Managing ECG workflow your way

Philips IntelliSpace ECG
Release A.01

Product description
IntelliSpace ECG is an advanced clinical data management solution that automates the processing, storage, and distribution of ECG data acquired from multiple sources across enterprises large and small. The system provides a rich set of software applications to analyze, view, edit, and compare ECG records, as well as generate, manage, and distribute reports in various formats to meet specific needs.

Multi-modality support
IntelliSpace ECG is an integral part of the clinical environment, starting with its multi-modality interfaces to a variety of ECG data sources. These include not only cardiographs, but also stress and Holter systems and nontraditional sources such as patient monitors, telemetry systems, and defibrillators.

Multi-vendor interfaces
Recognizing that institutions frequently have an installed base of a variety of ECG solutions from multiple suppliers, IntelliSpace ECG can interface directly with third-party solutions as well.

Enterprise interoperability
The system allows access to records from in-house networked standard PCs, other web-enabled client computers and workstations, and non-traditional clients such as cardiographs and monitors. Access can be from almost anywhere, whether in the remote clinic or home office, or even out-of-office via common mobile devices.

Enhanced ECG review
Stacked and side-by-side views allow ready comparison of a current ECG with previous ones.

Interoperability with hospital information, order management, ADT and departmental solutions can be managed via IntelliBridge Enterprise, a single flexible platform for bi-directional communications.

IntelliSpace ECG can also establish active bi-directional communications with the PageWriter TC-series and Touch cardiographs. Order worklists can be downloaded, demographic files retrieved, and time synchronized with institution network time. The PageWriter TC-series and Touch cardiographs can retrieve previous ECGs or lists of ECGs automatically, for ready reference at the point of decision. With the Philips IntelliVue Patient Monitoring System, IntelliSpace ECG can provide for not only acquisition of ECGs, but also fast access to previous ECG records.
Workflow Management
In addition to providing enhanced ECG viewing, measurement, and editing tools, IntelliSpace ECG provides sophisticated Workflow Management software, enabling a high level of automation for routine tasks from overreading and editing to emailing and faxing, to report export, results reporting, and distribution.

Scalable architecture
IntelliSpace ECG moves away from the proprietary platforms associated with older systems. The software architecture is built on industry standards and uses a state-of-the-art three-tier software design allowing for considerable scalability, from the cardiology clinic to the large, multi-facility medical enterprise, from 1000 to 1,000,000 ECGs annually.

The software-only solution can support distinct configurations, including customer-supplied hardware and virtual environments, supporting institution IT standards. Blade server and virtual machine support can provide for ultimate flexibility and scalability with modular application expansion, full redundancy for high availability, and automatic seamless failover functionality.

The extensive use of industry standards and implementation of state-of-the-art design provides IntelliSpace ECG the scalability, high availability, interoperability, and security capabilities that are increasingly in demand, but were not readily available in the past with older, proprietary designs.

Features

12- to 16-lead ECG acquisition
• Cardiographs, including:
  – Philips PageWriter TC70, TC50, TC30, and TC20 cardiographs, in XML format, via LAN, wireless LAN, modem, or USB memory stick
  – Philips PageWriter Touch, in XML format, via LAN, wireless LAN, modem, USB memory stick, or 3.5” disk
  – Philips PageWriter Trim II and Trim III, in XML format, via LAN, wireless LAN, modem, or USB memory stick
  – Philips PageWriter XLI via modem or 3.5” disk
  – Third-party cardiographs (optional); ECGs converted from proprietary to XML format
• Wireless LAN access
  – Via industry standard 802.11 using existing enterprise infrastructure
  – Cisco CCX v4 certified authentication and encryption protocols for secure communication with PageWriter TC70, TC50, and TC30 cardiographs over 802.11b/g wireless network
  – No dedicated or optional system interfaces required
• Inpatient monitoring locations including:
  – Philips IntelliVue patient monitors, in XML format, through the IntelliVue Information Center via LAN
  – Philips Telemetry, in XML format, through the IntelliVue Information Center via LAN
• Pre-hospital locations from
  – Philips HeartStart MRx monitor/defibrillators through the HeartStart Telemedicine Server via LAN
  – Third-party defibrillators (optional)

IntelliSpace ECG Three-Tier Architecture

Scalable software and hardware architecture
Three-tier software architecture and modular system components allow for scalability of client, application, and database layers to meet the current and future needs of any size enterprise.

1. Specific features may be optional based upon configuration.
Multi-modality report acquisition
• Philips Holter system in vector PDF format
• Third-party Holter systems in PDF format (optional)
• Philips ST80i Stress Testing System in vector PDF format
• Third-party stress systems in PDF format (optional)
• Reports from other modalities in PDF format (optional)

Order worklist and demographic information acquisition (optional)
With the optional Orders Management application and IntelliBridge Enterprise integration, IntelliSpace ECG supports:
• Transfer of order worklists and associated patient demographics to PageWriter Touch and TC-series cardiographs based upon specific institution-defined protocols and extensive cardiograph configurability
• Worklist transfer via:
  – LAN, wireless LAN, USB memory stick for PageWriter TC-series and Touch cardiographs
  – USB memory stick for PageWriter Trim II and Trim III cardiographs
• User-initiated search for specific orders from PageWriter TC-series and Touch cardiographs
• Support for HL7 orders
• ADT update to orders included with HL7 orders application

ADT interface and demographic information acquisition (optional)
ADT functionality is also optionally supported, in conjunction with order worklists or independently to support local requirements.

Cardiograph query and system communication support
With PageWriter TC-series cardiographs, IntelliSpace ECG supports advanced system interactions including:
• Pre-configured retrieval of order worklists, based upon location, user, time windows, order status, and other order characteristics
• Ad hoc query for specific order or worklist based upon user requirements
• Query for specific order and/or demographic information
• Automatic retrieval of previous ECG or list of available ECGs for current patient for immediate display and printing
• Retrieval of selected ECGs for display and printing
• Synchronization of cardiograph time with system network time

Departmental ECG access and management
ECGs are typically reviewed and edited using a web-based client application utilizing Microsoft .NET technology:
• No pre-loaded proprietary software is required
• Standard capability; no additional charge for remote access application
• Number of concurrent users limited only by performance and network access

The IntelliSpace ECG client application provides for easy and secure access from:
• Standard PCs on the enterprise network
• PCs from remote site with access to the enterprise network
• ECG report bar coding facilitates rapid retrieval of specific ECGs with optional bar code reader
• Additional Advanced Search function for searches by criteria such as ECG type, severity, source, and up to eight user-defined fields
• Ability to select ECGs for batch processing, such as editing, printing, faxing, and confirming

With the optional Order Management application:
• Integrated Quick Search and Advanced Search provide for listing of ECGs without matching order and fast color-coded assessment of current order reconciliation status
• Specialized integrated Order Search functionality provides fast management access to current orders workflow status
• Simplified reconciliation of an order to an ECG record speeds workflow; can be automatic when order number transferred with demographics from cardiograph
• Fast look-up of order and demographic information from within client application
  – Criteria for order match set by individual institution requirements
  – Automatic transfer of information to current ECG record upon confirmation of match

Multi-modality and multi-vendor support
In addition to ECGs, IntelliSpace ECG systems support review, addition of cover notes, and electronic sign-off of Holter and stress studies, including studies from third-party solutions.
Enhanced ECG waveform review options, including:
• Tab format for rapid access to previous ECGs and multi-modality reports
• Stacked or side-by-side presentation of previous ECGs with selected “anchor” ECG
• Wide variety of waveform formats in addition to acquired format, including 12x1 and overlapped averaged beats with annotated measurements
• Ability to select specific filter settings regardless of filter settings at acquiring PageWriter cardiograph
• Zoom and on-screen calipers
• Stored user preferences for display format

Enhanced on-line ECG editing capabilities, including:
• “Type-ahead” functionality for rapid access to codes, associated statements, and modifiers
• Custom codes to speed addition of interpretive statements
• User-defined favorite codes and statements enhance editing
• Code and statement “aliasing” permits use of institution-defined codes and statements to replace default settings
• Stored user preferences for standard search, report format, codes, workflow options
• "Hot keys" for rapid access to standard functions
• Edit from a variety of user selectable screens
• Analysis performed automatically via workflow rules or as selected by the user
• Serial comparison performed automatically via workflow rules or as selected by the user; undo feature available
• Electronic signature applied when the overreading physician is logged on and is confirming ECGs online
• Stored user preferences for standard search, report format, codes, workflow options

Multi-modality report access and management
Multi-modality reports can also be accessed and reviewed from the IntelliSpace ECG client. Product support for Philips’ solutions is standard, while support for third-party solutions is optional. Configuration and implementation services are additional charge.

Support for multi-modality reports includes:
• Report review, in patient context or by modality
• Fast look-up of order and demographic information from within client application (with IntelliBridge Enterprise)
• Simplified reconciliation of an order to a study speeds workflow (with IntelliBridge Enterprise)
• Ability to add cover letter with comments and final conclusions; cover letter is integrated into final PDF report
• Electronic signature can be applied when the reviewing physician is logged on and is confirming

Mobility Support
IntelliSpace ECG supports mobility solutions, making time-sensitive ECG information available on a variety of common mobile devices including smartphones and tablet PCs.

Mobility Support
• ECGs can be viewed on mobile devices as vector PDF email attachments
• Emails can be generated automatically via Workflow Management or specific ad hoc request from PageWriter or IntelliSpace ECG clients
• Support for partner-supplied notification services and native ECG viewing apps for mobile platforms (optional)

Workflow Management
The IntelliSpace ECG system includes sophisticated Workflow Management software that provides for rule-based, automated handling of ECG records and multi-modality studies from acquisition and review through storage and distribution.

Multiple rules can be established on the basis of the ECG object “signature,” including:
• Acquiring institution, facility, or department
• Source of ECG, such as cardiographs, monitors, defibrillators, stress and Holter systems, and telemetry
• Type of ECG, such as 12-lead, 16-lead, or EASI format
• Pediatric or adult ECG
• State, such as new or confirmed
• Critical Values
• Priority and severity
• User-defined values and attributes from up to four user-defined fields
Based upon the above signature, rules can provide for specific actions, including:

- Server-side analysis, for example for ECGs from third-party ECG devices
- Serial comparison
- Assignment to a specific “Inbox”
- Notification of receipt or copy of report via email
- HL7 messaging (optional), such as URL pointers, results, complete encapsulated reports
- Forwarding of reports to referring physicians
- Printing of reports at specified locations
- Anonymized printing of reports for teaching or research purposes
- Exporting of records in specified formats
- Faxing of reports

A central registry is maintained for physician email addresses and fax numbers.

**Workflow Management**

IntelliSpace ECG adds a high level of sophistication to workflow management. The flow of ECG records can be automatically managed via rules from the moment of acquisition, through the reviewing and editing process, to final storage and report distribution.

**Clinical functions**

- Philips DXL 12/15/16-Lead Algorithm (PH100B) supported
  - Provides analysis for 12- to 16-lead ECGs
  - Extended diagnostic and reporting capabilities for STEMI ECGs
  - Consistent with AHA/ACCF/HRS statement nomenclature recommendations (2007)
  - Consistent with AHA/ACCF/HRS ischemia and infarct recommendations (2009)
- Previous Philips Algorithm versions supported
  - Serial comparison
  - Supports 12- to 16-lead adult ECGs
  - Compatible with DXL and earlier Philips algorithms
  - Consistent with AHA/ACCF/HRS nomenclature recommendations (2007)
  - Compatible with selected third-party ECG devices (when used with DXL server-side analysis)
- Server-side analysis with DXL Algorithm
  - Automatic or upon approval when updated demographics could alter interpretation
  - Automatic or upon request when ECG analyzed by earlier version Philips algorithms
  - Can be used with selected third-party ECG devices to provide consistent DXL Algorithm across enterprise
- Fully integrated pediatric algorithm
- Display and storage for EASI ECG records

**Management reports**

- Over 20 pre-configured management reports
- Standard SQL report tools such as Crystal Reports (not included) can be used for custom management reports to meet specialized requirements
- Published data dictionary

**Security**

- SSL supported for secure LAN communications
- Cisco CCX v4 certified authentication and encryption protocols for secure communication with PageWriter TC-series cardiographs over 802.11b/g wireless network
- Access Control application provides for access to ECG records on the basis of:
  - User classification (12 user types)
  - Specific institution, facility, and department
  - Specific activity (17 types, including editing and record export)
- Secure user log on and password management integrated with Microsoft Active Directory security model
- Support of “pass through authentication”
- Active Directory can be integrated with enterprise security model for single sign-on
- Automatic log-off when client application is idle for user-defined period
- Audit trail and transaction log record events by user, date, time, and activity; logs cannot be edited
- Back-up and anti-virus applications can be consistent with enterprise IT protocol
- Additional features included to assist in establishing enterprise protocols to support HIPAA, 21 CFR Part 11, and other security and privacy mandates
Enterprise support
IntelliSpace ECG is designed to be scaled from the clinic, to the community hospital, to the larger distributed enterprise, including multiple hospitals. Among the software applications that are supplied to support the distributed enterprise:

• Three-level hierarchy of locations (Facility in addition to Institution and Department) to allow for the tailoring of workflow and security to meet specific requirements
• Isolation of ID numbers at multiple Institutions and Facilities, allowing redundant use of ID numbers without commingling of the records of distinct patients
• Three-tier software design that supports expansion of the system to support increasing throughput requirements for performance and high availability

Interoperability
IntelliSpace ECG is designed to work within the interconnected hospital enterprise. Using standard integration tools from HL7, the system can interoperate with third-party EMRs, HIS, customer portals, and departmental systems. For further information please refer to the IntelliBridge Enterprise Technical Datasheet.

Connected Cardiology
Our streamlined, interfaced solutions give you the power to manage the workflow and clinical and administrative records for the cardiovascular service line.

• Philips Xcelera
  – ECG, stress, and Holter reports can be included with the report listing
  – Individual records can be retrieved via web API for viewing within the Xcelera patient context
• Philips IntelliVue
  – Previous ECG records can be viewed at the IntelliVue patient monitor and Information Center

Pharma application
The Pharma application (optional) merges specialized clinical research capabilities with the proven ECG record management capabilities of IntelliSpace ECG.

Among the incremental capabilities:

• Specialized trending displays for rapid assessment of QT changes
• Efficient extraction and export of files associated with a study
• Generation of HL7 V3.0 “annotated ECG” records for FDA submittal
• Additional XML schema enhancements to provide for enhanced quality reports
• Expanded Access Control application to support tighter process control
• Support for the archiving of records from over 100,000 distinct studies

An additional Pharma option provides the CalECG application, an integrated high-resolution, industry-proven measurement and annotation tool.

Storage

• Standard storage capacities
  – 10,000 to 10 million ECGs
  – Expandable
• Single enterprise-wide relational database stores all ECGs in native SQL format
• Published XML schema
• Stored ECG records include:
  – Full fidelity, 500 Hz, 12 lead by 10 second waveform data; ECG waveform is not downsampled for storage purposes
  – Averaged beats for 12/15/16 leads
  – Extended measurement matrix
• GUID (Globally Unique Identifier) associated with each ECG record serves as surrogate key preventing storage of redundant records
Documented XML protocol
Unlike older proprietary systems, IntelliSpace ECG acquires, stores, and exports ECG records in an XML format – even if those records are from third-party cardiographs.

ECG record export
• ECG records sent to designated networked HP LaserJet printers for non-fade records
• Fax output to any Group III fax device over a dial-up phone line for convenient communication of patient results
• Attachment to email for ready access from remote and mobile solutions
• XML ECG document generation; can include demographic data, report, and complete 500 Hz waveform with annotated representative beats
• TIFF report generation
• Vector PDF report generation
• HL7 V2.3 support (optional) allows ECG data to be exported to support orders, billing, results reporting (textual and waveform), and EMR integration
• HL7 V3.0 support (optional) allows ECG data to be exported for clinical trial purposes
• Customized HL7 message export (optional)
• Native DICOM export for access or storage in PACS (optional)
  − 12- to 16-lead ECG records
  − SOP Classes: 12-lead ECG Waveform Storage and General ECG Waveform Storage; IHE REWF compatible
• Enterprise Manager application provides ability to bulk export large numbers of ECGs meeting user-specified criteria (location, user fields, etc.)

System specifications
Application software
IntelliSpace ECG is supplied as an application software-only solution for implementation on the customer’s IT platform. The solution can be installed on a “tower” or blade server. The solution is also validated for use within the VMware ESXi Version 5 environment.

Full minimum and recommended specifications for specific software solutions are documented separately. The minimum environment is validated prior to software installation.

Test server software
Available at no charge is a test server software license in the same configuration as the production system for use on customer-supplied hardware.

Server hardware
Also available are base server configurations for those customers requiring a single provider for the complete system. For further details please reference the hardware specifications at www.philips.com/IntelliSpaceECG.

Client requirements (minimum)
• 500MHz Pentium III PC with 512MB RAM
• 4GB internal hard disk drive
• 100 Mbps network interface
• 17-inch SXGA display (recommended minimum resolution of 1280 x 1024)
• Microsoft Windows XP Professional or Windows 7 Professional
• Microsoft Internet Explorer 6.0 or higher

Clients are also validated for use in a Citrix environment, XenApp 6.0 or later.

Network requirements
• 100 Mbps network
• Single interface supports all LAN and wireless LAN access requirements

Phone line requirements
Dedicated analog phone line connections are necessary to support the following:
• FAX transmission capability (modem not included)
• Port for ECG acquisition via modem if LAN not used (modems not included)

Documentation
On-line help is provided for the client application. Comprehensive documentation and training materials are provided on CD-ROM and on-line.
Localization
Localization covers the client applications and Instructions for Use.

Regulatory
System hardware is certified to appropriate standards for information technology (IT) equipment.

Implementation
Project management and implementation services are required and quoted separately, based upon specific customer needs. The following services are typically included in the base implementation services package:

- Dedicated project manager
- Implementation planning service
- System software configuration
- System administrator training
- Train-the-trainer workshop for client end users and training for technicians, physicians, and overreaders
- Transition of site to Philips support organization

Additional implementation services include:

- Services and training for additional sites and multiple campus installations
- Additional days of on-site user training
- Additional workflow consultation services
- Setup of additional printers
- Network testing and validation
- Customized report preparation
- Custom code configurations
- HL7, web API, and DICOM communications planning and configuration
- Implementation services for optional capabilities, including order worklist, multi-modality, multi-vendor, and high availability solutions

Ordering information
- 860426: IntelliSpace ECG software application
- 860289: ECG Migration Services
- 860331: IntelliBridge Enterprise Interoperability Solutions (DECG)
- 866183: ECG Mgmt Connect License

IntelliSpace ECG is configurable and scalable to meet specific user requirements. Note that some options may not be available in some configurations. Consult with your local specialist for specific configuration information.

System upgrades
Multiple upgrade paths are available for existing users:

- Legacy TraceMaster and TraceMasterVue systems can be upgraded to IntelliSpace ECG
- Legacy third-party systems can also be transitioned to IntelliSpace ECG
- IntelliSpace ECG systems can be expanded to meet increased capacity and site requirements
- Upgrades can be supported on a variety of server platforms or virtual environments

ECG file migration
ECG files from legacy systems (including third-party systems) can be migrated to IntelliSpace ECG for continued access and use.

* Currently available with Mobile ECG Apps in North America only.

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