Introduction

Occlusion of the coronary arteries that supply oxygenated blood to the heart muscle is referred to as ischemic heart disease (IHD). IHD is the most common, serious, chronic, life-threatening illness in the developed world. Currently, the most widely used tool for diagnosing IHD is the electrocardiogram (ECG), which records the electrical activity of the cardiac muscle as it generates the stages of the cardiac cycle. Specific changes in the ECG recorded during physical stress protocols are used for the non-invasive detection of IHD. Patients with positive stress test results are usually referred for further investigation. However, the sensitivity of the standard ECG, even during stress tests, is relatively poor, and is generally considered to be between 50% and 70%, and in some studies has been reported to be even lower. That, in other words, means that 30-50% of all IHD patients are not diagnosed correctly by standard stress ECGs.

Traditional ECG analysis is performed in the 0.05 – 100Hz frequency range. However, a significant body of evidence accumulated during recent years indicates that higher frequency spectral components of the ECG signal contain valuable information for the detection of IHD. Studies published by Prof. Shimon Abboud, BSP's chief scientist, and Dr. Amir Beker, BSP's founder and CEO, have shown that the presence of ischemic pathologies in the heart is highly correlated with specific changes in the high-frequency spectral components of the ECG. BSP has pioneered the clinical implementation of high-frequency ECG and has developed it into a valuable diagnostic application. The company's proprietary HyperQ™ technology extracts and analyses the high-frequency components of the ECG. BSP has pursued the development of its HyperQ™ technology in two parallel, highly correlated, pathways: (a) acquisition and reliable production of the HyperQ™ signal, and (b) analysis of the HyperQ™ signal for extracting clinical and diagnostic information. BSP developed proprietary signal processing techniques to enhance the quality of the HyperQ™ signal, and to eliminate irrelevant phenomena occurring in the same frequency band. The analysis and diagnosis of the HyperQ™ signal is aimed at isolating significant diagnostic parameters and evaluating the severity of the pathological state.

Production of the HyperQ™ Signal

The physical acquisition of the HyperQ™ signal does not require any deviation from the standard ECG recording process. Standard ECG is amplified and digitized at a sampling rate of 1000 samples per second. The signal-to-noise ratio of the high frequency ECG components is markedly inferior to that of the standard ECG, in many cases the high frequency components are completely masked by noise. Therefore, a simple band-pass filter is not sufficient to enable analysis of the signal and more elaborate signal processing techniques are required.

BSP uses a multifaceted process for extracting the HyperQ™ signal, including identification of the QRS complexes, rejection of corrupted signals, several alignment procedures, and optimization of the balance between the noise reduction procedure and the integrity of the HyperQ™ signal.

Figure 1 presents a typical example of the HyperQ™ signal during stress testing of a patient with IHD. The first row indicates the heart rate. The second represents the subject's standard ECG signal, and the third represents the corresponding HyperQ™ QRS signal. As evident in Figure 1, the HyperQ™ signal changes significantly as the exercise test progresses.

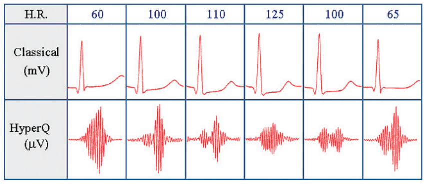

Figure 1: HyperQ™ vs. classical ECG for a patient with ischemic heart disease, obtained during stress test.

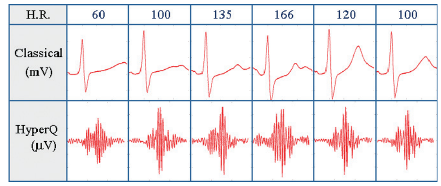

Figure 2: HyperQ™ vs. classical ECG for a non-ischemic subject, obtained during stress test.

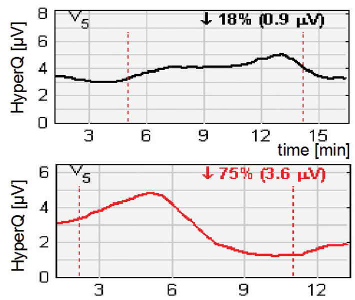

Figure 3: HyperQ™ time-intensity curves obtained from lead V5 during a stress test in a non-ischemic (top) and ischemic (bottom) subjects. The vertical dotted lines indicate the start of exercise and recovery phases.

Figure 2 presents a typical example of the HyperQ™ signal during stress testing of a non-ischemic subject. As in Figure 1, one may follow the evolution of both the standard ECG and the HyperQ™ signals. In contrast with Figure 1, no significant change in the HyperQ™ signal occurs, and no ischemic episode is detected.

Analysis and Diagnosis Tools

HyperQ™-based diagnostics involve the identification and isolation of the phenomena directly related to the ischemic condition of the heart. The signal's features that indicate ischemia include the energy content of the signal, its amplitude, and changes in its morphology.

Figure 3 demonstrates the dynamics of the signal intensity in one lead from non-ischemic and ischemic patients. The use of such information has been proved to be highly indicative of Ischemia BSP has also developed a novel graphical representation for the HyperQ™ signal.

The ischemic patient's HyperQ™ signal clearly undergoes a significant reduction during the stress test and returns to baseline during recovery. In contrast, the HyperQ™ signal of the non-ischemic subject shows no significant changes during the stress test. The red zone remains stable and even increases slightly, over the course of the test.

The HyperQ™ Stress System received US FDA clearance (510K) and CE marking.