

PHILIPS

Cardiology

PageWriter TC35

In touch with you

Advanced yet easy to use, the PageWriter TC35 is an affordable and compact solution that can grow with you as your workflow needs evolve. Native DICOM modality worklists can be downloaded or ADT information retrieved, providing patient demographics at the bedside. ECG reports can be wirelessly exported using 802.11 b/a/g/n/ac WiFi 5 speed and WPA3 (Personal and Enterprise) wireless data security to an electronic medical record. With advanced systems communications, the previous ECG can be automatically retrieved at the bedside. PageWriter's native DICOM interoperability provides direct access to ECG orders from your current DICOM MWL provider and storage of resulting DICOM format ECGs to your existing PACS. The result – a fast, efficient clinical workflow with reliable operation for you and your patients.

Key advantages

- Fast 1-2-3 operation with touchscreen and light-guided buttons
- Streamlined workflow with wired and WiFi 5, WPA3 (Personal and Enterprise) wireless connectivity via HL7, XML, and native industry standard DICOM
- Exceptional clinical decision support with DXL Algorithm



PageWriter TC35 Cardiograph (860437)

Features

Regulatory Clearances

EUMDR Clearance / 2023

CE Marked

FDA 510(k) Clearance 2022

ECG Functions

Simultaneous lead acquisition 12 leads

ECG reports 3x4, 3x4 1R, 3x4 3R, 3x4 1R plus ST maps, 6x2, 12x1 Standard and Cabrera formats, plus Pan 12 Cabrera

Standard measurements (D03) • Ten interval, duration, and axis measurements
• Configurable QT correction methods

Rhythm strips • Up to 12 configurable leads
• 30 to 60 sec. 12-lead rhythm strip export (XML)

Disclosure (D05) • Five-minute history of all 12 leads
• Complete ECG report of any selected 10 seconds

Event marking (D05) • Six independent events can be marked for later review and analysis
• Event markers appear on ECG reports
• Note can be added for each event

Timed ECG Support for pharma stress protocols

Report storage and transfer Full fidelity at 1000Hz of 10 seconds for all 12 leads

Export Data Formats • PDF
• XML
• DICOM 12-Lead ECG
• DICOM General ECG
• DICOM Encapsulated PDF

Pace pulse detection • 0.02 mVms (e.g., 0.2mV*0.1ms pulse or 0.1mV*0.2ms pulse)
• Exceeds proposed standard by 5X¹

Wireless Patient Interface Module (WPIM)

Number supported • Up to 2 WPIMs per Workstation
• Selectable from Workstation
• Mix and match with wired PIMs

Range • 15 m (49 ft) unobstructed

Lead wire connectors • 3 mm and 4 mm pin-ends for tab electrodes

Use models • Patients under precaution
• Workflow management

DXL ECG Algorithm^{2,3,4} (D03)

Interpretive statements • > 600 interpretive statements
• Integrated pediatric analysis

Borderline statement suppression Three configurable settings

Nomenclature Aligned with 2007 AHA/ACCF/HRS Recommendations, Part II

Extended measurements • 46 measurements of morphology analysis in each of the 12 leads
• 21 parameters of rhythm analysis

Reasons Selectable explanations of all interpretive statements

STEMI Diagnostic Aids (D03)

Graphical ST presentation • Two ECG reports with polar ST Maps
• Frontal and transverse planes

Age and gender criteria Based upon Fourth Universal Definition of Myocardial Infarction, 2018

STEMI-CA (Culprit Artery) • Criteria that suggest any of four probable sites of the occluded coronary artery
• Based upon 2009 AHA/ACCF/HRS Recommendations, Part VI

Critical Values Highlights four conditions requiring immediate clinical attention

QT measurements (D03)

QTc measurements • Bazett
• Fridericia
• Hodges
• Framingham

Correction of QT interval & QRS duration Rautaharju

Advanced Bi-directional Network Communications⁵

Central time management Time can be manually or automatically synchronized to a Network Time Server

Orders worklist (D01) • Download orders worklist from up to 128 inboxes
• Configurable workstation-specific worklists
• User-configurable lists (e.g., by location)
• Ad-hoc order query based on multiple search criteria (e.g., patient ID, last/ first name)
• Open Worklist with IntelliBridge Enterprise and select departmental systems
• HL7 interface via IntelliBridge Enterprise
• DICOM Modality Worklist

ADT (D02) • Query and retrieval of patient demographic information
• Based upon user-entered or scanned search criteria (e.g., patient ID, last/first name)
• Supported by standard HL7 interface via IntelliBridge Enterprise for hospital systems

Previous ECG reports (requires Intellispace ECG) Automated retrieval and display of multiple previous ECG reports for comparison with current ECG report

DICOM ECG report output (D08) • DICOM 12-lead ECG
• DICOM General ECG
• DICOM Encapsulated PDF

Privacy and Security

Password framework • Role-based

User authentication AD/LDAP

Data encryption at rest SHA-256 and AES-128

Network access Initiated by cardiograph only

Network communications TLS 1.2 or greater for communications within hospital network

Security configuration capabilities behind customer-defined password • USB port access (on/off)
• HTTP, HTTPS
• Encryption at rest (on/off)
• Delete archived ECG after transfer (on/off)
• User Authentication (on/off)
• FTP/SFTP
• Secure DICOM
• Consistent security approach across Cardiac Workstations and PageWriter TC-Series Cardiographs

Domain user accounts Lightweight implementation for domain user accounts not defined on the TC35

Device Management Dashboard

Fleet Management	<ul style="list-style-type: none">Centralized Management of fleet configuration and software revisionsIn-scope solutions: PageWriterTC20/TC30/TC35/TC50/TC70, SureSigns VS3/VS4, EfficiaCM10/CM12, Efficia CM100/CM120/CM150, EarlyVue VS30Cardiac Workstation verified to Dashboard A.02.02, planned for release Q4 2024
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Signal Quality Indicators

Leads-off advisory	Anatomical lead map displays the location and label of loose or disconnected leads/ electrodes
Lead color	Four colors to indicate quality of individual leads
LeadCheck	Lead-placement software detects 20 different lead reversals
Heart rate	Continuous display of patient heart rate
Print preview	Full-screen preview of ECG waveforms prior to printing and/or export

User Training and Self-help

Training mode	Integrated waveform simulation
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User Interface

Touchscreen	<ul style="list-style-type: none">1-2-3 operationFive-wire, resistive touchscreen
Keyboard	<ul style="list-style-type: none">Backlit 1-2-3 buttons65-button, standard full alphanumeric keyboardSpecial characters supported
Membrane keyboard cover	Silicone-based flexible cover protects keyboard from particulate and liquid ingress

Trolleys (860352, 860353)

Height-adjustment	<ul style="list-style-type: none">860352: Fixed height860353: Adjustable height (25 cm)
Fleet coverage	Above trolleys also compatible with: <ul style="list-style-type: none">Cardiac Workstation 7000Cardiac Workstation 5000PageWriter TC70PageWriter TC50
Wheels	<ul style="list-style-type: none">All 4 wheels lock and swivelAnti-static conductive caster
Desktop	Open desktop workspace
Storage	<ul style="list-style-type: none">Standard storage for 400 extra ECG paper sheetsStandard storage for cleaning wipes/gloves/ electrode gel/gauze, etcOptional concealed drawerOptional closable waste binOptional wire basketOptional hanging leadwire holder

Technical Specifications

Display

Size	6.5in TFT active matrix
Resolution	640 × 480 VGA
Colors	64K colors
Screen adjustability	18 degrees tilt

Patient Connections

Integrated lead set	<ul style="list-style-type: none">Defib-protected ECG acquisition provides 1µV resolutionAcquire data at 8,000 samples per second, per lead wire
Long lead set (H23)	Extended-length lead wires enable greater distances between the cardiograph and the patient connections

End Connectors (Adaptors)

Welsh bulbs (E04)	Six Welsh bulbs and four limb clamps
Snap/Tab adaptor (E06)	Fits both snap and tab electrodes with metal on both sides
Other compatible adaptors	Compatible with 4 banana adaptors, 3 wide mouth adaptors

Printer

Resolution	<ul style="list-style-type: none">High-resolution, digital-array using thermal-sensitive paper200 dpi (voltage axis) by 500 dpi (time axis) at 25 mm/sec
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Connectivity

LAN	10/100 Base-TX IEEE 802.3 ethernet via on-board RJ45
Wireless (D24)	802.11 b/a/g/n/ac (WiFi 5)
Wireless credential (D24)	<ul style="list-style-type: none">WPA3 - Personal and Enterprise
FIPS	Communication supported by FIPS 140-2 certified encryption algorithm
Archive / Internal storage (D06)	200 ECGs
External storage (D06)	200 ECGs with optional USB device
1D/2D barcode reader (H13)	High scan speed, motion tolerance, curved surfaces, trigger-style, healthcare white

Automated Data Input

1D barcode reader (H12)	<ul style="list-style-type: none">Reads Code 39 SymbologyReads up to 80 characters
1D/2D barcode reader (H13)	High scan speed, motion tolerance, curved surfaces, trigger-style, healthcare white
1D/2D barcode reader (H17)	High scan speed, motion tolerance, curved surfaces
RFID reader (H19)	13.56 MHz (HF), 125/132 kHz (LF)
1D / 2D / RFID reader (H20)	<ul style="list-style-type: none">1D/2D: High scan speed, motion tolerance, curved surfacesRFID: 13.56 MHz (HF), 125 KHz (LF)

Configurable Filters

AC noise	50 or 60 Hz
Signal processing	Artifact rejection and baseline wander

Presentation Filters – 10-sec Reports

High pass	0.02, 0.05, and 0.15Hz
Low pass	40, 100, 150 and 300Hz

Presentation filters – rhythm

High pass	0.02, 0.05, and 0.15Hz
Low pass	40, 100, 150 and 300Hz

Electrical

Battery	Lithium ion
Battery capacity ⁶	<ul style="list-style-type: none">• 10 hours of continuous operation without printing, or• 13.9 hours of normal operational cycles (7 minutes run, 1-page print, 8 minutes standby), or• 55 ECGs produced during normal operational cycles, or• 3 hours of continuous rhythm printing
Battery recharge	Four hours to full capacity
Main power	100-240VAC, 50/60Hz
Power consumption	60W max

Battery Management Statistics

Statistics	<ul style="list-style-type: none">• Current status• Voltage• Expected max error (%) of charge calculation• Predicted capacity when fully charged• Remaining capacity in mAh• Current charge and state of health %• Charge current: value while charging• Discharge current: value while discharging• Cycle count: number of full charge and discharge cycles• Temperature• Battery unique ID, supplier information, device name, DOM, and SN
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Mechanical

Dimensions	31 × 40 × 21cm (12 × 16 × 8in)
Weight	8.6kg (19lb) includes battery, lead wires, clips, electrode pack, and paper pack

Environmental

Operating conditions	<ul style="list-style-type: none">• 10° to 40°C (50°F to 104°F)• 10% to 90% relative humidity (non-condensing)• Up to 3,048 m (10,000 ft) altitude
Storage conditions	<ul style="list-style-type: none">• -20°C to 50°C (-4°F to 122°F)• 10% to 90% relative humidity (non-condensing)• Up to 4,572 m (15,000 ft) altitude

Safety and Performance

International standards and regulations	<ul style="list-style-type: none">• General Requirements for Safety IEC 60601-1: 2005+A1: 2012• Particular Requirement for Safety of Electrocardiographs IEC 60601-2-25 2011 Edition 2.0• Electromagnetic Compatibility IEC60601-1-2 2014
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Cleaning and Disinfecting⁷

Approved solutions ⁷	Any of the following 15 solutions can be used to safely, effectively clean TC35, including WPIM base and WPIM pin-end lead sets: Generic solutions <ol style="list-style-type: none">1. Mild soap and water**2. Isopropyl alcohol (consisting of 70% solution)**3. Chlorine bleach (5.25% sodium hypochlorite content) mixed as 3% solution in water**4. Diethylene glycol butyl ether (5-10% by weight)5. Ethanol (ethyl alcohol) 70% (v/v)6. Ethylene glycol monobutyl ether (1-5%) with isopropanol (17%) mix7. Phenol 2% (v/v) Branded solutions <ol style="list-style-type: none">1. Metrex Caviwipes® Disinfectant (Benzethonium Chloride and Isopropanol mix)2. Gama Healthcare Clinell® Universal Range Disinfectant (Benzalkonium chloride, Didecyl dimethyl ammonium chloride, and Polyhexamethylene biguanide (PHMB) mix)3. Steris Coverage Plus NPD (Quaternary ammonium compounds mixed as one-half fluid ounce per gallon water, or one part Coverage Plus NPD to 256 parts water)**4. PDI Super Sani-Cloth®5. Dr. Schumacher Cleanisept Wipes6. Clinell Peracetic Acid Wipes7. PDI Easy Screen Cleaning®8. PDI Sani-Cloth® AF3
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** These 4 cleaning agents may also be used to clean WPIM grabber-end lead sets.

1. New standards for ECG equipment. *Journal of Electrocardiology* 57 (2019) S1–S4.

2. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram, Part II: Electrocardiography Diagnostic Statement List. *J Am Coll Cardiol*, 2007; 49:1128-135.

3. Fourth Universal Definition of Myocardial Infarction. *Circulation* 2018; 138 (2): pg e618-e651.

4. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram, Part VI: Acute Ischemia/Infarction. *Circulation*. 2009; 119:e262-e270.

5. When networked with select hospital and departmental solutions; refer to supplier specifications.

6. Performance can vary in different environmental conditions.

7. All trademarks, logos, and brand names referenced in this documentation are the property of their respective owners.

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