

HyperQ™ AN-S

User Manual

MA-010 rev 6



CE Marking Information

The BSP HyperQ System bears CE marking CE-0344 indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex II of this directive.

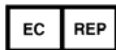
The country of manufacture and appropriate Notified Body can be found on the equipment labeling.

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Disclaimer

This software is intended as a decision support application **for persons who have received** appropriate medical training, and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any application of medical information from the program, other than the original design or intended use thereof, is not advised and considered a misuse of the software product.



Warning

US Federal Law restricts the sale of this device to a physician, or on the order of a physician.

Table of Contents

1. Introduction	1
1.1 Manual Purpose	1
1.2 Intended Audience	1
1.3 Definitions, Acronyms and Abbreviations	1
1.3.1 Illustrations	1
1.3.2 Definitions	1
2. Indications for Use of HyperQ AN-S	3
2.1 ECG Intended Use	3
2.2 Stress Test Intended Use	3
2.3 HyperQ Intended Use	4
2.4 Contraindications for Use and Adverse Effects	4
3. Preliminary Steps	5
3.1 Conducting a Stress Test	5
3.2 Launching the HyperQ AN-S	5
4. The HyperQ AN-S Application	7
4.1 Opening a Test for Analysis	7
4.1.1 Test analysis history	8
4.2 View HyperQ Analysis	9
4.2.1 HyperQ Trend Screen	11
4.2.2 Viewing Individual Leads	11
4.2.3 Visual Indicators	12
4.2.4 Relative and Absolute Reduction Rates	12
4.2.5 Noise Reduction	13
4.3 HyperQ Maps Screen	13
4.4 Configure parameters	14
4.4.1 Settings button	15
4.4.2 Properties File	15
4.5 Print the HyperQ AN-S Report	16
5. License	17
5.1 Hardware License	17
5.2 Software License	17
5.2.1 Update License Manually	18

1. Introduction

This section contains general information regarding this manual.

1.1 Manual Purpose

This manual contains the instructions necessary to operate the application in accordance with its function and intended use. These instructions include but are not limited to:

- An explanation of the function of controls and indicators
- The sequence of operation

Where necessary, the manual identifies additional sources of relevant information and/or technical assistance.

1.2 Intended Audience

This manual is designed for use by the person who operates, maintains, or troubleshoots this product.

1.3 Definitions, Acronyms and Abbreviations

- **ECG** Electrocardiogram
- **ID** Identification
- **NA** Not Applicable
- **HFQRS** High frequency QRS components

1.3.1 Illustrations

All illustrations in this manual are provided as examples only. They do not necessarily reflect your equipment setup or data displayed. In this manual, all names appearing in examples and illustrations are fictitious. The use of any real person's name is purely coincidental.

1.3.2 Definitions

Pay particular attention in a procedure when one of the following messages appears:

Warning

Warnings call attention to possible hazards involving potential damage or injury to persons.

**Caution**

Cautions refer to practices necessary to protect against potential damage to or loss of equipment. Pay careful attention to instructions.

Note

Notes provide pertinent information to help optimize performance from the software or signify an important step or procedure that requires special attention.

Tip

Tips suggest alternative ways of performing a particular task.

Important

Important tips give information that is critical to the current topic.

2. Indications for Use of HyperQ AN-S

The HyperQ AN-S software can be used as an aid in the detection and diagnosis of specific cardiac conditions, together with other diagnostic tools. This section describes how to combine the use of different diagnostic tools, namely ECG and HyperQ AN-S.

- [ECG Intended Use](#)
- [Stress Test Intended Use](#)
- [HyperQ Intended Use](#)
- [Contraindications for Use and Adverse Effects](#)

2.1 ECG Intended Use

An ECG is intended to disclose either normal conditions or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases:

- Patients with suspected cardiac abnormalities
- Patient populations in whom a routine baseline evaluation of ECG characteristics is desired

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present.

Stress testing is the most widely used method to determine whether chest pain is related to myocardial ischemia, and thus to coronary artery disease. In stress testing, the electrocardiographic response to exercise is monitored via ECG. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise workloads are determined by predefined protocols. The ECG signals, as well as the HF-QRS signals, are recorded throughout the resting, exercise, and recovery phases of the exercise protocol. The changes in ECG waveforms are compared to the resting ECG records. In the HyperQ stress test, changes in the high frequency of the mid QRS complex, calculated as root-mean-square (RMS) values, are compared to the resting values.

Although not essential, most commercial stress test systems automatically control the bicycle or treadmill according to the requirements of the specified protocol.

2.2 Stress Test Intended Use

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease.

The significance of the ST segment changes must be determined by a physician.

2.3 HyperQ Intended Use

The HyperQ software is intended to enhance the stress ECG test by analyzing the high frequency components present within the central portion of the QRS complex.

The significance of the HF-QRS changes must be determined by a physician. For further information on this subject, refer to the BSP physician's manual.

2.4 Contraindications for Use and Adverse Effects

The software has no contraindications or adverse events.

3. Preliminary Steps

Before starting the HyperQ AN-S, several preliminary steps must be performed.

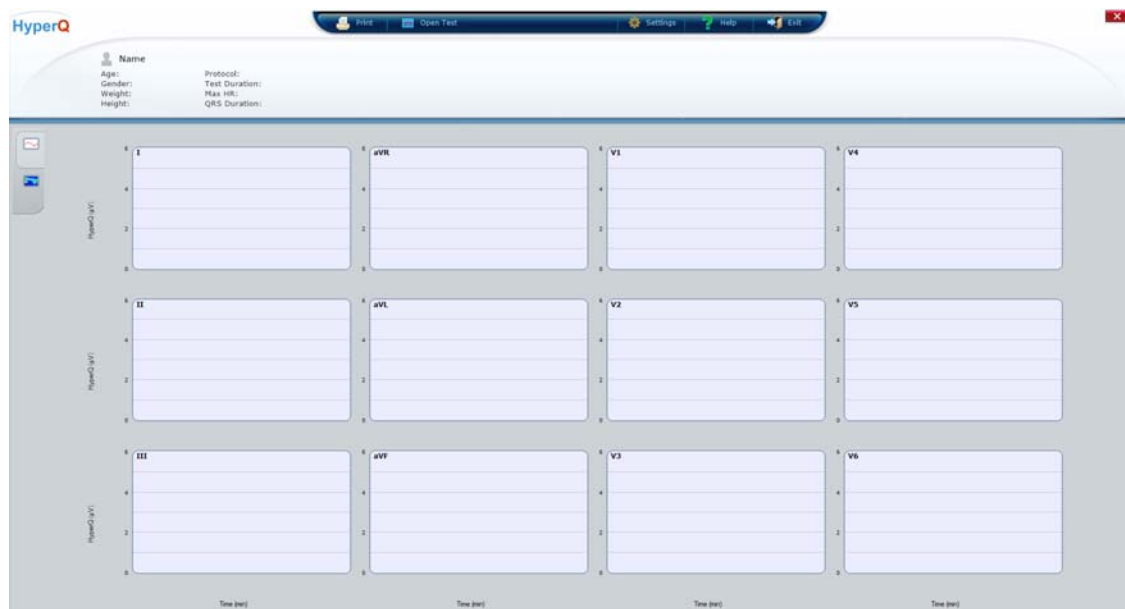
The following sections explain these steps:

- [Conducting a Stress Test](#)
- [Launching the HyperQ AN-S](#)

3.1 Conducting a Stress Test

The HyperQ AN-S performs HyperQ diagnostics on a given stress test data collected from a patient during a regular ECG test. The only addition to the standard stress test protocol for HyperQ AN-S is that it **requires 2.5 minutes of rest ECG be obtained in the standing position**. The stress test data should be exported to a specific directory where the HyperQ AN-S executes its calculation on the data.

Figure 1: HyperQ AN-S Screen



3.2 Launching the HyperQ AN-S

To Launch the HyperQ application, use the HyperQ button from the ECG system after conducting the stress test. HyperQ will automatically open and analyze the stress test that is viewed in the ECG system. The **HyperQ Trend** screen appears (Figure 6).

It is also possible to launch the HyperQ system independently from the Windows operating system. In this case, the main screen (Figure 1) will open without any test data.

- From the Start menu, select **BSP HyperQ Analyzer > Analyzer Stress**.



- Alternatively, double-click  on the desktop.

The HyperQ AN-S screen appears (Figure 1).

The HyperQ AN-S screen contains the main options available for viewing and performing HyperQ analysis on a selected stress test. From the toolbar, the user can access the following functions:

- **Print:** Prints the current view of the HyperQ AN-S.
- **Open Test:** Opens a saved test. Refer to [Opening a Test for Analysis](#).
- **Settings:** Opens the configuration menu. Refer to [Configure parameters](#).
- **Help:** Opens the online help file.
- **Exit:** Exits the HyperQ AN-S application.

4. The HyperQ AN-S Application

The following sections describe how to run the HyperQ AN-S:

- [Opening a Test for Analysis](#)
- [View HyperQ Analysis](#)
- [HyperQ Maps Screen](#)
- [Configure parameters](#)
- [Print the HyperQ AN-S Report](#)

4.1 Opening a Test for Analysis

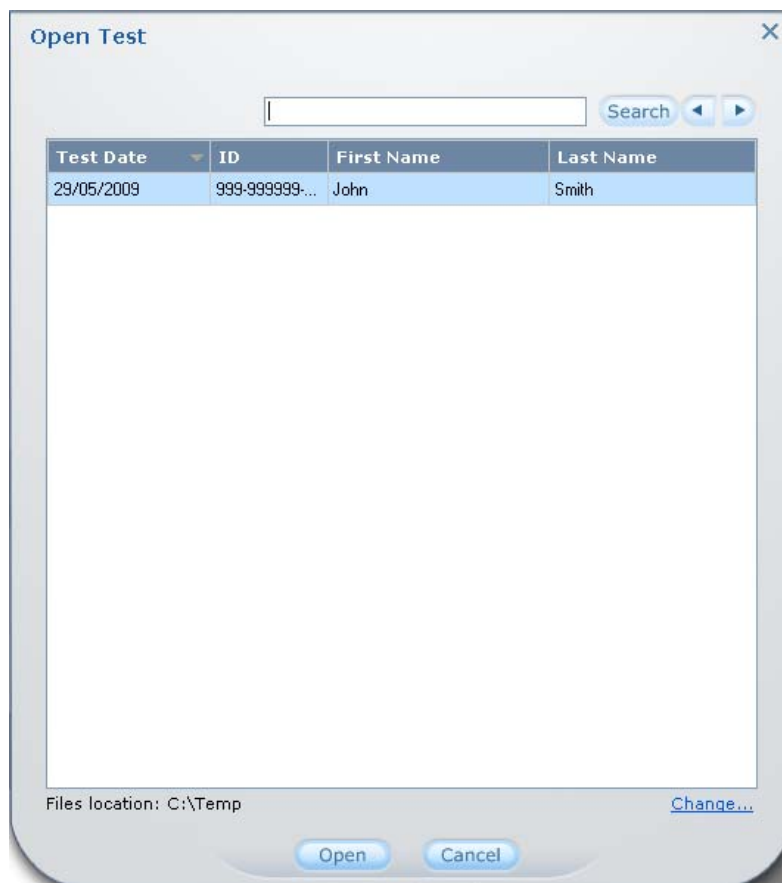
This procedure describes how to open a saved test so that the results can be viewed and analyzed.

- 1 In the **HyperQ AN-S** screen (Figure 1), click



The **Open Test** screen appears (Figure 2).

Figure 2: Open Test Screen



- 2 Highlight the recording to be loaded.

Note

To search for a recording, in the **Search** field, type the **ID, First Name, or Last Name**, and click **Search**.

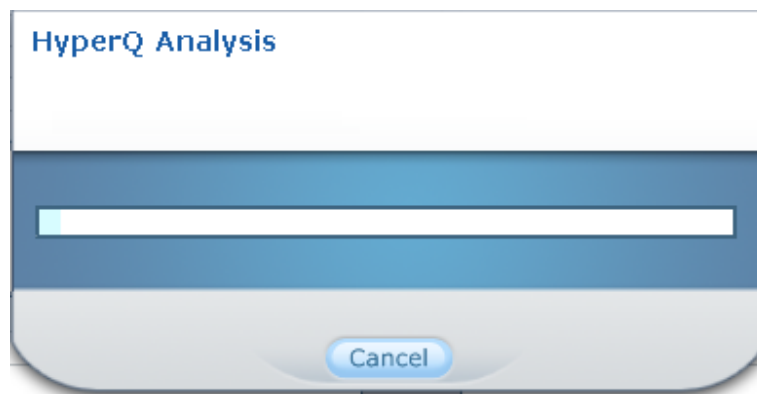
Note

To change the file location directory, select **Change...** and select the path to the directory containing the saved files.

- 3 Click **Open**.

A progress bar is displayed while the HyperQ AN-S is calculated (Figure 3). When the calculations are complete, the **HyperQ Trend** screen appears (Figure 6)

Figure 3: HyperQ AN-S Progress Screen




Note

If the HyperQ AN-S has already been calculated, the **HyperQ Trend** screen appears immediately.

4.1.1 Test analysis history

The HyperQ AN-S saves the history of test analyses that have been performed in the past on every test. Thus, it is possible to view previous results and the configuration of parameters that have been used to achieve these results.

When a test that has been analyzed before is opened, a history button  appears on the menu bar. By pressing this button, the user can view results of previous analyses of this specific test. Test data is analyzed each time the test is opened using the "Open Test" button and also each time the settings are changed using the


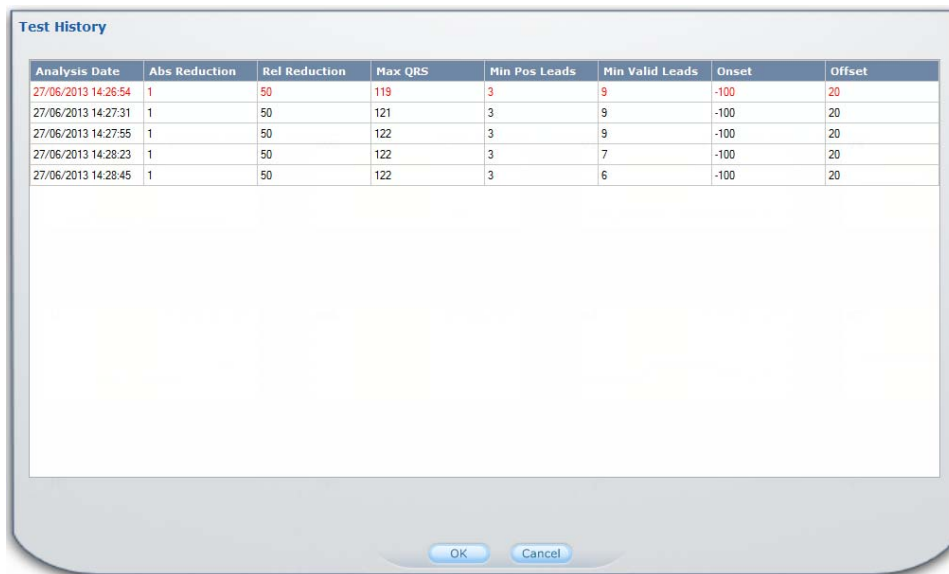
 button (see section 4.4 below). In the former case, the current settings of the system are used and in the latter the currently opened test is analyzed. In both cases a new instance of analysis results is created.

Figure 4: Test History Screen


The screenshot shows a window titled "Test History" containing a table with the following data:

Analysis Date	Abs Reduction	Rel Reduction	Max QRS	Min Pos Leads	Min Valid Leads	Onset	Offset
27/06/2013 14:26:54	1	50	119	3	9	-100	20
27/06/2013 14:27:31	1	50	121	3	9	-100	20
27/06/2013 14:27:55	1	50	122	3	9	-100	20
27/06/2013 14:28:23	1	50	122	3	7	-100	20
27/06/2013 14:28:45	1	50	122	3	6	-100	20

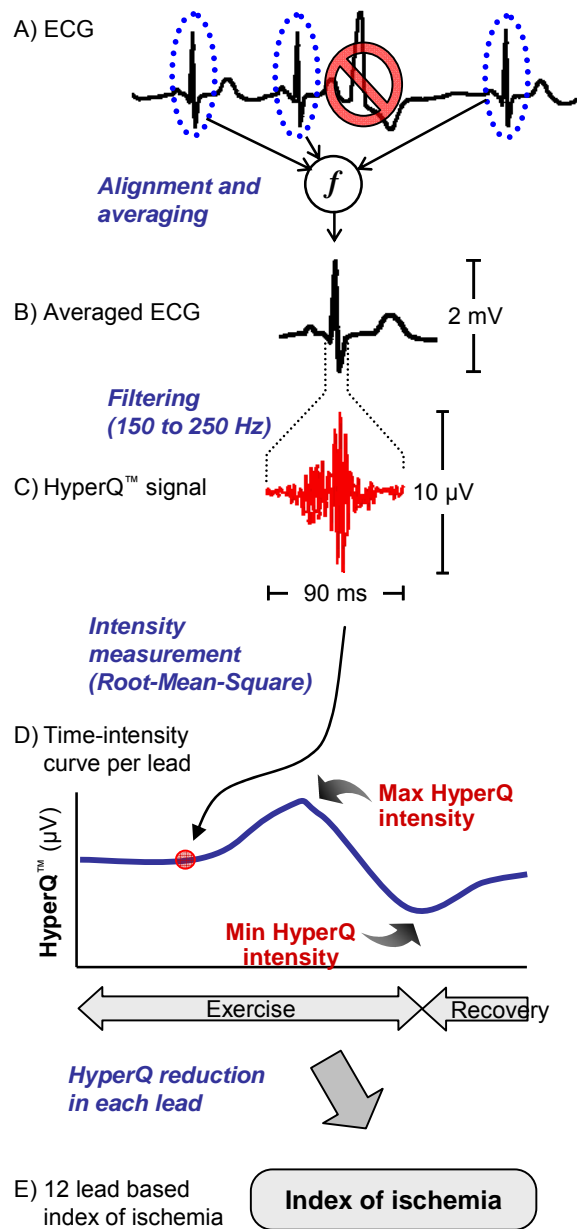
At the bottom of the window, there are two buttons: "OK" and "Cancel".

Figure 4 depicts the "Test History" screen which is opened when the history button is pressed. In this screen the user can view a list of test analyses that were performed with their respective configuration of parameters. The original analysis (the first time this test data was analyzed) appears in red. Other results appear in black and each line displays the date of the analysis. Note that this date does not necessarily correspond to the "test date" which is when the ECG measurements were done. By selecting one of the lines the user can view the results according to the specific configuration of that analysis.

4.2 View HyperQ Analysis

The HyperQ signal analysis was designed to provide additional information to conventional ECG diagnosis. As opposed to traditional ECG, which is measured in the 0.05–100Hz frequency range, the HyperQ signal is measured in the 150–250Hz frequency range. The HyperQ signal appears during the ventricular depolarization phase and is in synchronization with the QRS complex. In each ventricular depolarization phase, the low frequency range is represented by the conventional QRS complex, while the high frequency range is represented by the HyperQ signal.

HyperQ examines the changes in intensity of the HyperQ signal to establish the probability of ischemia. The reduction in the intensity of the HyperQ signal is measured by calculating the relative reduction in intensity of the signal. Figure 5 illustrates the schematic flow.

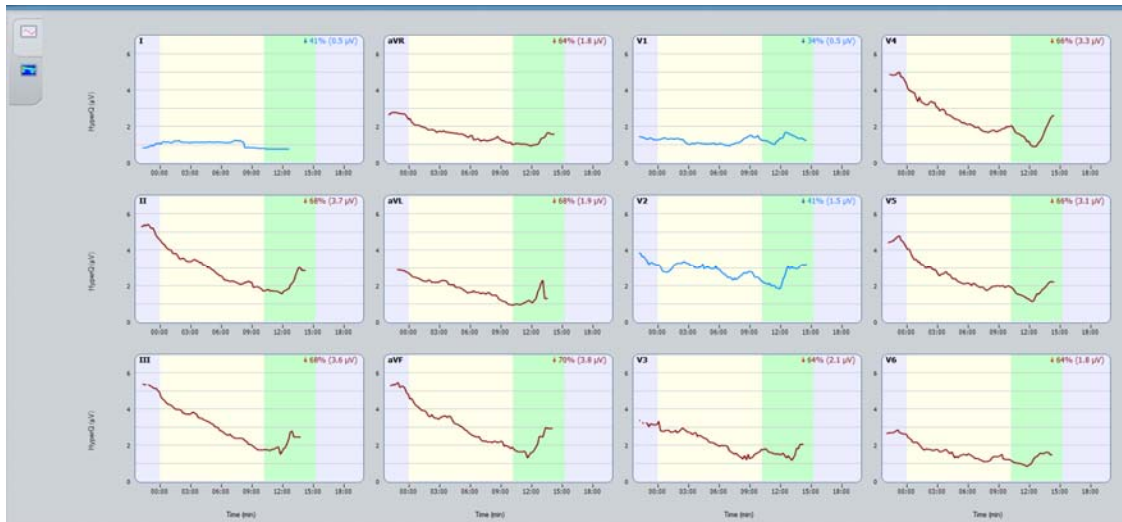
Figure 5: Schematic Flow of the Production of the HyperQ Signal

Initially, the QRS complexes are detected, while excluding arrhythmias and noisy complexes. The detected QRS complexes are carefully aligned and averaged. The averaged QRS complex is then filtered in the 150–250 Hz band to produce the HyperQ signal. HyperQ intensity is obtained by calculating the root-mean-square value of the HyperQ signal.

4.2.1 HyperQ Trend Screen

The 12-lead graphs display the HyperQ time-intensity curves for each lead throughout the stress test. The lead name is displayed in the upper left corner. The x-axis in each graph represents time in minutes from the beginning of exercise and the y-axis indicates the intensity of the HyperQ in μV . The value is calculated as the root-mean-square (RMS) value of the HyperQ signal. The exercise period is indicated in light yellow and the recovery period in indicated in light green.

Figure 6: HyperQ Trend Screen



4.2.2 Viewing Individual Leads

Figure 7 shows a single HyperQ lead. [Table 1](#) details the lead elements.

Figure 7: HyperQ Single Lead View

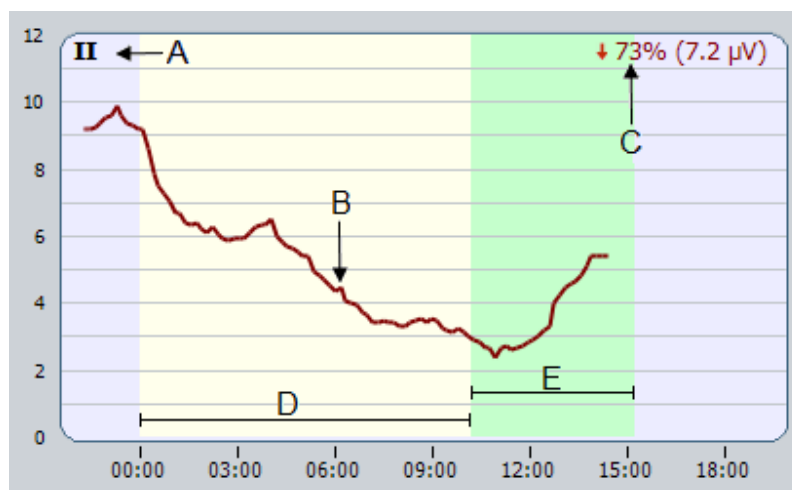


Table 1: HyperQ Single Lead View Elements

Element	Description
A	Lead Name
B	Visual Indicator. For further explanation, see Visual Indicators
C	Relative and absolute reduction in HyperQ intensity (decreased by 73% which in this case is equivalent to a reduction of 7.2 μV)
D	Exercise period
E	Recovery period




4.2.3 Visual Indicators

HyperQ provides visual indicators to easily identify when the results indicate the likelihood of ischemia or the system's inability to calculate results due to poor signal quality. The indication is based on three thresholds, where the first two can be configured by the user.

- **Relative Reduction Threshold:** A value (in %) indicating the minimum relative reduction in the signal's intensity required to determine ischemia.
- **Absolute Reduction Threshold:** A value in (μV) indicating the minimum absolute reduction value required to determine ischemia.
- **Signal to Noise Threshold:** A value indicating the minimum signal-to-noise ratio to provide accurate results. The HyperQ signals at rest are required to exhibit signal-to-noise ratio above this threshold.

According to these thresholds, the graphs are visually marked as shown in [Table 2](#).

Table 2: Visual Indicator Description

Indicator	Description
	HyperQ signal is below the-signal to-noise threshold and therefore these leads are not included in the analysis.
	Either one or both HyperQ relative and absolute reduction values are below their thresholds. Results are not indicative of ischemia.
	Both HyperQ relative reduction and absolute reduction values are above their thresholds. Results are indicative of ischemia.

4.2.4 Relative and Absolute Reduction Rates

The absolute reduction (in microvolts (μV)) and the relative reduction (as a percentage) in the HyperQ intensity signal are measured by calculating the maximum signal reduction within the time frame. The relative and absolute reduction rates are displayed in the upper right corner of each lead graph using the following format:

Relative reduction rate in % (absolute reduction intensity in μV)

Example: 36% (0.9 μV)

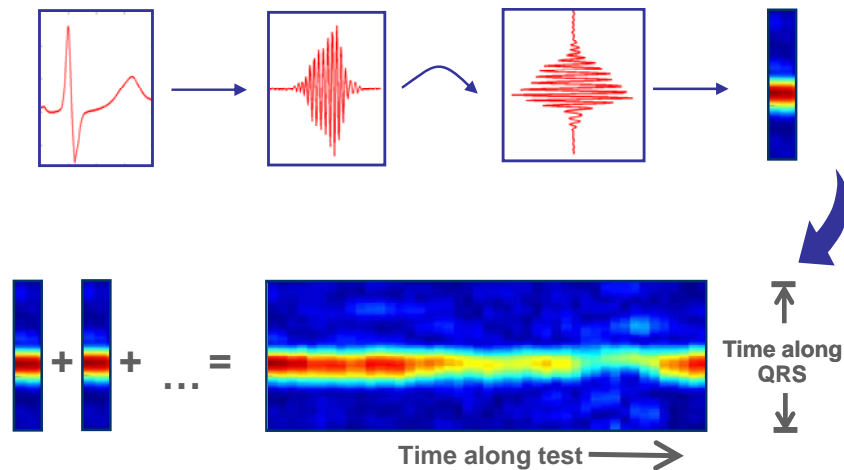
4.2.5 Noise Reduction

The HyperQ signal is measured in microvolts, as opposed to conventional ECG which is measured in millivolts. At this amplitude level, the signal-to-noise ratio of the high frequency components of the ECG is substantially inferior, and in many cases the HyperQ signal is completely masked by noise. This increased sensitivity is compensated for by sophisticated noise-filtering algorithms. If the HyperQ signal of a certain lead cannot be significantly differentiated from noise, due to either low intensity of the signal or high level of noise, it will be excluded from the analysis and the user can review the ECG signal in the host system.

4.3 HyperQ Maps Screen

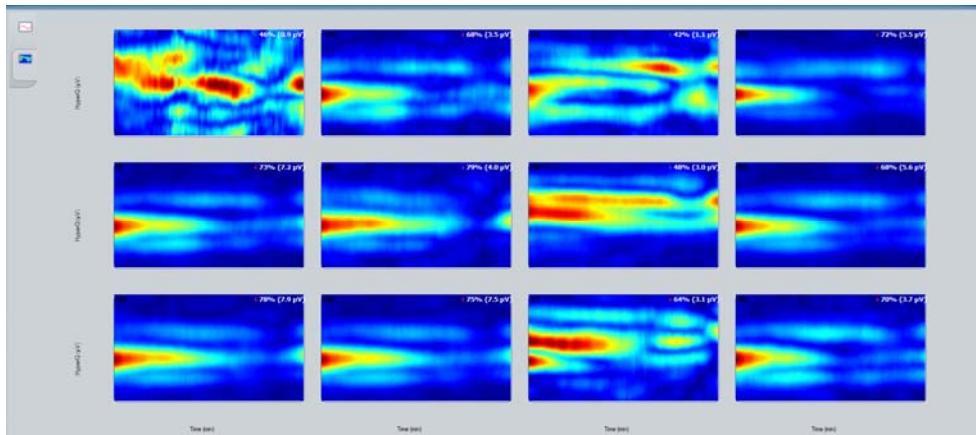
The HyperMap™ graphic is an efficient presentation of the dynamic changes of the HyperQ™ signal during stress, which shows the patient's ischemic status by depicting the proportion of high amplitude sections of the signal to low amplitude sections.

Figure 8: HyperMap Lead View



Filtered QRS signals are converted into colored columns. Different colors are assigned to different amplitudes, where red represents high amplitude and blue represents low amplitude (Figure 8). Accurate horizontal alignment of the QRS color columns produces the charts shown below. In the resulting time-time-amplitude chart, the Y-axis represents time along the QRS, the X-axis represents running time, and the hue represents the signal's amplitude.

The HyperQ data can be displayed lead-by-lead in the HyperQ map view (Figure 9).

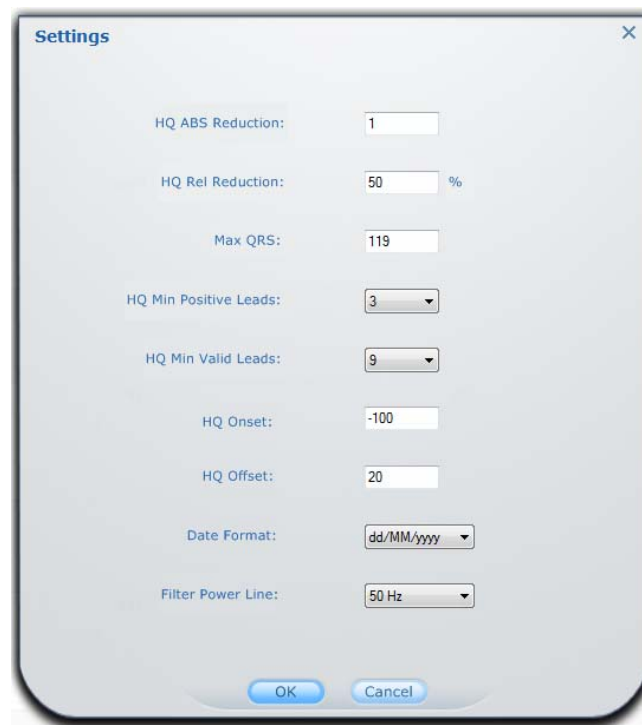
Figure 9: HyperQ Maps Screen

4.4 Configure parameters

The HyperQ AN-S has several configurable parameters. There are two types of customized parameters:

- Dependent on location or user's personal choice
- HyperQ calculation thresholds

These can be customized by the user in two ways: from the menu or by directly editing the configuration file.

Figure 10: Settings menu

4.4.1 Settings button


By clicking the "Settings" button  from the main menu, the user can access the "Settings" menu. This menu is password protected to minimize the probability of accidentally modifying parameters by an unauthorized user. The default password is "HyperQ". The password may be modified by editing the properties file as explained in 4.4.2 below.

Table 3: List of parameters

Parameter	Description
HQ_ABS_REDUCTION	The minimum absolute reduction (in μV) in HyperQ needed to indicate a significant change
HQ_REL_REDUCTION	The minimum relative reduction in HyperQ needed to indicate a significant change
HQ_MAX_QRS	The maximum QRS duration for which the HyperQ summary will be provided
HQ_MIN_POS_LEADS	The minimum number of leads having a significant HyperQ change required for a positive HyperQ summary
HQ_MIN_VALID_LEADS	The minimum number of valid HyperQ leads required for a negative HyperQ summary
HQ_ONSET	The shift of time frame for HyperQ analysis relative to the exercise onset. A negative value indicates that the time frame begins before exercise onset
HQ_OFFSET	The shift of time frame for HyperQ analysis relative to the exercise offset. A positive value indicates that the time frame ends after exercise offset
POWERLINE_FILTER	The frequency for the AC line filter
DATE_FORMAT	The date format to be displayed

4.4.2 Properties File

Another way to change the settings is by editing the **bsp.properties** file under *<installation directory>/Config*

Note

When editing the properties file, the application must be closed and reopened before any changes can take effect.

All of the parameters that can be set in the settings window can also be edited in the properties file. The following properties cannot be set in the settings window, but can be set in the **bsp.properties** file:

FILES_DIRECTORY	The location where files are saved
SETTING_PASSWORD	Change the password for accessing the settings window

4.5 Print the HyperQ AN-S Report

HyperQ provides a printed summary of the HyperQ diagnostic indexes.

The report contains the following information:

Table 4: Common Report Data

Specification	Description
Age	Patient age
Gender	Patient gender
Weight	Patient weight
Height	Patient height
Max HR	Maximum heart rate achieved during the test. The absolute number and percentage of the target HR are given
Test Duration	Total test time (rest and recovery stages are not included)
Protocol	Test protocol used
QRS duration	QRS time

Table 5: HyperQ Summary



Specification	Description
Relative (%)	The relative change in RMS
Absolute (μ V)	The absolute change in RMS

5. License

A valid license is required for any new HyperQ analysis.

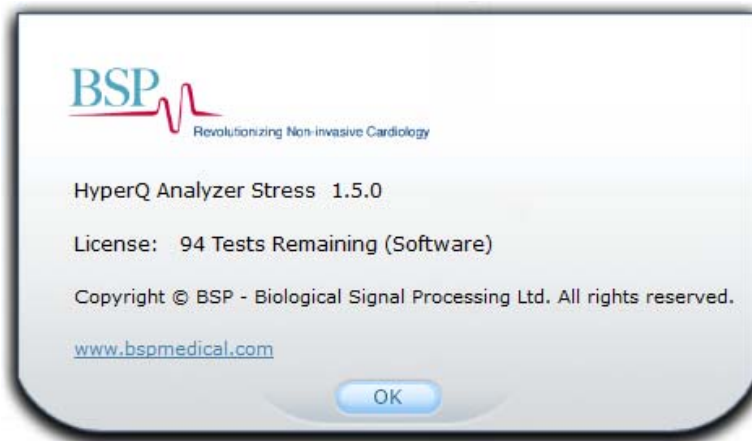
There are two types of licenses:

- **Unlimited License** - this type of license provides an unlimited number of tests.
- **Limited License** - this type of license provides a specific number of tests.

To view the type of license, select  from the main menu and then click the  button.

The license type will be shown in the About window:

Figure 11: About window



5.1 Hardware License

This license is provided as a HASP hardware key, connected through a USB port.



5.2 Software License

This license is provided as a product key.

When opening a test for a new analysis, if no valid license was found or the license has expired, a license window as in Figure 12 will pop up, and a product key can be applied:

Figure 12: License window

5.2.1 Update License Manually

To apply a new license manually, select  from the main menu, and then click on the  button. This will open a new license window where the product key can be entered.

This way the user is able to extend a limited license.

Note

This button will not appear when there is an unlimited software license.
