BSP

Revolutionizing Non-invasive Cardiology

HyperQ™ Analyzer Rest

User Manual

CE Marking Information

0344

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

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

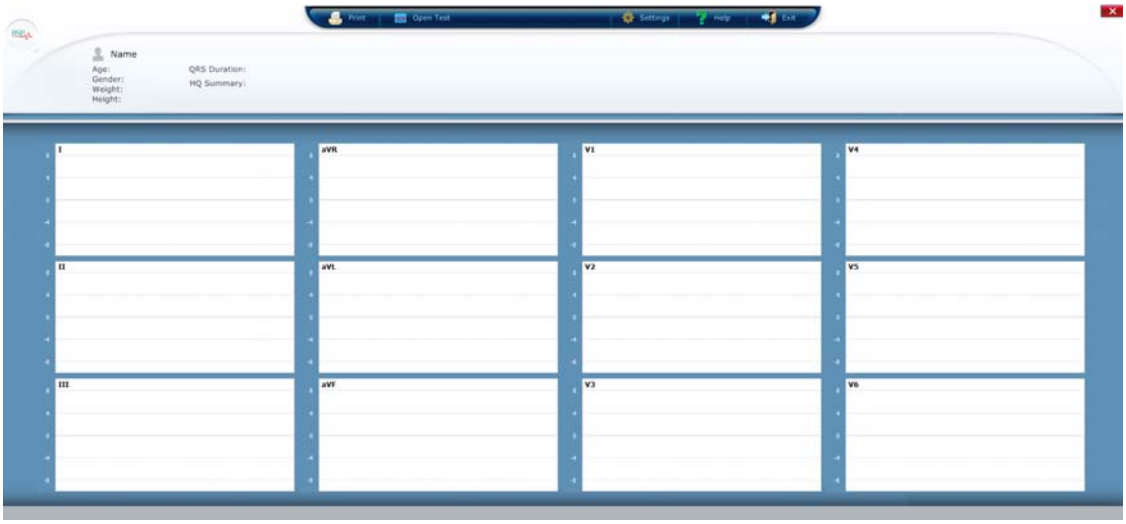
The HyperQ Analyzer Rest screen contains the main options available for viewing and calculating HyperQ analysis on a selected test.

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

  Alternatively, double-click  on the desktop.

  The HyperQ Analyzer Rest screen appears (Figure 1).

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.
- **Help**: Opens the online help file.
- **Exit**: Exits the HyperQ Analyzer Rest application.

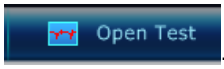
4. The HyperQ Analyzer Rest Application

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 

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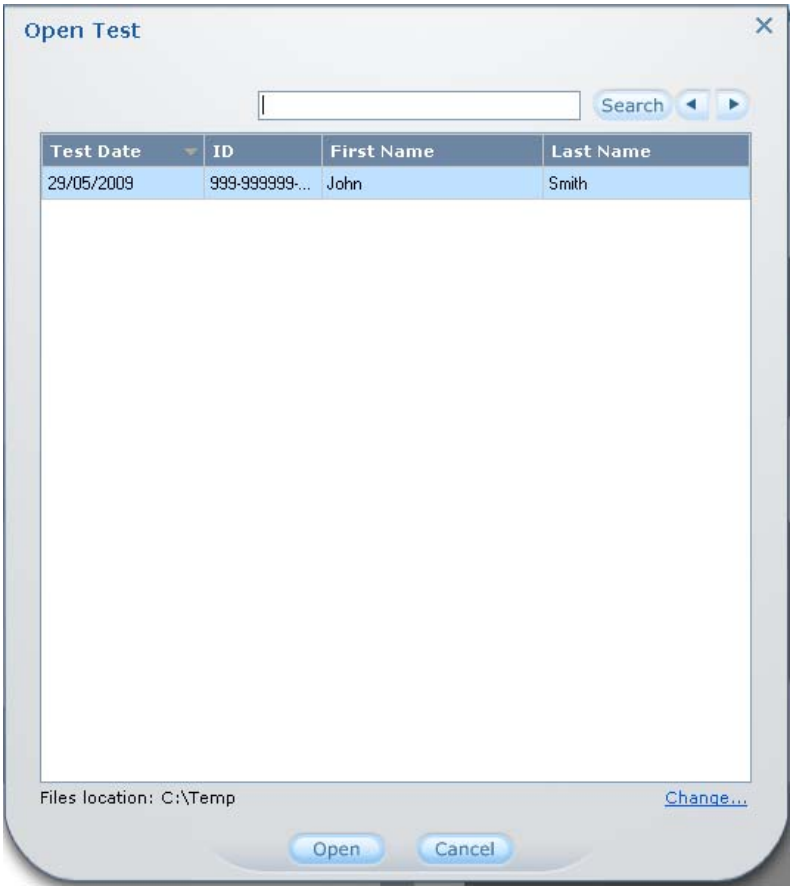
The **Open Test** screen appears (Figure 2).

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**.

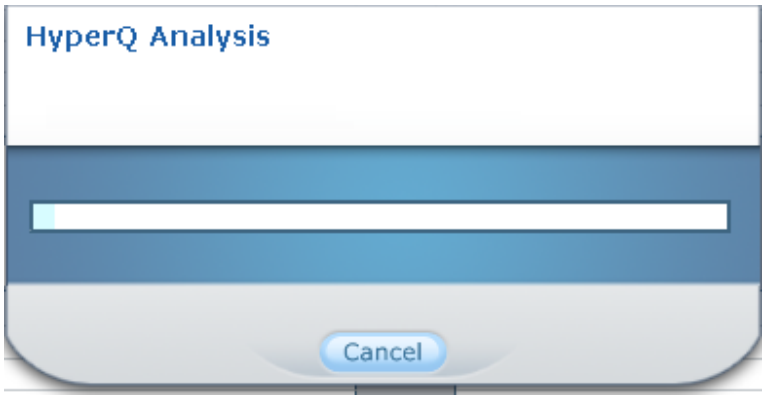
Note

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 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

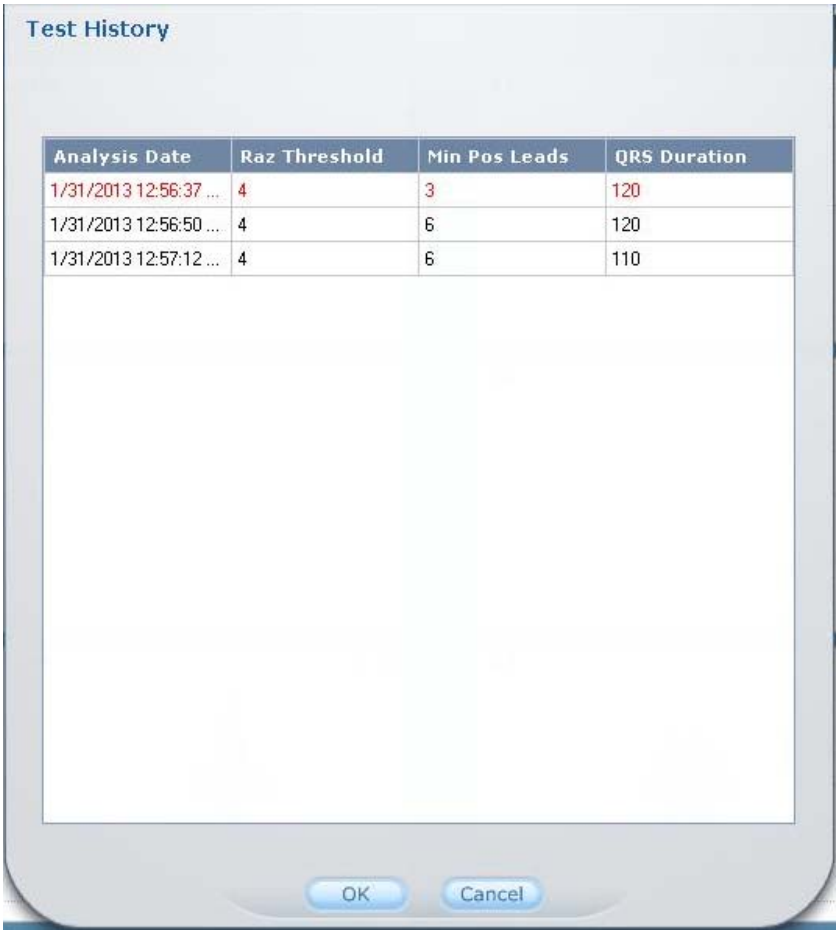


Figure 4 depicts the "Test History" screen which is opened when the history button is pressed. In this screen the user can view a list of test analyses that were performed with their respective configuration of parameters. The original analysis (the first time this test data was analyzed) appears in 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 where 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

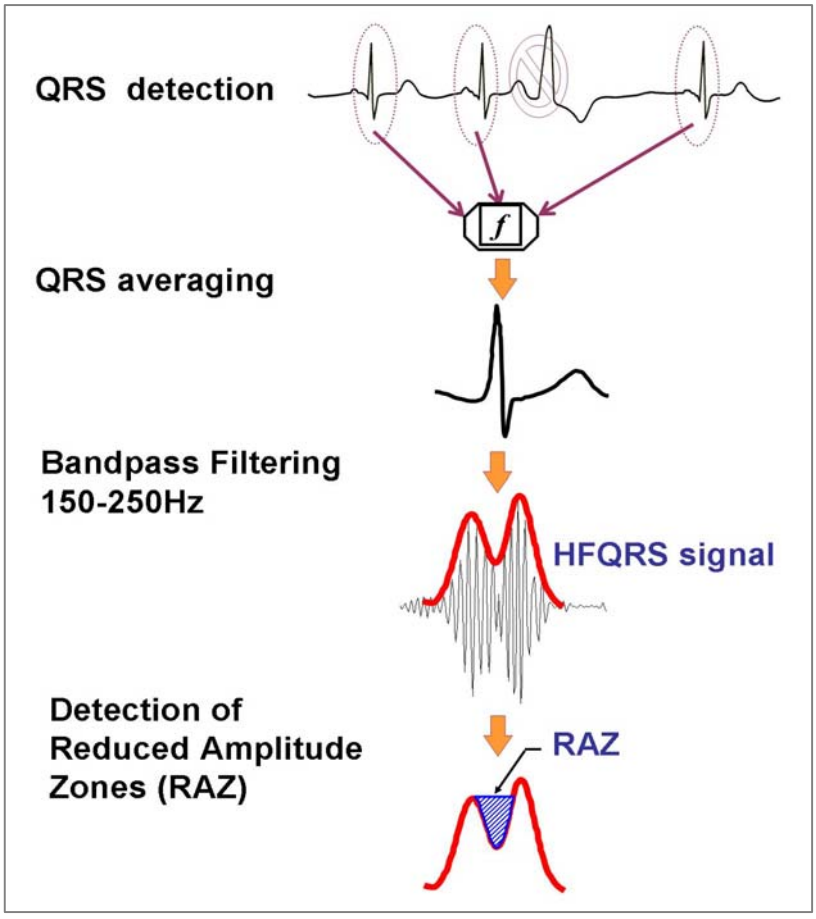
the 150 – 250 Hz frequency range. The HyperQ signal appears during the ventricular depolarization phase and is synchronized with the QRS complex. During each ventricular depolarization phase, the low frequency range is represented by the conventional QRS complex, while the high frequency range is represented 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 HFMI index 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 shows schematically the steps in the processing of the HyperQ signal.

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

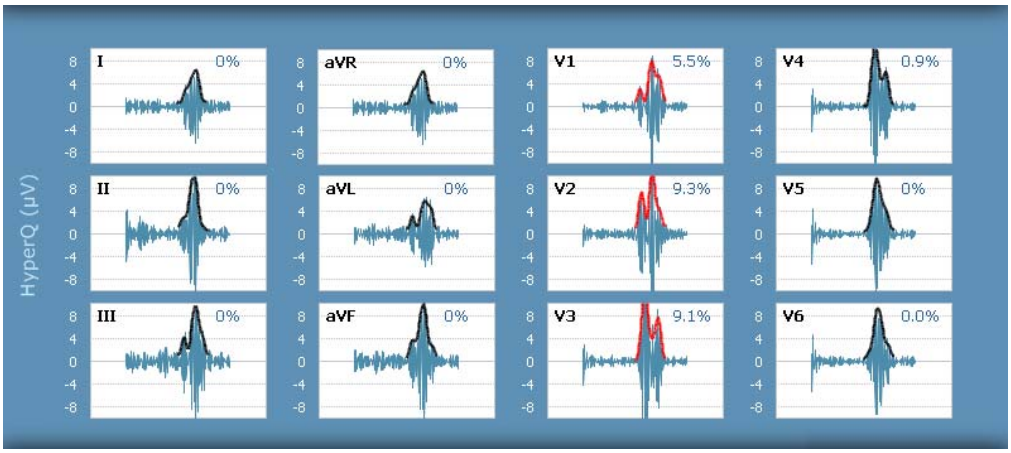


Initially, the QRS complexes are detected, while excluding arrhythmias and noisy complexes. The detected QRS complexes are carefully aligned and averaged. The averaged QRS complex is then filtered to produce the HyperQ signal. The envelope of the filtered signal is detected and zones of reduced amplitude 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, as specified in 4.4.1, 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.

Note

Some of the thresholds that determine whether a test is considered to have significant HyperQ changes are controlled by the user (see section 5 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 high frequency analysis of the ECG data results 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 5 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

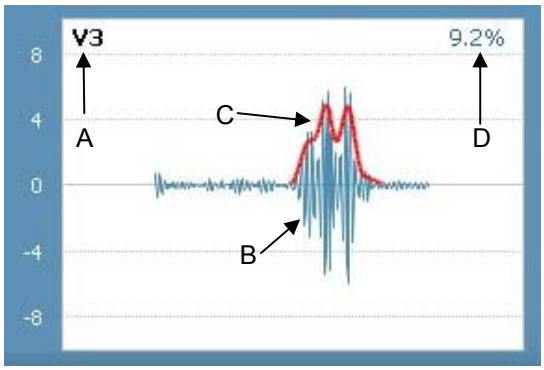


Table 1: HyperQ Single Lead View Elements

Element	Description
A	Lead Name
B	HyperQ signal
C	HyperQ envelope signal (black line for negative value and red line for positive value)
D	High-frequency morphological index (HFMI)

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. For the list of configurable parameters please see section 5 below.

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.

4.4.1 Reading the Report

The report contains the following information:

Table 2: 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. Setting Options

This section describes how to configure the HyperQ Analyzer Rest customizable options.

There are two types of customized parameters:

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

To change the settings, the user may either use the "Settings" menu as described in section 4.3 or edit the **bsp.properties** file under <*installation directory*>/Config

Note

The application must be closed and reopened before any changes can take effect.

Parameter	Description
HQ_RAZ_THRESHOLD	Minimum HFMI threshold for 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
FILES_DIRECTORY	The location where files are saved