

Section 2 - Safety and Effectiveness Information

2.1 Summary of Safety and Effectiveness Information

Safety

Stress and ECG systems can be sources for macroshock and microshock hazards for the patient and the user. Details and protection requirements are explained in 'Medical Instrumentation: Theory and Application', J.G. Webster, Ch. 13, 1978. These protection requirements are compiled into National and International Safety Standards. The most comprehensive ones are ANSI/AAMI/ES-1 and IEC 601-1 and 2.

For safe use of Stress and ECG systems, labeling and documentation must be complete. Standards for these are also covered in the above mentioned standards and also in ANSI/AAMI EC11-1982.

Effectiveness

Stress and ECG systems contain digital and analog hardware, associated firmware and software, which must perform effectively, accurately, and reliably. Standards and test methods for the performance of these systems are compiled in detail in ANSI/AAMI EC11-1982 and IEC 601-2 and 3.

In addition to these, because of lack of proper user training, problems may arise regarding the following:

(a) Lead placement (Correct positions for electrodes are explained in ECG textbooks such as "Harrison's Principles of Internal Medicine", Eds. R.G. Petersdorf, R.D. Adams, E. Braunwald, K.J. Isselbacher, J.B. Martin and J.D. Wilson, 10th edition, pp: 1320-21. McGraw Hill, 1983).

(b) Line Interference (A comprehensive reference list for causes and reduction methods for line interference is given in "A new technique for line interference monitoring and reduction in biopotential amplifiers", Y.Z. Ider and H. Koymen, IEEE Trans. Biomedical Engineering, Vol. 37, pp. 624-31, 1990.) 50/60 Hz Notch filters can reduce partially or substantially an problems with line interference.

(c) EMG (myopotential) interference (A low pass filter may be provided as an option as too much muscle interference may be encountered during an ECG or stress recording. Users should be notified continuously when this filter is in use, since low pass filters may affect the diagnostic value of the ECG recording information. The PC ECG 1200 ECG and Stress Electrocardiography System provides such notification on screen.)

(d) Baseline wander (High pass correction filters may be provided as an option as baseline wander may occur during ECG or stress recording. Users should be notified continuously when this filter is used, since baseline wander filters may affect the diagnostic value of the recording. The PC ECG 1200 ECG and Stress Electrocardiography System provides such notification on screen.)

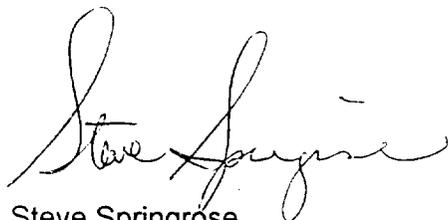
(e) Averaging (In Stress and ECG systems, ST level changes must be accurately measured for each lead and at each exercise step. Due to myopotential, baseline wander and other noise interference, such measurements cannot be reliably made using a single beat. Therefore,

beats are averaged and measurements are made from average beats to minimize errors. These average beats must be recorded for every exercise step level during stress testing.)

(f) Diagnostic Accuracy (In Stress and ECG systems that measure heart rate, ST values and other ECG parameters, the algorithms used to make such measurements and report trends to the physician influence the quality of information provided to the physician. Testing of the diagnostic accuracy of the ST measurements, QRS detector and VE detector are necessary to evaluate the value of the measurements and trends supplied to the physician for review.)

2.2 Certification:

I certify that we have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the PC ECG 1200 ECG and Stress Electrocardiography System. I further certify that I am aware of the types of problems to which the PC ECG 1200 ECG and Stress Electrocardiography System is susceptible and that the above summary of the types and causes of safety and/or effectiveness problems about the PC ECG 1200 ECG and Stress Electrocardiography System is complete and accurate

A handwritten signature in cursive script, appearing to read "Steve Springrose".

Steve Springrose
President
Biosensor Corporation
January 23, 1996