Reliable, Accurate
12-Lead ECG Data Analysis

Executive Summary

The Philips 12-Lead Algorithm is an advanced ECG analysis program developed by the Advanced Algorithm Research Center (AARC) that uses sophisticated mathematical processes for interpreting cardiac data. Available with select patient monitoring systems from Philips, the 12-lead algorithm analyzes up to 12 simultaneously acquired ECG waveforms recorded over a ten-second period using interpretative criteria triggered by patient-specific information.

To support more accurate diagnosis and treatment, the Philips 12-Lead Algorithm analyzes ECG data and produces an interpreted report that helps clinicians to assess a patient's condition. The 12-lead algorithm delivers significant advancements in the speed and consistency of ECG data acquisition, as well as in the sophistication and reliability of ECG data interpretation—particularly in the areas of pediatric analysis, pacemaker pulse classification and ST Elevation AMI (STEMI) detection. In addition, the algorithm supports the reporting, storage and transmission of ECG data in the XML format.

The Philips 12-Lead Algorithm offers a number of significant clinical benefits, which add up to lower costs, improved efficiency, and ultimately, superior patient care. This advanced ECG analysis program:

- allows physicians to read and interpret ECG findings more quickly and efficiently for notable time and cost savings
- provides accurate, validated ECG measurements to facilitate physician overreading and improve treatment decision-making
- generates detailed findings that highlight areas for physician review, making it a trusted second opinion for improved patient assessment
- provides high levels of reproducibility for more consistent ECG interpretation, no matter which physician is reading the report

Introduction

Philips pioneered the development of computerized ECG data analysis, introducing its first 12-lead algorithm to the health care market almost thirty years ago. Today, this experience and expertise is reflected in the Philips 12-Lead Algorithm, a highly sophisticated program designed to analyze up to 12 simultaneously acquired ECG waveforms recorded by noninvasive patient monitoring systems over a ten-second period. The result of three decades of ongoing research, development and enhancement, the Philips 12-Lead Algorithm measures the morphologies of ECG waveforms and analyzes rhythm to produce an interpretation[1] that offers high levels of accuracy and repeatability. The algorithm is a valuable tool for assisting clinicians in making more informed patient assessments in a broad range of clinical settings including hospitals, labs and physicians' offices.

[1] Interpretations have been validated using standard diagnostic 12-lead placement ECGs against widely used ECG databases.

PHILIPS

Based on high-quality ECG signals acquired from ten electrodes (12 leads), the Philips 12-Lead Algorithm monitors signal quality, measures waveform components, recognizes patterns, and performs basic rhythm analysis. For greater accuracy and repeatability, it measures every beat in every lead individually, and then groups and averages like beats to provide a representative beat. Computerized signal processing removes noise and artifact while minimizing distortion of the ECG waveform. Using the extended measurements and patient-specific information, the 12-lead algorithm generates those interpretive statements from the criteria program that summarize the findings for the ECG and highlight key areas of concern for physician review. The result is a highly accurate and reproducible ECG, complete with computerized commentary, which facilitates physician overreading and provides a trusted head start on patient assessment.

Dedicated to helping our customers achieve clinical excellence without compromise, Philips designed its 12-lead algorithm to support seamless transmission of digital ECG data using the XML format. By building support for the XML data format into our ECG interpretive reporting capabilities, Philips is giving customers greater flexibility in how they report, share and manage ECG data across the care continuum. The algorithm's support for the XML data format also allows the ECG data to be easily converted for use by the FDA in its drug study reviews.

Key features and benefits of the Philips 12-Lead Algorithm include:

- Ten-second simultaneous 12-lead data acquisition and analysis for quick, consistent ECG reporting
- Calculation of lead and global measurements based on individual and average representative beats for improved accuracy and repeatability
- Incorporation of an ever-expanding range of state-of-the-art interpretation criteria, including age- and gender-driven criteria, for greater depth and breadth of analysis
- Noise-adaptive pacemaker pulse detection, advanced pacemaker rhythm classification and the ability to identify non-paced QRS complexes for morphology analysis in ECGs with paced and non-paced beats
- Accurate detection of ST Elevation AMI
- Advanced pediatric interpretation program with improved classification of mild RVH and IRBBB by combining vectocardiogram (VCG) transverse plane measurements with scalar ECG measurements
- Enhanced QT interval measurement capabilities for more accurate detection of prolonged QTc and QT dispersion

Average Representative Beat

Based on ECG signals acquired via the 12 leads (10 electrodes) of a patient monitoring system, the Philips 12-Lead Algorithm measures each component of the waveforms and performs basic rhythm analysis to produce a comprehensive set of measurements. These measurements are then used to determine the appropriate interpretive statements. For greater accuracy and repeatability, the algorithm measures every beat in every lead individually, and then groups and averages like beats to provide a representative beat. The Philips 12-Lead Algorithm calculates lead and global measurements from combinations of the comprehensive set of measurements for each beat and the representative beats. The algorithm's ECG criteria program can use any combination of these two types of measurements, thereby enhancing the flexibility and power of its interpretive capabilities.

Advanced Pacemaker Pulse Detection & Paced Rhythm Classification

Approximately 2-5% of routine diagnostic ECGs are acquired from patients with implanted cardiac pacemakers, devices which have become more capable, efficient and complex over the past few years. To keep pace with these pacemaker developments, Philips built a sophisticated pacemaker pulse detector and paced rhythm classifier into its 12-lead algorithm. The algorithm is designed to understand a variety of atrial, ventricular, and A-V sequential pacing modes and to recognize asynchronous pacing typically seen with a magnet in place. In addition to automated detection capabilities, the algorithm provides user-

selected configuration of "pacemaker patient" or "non-pacemaker patient" for more accurate analysis.

Today's pacemakers use bipolar lead systems, which produce very small pulse amplitudes and widths, thereby making the pulses difficult to detect during ECG testing and cardiac monitoring. The Philips 12-Lead Algorithm employs a new noise-adaptive pulse detector that is run on all ECG leads. Agreement among leads differentiates true pulses from noise.

If a pacemaker is known to be present, the sensitivity of the algorithm's pacemaker pulse detector can be increased to improve detection of extremely small pacemaker pulses. In addition, analysis of pacemaker pulse locations with respect to P-waves and QRS complexes permits classification of a variety of pacemaker rhythms and identifies non-paced QRS complexes for morphology analysis in ECGs with paced and non-paced beats.

Age- and Gender-Specific ECG Interpretation

As cardiac medicine continues to advance, the health care community learns more about how various factors, such as age or gender, impact a patient's risk for developing specific forms of heart disease. The Philips 12-Lead Algorithm leverages this knowledge, using advanced gender-specific interpretation criteria to take into account key physiological differences between men and women. For example, it applies gender-specific evaluation of Q waves for improved detection of Acute Myocardial Infarction (AMI), the diagnosis of which is more often missed in female patients. What's more, the 12-lead algorithm uses gender-specific axis deviation criteria, Cornell gender-specific criteria for detection of Left Ventricular Hypertrophy (LVH) and Rochester and Rautaharju age- and gender-specific criteria for detection of prolonged QT. Application of these gender-specific criteria results in an interpreted ECG that helps clinicians more accurately assess the cardiac state of patients, leading to earlier intervention, lower health care costs, and improved outcomes in patients of both sexes.

The Philips 12-Lead Algorithm considers both age and gender simultaneously for more accurate detection of specific conditions including hypertrophy and QT prolongation, as well as early repolarization and myocardial infarction.

Pediatric ECG Analysis Capabilities

The Philips 12-Lead Algorithm includes an advanced Pediatric Criteria Program, which uses age to select clinically relevant interpretive statements—with variations in severity and probability—related to cardiac rhythm and morphology. Age—recognized in units of hours, days, weeks, months or years—determines whether adult or pediatric interpretation criteria are used for ECG analysis.

If the patient's age is less than 16 years, the 12-lead algorithm automatically uses pediatric ECG interpretation criteria, which take into account a pediatric patient's higher heart rate and narrower QRS complexes. In the Pediatric Criteria Program alone, 12 distinct age groups are included to ensure that the most age-relevant interpretation criteria are applied for analyzing the patient's ECG data. In fact, patient age is used throughout the criteria program to define normal limits in heart rate, axis deviation, time intervals, voltage values for interpretation accuracy in tachycardia, bradycardia, prolongation or shortening of PR and QT intervals, hypertrophy, early repolarization, myocardial ischemia and infarct, and other cardiac conditions.

Taking advantage of Philips' advanced pacemaker detection and classification algorithm, the 12-lead algorithm's Pediatric Analysis Program reliably distinguishes pacemaker pulses from the very narrow QRS complexes often produced by neonatal and pediatric patients. It also reduces the likelihood of false diagnoses in non-paced patients, while enabling more accurate paced rhythm analysis for the pediatric age group.

The algorithm's Pediatric Arrhythmia Program provides analysis and classification to support more accurate detection of sinus, atrial, junctional, accelerated junctional and ventricular bradychardia,

tachycardia and arrhythmia, as well as atrial fibrillation and atrial flutter.

In pediatric ECG analysis, right ventricular hypertrophy (RVH), and especially mild RVH, are often confused with incomplete right bundle branch block (IRBBB). The difficulty in distinguishing between these conditions has long proven problematic for computer ECG analysis algorithms and even for most experienced pediatric cardiologists. To address this long-standing diagnostic dilemma, the Philips 12-Lead Algorithm provides better classification of mild RVH and IRBBB by combining 12-lead synthesized vectocardiogram (VCG) transverse plane measurements with scalar ECG measurements.

In addition, the Philips 12-Lead Algorithm provides improved QT measurements, now allowing prolonged QT statements in pediatric patients.

Highly Accurate ST Elevation Acute Myocardial Infarction (STEMI) Detection

ST segment elevation in ECG tracings provides highly effective risk stratification in early acute coronary syndromes. For patients with ST segment elevation acute myocardial infarction (STEMI), the most critical factor in improving survival rates is the earliest possible administration of reperfusion therapy. The Philips 12-Lead Algorithm provides advanced capabilities for fast, accurate detection of STEMI, thereby providing clinicians with a valuable decision support tool when working with patients presenting symptoms that suggest acute coronary syndromes.

Other cardiac conditions, such as benign early repolarization and acute pericarditis, tend to mimic the ECG diagnosis of STEMI and degrade algorithm performance. To address this problem, the Philips 12-Lead Algorithm separates the confounders by examining the patterns of the ST elevation. With improved measurements in ST deviation, the algorithm provides both high sensitivity and high specificity for more accurate STEMI detection.

Philips Medical Systems is part of Royal Philips Electronics
www.medical.philips.com
medical@philips.com
fax: +31 40 27 64 887

United States
(800) 934-7372

Canada
(800) 291-6743

Europe, Middle East and Africa
(+49) 7031 463 2121

Latin America
(954) 835-2600

Asia Pacific
(852) 2821-5888

Printed in the United States
December 2002
5990-0724EN