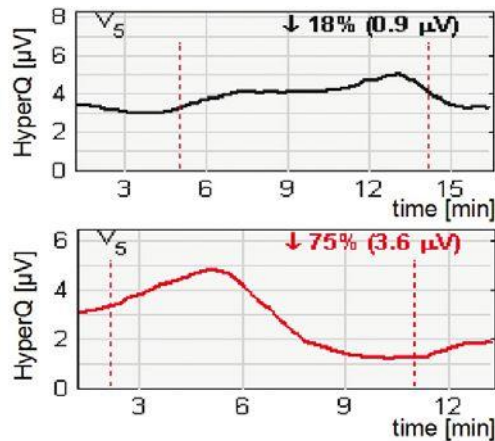
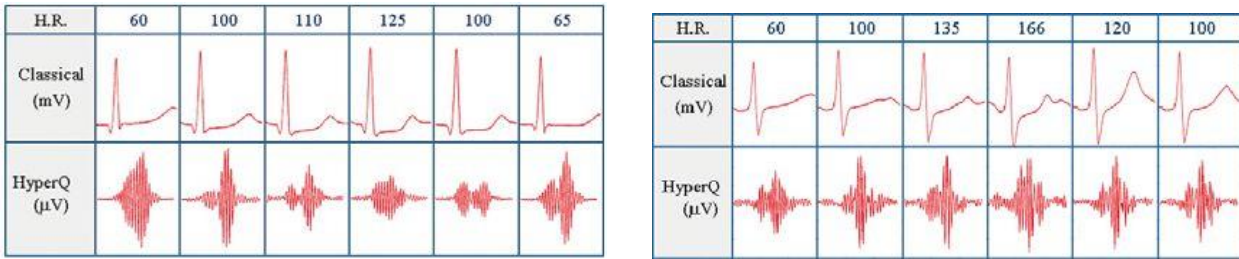


Advantages of HyperQ™ in ECG Testing



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). 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 – 250Hz frequency range. 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. 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 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.

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.

Traditional exercise ECG testing is based on ST segment analysis, yet with limited diagnostic accuracy. Scientific evidence indicates that the identification of depolarization abnormalities, which can be quantified using analysis of high-frequency QRS signals, is more accurate in detecting ischemia than the identification of ST segment deviations.

Stress ECG is the most popular screening test for Coronary Artery Disease (CAD). Around 40 million stress ECG tests are done annually. However, stress ECG has a low diagnostic accuracy for ischemia where sensitivity and specificity may fall below 60%. HyperQ™ simply adds another layer of information to conventional stress ECG. Numerous clinical studies demonstrate that HyperQ™ dramatically improves diagnostic capabilities. They show that HyperQ™ identifies up to 80% more patients with ischemia when compared to traditional ECG. The Ischemia detection rate almost



doubles with HyperQ™. The HyperQ™ System has received US FDA clearance (510K) and CE marking. The American Heart Association (AHA) included HyperQ™ in a statement on exercise standards for testing (published in August 2013), pointing out that it has been found to have useful test performance for the detection of CAD.

Women are more likely to have “false-positive” stress ECG results. Still, stress ECG testing is the most commonly used method of diagnosing CAD in women. A women-oriented Clinical Study shows that HyperQ™ reduces the false alarm rate in women by more than 50% thereby helping in closing the gap in the accuracy of stress ECG diagnosis between men and women.

Solutions for Resting ECG Hyper Q enable early detection and monitoring of Acute Coronary Syndrome (ACS).

Kohli et. al., Circulation. 2010;122:2570-2580