HES[®] HANNOVER ECG SYSTEM

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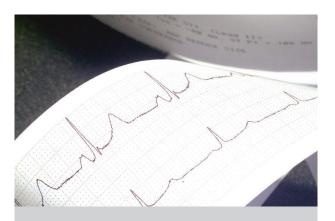
The need for accurate analysis of ECG signals has grown significantly over the last years, especially clinical trials require an accurate interpretation of the 12 lead ECG. But also for standard or emergency examinations, it is more and more common to support the diagnosis of the doctor with computer based algorithms to measure the relevant parameters, such as QT interval. This saves important time during medical examinations and supports the doctor with the diagnosis of difficult cardiac disease patterns.

The HES[®] is an ECG diagnostic program developed in cooperation with leading cardiologists since more than 35 years and is based on a large database. The HES[®] algorithm achieves best results in the field of diagnosis and is very accurate with its interpretation. But besides the overall algorithm accuracy, it is also important to look at the stability of the algorithm. The algorithm is extremely stable and even here, HES[®] shows best performance. Therefore, the HES[®] algorithm is one of the leading applications worldwide in the field of ECG analysis and interpretation and has been implemented in FDA and CE registered devices since many years now.

The Hannover ECG System is available for 1, 3, 6 and 12 leads and with a multiple range of possible applications. HES[®] is applicable for the analysis of resting ECGs and exercise ECGs as well as for short and long-term ECG interpretation. In the area of event monitoring HES[®] can be applied for the interpretation of real time monitoring ECG signals.

Due to the fact that HES[®] supports the data format SCP, it can be implemented to different kinds of systems. Already existing ECG monitors can be upgraded with interpretation and analysis function. The HES[®] algorithm is also designed for the utilization in embedded solutions. It can be integrated directly on DSPs or microcontrollers and is suitable for the usage in mobile applications like hand held devices.

The Hannover ECG System is the ideal addition to the Corsci- ence product and service range. As Corscience is an established service provider for medical products, the HES[®] algorithm can also be adapted to individual needs of the customers.



HES[®] at a glance:

Software Modules:

- Resting ECG
- Exercise ECG
- Real Time Monitoring (RTM)
- AED

Supported Operating Systems:

- Embedded Systems (DSPs or ARM)
- Microsoft Win 32 + 64 bit
- MacOS 32 + 64 bit
- Linux 32 + 64 bit
- Android
- iOS
- WinCE

Supported Documentation:

- DoC of 62304
- List of known issues
- List of risks

HES[®] Resting ECG Analysis



The HES[®] Resting ECG analysis program is one of the most accurate and comprehensive systems currently available – it performs full scope measurement and interpretation of 12 lead ECGs.

Program Features:

- Accurate beat localization and typing
- Averaging of dominant (normal) beats and up to three types of PVC
- Accurate wave point detection
- Noise detection and removal
- Measurement tables for: P, QRS, ST, QT, QTc, etc. for overall ECG and per lead
- Detailed rhythm analysis: VES, SVES, couplet, triplet, salve, pause, bigeminy, trigeminy, ventricular tachycardia, bradycardia, fibrillation/flutter...
- Detailed interpretation, e.g.:
 - P-wave interpretation (e.g., atrial overload, prolonged atrial conduction)
 - Repolarization abnormalities and T-wave changes (e.g. ischemia)
 - Intraventricular conduction defects (e.g., bundle branch blocks and preexitation syndrome, left anterior hemiblock)
 - QRS-T interpretation (e.g. normal, infarction with location and age, right, left and biventricular hypertrophy)
- The HES[®] textual output is available in English, German, French, Dutch, Spanish, Catalan, Italian, Portuguese, Czech, Polish, Russian, Ukrainian, Danish, Finnish, Norwegian and Swedish (Further languages on request) and provides output in several formats, e.g. SCP.
- HES® can be combined with our SCP-compression / decompression algorithms to increase efficiency of data transmission.

Available Lead Systems:

• 12 leads (full scope interpretation)

Supported Norms and Regulations:

• IEC / EN 60601-2-25

License Models:

- Individual license
- Server license

Performance and Technical Specification:

The HES[®] programs have taken part in the Project "Common Standards for Quantitative Electrocardiography", CSE. The program results were analyzed independently and were published in the New England Journal of Medicine, Vol. 325, No. 25, page 1769, 1991:

Identifier	Normal (n = 382)	VHT (n = 291)	MI (n = 547)	Tot. accuracy (n = 1220)
Marquette	86,3	61,1	69,7	69,8
HES [®] Program	86,3	72,1	79,0	75,8
Hewlett Packard	93,5	51,0	64,5	69,3
Medis	91,3	49,4	62,5	67,6
Nagoya	89,3	42,6	63,7	65,6
Glasgow	94,0	51,0	67,7	69,7
Padova	89,8	61,3	47,1	62,0
Means	97,1	42,5	67,2	69,8
Leuven	91,5	67,0	82,1	77,3

VHT = Ventricular Hypertrophy, MI = Myocardial Infarction

HES[®] Exercise ECG Analysis

The exercise or stress ECG test is one of the most frequently performed "dynamic" non-invasive tests to assess the cardiac performance of a patient. Of particular interest with regard to the electrocardiogram is the observation of ST-changes throughout the test, an evaluation of the cardiac rhythm, e.g., whether the rhythm remains regular or whether arrhythmias, premature ventricular contraction beats (PVCs) or conduction defects can be provoked. Stress or exercise ECGs are usually performed with a bicycle ergometer or a treadmill. The HES® Exercise algorithm is designed to work together with the HES® Resting ECG analysis. Recording starts with a 10 second resting ECG and then continues with the stress recording. The resting ECG is used as reference for the tested patient.

Program Features:

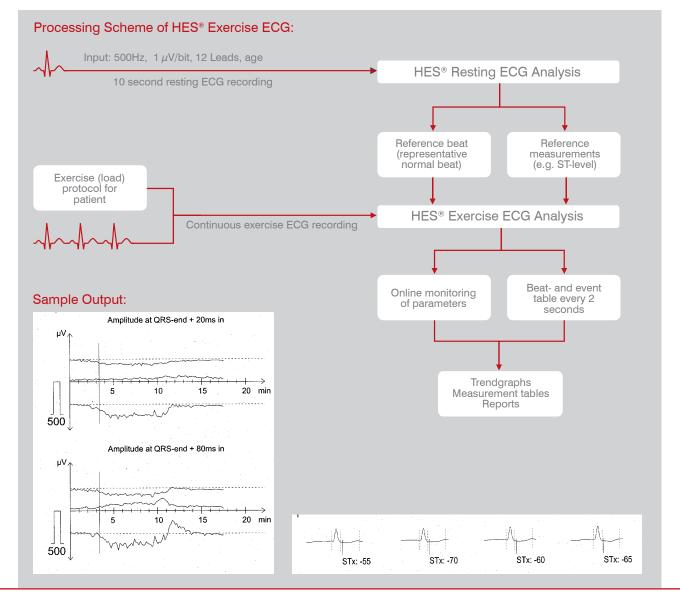
- Noise filtering
- Accurate beat localization and typing during stress test
- Averaging of dominant (normal) beats about 10 seconds
- Accurate wave point detection for dominant beats
- Measurement tables for: P, QRS, ST, QT, QTc, etc. for overall ECG and per lead
- Continuous measurement of: ST, QT, HR
- Detailed rhythm analysis: VES (up to 20 types), SVES, couplet, triplet, salve, pause, bigeminy, trigeminy, ventricular tachycardia, bradycardia, fibrillation/flutter in real time every two seconds

Supported Norms and Regulations:

- IEC / EN 60601-2-47
- ANSI / AAMI EC 38
- ANSI / AAMI EC 57

Available Lead Systems:

• 12 leads



HES[®] RTM & AED



HES® RTM

The HES® Real Time Monitoring algorithm is specifically designed for real time monitoring of ECG signals. The system can be applied to any kind of bed-side or intensive care monitors or embedded into small event recorders.

Program Features:

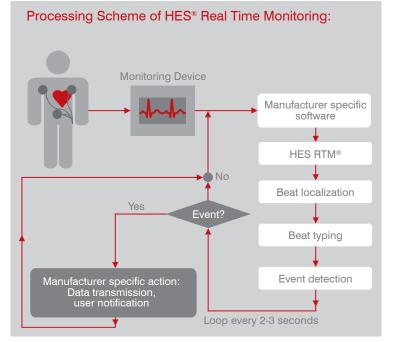
- Accurate beat localization and typing normal beats (several templates) PVC, artifacts (several templates) with only 2 seconds delay
- Detailed event analysis: couplet, triplet, salve, pause, bigeminy, ventricular tachycardia, bradycardia, fibrillation/flutter...
- Optional features for bed-side monitors:
 Representative cycles of dominant (normal) beats of the last 10 sec (real time update)
- VF/VT detection algorithm for defibrillators
- Fast R-wave detection for cardioversion
- Low CPU usage

Available Lead Systems:

1 lead

Supported Norms and Regulations:

- IEC / EN 60601-2-47
- ANSI / AAMI EC 38
- ANSI / AAMI EC 57



HES® AED

The HES® AED algorithm can be used for analysing existing ECG-signals for the presence of VF/VT in order to recommend the necessity of shock therapy.

As part of the HES[®] family the HES[®] AED algorithm is delivered as a library (object code) and has to be integrated into the customer's application. It can be compiled for any operating system or as embedded version.

HES® AED is a software item for medical products and is suggested to be software safety class C according to DIN EN ISO 62304:2006!

HES® AED Features:

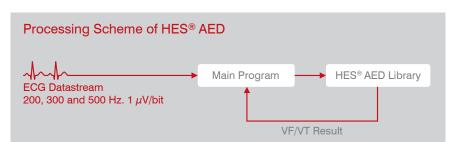
- VF/VT analysis with shock recommendation every second.
- Special algorithm for pediatric ECGs.
- Compatible with 200, 300 and 500 Hz ECG sample frequency.
- Low CPU usage
- Cross platform support (bare metal naked Cortex M3 up to 64 bit Linux systems)
- Short reaction times for shock analysis

Available Lead Systems:

1 lead

Supported Norms

IEC 60601-2-4



CTS Database & **HES®** Services

CTS Database

The "Conformance Testing Service" database offers the possibility of extensively testing analog or digital electrocardiography equipment. The data in the CTS database consists of calibration signals and analytical signals, known as CAL and ANE files.

In comparison to sinusoidal signals or other non-ECG-like signals, the hardware characteristics of a nonlinear ECG system can be tested with the signals from the CTS database in a profound and standardized manner.

In addition, the ANE signals are based on the biological form of the ECG. Thus, it is possible to test the software performance of the ECG system with respect to the measurement of the signal parameters amplitude and time.

You can purchase the CTS database and CTS testing exclusively at Corscience. Please contact us for further information.

Development Kit:

For every supported platform we can deliver a development kit.

The development kit allows you to perform a fast system integration and learn how to use the HES® API. It contains a comprehensive integration manual and includes integration support from our engineers.

It consists typically of a simple standalone program which gets input and output from files and uses the specified API to access the specific HES[®] module.

The license of the development kit for Windows, OSX and Linux is dongle restricted and time limited.

Your developed SW can easily be switched to production mode by simply replacing the DevKit license, no recompilation is needed.

Maintenance & Care:

To provide full service for our Licensees, Corscience provides a Maintenance & Care range of service packages.

- (a) BASIC support: on request by customer separate offer for updates, upgrades or other support. Payment per hour.
- (b) STANDARD support: one update per year including 8 hours of support per year. Reaction time on requests is 10 working days. Additional work is done by payment per hour.
- (c) **PREMIUM** support: one update per year including 24 hours of support per year. Reaction time on requests is 2 working days. Additional work is done by payment per hour.

On request:

- ST Trending and STEMI indication: Current software in emergency devices delivers only the analysis over a short time interval.
 For infarction detection it is important to have an ongoing measurement table for the representative beat for up to 12 leads.
 The tracking of the ST parameters and a feedback according to the current STEMI guidance, possible in form of a traffic light, completes the software.
- Holter ECG: HES[®] LTE is an offline analysis SW and designed for ECG recordings of variable lengths, such as classical Holter ECGs. The program delivers beat and event tables, with time and duration: Accurate beat localization and typing, noise detection and removal, detailed event analysis, measurement tables for the representative beat and is prepared for up to 12 leads.
- Statistics: HES[®] STA is designed for statistical analyzing of ECG measurement tables, such as HES[®] LTE or HES[®] Exercise. It provides detailed statistical output over the complete record to point physicians/ cardiologists to the significant events and reduces over-reading time: Event-extraction with time pointers, NN-Analysis or Heart Rate Variability (HRV) analysis in time and frequency domain for example.
- Multichannel Measurement: Current available analysis software on the market support only up to 12 leads. Corscience is working on solutions for multichannel software. The output is a measurement table for the representative beat for every desired lead.

ECG detection further Analysis



Many years of experience in algorithm development makes Corscience an expert partner for the acquisition, analysis and evaluation of biological signals. Corscience realizes innovative solutions in monitoring, diagnostics and therapy with modern signal processing methods, and will support its customer from the first business case to algorithm implementation.

In addition to HES® , Corscience provides further algorithms like:

- Pulse-wave transit time analysis
- ECG beat detection
- Detection of pulseless electrical activity
- Ischemia detection
- Heart rate turbulence analysis
- AF detection
- VF/VT detection

In addition to the algorithms, Corscience's ECG portfolio offers also the right hardware for all classical examination methods. Whether you're looking for approved 3/6 or 12 channel ECG devices or different ECG OEM modules for integrating into your system, Corscience has a wide experience in ECG hardware as well as in software. Also if you prefer an individually adapted ECG solution for your system – Corscience is a reliable partner for development services. For further information about Corscience and its know-how or technology examples please visit our homepage www.corscience.de or contact us at info@corscience.de .