ANY TIME WITH THE START/STOP KEY.

5. Patients should not take the device off at night.

6. The batteries can be replaced during a study without data being lost, or interrupting the monitoring schedule.

Downloading the Data to the Computer

STEP 7: Collecting the Patient's Data
1. Remove the ABP monitor from the pouch.
2. Connect the PC cable to the unit and computer,
   as shown on page 11, figs 4 & 5.
3. Start PGMAPWIN Pro program (refer to page 11)—Step 6 (creating and uploading
   a BP Measurement plan)

Configuring the Port:
1. Select the DOWNLOAD function from the file menu
   then select CONFIGURE PORT
2. Select the communications port to which the PC cable is connected.
3 Select AMBULATORY BLOOD PRESSURE MONITOR (to automatically detect
   which unit you are currently using)
4. Select OK when finished
5. This procedure need not be repeated unless switching serial ports.

Downloading Data:
1. Select the DOWNLOAD function from the file menu or click
   on the DOWNLOAD icon.
2. Click DO DOWNLOAD - The dialog box on the screen will show
   the progress as the data is transferred
3. After completion, a dialog box will prompt for the patient name
   and ID number. (you may accept the default values or enter
   a new name and ID number)
4. Click on the OKAY button to save data and complete
   download process.

NOTE: If you do not download the data to the computer this data will be lost when you upload another study.

Edit/Print Downloaded Data

Edit Data
Because the ABP monitor unit collects blood pressure readings while the patient is going about his or her daily activity, some readings may be disrupted by excessive patient movement or for various technical reasons. All readings taken by the ABP monitor have test codes and quality codes which indicates the reliability of the particular BP data.
When the ABP monitor data is downloaded to the PC all the readings which have suspect Test Codes or Quality Codes will be "tagged". "Tagged" records are omitted from the statistics and are printed in a separate part of the report. All "tagged" readings are not necessarily invalid. If you are confident the "tagged reading is valid you may "untag" it. Conversely, if you feel a reading is not valid but was not "tagged" you may do so. If you would like to edit the data and remove erroneous readings you may:

• Click on the left-most column and select the row in question.
• To untag it, just select the row again.
• When you are done click OKAY.

All "tagged" data will be cleared from the report and now you will be able to view the patient's data in a graph.
To expand or reduce the graph for a different view of the data:

Bring the mouse arrow down into the numbers along the bottom of the graph or place the arrow on the side numbers of the graph. You will notice the arrow turns to a double-sided arrow, in this mode you may hold down the left mouse button and drag the graph to the right or left to expand or reduce the graph. You may also choose the type of graph by clicking on GRAPH. You have the option of viewing the data by line graph or bar graph.

Print Report:
Review Function
• Select REPORT on the menu bar and select PRINT
• To configure your report select CONFIGURE REPORT
• Select EDIT REPORT - This function determines which pages to print in a report.
• To select a page, check the checkbox to the left of the page name. To omit a page, remove the check from the checkbox. Note that at least one page must be selected.

Product and Accessories

Description	Item Number	Qty.
ABP Monitor w/ 4ft Patient Hose Assembly	97-0012-00	1
Adult cuff w/ Anchor Clip	98-0034-00	1
Pouch	98-0032-01	1
Strap	98-0036-00	1
Belt	98-0037-00	1
AA Alkaline Batteries	17-0004-00	4
Cuff Anchor Pads	98-0007-00	10
Users Manual	80-0011-00	1
Quick Start Guide	82-0007-00	1
PGMAPWIN Pro Software on CD (English Version)	27-0016-00	1
PC Interface Cable	91-0056-00	1
Optional Items		
Large Adult Cuff	98-0010-00	1
Small Adult Cuff	98-0013-00	1

Your ABP monitor package should contain the following items excluding the optional items. If you are missing any item please contact GIMA immediately (refer to page 19 for contact information).

Trouble-Shooting Guide

Event Code	Description in PGMAPWIN Pro	Solution
1	Weak or no oscillometric signal	Check position of cuff, tighten cuff
2	Artifact/Erratic oscillometric signal	Remain still during BP reading
3	Exceeded Retry Count (4 inflate attempts)	Remain still during BP reading
4	Exceeded Measurement time Limit (120 seconds)	Check air hose connections and make certain cuff is tight
85	Reading Aborted (blocked valves or pneumatics)	Check air hose connections and make certain air tubing is not crimped.
86	Reading Aborted	Push START/STOP button to start reading.
87	Reading Aborted (inflate time-out or air leak)	Check air hose and cuff
88	Reading Aborted (safety time-out)	Retry reading, push START/STOP button. If problem persists return unit for servicing.
89	Reading Aborted (cuff over-pressure)	Check for blocked or kinked air hose.
90	Service Required (power supply out-of-range or other hardware problem)	Replace betteries. If problem persists return for servicing.
91	Service Required (safety over-ride fitted or autozero out-of-range)	Retry by pushing START/STOP button. If problem persists return unit for servicing.
97	Service Required Transducer out-of-range	Return for servicing.
98	Service Required (A/D out-of-range)	Return for servicing.
99	Service Required (EEPROM calibration data CRC failure)	Unit needs to be recalibrated. Return for servicing.

Maintenance and Cleaning

The ABP monitor performs a range of systems and software checks during normal operation, reporting to the user, the operational status via the report and display. However, preventative maintenance is an important function that should be routinely performed to ensure the safe and efficient operation of the monitor.

DO NOT use the monitor if it has failed any of its diagnostic self tests, or if it displays a greater than zero pressure with no cuff attached.

The preventative maintenance should include the inspection of cables and pneumatic hoses for cracks, fraying or kinks.

DO NOT use the monitor if there are any signs of damage.

WARNING: Fire, Explosion, and Severe Burn Hazard. Ensure battery is inserted with correct polarity. The PG MAP does not contain any user serviceable parts and should only be opened by an authorized service representative.

DO NOT remove covers or break the warranty seal, as this will invalidate the manufacturer's warranty. For details of any service inquiry please contact:

GIMA S.P.A
Italia: tel. 199 400 401 - fax 199 400 403
Export: tel. +39 02 953854209/221/225 fax +39 02 95380056
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com
It is recommended that the ABP monitor be calibrated annually to verify the accuracy of cuff pressure transducers/indicators by an authorized service center.

Cleaning:
The ABP monitor unit is not sterilizable. DO NOT immerse the monitor in any fluid, or attempt to clean with any liquid detergents, cleaning agents, or solvents. Remove dirt and dust from the monitor by wiping it with a soft, damp cloth. If the unit does become immersed in water, do not use and send to our service department to the address listed above. The cuff may be disinfected by a solution such as Cidex. Please refer to the manufacture's instructions on proper and safe use. The inside nylon bladder should not be removed.

DISPOSAL

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.
This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel travelling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty.
The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use.
GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from.
Products sent to GIMA will be rejected.

Declaration of Conformity

Applications of Council Directive: 93/42/EECMedical Devices Directive	CE 0413
Standards to which conformity is declared	EN60601-1, EN60601-2-30, Internally powered, with type BF applied part, continuously rated EN60601-1-2 (EMC), EN 1060-1, EN 1060-3, AAMISP10,
Manufacturer's name and address	SUNTECH Medical Instruments, Inc. 8917 Glenwood Avenue Raleigh, NC 27612 USA
Distributor's name and address	**GIMA S.P.A.** Italia: tel. 199 400 401 - fax 199 400 403 Export: tel. +39 02 953854209/221/225 fax +39 02 95380056 gima@gimaitaly.com - export@gimaitaly.com www.gimaitaly.com
Type of equipment	Oscillometric ambulatory blood pressure monitor
Model	**PG MAP**

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s)

Name: Dayn McBee
Position: Chief Operating Officer
SUNTECH Medical Instruments, Inc.