# Ambulatory Blood Pressure Monitor - **Piesometer** MK-1


## The beauty of art and the accuracy of engineering in ambulatory blood pressure systems

Piesometer MK-1 measures systolic, diastolic blood pressure and heart rate using auscultatory methodology and adaptive interference cancellation.

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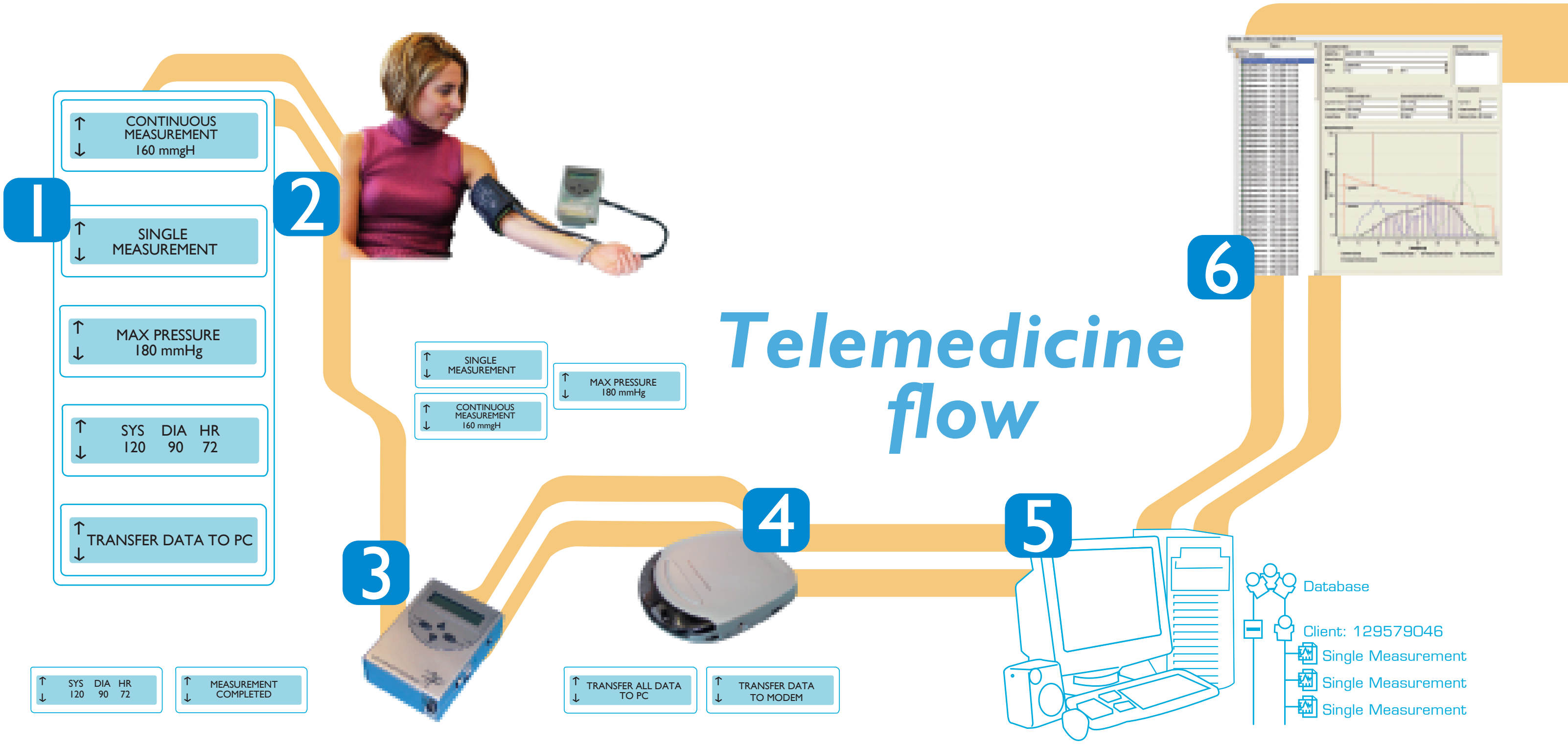
*Our company is ISO 13485 : 2003 Registered*

# *This is how the Piesometer MK-1 works*




*This unit measures systolic, diastolic blood pressure and heart rate using auscultatory methodology and adaptive interference cancellation.*

## **Piesometer** MK-1

### *Graphic User Interface and PC - based software*

Allows users of the Piesometer MK-1 to verify accuracy of measurements. 6

Software is simple and requires minimal self-training to operate the device and organize patient records with statistics and graphics. 1, 6

### *Simple to use*

Canamet Piesometer MK-1 is one of the most accurate blood pressure monitors on the market.

It is a robust device for continuous and remote patient monitoring with a complete set of telemedicine functionalities. 1 - 6

The Piesometer MK-1 provides a versatile solution to medical practitioners for reliable blood pressure measurements in hospital environments, ambulances, search & rescue operations and home care.

# Specifications Sheet

## Piesometer MK-1

*The Piesometer MK-1 is an ambulatory blood pressure system that is highly accurate, and user friendly. The CANAMET PIESOMETER is protected by U.S. Patents 6,520,918 and 6,805,671. The advanced technology employed by the Piesometer MK-1 allows readings to be taken in noisy environments and/or while a patient speaks.*

| | |
|---|---|
| **Method of Measurement** | Auscultatory: Simulates method used by health care providers (e.g. cuff, stethoscope and mercury sphygmomanometer). |
| **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** | ± 1 mmHg |
| **International Standard** | ▪ CAN/CSA CSA C22.2 No 601.1-M90-Medical Electrical Equipment Part 1: General Requirements for Safety<br>▪ UL 60601-1 Medical electric equipment, Part 1: General requirements for safety<br>▪ IEC 60601-1-2 Collateral Standard: Electromagnetic compatibility-Requirements and Tests<br>▪ ANSI/AAMI SP10:2002<br>▪ The FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance<br>▪ FDA 510(k) pre-market clearance K041169<br>▪ Canadian Medical Device Regulations (MDR)<br>▪ European Commission Medical Devices Directives (MDD 93/42/EEC) |
| **Power** | At least 65 measurements per charge |
| **Safety Features** | Maximum inflation pressure limited to 300 mmHg<br>Auto safety release valve for power or system failure |
| **Operating Temperature** | -5℃ to 45℃ |

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# OVERVIEW of Blood Pressure Measurement Methodologies

## and Comparison Between the Traditional Auscultatory Method (Golden Standard), Oscillometric Method and CANAMET's Adaptive Auscultatory Blood Pressure Methodology

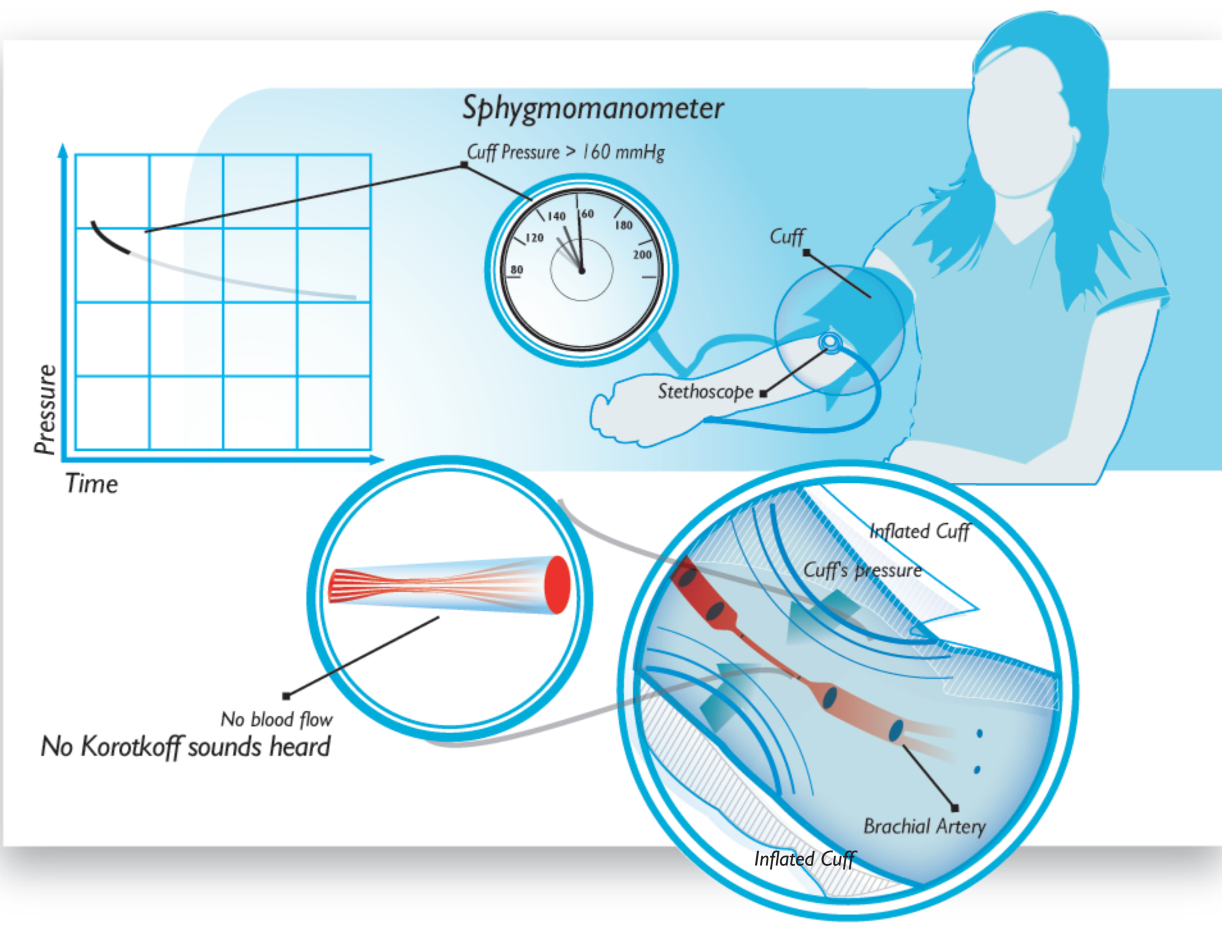
*The first method, which is the Golden Standard used by Health Care practitioners, is the **Auscultatory Method** that incorporates stethoscope and mercury sphygmomanometer. The second is the **Oscillometric Method**, which is being implemented in most of the automated blood pressure systems and finally, the third method is **CANAMET's Adaptive Auscultatory Blood Pressure Methodology**, (US patents 6,520,918 and 6,805,671). CANAMET's adaptive auscultatory methodology with the use of its Graphic User Interface emulates graphically the traditional auscultatory method, thus it provides the means to graphically verify the accuracy of its blood pressure estimate provided by CANAMET's ambulatory blood pressure system, the PIESOMETER MK-1.*

## Traditional Auscultatory Method (Golden Standard)

*The traditional auscultatory method consists of three basic steps that are graphically illustrated in the following three figures.*

## Step I

*The cuff is inflated to a level one would consider higher than the systolic pressure. The artery is occluded and blood flow is stopped, therefore the artery is still silent. The Pressure vs. Time illustrated in the graph shows the pressure in the cuff during the period that the cuff deflates.*



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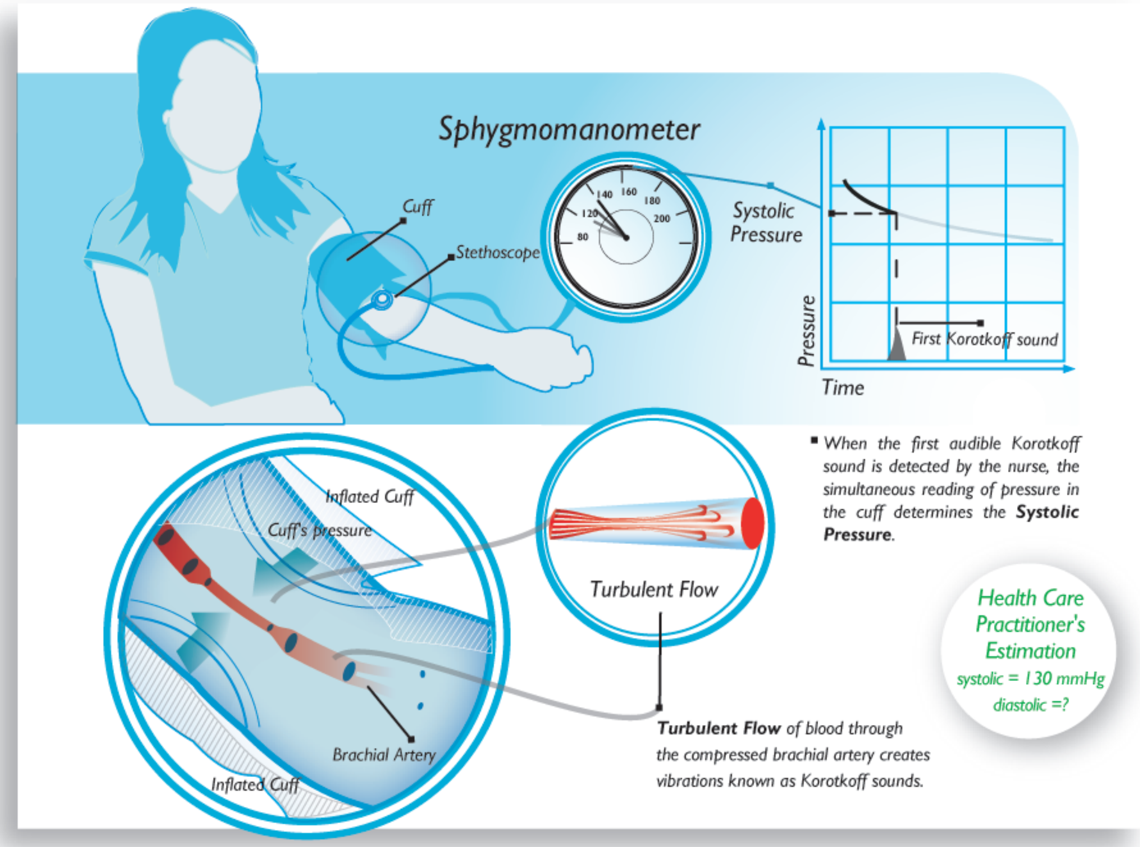
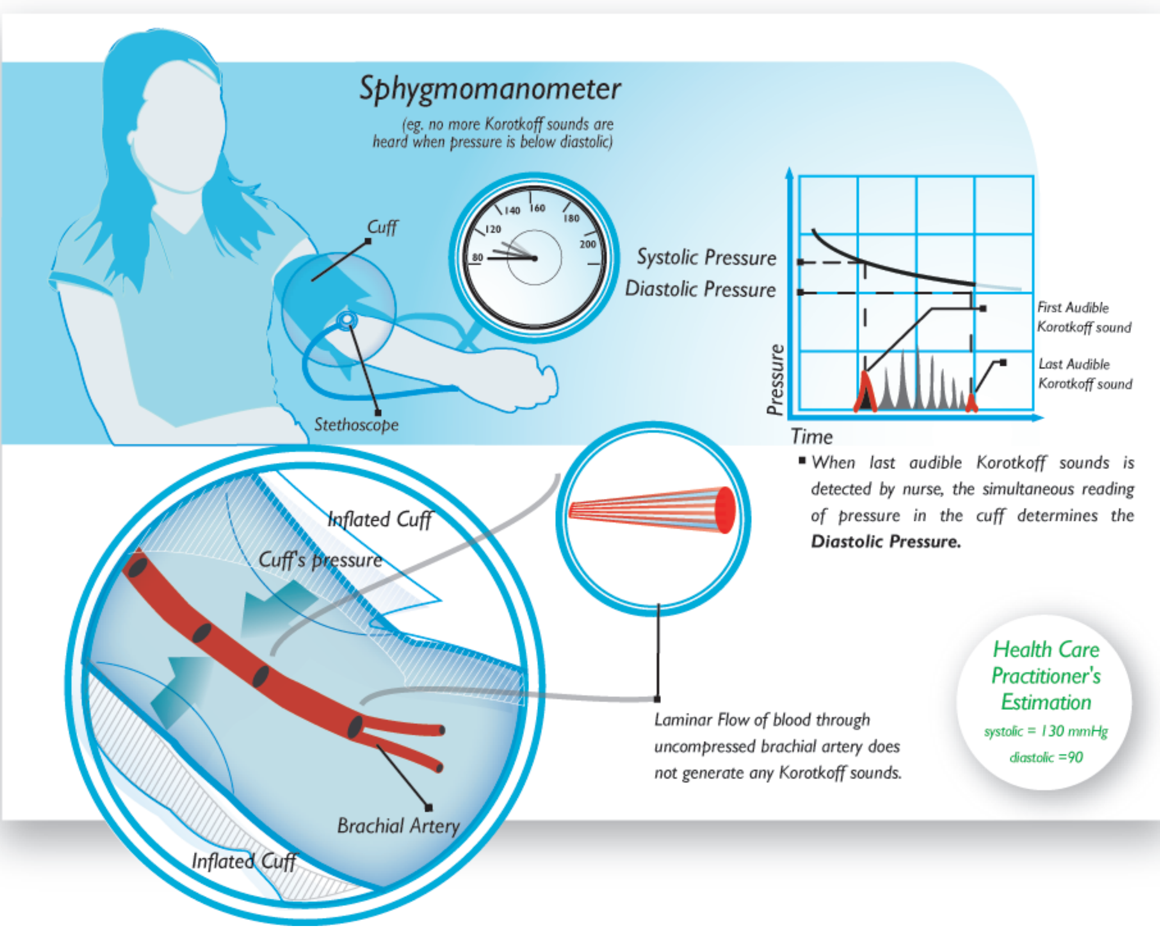



# Step 2

As the cuff pressure is slowly deflated, a point is reached where the cuff pressure equals the **systolic blood pressure.** When blood begins to jet through the compressed brachial artery, the turbulent flow is audible due to friction of the blood at the artery wall, as the artery opens while the cuff pressure changes.

The vibrations created from the artery walls are the Korotkoff sounds. The moment that the last audible Korotkoff sound is heard by the health care practitioner, a person's Diastolic Blood Pressure is defined.

The illustration of the Pressure vs. Time in the graph shows the visualization of the Korotkoff Sounds and the definition of the Systolic Blood Pressure.

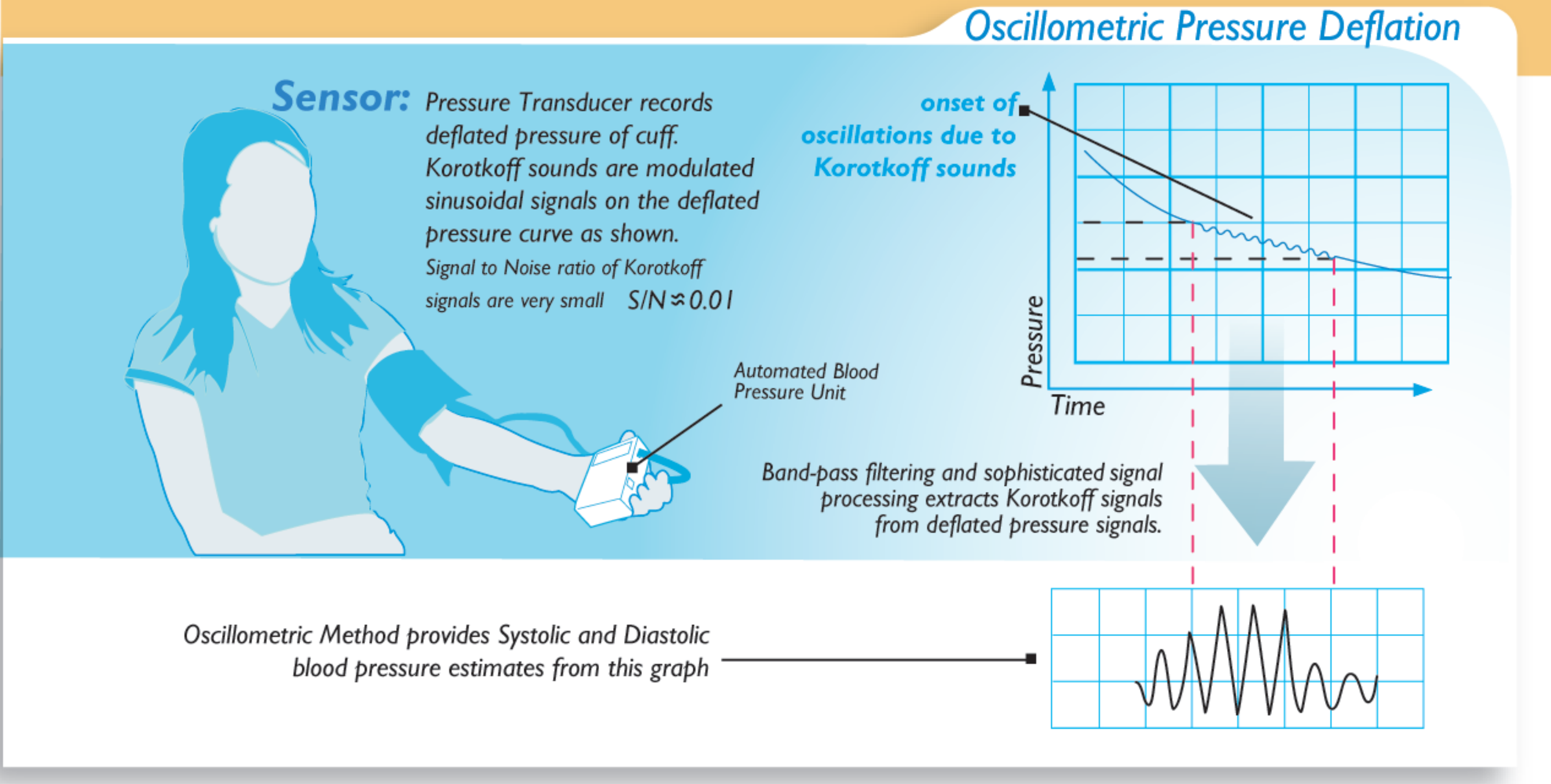



# Step 3

Once the deflated cuff's pressure reaches the person's **diastolic blood pressure**, the artery is widely open. Then, the flow of blood in the brachial artery becomes laminar and smooth, and the Korotkoff sounds disappear. The moment that the last audible Korotkoff sound is heard by the health care practitioner, a person's Diastolic Blood Pressure is defined.

The illustration of the Pressure vs. Time in the graph visualizes the Korotkoff Sounds and the definition of the Diastolic Blood Pressure.

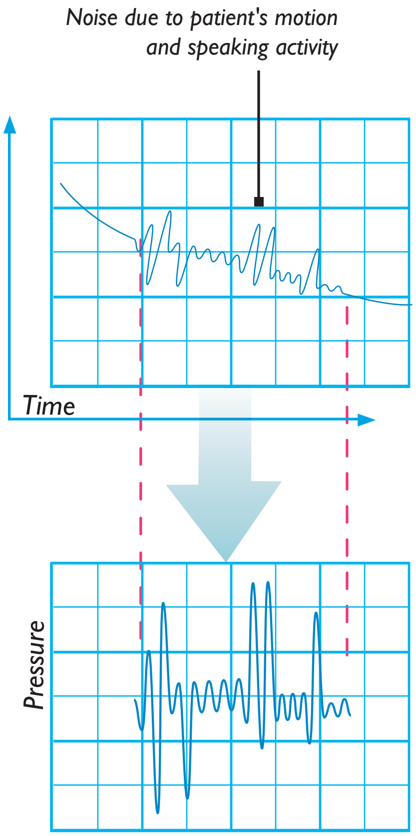
# Oscillometric Method




# Remarks

*Due to the low signal-to-noise ratio inherent by the oscillometric method when measuring blood pressure, any minor movement by the patient or speaking activity will induce random noise on the Korotkoff recorded signals as shown in the diagram.*

*The end result of the oscillometric method is sensitivity to movement since the Automated Blood Presure Systems that use this approach tend to be sensitive to patient's movement and environmental vibrations. Thus, the use of these systems is restricted to motionless environments to ensure reliable measurements.*




## Note

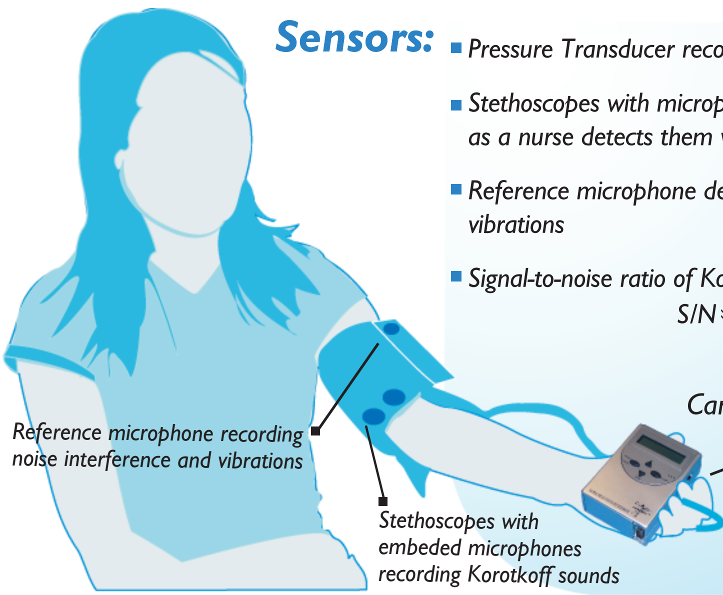
*Most of the automated electronic blood pressure systems use the oscillometric method. No stethoscope is required between the cuff and the subject's skin. While blood is flowing through the patient's artery, the throbbing of the artery causes microscopic oscillations that are superimposed (modulated) on the macroscopic drop of the cuff pressure - as illustrated in the Oscillometric Pressure Deflation Curve. These oscillations are interpreted in lieu of Korotkoff sounds.*

*To estimate the systolic and diastolic blood pressure, the peak oscillation signifies the mean pressure. The systolic, diastolic pressure estimates are derived from the largest positive and negative derivatives of the envelope of the oscillatory response relevant with the Korotkoff sounds.*

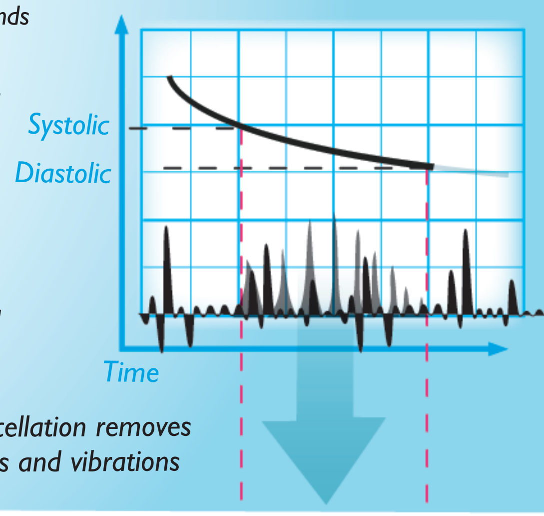
# Canamet's adaptive auscultatory blood pressure technology

## Sensors:

- Pressure Transducer records deflated pressure of cuff
- Stethoscopes with microphones record Korotkoff sounds as a nurse detects them with a stethoscope
- Reference microphone detects interference noise and vibrations
- Signal-to-noise ratio of Korotkoff sounds is high $S/N \approx 0.5$




Canamet's Piesometer MK-I

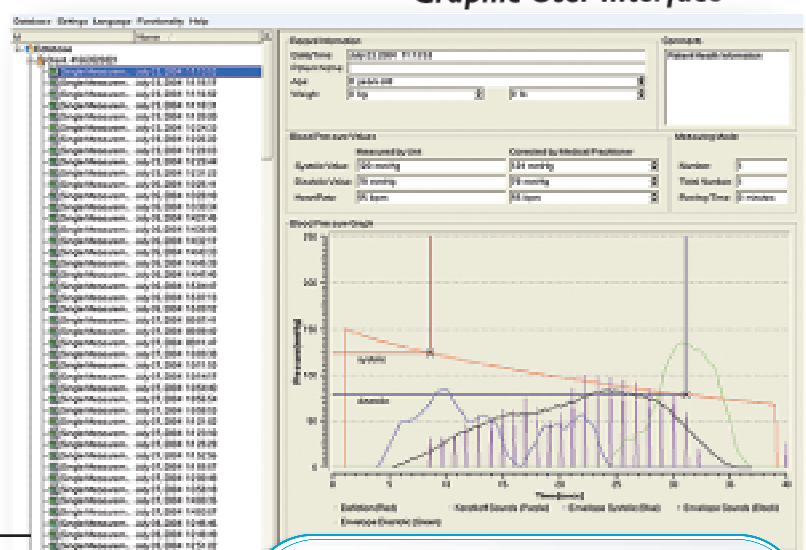



Adaptive noise cancellation removes noisy interferences and vibrations

Canamet's Adaptive Auscultatory Technology emulates the traditional auscultatory method in the same way as a nurse operates a stethoscope and a mercury sphygmomanometer to estimate the systolic and diastolic blood pressure.

The **Graphic User Interface** provides a visual interpretation of the traditional auscultatory methodology since the recorded Korotkoff sounds, shown by the purple spikes in this graph, are real representations of the blood flow sounds in the brachial artery.

**Graphic User Interface**



# Remarks

**Piesometer** MK-1

With the high signal-to-noise ratio inherent by Canamet's adaptive auscultatory methodology, any minor movement by the patient or speaking activity will only have a minor impact in estimating the patient's systolic and diastolic pressure.

The end result of Canamet's adaptive auscultatory methodology is that it can be used in any kind of emergency and hospital environment including ambulances, ER, IC, and home care by trained medical practitioners. Furthermore Canamet's Graphic User Interface allows for visual verification of each individual blood pressure measurement as shown by the graph.

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