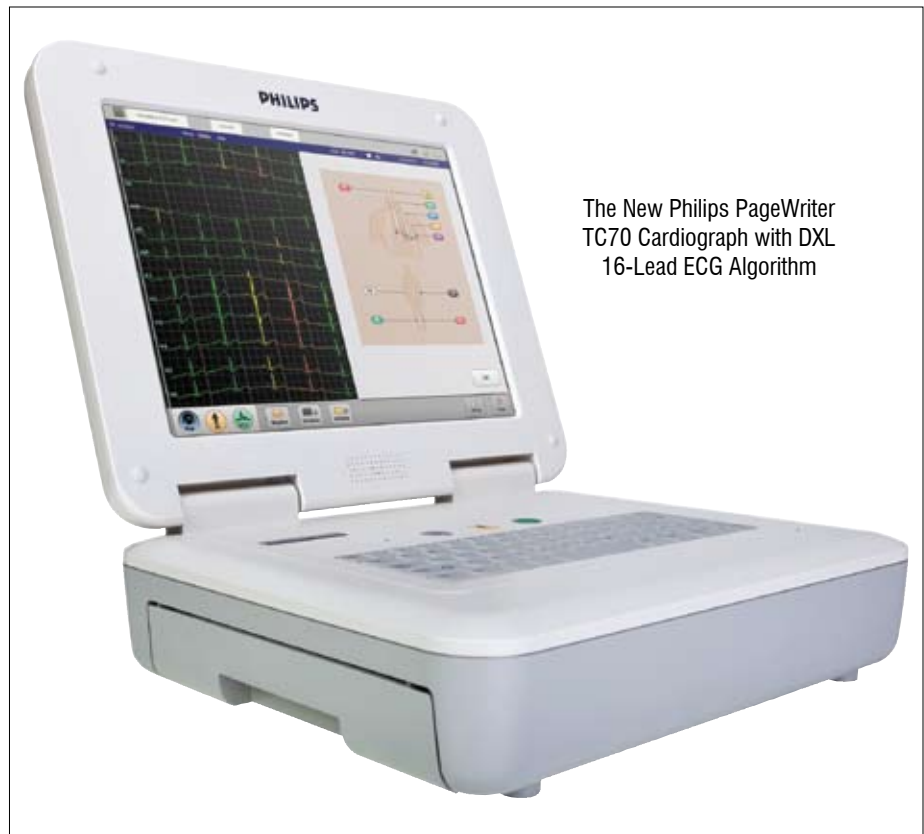


Advanced ECG Algorithms & Novel Cardiograph Speed Cardiac Diagnosis and Further Reduce Door-to-Balloon Time

Reducing the length of time between discovery and treatment in severe cardiac incidents remains the key to saving lives. The numbers tell the story: more than 1.2 million Americans suffer a heart attack in any given year. About 460,000 of these Myocardial Infarctions (MIs) will be fatal.¹ Almost half of those fatalities occur within an hour of the onset of symptoms – frequently before the patient has arrived at the hospital. Those grim statistics can be improved by adopting advanced algorithms that provide detailed diagnostic information leading to earlier care. In fact, the move toward adopting technology to provide very rapid, diagnostic information improves real-time decision support and is becoming essential. Research clearly shows that “smarter” diagnostic tools enable faster diagnosis and treatment of heart attack patients, yielding two key benefits: improved patient care and reduced costs.

Increasingly, healthcare facilities are adopting the American Heart Association/American College of Cardiology recommended guidelines that call for a Door-to-Balloon (D2B) time of 90 minutes or less for STEMI (ST-Segment Elevation Myocardial Infarct) patients. Results are so positive that the 90-minute Door-to-Balloon guidelines may soon become the U.S. standard of care. One innovative company, Philips Healthcare, has developed an easy-to-use ECG processing algorithm that allows clinicians to quickly reach a more accurate diagnosis. This diagnostic information will soon be able to be transmitted from the ambulance before the patient even arrives at the hospital, helping to assure that the emergency department and cath lab receive the information needed to prepare and plan for the procedures required when the patient arrives. This improves care and can improve patient survival, helping hospitals achieve their D2B goals.

Need for Improved Diagnostic Tools is Critical Cardiac misdiagnosis contin-



The New Philips PageWriter TC70 Cardiograph with DXL 16-Lead ECG Algorithm

ues to be a serious matter as statistics show that 11% of the more difficult to detect, right-side MIs are missed. Posterior MIs are also likely to be missed. Women in general are often misdiagnosed, as their cardiac symptoms frequently present differently from symptoms in men, who are more often studied in cardiac treatment trials.

Philips is addressing this important issue, according to Jeff Corliss, Philips Diagnostic ECG Marketing Director, by enhancing older, traditional 12-lead electrocardiograms (ECGs) so that they are more useful in identifying and triaging MI-patients needing urgent care. (See sidebar article on pg. 15).

The New Philips DXL 16-Lead ECG Algorithm Provides Better, Faster Diagnostics This powerful new diagnostic tool sets a new standard in ECG system design by speeding the identification and management of ST-Segment Elevation Acute Myocardial

Infarction (STEMI) patients. This latest “diagnostic engine” is the heart of the Philips PageWriter TC70, the newest Philips cardiograph. It will soon be integrated into the Philips HeartStart MRx defibrillators as well.

The DXL 16-lead algorithm is so named because it offers extended diagnostic capabilities (DX) combined with four extra leads (XL). It improves upon traditional 12-lead ECG interpretation by using 16-leads acquired simultaneously and presenting an expanded set of STEMI diagnostic aids in a readily usable format. The DXL algorithm, with its accurate, immediate interpretation of ECGs, is the engine that empowers faster emergency department (ED) triage of cardiac patients.

The New DXL ECG Algorithm Can Even Identify the Culprit Artery Sixteen-lead analysis uses extra leads placed on the right side of the chest – improving detection of right side MIs, and on the back – increasing detection

Faster Diagnosis Enables Door-to-Balloon Time Under 90 Minutes

Code STEMI – a major life crisis met with a powerful response in just 90 minutes. As cardiac care focuses increasingly on the fact that “Time is Muscle,” and loss of cardiac functioning happens very quickly, improved diagnostic tools are allowing hospitals to change the way hospitals work. The goal is both straightforward and challenging: 90 minutes from the heart attack patient presenting at the ED “door” to the delivery of effective treatment (balloon angioplasty or other therapy).

A Plan That Works Here’s how a coordinated approach could work. The patient presents at the ED complaining of chest pain. Immediately, a basic ECG is ordered. After applying 16-leads – including those on the patient’s chest and back – the ECG is collected and analyzed with a quick and simple, one-two-three push of buttons. Philips’ sophisticated new DXL ECG algorithm then presents results for immediate viewing. Information provided includes:

- STEMI-CA to point out the Culprit Artery causing the functional ischemia;
- Critical Values to identify conditions that require immediate attention;
- ST Maps to indicate the degree of ST abnormalities;
- Up-to-date criteria based upon the latest clinical research – including that for women’s health disease for 16 simultaneously acquired ECG signals.

ECGs collected by the Philips PageWriter cardiograph and HeartStart MRx defibrillator are transferred wirelessly to the hospital’s TraceMasterVue ECG system. ECG records can be automatically for-

warded both to the cath lab and to healthcare providers who need immediate access to this critical information.

Data Guides Treatments If the patient is transported to the cath lab, a balloon catheter (or catheters) is or are inserted to open blockages in the blocked or narrowed arteries that are responsible for the acute ischemia or infarct. The procedure is completed and, in many cases, the patient’s life has been saved. With streamlined protocols, it can all be accomplished within 90 minutes from the emergency department door to the cath lab balloon inflation.

Heartstart MRx Soon to Have DLX Algorithm After the new DLX algorithm is integrated into the Philips HeartStart MRx Monitor/Defibrillator, even more time will be saved because data gathered in the ambulance will be transmitted to the hospital’s ED and beyond, then confirmed back to the ambulance.



ECGs collected by the Philips PageWriter cardiograph and HeartStart MRx defibrillator can be automatically forwarded to the cath lab by the Philips TraceMasterVue.

This will allow hospital physicians to examine the ECG report, compare it with previously available ECGs and determine whether angioplasty is indicated. If so, the ambulance staff will be alerted to take the patient directly to the cath lab upon arrival – bypassing the ED (triage time and delays) entirely.

The EMTs will continue to monitor and transmit cardiac function data, as the hospital staff prepares the cath lab to perform the exact procedure indicated by the ECG information being transmitted. The earlier diagnostic information made available in real-time provides enhanced diagnosis and faster delivery of life-saving therapy.

DXL Accommodates Latest Pacemaker Advances Accurate identification of pacemaker spikes is critical for the accuracy of any ECG algorithm. From 2 to 5% of patients who have routine diagnostic ECGs already have implanted pacemakers. As pacer and ICD technologies have developed, ECG technology must also evolve to keep pace with the variety of atrial, ventricular, and A-V sequential pacing modes found in currently marketed pacemakers.

The new DXL algorithm, through use of a sophisticated noise-adaptive pulse detector, is incorporated in all leads. The multiple leads then together differentiate true heart pulses from pacemaker noise.

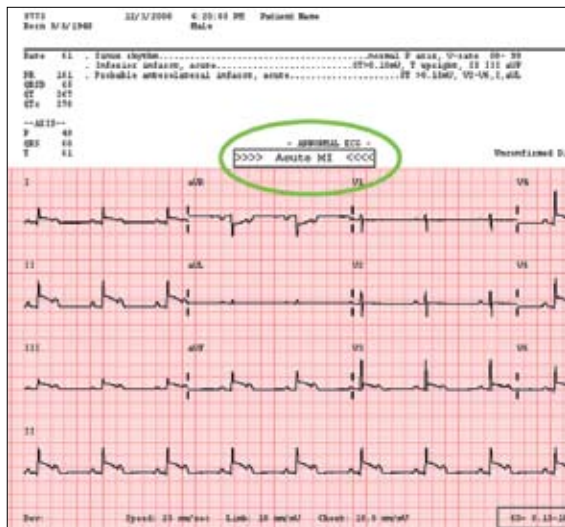
If the patient is conscious and able to report that he/she has a pacemaker, the algorithm pulse detector sensitivity can be increased to improve detection of even extremely small pulses. It can also analyze pacemaker pulse locations in order to classify a variety of pacemaker rhythms and to distinguish them from non-paced beats.

of the frequently-elusive posterior infarction, as well as enhanced interpretation of adult chest pain. This is vital for faster triage in the emergency department. This 16-lead technology not only helps to improve diagnosis and save lives, it can also contribute to improving productivity and speeding ED workflow since it eliminates the need to take, and interpret, multiple

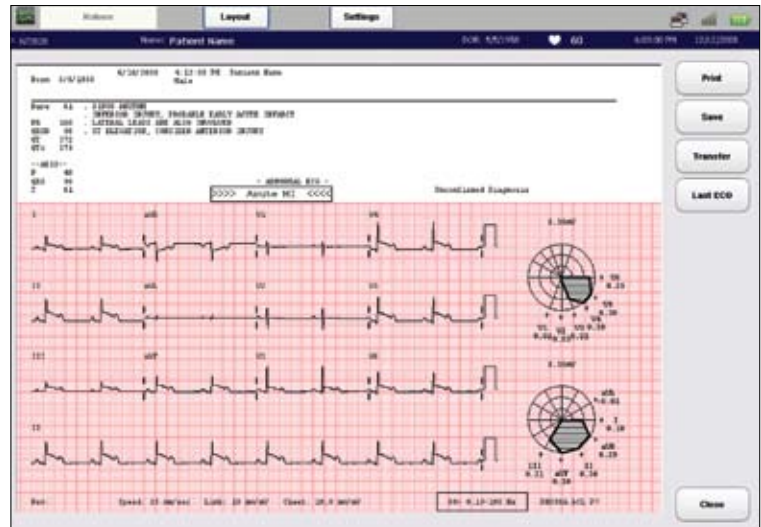
ECGs, each done with a smaller number of leads available on conventional 12-lead cardiograph architectures.

For STEMI patients, the DXL ECG algorithm can even identify the culprit artery or probable anatomical site causing the functional ischemia. This can help pinpoint the offending lesion when multiple obstructions are

present. The DXL algorithm’s patent-pending STEMI-CA technology can highlight the culprit artery – left anterior descending (LAD), right coronary (RCA), left circumflex (LCx), and left main or multi-vessel disease (LM/MVD) – when making initial diagnosis, which facilitates faster diagnosis. It provides the basis for admitting the patient directly to the cath lab, avoiding ED



Critical Values indicate on the display and on the record those ECGs that need immediate clinical attention.



The ST Map, shown here on the display of the new PageWriter TC70, provides for a rapid assessment of the location and degree of ST abnormalities.

triage delay, and can potentially help optimize treatment protocols reducing Door-to-Balloon time and Door to Cath time. It can also be vital in diverting patients who will need a balloon procedure before they arrive at hospitals that don't offer rapid cath services.

Critical Values Pre-Sort Data to Speed Diagnosis The Philips DXL algorithm pre-sorts 30 life-threatening interpretive statements into four key areas, or Critical Values that include: acute MI, acute ischemia, complete heart block, and very high heart rate. These are highlighted visually on screen as well as on printed ECG reports. This simplifies the process for ED personnel, EMTs, and other caregivers without special-

ized cardiology-interpretation training, alerting them to seek appropriate medical consult quickly and begin treatment even before the patient arrives in the emergency department.

Other Key Benefits Include Unique (Patented) ST-Maps ST-Maps (shown upper right) are designed to provide a fast visual snapshot of ST-vectors in both the frontal and transverse plane views in "Cabrera sequence" to emphasize spatial orientation. This enhances rapid assessment of the location and degree of ST-abnormalities. Distinct patterns for different anatomic sites of infarcts, global ischemia, pericarditis and other conditions can easily be spotted from these maps.

The DXL Algorithm Helps Users Respond to D2B Pressures With the Door-to-Balloon clock ticking, the DXL ECG algorithm is a unique tool because with a single glance at the Critical Values, the clinician knows if there is a need for immediate clinical attention. If the patient is admitted to the ED, the Critical Values statement information allows the cardiograph operator/nurse to alert cath lab and other staff to activate D2B processes. For the patient in the ambulance being transported to the hospital with a DXL-algorithm defibrillator, Critical Values allows the EMT to notify the hospital of the patient's ST-status by transmitting the detailed ECG report

Philips Has a Long History of Innovation with Algorithms for Diagnostic Use

Philips acquired the former Hewlett-Packard Medical Products Group that pioneered the development of computerized ECG data analysis, and began work on design of specialized diagnostic algorithms in the late 1960s. That effort accelerated in the 1970s. In 1978, Philips introduced its first multi-lead, 12-lead analysis program, the first-in-field among the major cardiology companies.

Philips has continued to lead in ECG analysis, with significant innovations and firsts in serial comparison, gender-specific analysis, pediatric analysis, pacemaker detection, sophisticated QT analysis, and support of the XML data format. In the course of that effort, a specialized ECG lan-

guage – ECG Criteria Language (ECL) – was developed. This, in turn, encouraged broader participation and speeded development of sophisticated algorithms.

This long history of innovation is reflected today in the Philips DXL ECG algorithm, with its expanded analysis capabilities, which include the much-in-demand ability to help reduce Door-to-Balloon Time.

The DXL Algorithm Continues Philips' Tradition of Providing Gender-Specific Algorithms It has been recently recognized and confirmed that frequently women present with chest pain – but without the significant discrete lesions that are

readily visible in the cath lab. This recognition has resulted in addition of new criteria for "acute global ischemia," in the DXL algorithm. The addition is crucial since the acute global ischemia diagnosis can be difficult to make from angiography data alone. Philips has been incorporating gender-specific data (including gender, age, and lead limits for improved detection of a silent MI) into its multi-lead algorithms since 1978 and has continually enhanced this data based upon continuing research. Similarly, STEMI criteria are subject to reduced ST limits in women. The new global ischemia criteria are part of this ongoing focus on gender-specific data.

so treatment preparations can be initiated before the patient even arrives. The first responder in the ambulance and the clinician in the ED can both look at the same ECG in reaching a patient care decision.

The 16-lead interpretation provides left, right and posterior heart information from a single exam on a single report supporting faster workup and increased sensitivity. Enhanced STEMI criteria help assure that the distinctive presentation of STEMI in women is recognized and not overlooked. The ECG algorithm features updated nomenclature and statements that reflect current AHA recommendations.

The powerful DXL 16-lead ECG algorithm is incorporated into a new cardiograph Philips is demonstrating at fall trade shows, like the American Heart Association (AHA) meeting.

The PageWriter TC70 offers a 15-inch touch screen display, illuminated 1-2-3



The Trident lead system unites three lead wires to reduce tangling & reversals.

buttons, new signal quality indicators that work in conjunction with the DXL 16-lead algorithm to significantly speed workflow, not only in the ED but everywhere throughout the hospital that ECGs are captured. More than ever before, improving the bottom line is top priority for every department manager and hospital administrator, and an investment in the PageWriter TC70 Cardiograph with the DXL ECG algorithm will drop real dollars to the hospital's bottom line.

This starts by enhancing staff workflow efficiency at the point of care. The highly automated TC70 significantly reduces ECG collection and processing time. Its ease of use begins with its new anatomic Patient Input Module, designed for intuitive use.

Lead wires emanate in the direction where leads need to be placed, and are designed to match the patient's body, with the leg leads longer than the arm leads. The PageWriter's new lead wires are also easy to use in the dark. In addition, the chest leads have



Start ECGs using the large touch screen, the keyboard, or the Patient Interface Module (by a tap on the green button).

been reorganized as two, easy-to-place sets of three leads each, eliminating time spent untangling chest lead wires.

Easy-to-Use Continues with a Simple Three-button Process Philips made it easy to obtain an ECG with a process that can be mastered in minutes. Long hours spent teaching staff to use the cardiograph are reduced. Increased productivity means fewer new hires required as test volume increases.

Button One, Map The cardiograph user simply has to touch "Map" to identify lead placement and to ensure that there are no loose or missing leads. Color-coded waveforms on all 16-leads indicate if and where there are signal quality issues.

Button Two, ID Shown on page 18, the clinician touches "ID," and uses the keyboard and menus (or, even faster, a barcode reader) to enter patient information. Alternately, the user can select the patient's order information from the "Work List" tab, and information is automatically placed on the ECG.

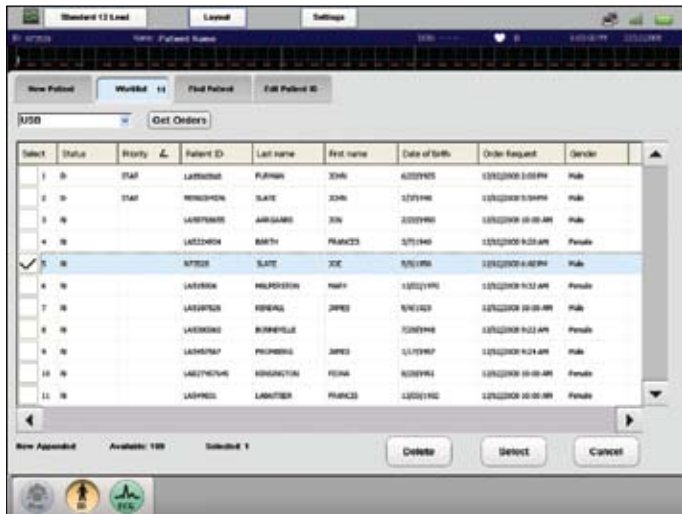
Button Three, ECG Once all leads are attached the user simply presses the "ECG" button. Alternately, the



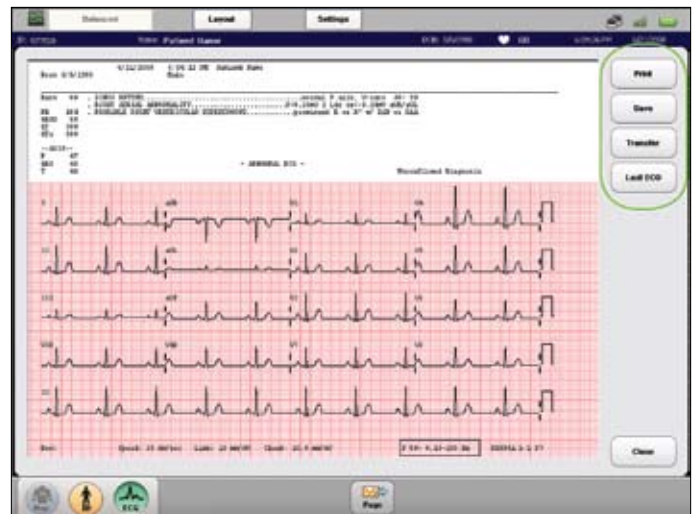
A compact user-friendly mobile cart gets the TC70 to any patient location.



User-friendly illuminated buttons speed workflow.



Button Two, ID: The clinician touches “ID,” and then uses the keyboard and drop-down menus or, even faster, a barcode reader, to enter patient information.



Button Three, ECG: Simply press the “ECG” button and the ECG will be acquired.

clinician can press the green button on the Patient Input Module (shown above) to acquire the ECG.

Automatic Lead Reversal Detection
If there is a lead reversal, Philips’ patented LeadCheck software will display a pop-up alert, telling the clinician to check (one of 19) possible lead reversals.

New Full-Disclosure Mode In addition to accelerating capture of routine diagnostic ECGs, the PageWriter TC70 supports specialized ECG needs. The DXL’s highly-specific clinical information immediately provides critical decision support data at the point of care, facilitating urgent medical treatment in those all-important minutes following a critical heart event. Both the DXL 16-Lead ECG algorithm technology and the new PageWriter TC70 cardiograph combine to speed and improve evaluation and treatment decisions. Together they provide a powerful catalyst to help reduce Door-to-Balloon times – increasing the possibility of a positive outcome.

The TC70 PageWriter’s Full-Disclosure mode allows continuous recording of up to 20 minutes of ECG waveforms

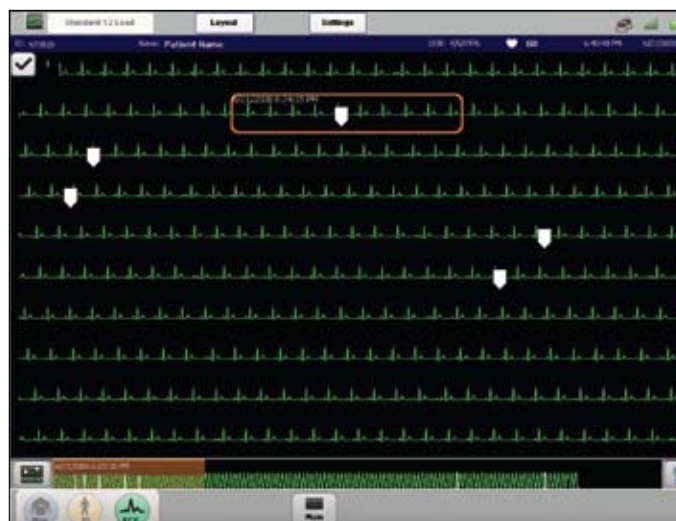
in all 16-leads simultaneously. This Full Disclosure option allows a clinician to obtain a more in-depth study and to quickly mark up to 15 different cardiac events for later review with a single touch of the screen.

Immediate Feedback Where You Need It The ECG report is immediately available for preview. Once accepted, it can be printed and saved to the internal ECG archive, and/or transferred wirelessly to Philips’ TraceMasterVue ECG Management System. Once transferred, the clinician may opt to retrieve the most recent previous ECG for comparison. Since previous

ECGs can be of crucial importance to cardiologists, the PageWriter’s capability to pull up previously-interpreted ECGs is critical for rapid patient triage. Previous ECGs can be retrieved automatically or be made available with a single click.

TraceMasterVue Automates Processing, Storage and Distributing of ECG Data The TraceMasterVue system automatically performs record keeping that previously consumed many staff hours. Typically, the 10-minutes spent taking an ECG is followed by other personnel assuring that the ECG order was correctly recorded and the ECG procedure was properly billed. If that last step is skipped, the lost reimbursement has a major impact on the organization’s revenues.

Bottom Line The TC70 is one of the most versatile and productive cardiographs that has yet appeared in the U.S. market. It is not only an advance in technology but can be life-saving when used as part of the hospital’s D2B program. Δ



TC70 PageWriter’s Full-Disclosure mode - Quickly mark up to 15 different cardiac events for later review with a single touch of the screen.