

HyperQ™ Analyzer Rest

User Manual

MA-06-002 rev 3



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.

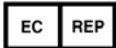
The country of manufacture and appropriate Notified Body can be found on the equipment labeling.

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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.

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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 Analyzer Rest

The HyperQ Analyzer Rest software can be used as an aid in the analysis of resting ECG tests. It can be used as a tool in the detection and diagnosis of specific cardiac conditions, together with other diagnostic tools.

2.1 Intended Use

The device is intended to analyze, display and record electrocardiographic information. The device is intended to be used under the direct supervision of a licensed healthcare practitioner. It is intended to be used by trained operators in a hospital or medical professional's facility environment to analyze ECG signals recorded from surface electrodes. The system has a single mode of operation – resting ECG mode.

The HyperQ™ software is intended to be used as an aid to the ECG test through the analysis of high frequency components present within the central portion of the QRS complex (HF-QRS). It is intended to display the morphology of the HF-QRS.

The significance of the HF-QRS signal **must** be determined by a physician

2.2 Contraindications for Use and Adverse Effects

Results in patients with incomplete or complete bundle branch block may vary. The HyperQ Analyzer Rest software should only be used in patients with QRS duration < 110 ms.

To date, no adverse events were observed or reported for the HyperQ Analyzer Rest.

3. Preliminary Steps

Before starting the HyperQ Analyzer Rest, several preliminary steps must be performed.

The following sections explain these steps:

3.1 Conducting a resting ECG Test

The HyperQ Analyzer Rest performs HyperQ diagnostics on given test data collected from a patient during a regular 12 lead rest ECG test. The only difference for HyperQ Analyzer Rest is that it **requires that at least 3 minutes of rest ECG be obtained**. The test data should be exported to a specific directory where the HyperQ Analyzer Rest executes its calculation on the data.



Caution

In order for the HyperQ analysis to provide significant results, it is essential that the ECG data is recorded for at least 3 minutes. Optimal performance may require 5 minutes of data in cases where noise level is high due to external interferences, excessive patient movements or other causes.

Note

To optimize performance it is important to minimize the noise level of the resting ECG test. Prepare the patient by carefully attaching the electrodes and verify that there is good electrical contact between the electrodes and the skin. Shave hair when necessary and apply a gel as needed. It is also important that the patient does not move or change position during the ECG recording.

3.2 Launching the HyperQ Analyzer Rest

To Launch the HyperQ application, use the HyperQ button from the ECG system after conducting the resting ECG test. HyperQ will automatically open and analyze the test that is viewed in the ECG system. The **HyperQ Results** 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.

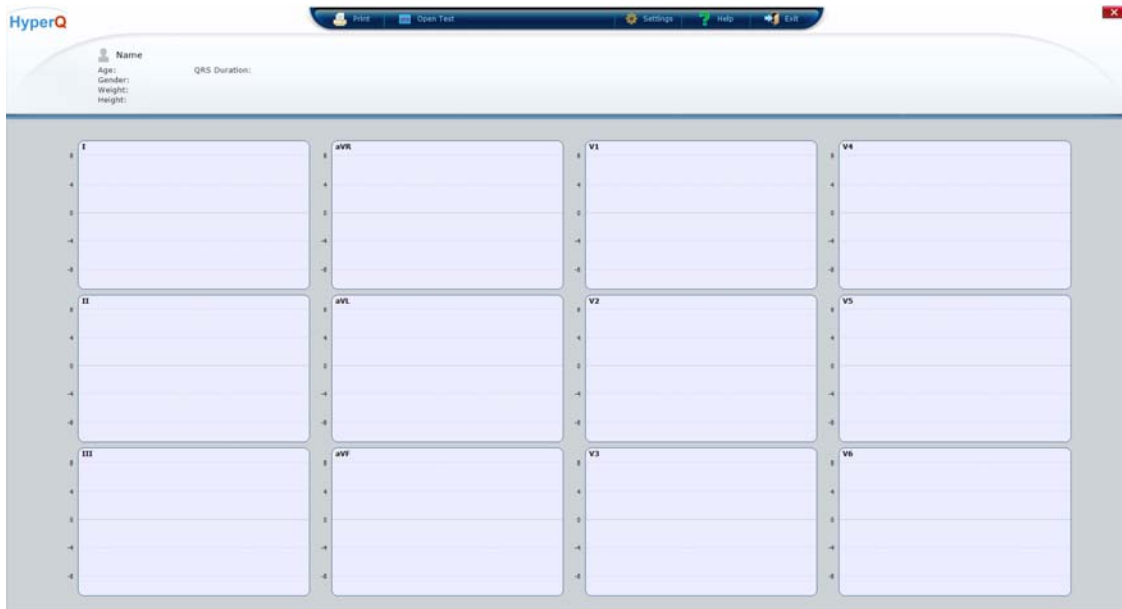
- From the Start menu, select **BSP HyperQ Analyzer > Analyzer Rest**.



- Alternatively, double-click  on the desktop.

The HyperQ Analyzer Rest screen appears (Figure 1). This screen contains the main options available for viewing and calculating HyperQ analysis on a selected test.

Figure 1: HyperQ Analyzer Rest Screen



On the toolbar, the user can access the following functions:

- **Print:** Prints the current view of the HyperQ Analyzer Rest.
- **Open Test:** Opens a saved test. Refer to [Open a Test for analysis](#).
- **Settings:** Configures the test parameters. Refer to [Configure parameters](#)
- **Help:** Opens the online help file.
- **Exit:** Exits the HyperQ Analyzer Rest application.

4. The HyperQ Analyzer Rest Application

The following sections describe how to run the HyperQ Analyzer Rest:

- [Open a test for analysis](#)
- [View HyperQ analysis](#)
- [Configure parameters](#)
- [Print the HyperQ Analyzer Rest report](#)

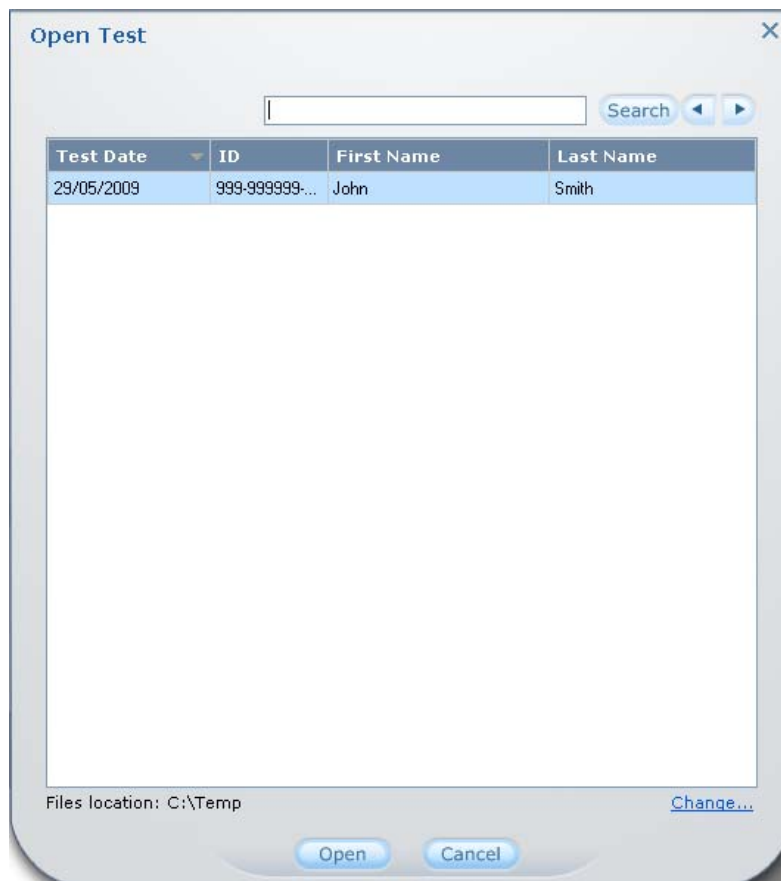
4.1 Open a Test for analysis

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

- 1 In the **HyperQ Analyzer Rest** screen ([Figure 1](#)), click 

The **Open Test** screen appears ([Figure 2](#)).

Figure 2: Open Test Screen



- 2 Highlight the recording to be loaded.

Note

Search field, type the **ID**, **First Name**, or **Last Name**, and click **Search**.

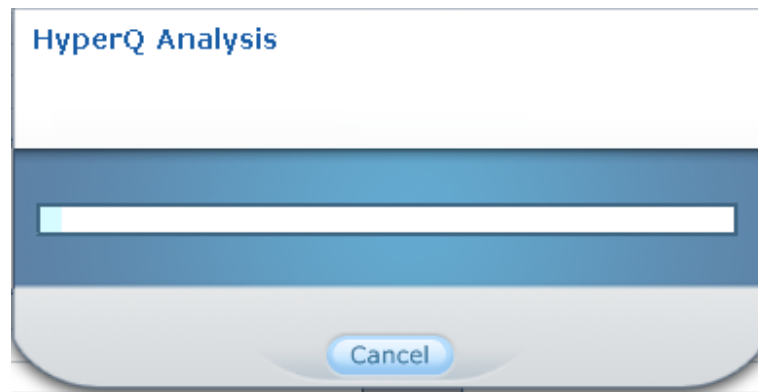
Note

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 Analyzer Rest is calculated ([Figure 3](#)). When the calculations are complete, the **HyperQ Results** screen appears ([Figure 6](#))

Figure 3: HyperQ Analyzer Rest Progress Screen




Note

If the HyperQ Analyzer Rest has already been calculated, the **HyperQ Results** screen appears immediately.

4.1.1 Test analysis history

The HyperQ Analyzer Rest 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


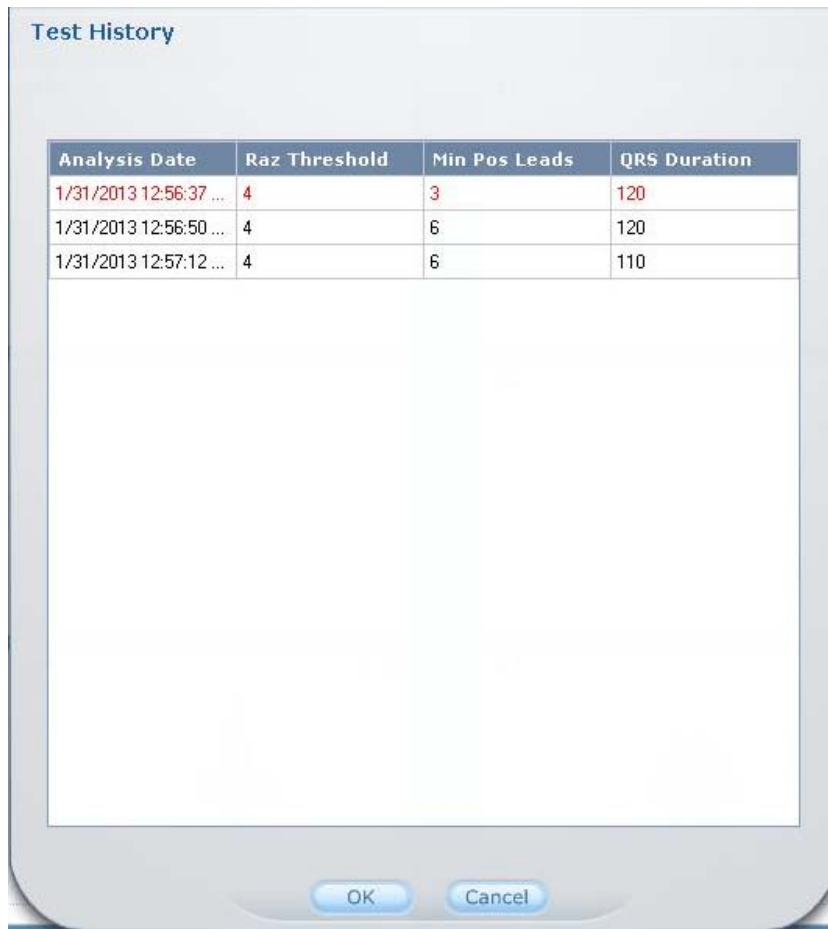
 button (see section 4.3 below). In the former case, the current settings of the system are used and in the latter the currently opened test is analyzed. In both cases a new instance of analysis results is created.

Figure 4: Test History Screen

Analysis Date	Raz Threshold	Min Pos Leads	QRS Duration
1/31/2013 12:56:37 ...	4	3	120
1/31/2013 12:56:50 ...	4	6	120
1/31/2013 12:57:12 ...	4	6	110

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

Note

The HyperQ Analyzer Rest software is intended to be used as an aid to the resting ECG test and should not be used as the sole basis for making clinical decisions pertaining to patient diagnosis, care or management.

The HyperQ signal analysis was designed to reveal information that exists within the ECG signal. As opposed to traditional ECG, which is measured in the 0.05-100Hz frequency range, the HyperQ signal is measured in the high frequency band such as

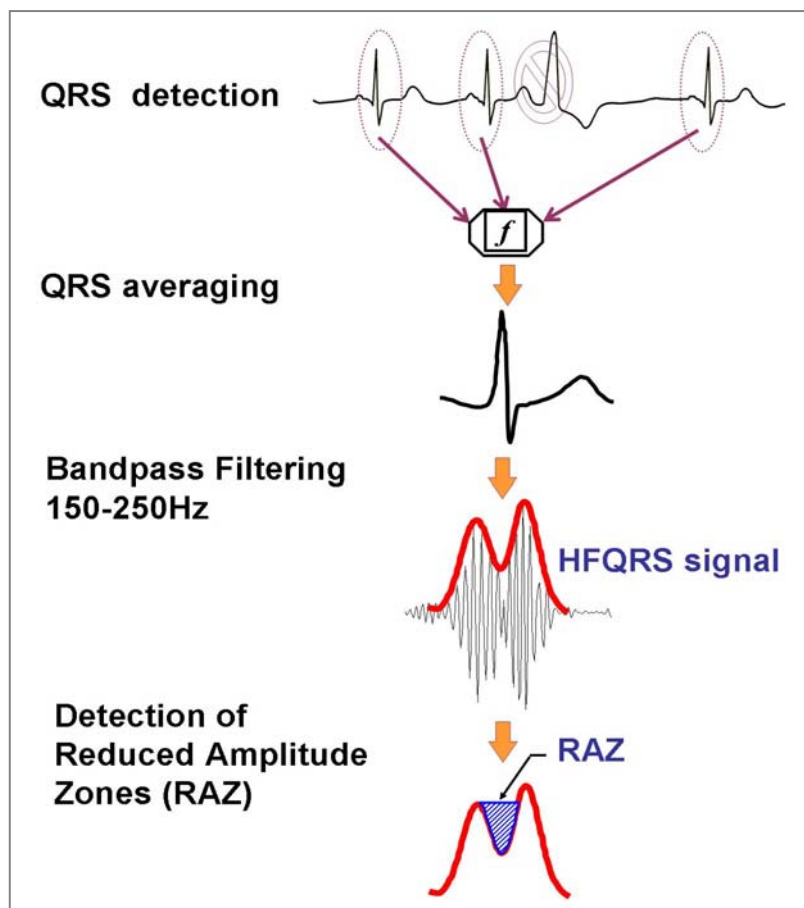
the 150 – 250 Hz frequency range. The HyperQ signal appears during the ventricular depolarization phase and is synchronized with the QRS complex. During each ventricular depolarization phase, the low frequency range is represented by the conventional QRS complex, while the high frequency range is represented by the HyperQ signal.

To extract the high-frequency morphological index (HFMI), QRS complexes are first detected and averaged. Noisy QRS complexes and QRS complexes originated during arrhythmias are rejected. The valid QRS complexes are then carefully aligned and averaged. The averaged QRS complex is bandpass filtered in a high frequency band to produce the HyperQ signal. The envelope of the HyperQ signal is then identified. The envelope signal measures the intensity of the HyperQ signal during the ventricular depolarization phase. The morphology of the HyperQ envelope is examined for existence of reduced amplitude zones (RAZ).

The level of RAZ of all 12 leads is quantified by the index named HFMI which was found to be indicative of the degree of myocardial ischemia. When the HFMI value in a lead is above a certain threshold, the lead is considered "positive". When there are more positive leads than a predefined threshold, the HyperQ changes are considered significant.

Figure 5 depicts the steps in the processing of the HyperQ signal.

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

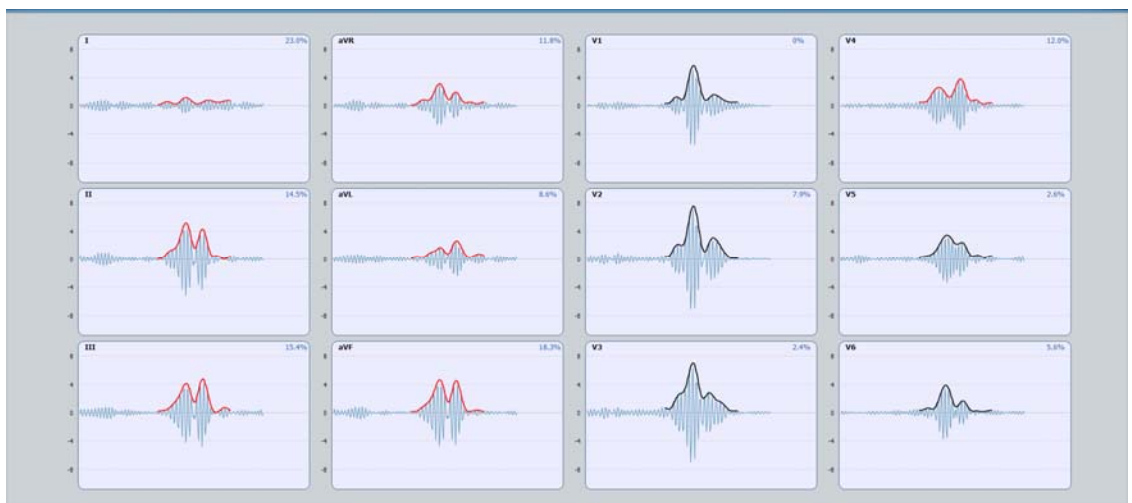


Initially, the QRS complexes are detected, while excluding arrhythmias and noisy complexes. The detected QRS complexes are carefully aligned and averaged. The averaged QRS complex is then filtered to produce the HyperQ signal. The envelope of the filtered signal is detected and zones of reduced amplitude are indicated. The final step is the calculation of the HFMI for each of the leads.

4.2.1 HyperQ Results Screen

The twelve-lead screen shows the HyperQ signal and HyperQ envelope during the QRS interval for each lead. The lead's name is displayed in the upper left corner. HFMI index for each lead is displayed in the upper right corner. The y-axis indicates the units of the HyperQ signal in μV .

Figure 6: HyperQ Results Screen



At the top of the screen patient information is displayed as well as the summary of the HyperQ results. The HyperQ summary has different categories:

4.2.1.1 Significant HyperQ changes

This category means that the high frequency analysis of the ECG data has crossed the specified thresholds of the system and thus the results indicate that significant "Reduced Amplitude Zones" exist. The process for determining that a resting ECG test is positive in terms of the high frequency analysis has two stages. First, every lead is analyzed individually and if the HFMI is above the specified threshold the lead is considered positive. In the second stage, the number of positive leads is compared to the respective threshold and if this threshold was crossed, the test is considered positive and the HyperQ summary indicates that there are significant HyperQ changes.

Note

Some of the thresholds that determine whether a test is considered to have significant HyperQ changes are controlled by the user (see section 4.3 for details). It is important to check the configuration when considering the significance of the HyperQ changes.

4.2.1.2 HyperQ changes within normal range

This category means that the results of the high frequency analysis of the ECG data are below the specified thresholds of the system.

Note

Some of the thresholds that determine whether a test is considered to have significant HyperQ changes are controlled by the user (see section 4.3 for details). It is important to check the configuration when considering the significance of the HyperQ changes.

4.2.1.3 HyperQ not available

In some cases the high frequency analysis is unable to determine whether there are significant HyperQ changes or not. There are three possible reasons for such an outcome:

- Wide QRS – when the duration of the QRS complex, as calculated by the system is longer than the defined maximum QRS duration the HyperQ result is unavailable
- Insufficient ECG quality – to ensure reliable results the system checks the high frequency signal to verify that the signal quality is adequate. In case such criteria are not met, the HyperQ result is unavailable. The user can repeat the test making sure that the patient preparation has been carefully performed. See paragraph 3.1 for details.
- Insufficient ECG data – to ensure reliable results, the system requires a minimal amount of data to process. In case the test was shorter than 3 minutes, the HyperQ result is unavailable. See paragraph 3.1 for details.

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

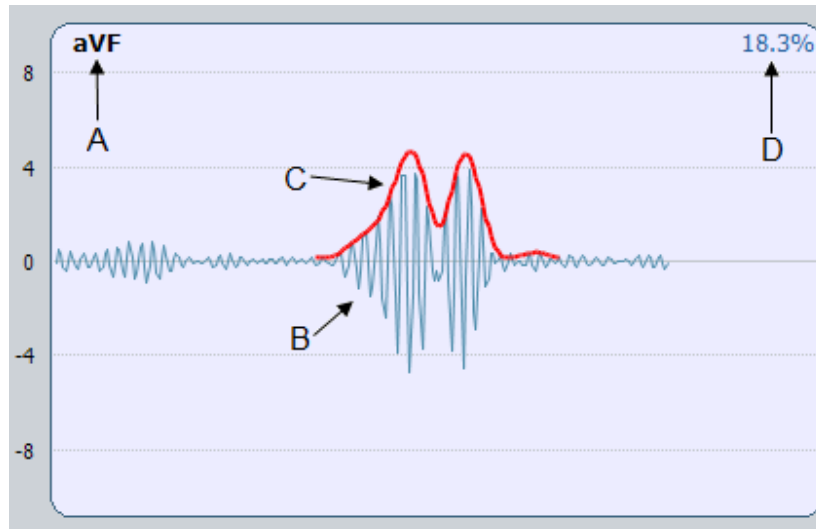



Table 1: HyperQ Single Lead View Elements

Element	Description
A	Lead Name
B	HyperQ signal
C	HyperQ envelope signal (a black line indicates a negative lead and a red line indicates a positive one)
D	High-frequency morphological index (HFMI) value in percent


Note

The lead graph may be empty in case of noisy ECG data

4.3 Configure parameters

The HyperQ Analyzer Rest has several configurable parameters. These can be customized by the user in two ways: by directly editing the configuration file or by using the "Settings" button  from the menu. The configurable parameters are listed below.

4.3.1 Settings button

By clicking the "Settings" button  from the main menu, the user can access the "Settings" menu (Figure 8). 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 4.3.2 below.

Figure 8: Setting Menu



Table 2: List of parameters

Parameter	Description
HQ_RAZ_THRESHOLD	HFMI threshold for a positive HyperQ diagnosis of a certain lead
HQ_MIN_POS_LEADS	Minimum number of positive leads for declaring significant HyperQ changes
HQ_MAX_QRS	The maximum QRS duration for which the HyperQ summary will be provided
POWERLINE_FILTER	The frequency for the AC line filter
DATE_FORMAT	The date format to be displayed

4.3.2 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

4.4 Print the HyperQ Analyzer Rest report

HyperQ provides a printed summary of the HyperQ diagnostic indexes. In case of any printer error or communication problems with the printer, the user can reload the test data and print the report after fixing the printer problem.

The report contains the following information:

Table 3: Common Report Data



Specification	Description
ID	Patient's ID number
Name	Patient's name
Date	Test date and time
HyperQ Summary	The HyperQ result summary
Gender	Patient's gender
Age	Patient's age
Weight	Patient's weight
Height	Patient's height
QRS Duration	Duration of QRS complex as detected by the application

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 9: 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 10 will pop up, and a product key can be applied:

Figure 10: 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,
