

CARDIOVISION® Model MS-2000

PROFESSIONAL CARDIOVASCULAR DYNAMICS MONITOR WITH BLOOD PRESSURE CAPABILITY

INTENDED USE OF THE CardioVision® Model MS-2000

1. The device can measure blood pressure (through the standard oscillometric method) according to standards established by AAMI for automated blood pressure monitoring devices.
2. This system stores and displays the pulse wave patterns obtained during the course of the entire blood pressure measurement.
3. This system is able to classify the patterns obtained into one of five standard groupings (i.e. representative patterns, A, B,C,D,E) in most cases. In cases where elements of two (or more) standard patterns are present, both groups are indicated.
4. An Arterial Stiffness Index (ASI) quantifies Pattern A (0-80), normal stiffness, AC (81-209), mild stiffness, and C (210 and greater), high to severely increased stiffness of the brachial artery. The ASI can range up to 750 and higher. It's units are mmHg X 10.
5. A correlation has been observed between the five representative patterns and various cardiovascular conditions. By matching the pattern obtained from a particular subject with the closest representative pattern, information useful to physicians (and other health care workers operating under a physician's direction), in the evaluation of the overall condition of the circulatory system can be obtained.
6. Correlation sufficient to provide meaningful information to the physician has been observed for the following cardiovascular conditions:
 - Normal
 - Anemia
 - Shock
 - Intense Stress
 - Arteriosclerosis
 - Arrhythmia
 - Heart Failure
7. The features of the device also make it useful to physicians (and other health care workers operating under a physicians direction) in screening or monitoring for the possible presence of the cardiovascular conditions listed above.
8. The device can store CardioVision® test results in an electronic database for future reference.
9. Other tests such as Total Cholesterol, LDL Cholesterol, HDL Cholesterol, Glucose and Triglycerides may be entered, permanently stored, and used later to produce a Framingham Score on a patient.