CardioVision®

The Science of the Arterial Stiffness Index (ASI)

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CardioVision®

CardioVision® is a non-invasive electronic device that uses cuff pressure to measure vascular dynamics. This device can measure systolic, diastolic, mean pressure, pulse, pulse pressure and arterial stiffness (ASI). The total time for a complete measurement is about 1 minute and it is completely painless. It is portable and designed to operated with any computer via an RS-232C serial port. It stores up to 9,999 patients in one data file with up to 100 measurements for each patient. A history on each patient is created to allow monitoring over time and all results can be printed or faxed instantly.

In addition, Cholesterol, LDL-Cholesterol, HDL-Cholesterol, Glucose, and Triglycerides data can be stored and saved to the Framingham Risk Analysis software to produce a "Percentage of a Coronary Heart Event in the next 10 years."

CardioVision® is an FDA cleared device requiring:
A Personal Computer with a free serial port, Pentium or higher processor, 3 2 MEG Ram or more, and Windows 98 SE, ME, 2000.

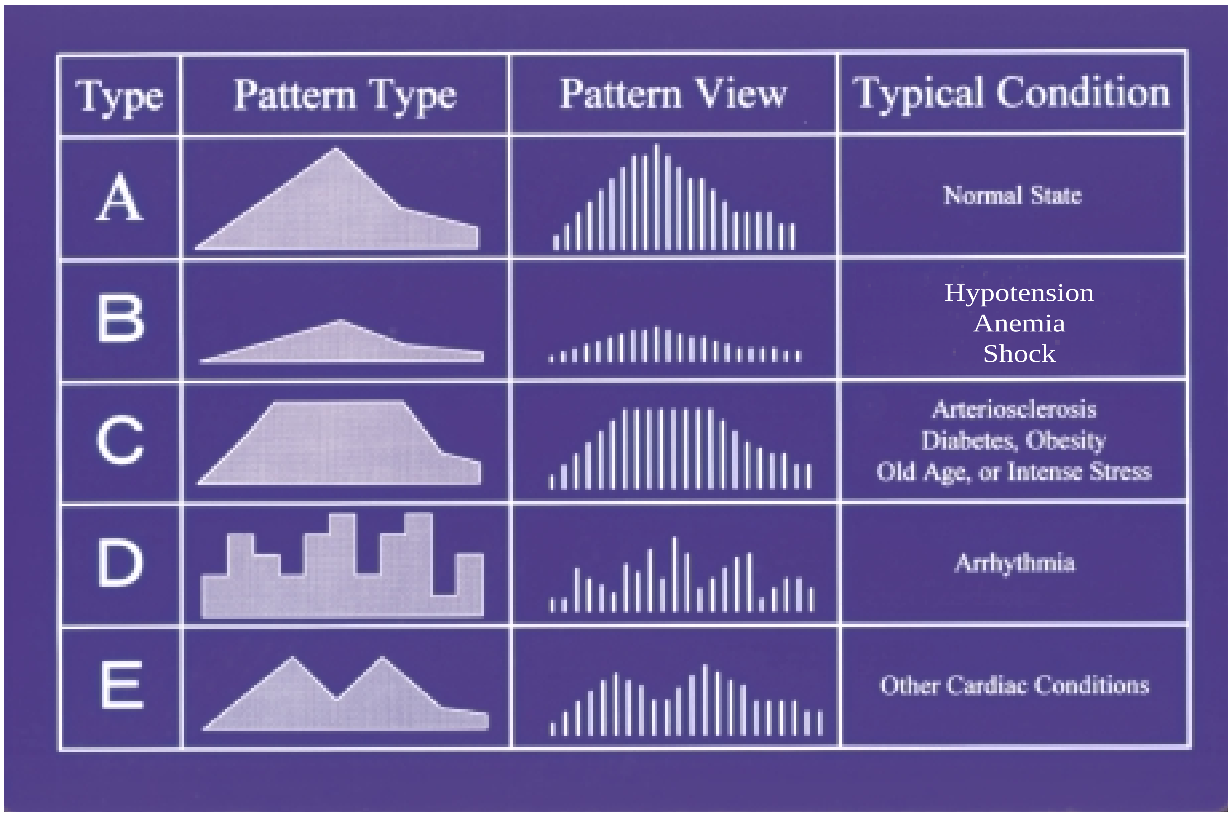
FDA 510k Clearance Number: K961144 Device Name: MS-2000

Indications for Use: " The MS-2000 is used by health care professionals to measure blood pressure data (systolic, diastolic and mean pressure) and heart pulse rate. The MS-2000 also generates pulse wave patterns which can be used as an initial screening device to determine if patients have potential underlying cardiovascular disease that might require more specific diagnostic evaluations by physicians or other health care providers."

CardioVision®
Theory of Operation

The CardioVision® utilizes the oscillometric method of blood pressure measurement. In the oscillometric method, the cuff pressure is first increased to a level above the systolic pressure and then gradually reduced. At its maximum, the cuff pressure constricts the brachial artery and prevents pulsation. When the cuff pressure descends to a level near the systolic pressure the pulsation of the brachial arterial vessel appears again. This pulsation is transmitted to the cuff as a minute change in the volume of the arm which then changes the volume of the cuff. Since the cuff is filled with air, the cuff volume change can be measured as a change in inner pressure. When the inner pressure of the cuff falls below the systolic pressure, minute pressure changes appear. As air within the cuff is released, and the pressure falls, the amplitude of the pressure variations increases. The artery itself does not completely open until the cuff pressure falls to the diastolic level.

The CardioVision® patented technology employs both software and hardware that demonstrates a high level of correlation between certain cardiovascular conditions and the type of patterns obtained from the oscillometric pulse measurement. These are obtained over the course of the entire cuff pressure drop from systolic to diastolic. CardioVision® software employs this data to provide five identified, distinct, graphical patterns and an Arterial Stiffness Index (ASI) which show close correlation to known cardiovascular conditions. The pressure/volume relationship of an artery is not linear. When blood is infused into a relaxed artery, a great deal can enter initially with no increase in pressure. This is true until the artery becomes full enough to create a measurable pressure change. As the internal pressure increases, the rigidity of the artery also increases. Therefore, the ratio of liquid volume to pressure becomes higher. This property of the artery is related to the dynamic character of the elastic fibers and collagen fibers that comprise the arterial wall. The elastic fiber is a soft, muscular fiber which maintains the expandability of the artery and the tension of the arterial wall when the inner pressure of the artery is low. The collagen fiber makes up the outer part of the artery and has low elasticity. As the artery stretches its further expansion is restricted.



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PULSE WAVE PATTERNS

Selected References

1. Shimazu, H. Kawarada, A., Ito, H., Yamakoshi, K. Electric impedance cuff for the indirect measurement of blood pressure and volume elastic modulus in human limb and finger arteries. Medical and Biological Engineering and Computing, pp. 477-483, 1989.
2. National Institutes of Health Consensus Development Conference on lowering blood cholesterol to prevent heart disease. JAMA, 252, 20802086,1985.
3. Sorenson, K. E., Kristensen, 1. B., Celermajer, D. S.; Atherosclerosis in the Human Brachial Artery. JACC 29, pp. 318-22, 1997.
4. Rediker, D., Greenwood, J. R., Shimazu. Evaluation of a Novel Noninvasive Blood Pressure Monitor to Screen for Coronary Artery Disease and Arrhythmia. Cardiovascular Health: Coming Together for the 21st Century. A National Conference. 1998.
5. Corretti, M. C., Plotnick, G.D., Vogel, R. A., Technical Aspects of Evaluating Brachial Artery Vasodilation Using High-Frequency Ultrasound. American Journal of Physiology. 268 (Heart Circ. Physiol. 37): H 1397 - H 1404, 1995

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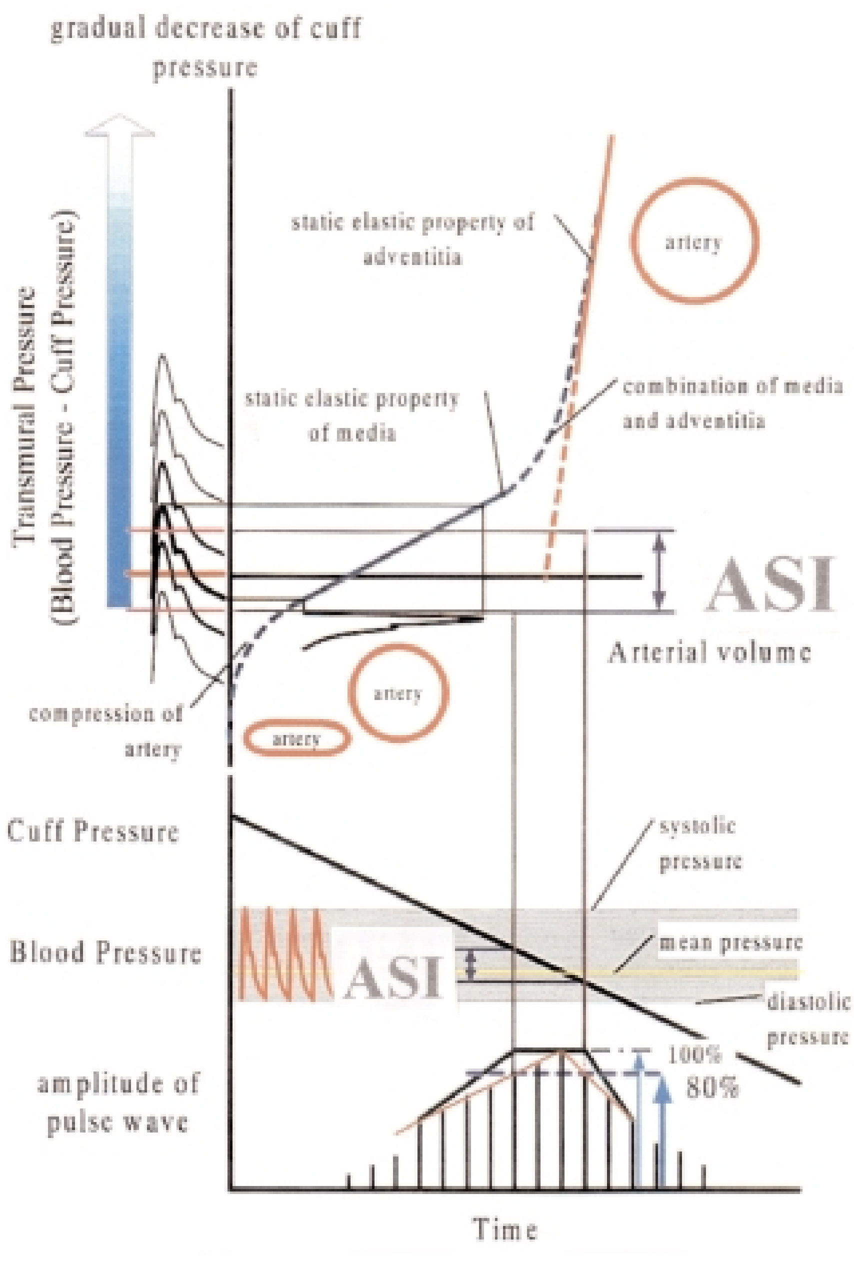
The Physics and Physiology of Arterial Stiffness



CARDIOVISION® occludes the artery by increasing the cuff pressure to above systolic. The cuff is then slowly released, resulting in increases in the amplitude of the pulse waves, as the volume in the artery slowly increases. The amplitude of the pulse waves is at the maximum at the mean arterial pressure. At this point the elastic properties, contributed by the media (smooth muscle coat), of the artery are also at their maximum.

The ASI (Arterial Stiffness Index) number is derived from the pulse wave pattern by taking 100% and 80% of the peak height at the mean arterial pressure. This peak height is then applied to the arterial compliance curve and at the tangent point where it is no longer linear with the curve, the ASI number is determined. After the pulse waves peak, the amplitude of the pulse waves decrease as the artery completely opens demonstrating the properties of the adventitia (outside collagen coat), as the cuff pressure returns to zero.

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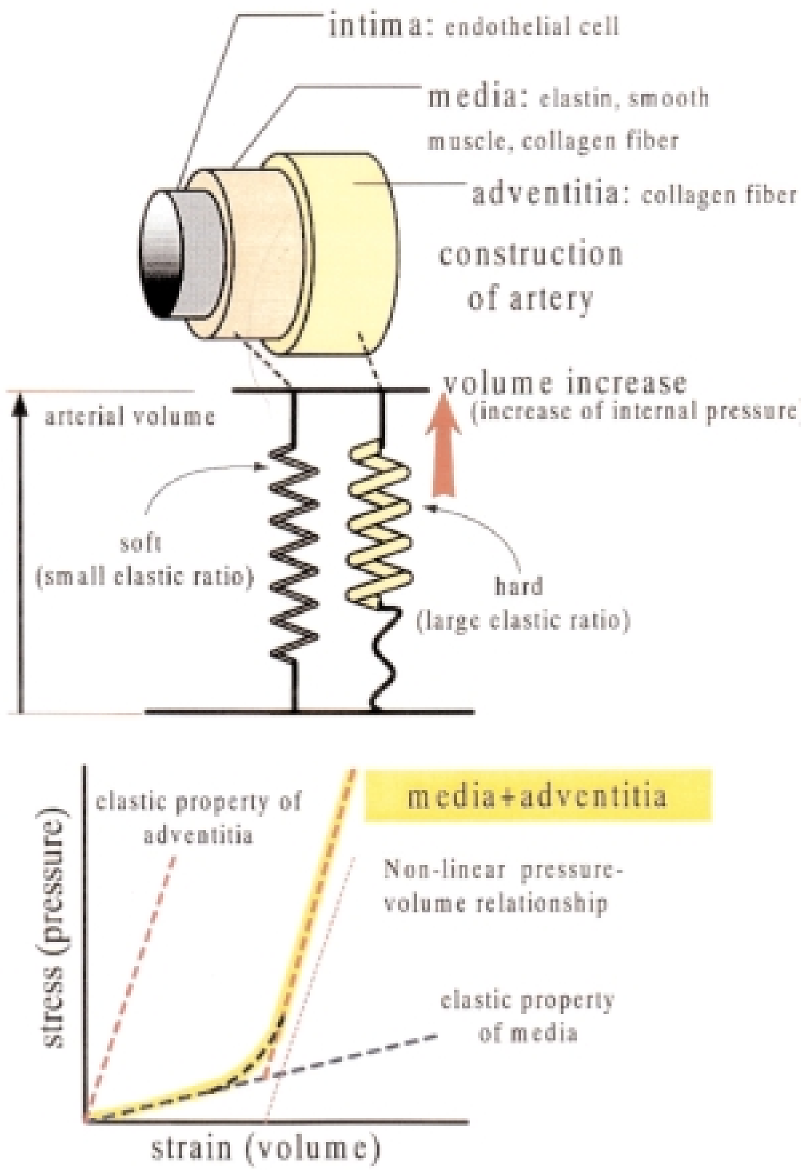
Understanding Pressure and Volume in Arterial Construction



The graph of the elastic property of the adventitia (outside collagen fiber) shows that a small volume change occurs with a large change in pressure. This linear change indicates a large elastic ratio and a very hard or STIFF structure.

The graph of the elastic property of the media (middle smooth muscle) shows a large volume change with a small change in pressure. This linear change indicates a small elastic ratio and a very soft or ELASTIC structure.

When the internal pressure applied to the blood vessel is low, the tension of the vascular wall is mainly supported by the elastic fibers of the media and the blood vessel exhibits a large expandability. On the other hand, when the blood vessel is expanded, the blood vessel exhibits a small expandability due to the restriction of the blood vessel outside collagen fibers. In order for the artery to maintain this hemodynamic balance it must be composed of both structures therefore the pressure volume relationship is nonlinear.

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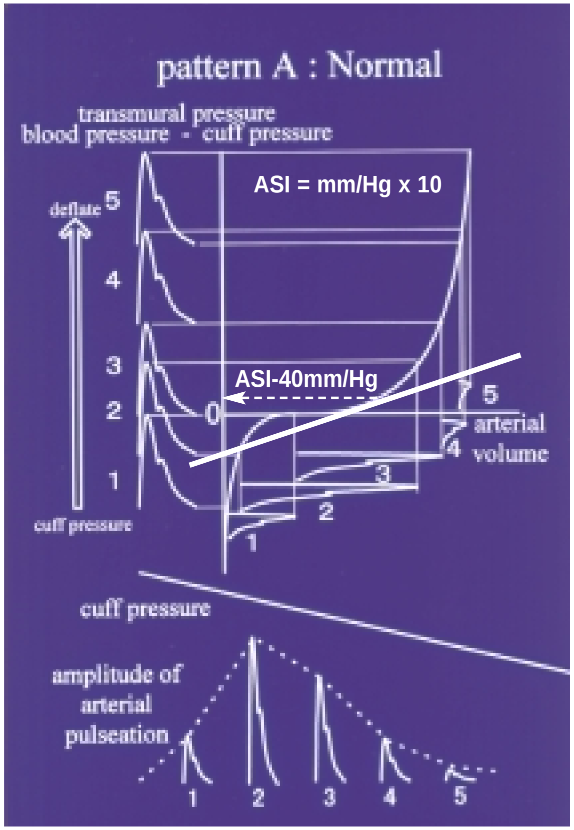
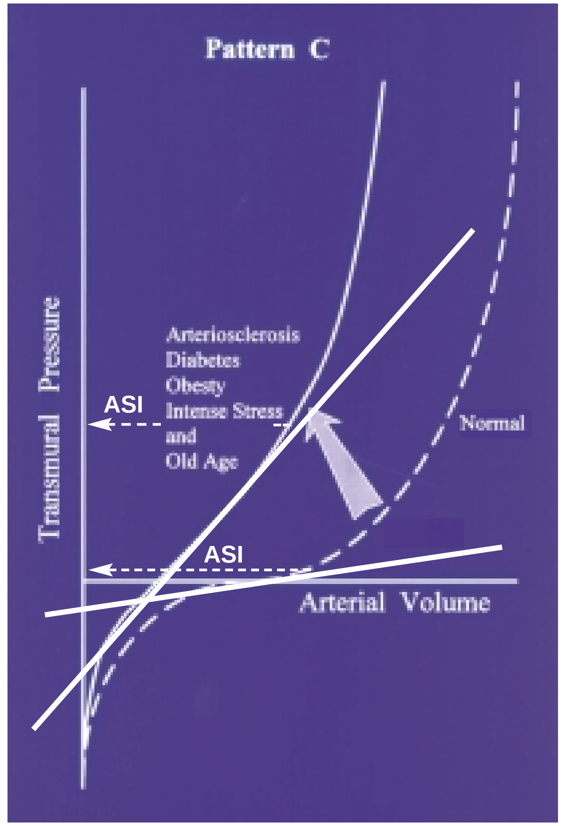
Understanding the Arterial Stiffness Index (ASI)



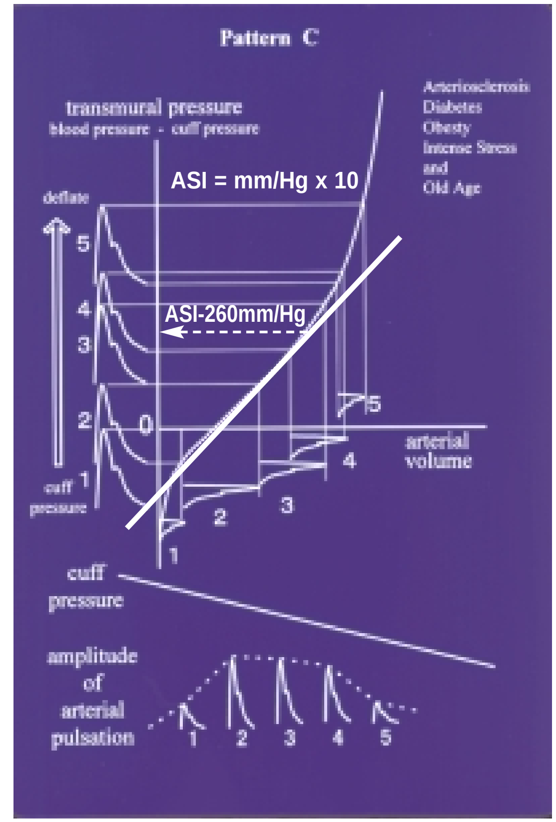
ASI - Normal Range (0-80)

A change in arterial volume as the pressure decreases from above systolic to below diastolic produces a characteristic "single peak mountain pulse pattern" in a normal elastic arterial segment. The peak is at the mean arterial pressure. The corresponding compliance curve (above) is nonlinear indicated by a low ASI (Arterial Stiffness Index) (**40**) number. The ASI is determined at the mean arterial pressure when the tangent line drawn to pressure volume curve is no longer linear.



A Shift from Normal to Stiff

A shift in the compliance curve from normal to stiff corresponding to an increase in the ASI number.



ASI - Moderate Stiffness (81-209)
ASI - Severe Stiffness (> 210)

In a stiff arterial segment the pulsation pattern produces a "flattened mountain pulse pattern". The corresponding compliance curve is more linear. A higher ASI number (**260**) results when the tangent line is drawn at the mean arterial pressure to the pressure volume curve.