

## Overview of the Piesometer MK-1

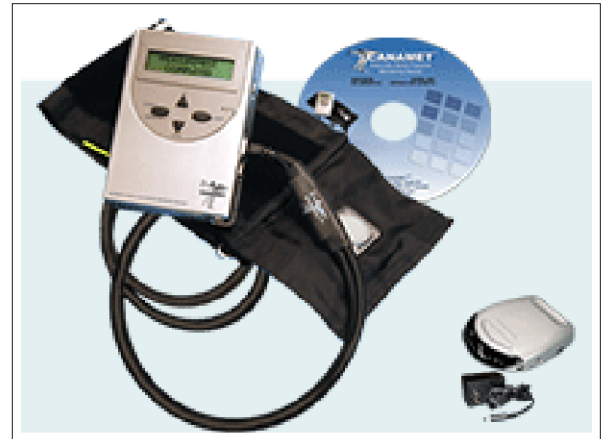
Menu-driven automated blood pressure monitor that is motion and noise tolerant  
Utilizes an adaptive noise cancellation algorithm for use in noisy environments  
Continuous monitoring over a period of 24 hours with timer and memory for automatic ambulatory blood pressure monitoring  
Includes a graphic user interface that allows for visual display and verification of the automated blood pressure measurements  
Records can be transmitted to a PC, fax, or to a remote data center through phone lines  
3 different cuffs available (each in multiple sizes) to insure accuracy, comfort, and convenience during blood pressure monitoring  
Benefits of the Piesometer MK-1 Blood Pressure Monitor

Measures the blood pressure accurately  
Capable of operating in noise and vibration intense environments such as:

- stress test ECG
- on ambulances
- on battle fields
- near or onboard helicopters and airplanes
- circumstances when patient movement is unavoidable

No mercury pollution

Eliminates the measuring errors in common electronic digital sphygmomanometers  
Effective for accurate monitoring of high-risk high blood pressure and heart disease patients  
Patients can send data from their home to a monitoring medical clinic through phone lines, thus reducing the number of visits to hospitals  
Provides full pressure data visually for analysis  
Shortens the time medical personnel spend measuring blood pressure and pulse



## Applications for the Piesometer MK-1

Automated blood pressure monitor that is motion and noise tolerant. Includes a graphic user interface that allows for verification of the automated BP measurements. Records can be transmitted to a PC, fax, or to a remote data center through phone lines.

- Applications
- Stress test ECG, cardiologists, primary care physicians, 24 hour ambulatory monitoring, home care, ambulances, helicopters, airplanes
- Effective for monitoring of high-risk high blood pressure and heart disease patients
- Can be used by military medics in battle fields and rescue operations
- Benefits
- Measure the blood pressure accurately
- Capable to operate in noisy and vibration intense environments such as Stress Test ECG, ambulances, near and/or onboard helicopters, naval vessels, airplanes etc.
- Provides full pressure data visually for analysis
- Shortens the time spent by doctors and nurses for measuring blood pressure
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- No mercury pollution, eliminates the measuring errors in common electric sphygmomanometers
- Effective for accurate monitoring of high-risk high blood pressure and heart disease patients
- High-risk patients can send data from their home to a monitoring medical clinic through phone lines, thus reducing the number visits to hospitals

## Specifications for the Piesometer MK-1

### Specifications for Piesometer MK-1 Automated Blood Pressure Monitor

- 3 year warranty
- Method of Measurement: Auscultatory
- Size: 13.4 cm x 9.5 cm x 4.4 cm
- Weight: 440 g
- Blood Pressure Range: 40 – 270 mmHg
- Maximum Inflation: up to 300 mmHg
- Accuracy:  $\pm 1$  mmHg
- Power: Minimum 65 measurements per charge
- Safety Features: Maximum inflation limited to 300 mmHg; auto safety release valve for power or system failure
- Operating Temperature: -5° C to 45° C
- U.S. patents 6,520,918 and 6,805,671

**International Standards**

- CAN/CSA CA C22.2 No 601.1-M90-Medical Electrical Equipment Part 1: General Requirements for Safety
- UL 60601-1 Medical electrical equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- The FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance
- FDA 510(k) pre-market clearance K041169
- Canadian Medical Device Regulations (MDR)
- ANSI/AAMI SP10:2002
- European Commission Medical Device Directives (MDD 93/42/EEC)

**Package Contents**

- Digital Automated Blood Pressure Monitor (the Piesometer unit)
- Electronic arm cuff
- Lithium-ion battery
- AC adaptor for recharging the lithium-ion battery
- CD-ROM for installation of computer interface software
- Serial RS232 cable for direct data transfer to PC
- User Manual
- Quick Reference Card (for telemedicine option)
- Modem with AC adapter and phone cord
- Carrying Pouch with belts

**FDA Requirement Certificate**

- The Piesometer MK-1 Automated Blood Pressure Monitor has passed all applicable EMC (Electromagnetic Compatibility) testing. Prescribed by the IEC 60601-1-2 Collateral Standard: Electromagnetic Compatibility Requirements and tests.
- This EMC requirement applies to medical devices selling in the U.S. and Europe (under the FDA and CE Mark requirements).