

# 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)/WPA2 (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)/WPA2 (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)	<ul style="list-style-type: none"><li>Ten interval, duration, and axis measurements</li><li>Configurable QT correction methods</li></ul>
Rhythm strips	<ul style="list-style-type: none"><li>Up to 12 configurable leads</li><li>30 to 60 sec. 12-lead rhythm strip export (XML)</li></ul>
Disclosure (D05)	<ul style="list-style-type: none"><li>Five-minute history of all 12 leads</li><li>Complete ECG report of any selected 10 seconds</li></ul>
Event marking (D05)	<ul style="list-style-type: none"><li>Six independent events can be marked for later review and analysis</li><li>Event markers appear on ECG reports</li><li>Note can be added for each event</li></ul>
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	<ul style="list-style-type: none"><li>PDF</li><li>XML</li><li>DICOM 12-Lead ECG</li><li>DICOM General ECG</li><li>DICOM Encapsulated PDF</li></ul>
Pace pulse detection	<ul style="list-style-type: none"><li>0.02 mVms (e.g., 0.2mV*0.1ms pulse or 0.1mV*0.2ms pulse)</li><li>Exceeds proposed standard by 5X<sup>1</sup></li></ul>

### DXL ECG Algorithm<sup>2,3,4</sup> (D03)

Interpretive statements	<ul style="list-style-type: none"><li>&gt; 600 interpretive statements</li><li>Integrated pediatric analysis</li></ul>
Borderline statement suppression	Three configurable settings
Nomenclature	Aligned with 2007 AHA/ACCF/HRS Recommendations, Part II
Extended measurements	<ul style="list-style-type: none"><li>46 measurements of morphology analysis in each of the 12 leads</li><li>21 parameters of rhythm analysis</li></ul>
Reasons	Selectable explanations of all interpretive statements

### STEMI Diagnostic Aids (D03)

Graphical ST presentation	<ul style="list-style-type: none"><li>Two ECG reports with polar ST Maps</li><li>Frontal and transverse planes</li></ul>
Age and gender criteria	Based upon Fourth Universal Definition of Myocardial Infarction, 2018
STEMI-CA (Culprit Artery)	<ul style="list-style-type: none"><li>Criteria that suggest any of four probable sites of the occluded coronary artery</li><li>Based upon 2009 AHA/ACCF/HRS Recommendations, Part VI</li></ul>
Critical Values	Highlights four conditions requiring immediate clinical attention

### QT measurements (D03)

QTc measurements	<ul style="list-style-type: none"><li>Bazett</li><li>Fridericia</li><li>Hodges</li><li>Framingham</li></ul>
Correction of QT interval & QRS duration	Rautaharju

### Advanced Bi-directional Network Communications<sup>5</sup>

Central time management	Time can be manually or automatically synchronized to a Network Time Server
Orders worklist (D01)	<ul style="list-style-type: none"><li>Download of orders worklist from networked server</li><li>User-configurable rules to retrieve cardiograph-specific worklists</li><li>User-configurable drop down lists (e.g., by location)</li><li>Ad-hoc query for specific orders based upon multiple user-entered or scanned search criteria (e.g., patient ID, last/ first name)</li><li>Supported by Open Worklist with IntelliBridge Enterprise and select departmental systems</li><li>Supported by HL7 interface via IntelliBridge Enterprise</li><li>Supported by DICOM Modality Worklist</li></ul>
ADT (D02)	<ul style="list-style-type: none"><li>Query and retrieval of patient demographic information</li><li>Based upon user-entered or scanned search criteria (e.g., patient ID, last/first name)</li><li>Supported by standard HL7 interface via IntelliBridge Enterprise for hospital systems</li></ul>
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)	<ul style="list-style-type: none"><li>DICOM 12-lead ECG</li><li>DICOM General ECG</li><li>DICOM Encapsulated PDF</li></ul>

### Privacy and Security

Password framework	<ul style="list-style-type: none"><li>Role-based</li></ul>
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	<ul style="list-style-type: none"><li>USB port access (on/off)</li><li>HTTP, HTTPS</li><li>Encryption at rest (on/off)</li><li>Delete archived ECG after transfer (on/off)</li><li>User Authentication (on/off)</li><li>Consistent security approach across Cardiac Workstations and Pagewriter TC-Series Cardiographs</li></ul>

### Device Management Dashboard

Fleet Management	<ul style="list-style-type: none"><li>Centralized Management of fleet configuration and software revisions.</li><li>In-scope solutions: PageWriter TC20/TC30/TC35/TC50/TC70, SureSigns VS3/VS4, Efficia CM10/CM12, Efficia CM100/CM120/CM150, EarlyVue VS30</li><li>Cardiac Workstation verified to Dashboard A.02.02, planned for release Q4 2024.</li></ul>
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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"><li>• 1-2-3 operation</li><li>• Five-wire, resistive touchscreen</li></ul>
Keyboard	<ul style="list-style-type: none"><li>• Backlit 1-2-3 buttons</li><li>• 65-button, standard full alphanumeric keyboard</li><li>• Special characters supported</li></ul>
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"><li>• 860352: Fixed height</li><li>• 860353: Adjustable height (25 cm)</li></ul>
Fleet coverage	Above trolleys also compatible with: <ul style="list-style-type: none"><li>• Cardiac Workstation 7000</li><li>• Cardiac Workstation 5000</li><li>• PageWriter TC70</li><li>• PageWriter TC50</li></ul>
Wheels	<ul style="list-style-type: none"><li>• All 4 wheels lock and swivel</li><li>• Anti-static conductive caster</li></ul>
Desktop	Open desktop workspace
Storage	<ul style="list-style-type: none"><li>• Standard storage for 400 extra ECG paper sheets</li><li>• Standard storage for cleaning wipes/gloves/ electrode gel/gauze, etc</li><li>• Optional concealed drawer</li><li>• Optional closable waste bin</li><li>• Optional wire basket</li><li>• Optional hanging leadwire holder</li></ul>

## 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"><li>• Defib-protected ECG acquisition provides 1µV resolution</li><li>• Acquire data at 8,000 samples per second, per lead wire</li></ul>
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

## Printer

Resolution	<ul style="list-style-type: none"><li>• High-resolution, digital-array using thermal-sensitive paper</li><li>• 200 dpi (voltage axis) by 500 dpi (time axis) at 25 mm/sec</li></ul>
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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"><li>• WPA3 - Personal</li><li>• WPA2 - Enterprise</li></ul>
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

## Automated Data Input

1D Bar code reader (H12)	<ul style="list-style-type: none"><li>• Reads Code 39 Symbology</li><li>• Reads up to 80 characters</li></ul>
2D Barcode reader (H17)	<ul style="list-style-type: none"><li>• High scan speed</li><li>• Motion tolerance</li><li>• Curved surfaces</li></ul>

## 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 <sup>6</sup>	<ul style="list-style-type: none"><li>• 10 hours of continuous operation without printing, or</li><li>• 13.9 hours of normal operational cycles (7 minutes run, 1-page print, 8 minutes standby), or</li><li>• 55 ECGs produced during normal operational cycles, or</li><li>• 3 hours of continuous rhythm printing</li></ul>
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"><li>• Current status</li><li>• Voltage</li><li>• Expected max error (%) of charge calculation</li><li>• Predicted capacity when fully charged</li><li>• Remaining capacity in mAh</li><li>• Current charge and state of health %</li><li>• Charge current: value while charging</li><li>• Discharge current: value while discharging</li><li>• Cycle count: number of full charge and discharge cycles</li><li>• Temperature</li><li>• Battery unique ID, supplier information, device name, DOM, and SN</li></ul>
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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"><li>• 10° to 40°C (50°F to 104°F)</li><li>• 10% to 90% relative humidity (non-condensing)</li><li>• Up to 3,048 m (10,000 ft) altitude</li></ul>
Storage conditions	<ul style="list-style-type: none"><li>• -20°C to 50°C (-4°F to 122°F)</li><li>• 10% to 90% relative humidity (non-condensing)</li><li>• Up to 4,572 m (15,000 ft) altitude</li></ul>

## Safety and Performance

International standards and regulations	<ul style="list-style-type: none"><li>• General Requirements for Safety IEC 60601-1: 2005+A1: 2012</li><li>• Particular Requirement for Safety of Electrocardiographs IEC 60601-2-25 2011 Edition 2.0</li><li>• Electromagnetic Compatibility IEC 60601-1-2 2014</li></ul>
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## Cleaning and Disinfecting<sup>7</sup>

Approved solutions <sup>7</sup>	<p>Generic cleaning solutions</p> <ul style="list-style-type: none"><li>• Mild soap and water</li><li>• Isopropyl alcohol, 70% solution</li><li>• Chlorine bleach (5.25% sodium hypochlorite content), 3% solution in water</li><li>• Diethylene glycol butyl ether (5-10% by weight)</li><li>• Ethanol (ethyl alcohol) 70% (v/v)</li><li>• Ethylene glycol monobutyl ether (1-5%) with isopropanol (17%)</li><li>• Phenol 2% (v/v)</li></ul> <p>Branded cleaning solutions</p> <ul style="list-style-type: none"><li>• Metrex Caviwipes</li><li>• Gama Healthcare Clinell Universal Range</li><li>• Quaternary ammonium compounds such as Steris Coverage Plus NPD, mixed as one-half fluid ounce per gallon water, or one part Coverage Plus NPD to 256 parts water</li></ul>
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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 Cardiology*, 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.  
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