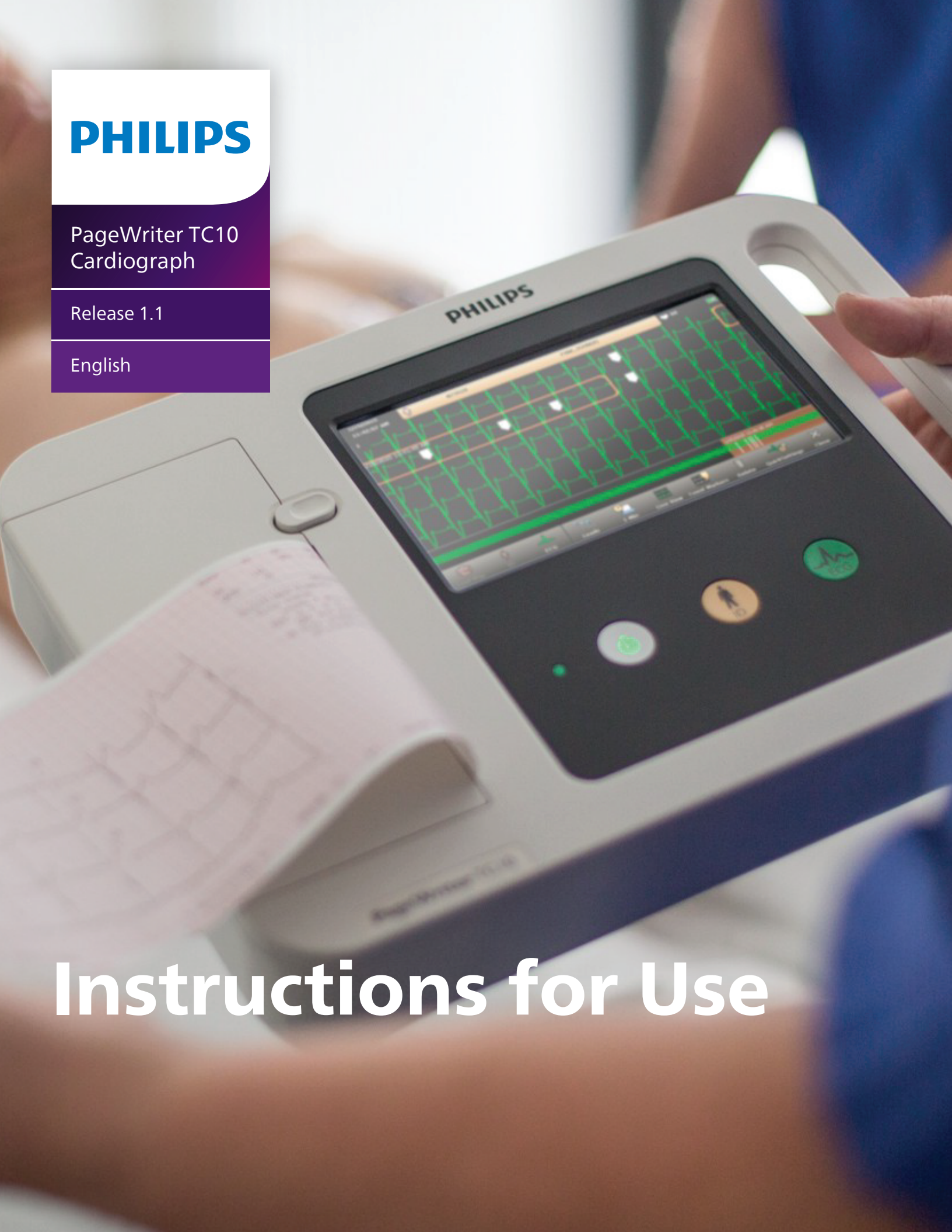
PHILIPS

PageWriter TC10 Cardiograph

Release 1.1

English



Instructions for Use

PageWriter TC10 Cardiograph

Instructions for Use

Revision E
May 2023

Notice

PN 453564461421
May 2023
Revision E, applicable to software version 1.1 and higher.
REF 860392

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Use of this document by unauthorized persons is strictly prohibited. Report violation of these requirements to the Philips Legal Department. This document must be returned to Philips when the user is no longer licensed and in any event upon Philips' first written request.

Warranty

Be advised that the product warranty could be voided by:

- service performed by an unauthorized service provider;
- use of the device outside of its intended purpose;
- any unauthorized device modifications;
- use non-Philips accessories or consumables.

For specific warranty details, contact your Philips representative or Customer Care Center.

Responsibility of Manufacturer

Philips only considers itself responsible for any effects on safety, reliability and performance of the product if:

- assembly operations, extensions, readjustments, modifications or repairs are done by persons authorized by Philips, and
- the electrical installation of the relevant room or vehicle complies with the IEC or national requirements, and
- the instrument is used according to the instructions for use presented in this manual.

Responsibility of Customer

The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Instructions for Use

This Philips product is intended to be operated only in accordance with the safety procedures and operating instructions provided in this *Instructions for Use*, and in accordance with the purposes for which it was designed. Installation, use, and operation of this product is subject to the laws in effect in the jurisdiction(s) in which the product is being used.

Users must only install, use, and operate this product in such a manner that does not conflict with applicable laws or regulations that have the force of law.

Use of this product for purposes other than the express intended purpose provided by the manufacturer, or incorrect use and operation, may relieve the manufacturer (or agent) from all or some responsibility for resultant non-compliance, damage, or injury.

Compliance

The Philips PageWriter TC10 Cardiograph complies with all relevant international and national standards and laws. Information on compliance will be supplied on request by a local Philips representative, or by the manufacturer.

CAUTIONS

THIS PRODUCT IS NOT INTENDED FOR HOME USE.

Rx: IN THE U.S., FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A PHYSICIAN.

Philips strongly recommends that your site not use patient identification numbers that are related to any other forms of identity, such as social security number or driver's license number. Using unique patient identification numbers is part of best practices for any information technology system as a way to help health care providers and patients avoid identity theft.

WARNING

As with all electronic equipment, Radio Frequency (RF) interference between the PageWriter TC10 Cardiograph system and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, should be evaluated carefully and any limitations noted before the equipment is placed in service.

Radio frequency generation from electrosurgical equipment and close proximity transmitters may seriously degrade performance.

Philips assumes no liability for failure resulting from RF interference between Philips medical electronics and any radio frequency generating equipment at levels exceeding those established by applicable standards.

Manufacturer's Address



Philips Medical Systems
Böblingen GmbH
Hewlett-Packard Strasse 2
71034 Böblingen
Germany

Australia and New Zealand Sponsor

Philips Electronics Australia Ltd.
65 Epping Road
North Ryde
NSW 2113
Australia

Medical Device Regulation

The PageWriter TC10 Cardiograph complies with the requirements of the Medical Device Regulation EU 2017/745, and carries the following mark accordingly:

CE 0123

Global Medical Device Nomenclature (GMDN)

The 5-digit GMDN code adjacent to the symbol is defined in the EN ISO 15225 standard.

GMDN 16231

Trademarks

Product and company names mentioned herein may be the trademarks or registered trademarks of their respective owners.

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About the Cardiograph

About the Instructions for Use

This *PageWriter TC10 Cardiograph Instructions for Use* is intended to assist users in the safe and effective use of the product.

Before attempting to operate this product, read this *Instructions for Use,* and note and strictly observe all Warning and Cautions as described in this document.

Pay special attention to all of the safety information provided in the Safety Summary section. For more information, see page xiv.

WARNING

Warning statements describe conditions or actions that may result in a potentially serious outcome, adverse event, or a safety hazard. Failure to follow a Warning may result in death or serious injury to the user or to the patient.

Caution

Caution statements describe when special care is necessary for the safe and effective use of the product. Failure to follow a caution may result in minor to moderate personal injury or damage to the product or other property, a remote risk of more serious injury, or may cause environmental pollution.

Note:

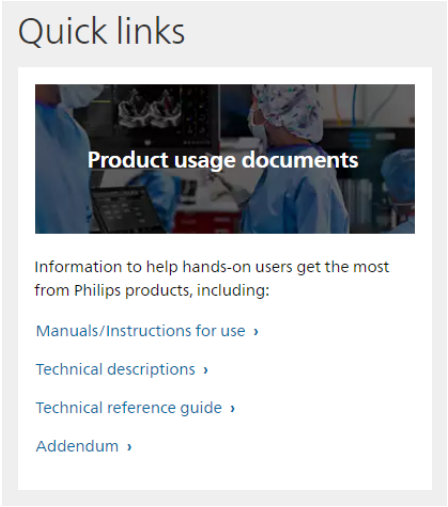
Notes contain additional important information about a topic.

Menu items and button names appear in bold no-serif font. Example: Touch **Setup**.

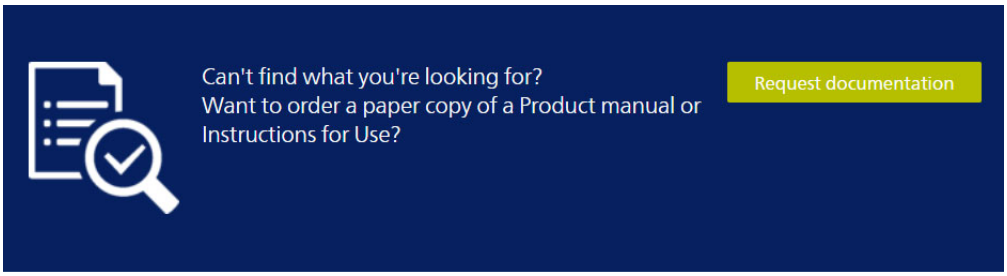
Obtaining a Paper Copy of the Instructions for Use

Paper copies of the *Instructions for Use* may be requested from the Philips Document Library (www.philips.com/IFU). To request a paper copy:

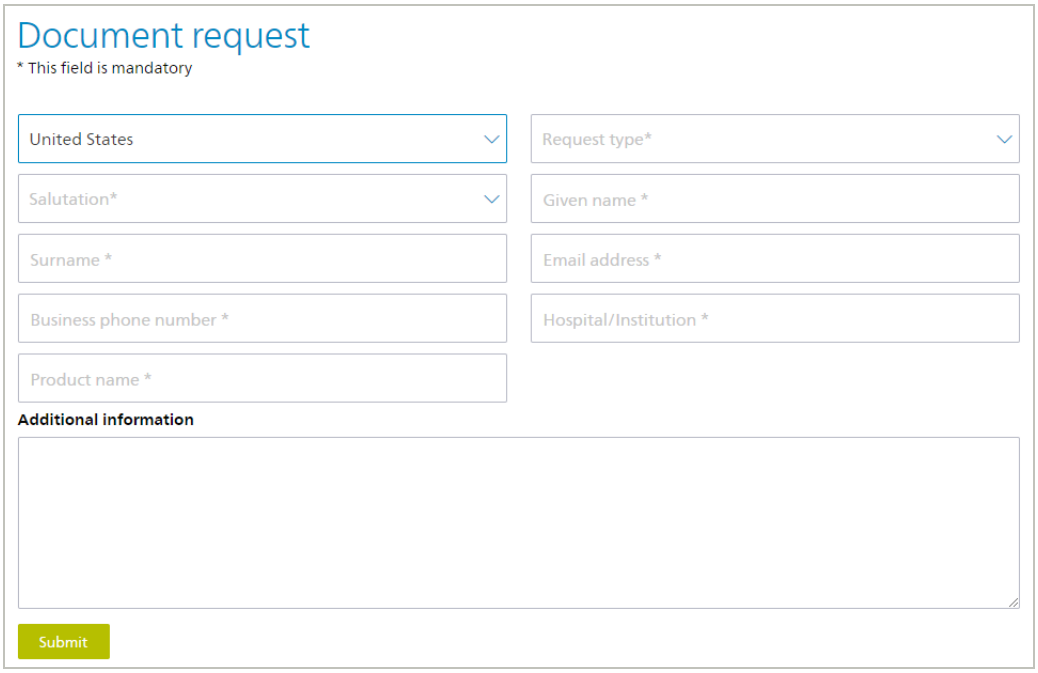
1. Under **Product usage documents**, select **Manuals/Instructions for Use**.



2. Scroll down to “Can't find what you're looking for? Want to order a paper copy of a Product manual or Instructions for Use? Click **Request documentation**.



3. Select your location and complete the remaining required fields. Be sure to enter the full product name (e.g., “PageWriter TC10 Cardiograph,” not “TC10”).



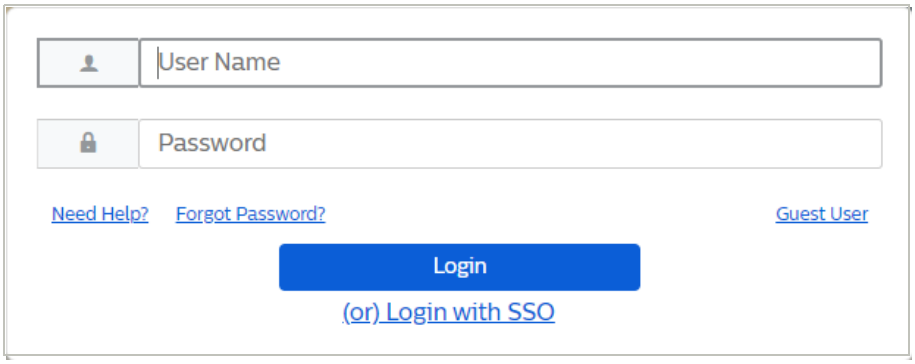
4. Under “Request type,” select **Paper**.

5. When all fields are complete, click **Submit**.

Using the Philips InCenter Site

The Philips InCenter site provides frequent updates to all Philips Cardiac Systems service documentation, product software and firmware.

The Philips InCenter site requires an active registration and password. To register, go to the InCenter site at https://philips.mizecx.com.



If you have an existing InCenter account, enter your user name and password, then click **Login**.

If you do not have an InCenter account, click on the **Need help?** link on the main page (located under the password field). On the following page, follow the directions under **For Externals** to receive a user name and password for the InCenter site.

About Adobe Acrobat Versions

Adobe Acrobat Reader version 9.0 or later must be installed on the PC that is used to access the Philips InCenter site. Previous versions of Acrobat Reader are not compatible with the Philips InCenter site, and attempting to access InCenter with a previous version of Acrobat Reader will result in error messages when opening documents. Uninstall all previous versions of Acrobat Reader, and then proceed for a free install of Acrobat Reader at www.adobe.com.

Any version of Adobe Acrobat Professional or Acrobat Elements are also not compatible with the Philips InCenter site, and error messages will appear when opening documents with these applications. Acrobat Reader must be installed in addition to Acrobat Professional or Acrobat Elements.

Follow this procedure when accessing documents on the Philips InCenter site.

To access documents on the Philips InCenter site:

1. Exit Acrobat Professional or Acrobat Elements (if open).
2. Launch Acrobat Reader.
3. Open Internet Explorer, and go to the Philips InCenter site. Keep Acrobat Reader open the entire time while accessing the InCenter site.

Safety Summary

Safety and Regulatory Symbols Marked on the Cardiograph

Symbol	Description	Standard/Reference
	See the *PageWriter TC10 Cardiograph Instructions for Use*.	ISO 7010¥, M002
	Indicates that the Instructions for Use is available in electronic form at www.philips.com/IFU	ISO 7000:3500
	ECG physio isolation is type CF, defibrillator proof. Suitable for all patient applications including direct cardiac application. System is in continuous operation.	IEC 60417† 5336
	Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials or hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information. It is advisable to contact your service personnel before disposing of this product.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1* 5.4.4
	Connect the patient cable to the connector located directly below this symbol.	—
	Connect the Ethernet RJ45 LAN cable to the connector directly above this symbol to establish LAN connectivity.	—

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs

Safety and Regulatory Symbols Marked on the Cardiograph (continued)

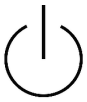
Symbol	Description	Standard/Reference
CE	CE Marking (EU certification mark)	European Medical Devices Directive 2014/53/EU
CE 0123	CE marking accompanied by the Notified Body identification number 0123. Indicates that the product complies with the EU Regulation 2017/745.	European Medical Devices Regulation (EU) 2014/745
Rx only	CAUTION: In the U.S., Federal law restricts this device to sale on or by the order of a physician.	21 CFR 801.109
	Identifies the manufacturer of the product., including name and address.	ISO 15223-1* 5.1.1
XX YYYY-MM-DD	Identifies the country and the date of manufacture. Two-letter code indicates country of origin in compliance with ISO 3166-1.	IEC 60417† 6049
SN	The number next to this symbol is the serial number of the cardiograph.	ISO 15223-1* 5.1.7
MD	Medical Device.	Medical Devices Regulation 2017/745/EU, Annex 1, 23, q.
UDI	Universal Device Identification information	US 21 USC 321 (h) Direction 2017/745 Article 2(1) of the European Parliament
REF	Catalogue number of the cardiograph.	ISO 15223-1* 5.1.6

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs

Safety and Regulatory Symbols Marked on the Cardiograph (continued)

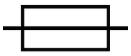
Symbol	Description	Standard/Reference
	Token Number	—
	Option Code	—
	Pressing this button for longer than 2 seconds while the unit is off powers up the unit if AC power is connected or battery capacity is higher than “Very Low.” Pressing this button for longer than 2 seconds while the unit is running puts the cardiograph into Standby (power-saving) mode. Pressing this button for less than 2 seconds while the unit is in Standby mode wakes the cardiograph if AC power is connected or battery capacity is higher than “Low.” Pressing this button for less than 2 seconds while the unit is running shuts down the system.	IEC 60417† 5009
	The connector near this symbol is used with a USB device.	—
	Interference may occur in the vicinity of equipment marked with this symbol.	IEC 60417† 5140
	Indicates that the PageWriter TC10 cardiograph is receiving alternating current.	IEC 60417† 5032
	Equipotential grounding post used for establishing common ground between instruments.	IEC 60417† 5021

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs

Safety and Regulatory Symbols Marked on the Cardiograph (continued)

Symbol	Description	Standard/Reference
	Identifies the terminal of a protected earth (ground) electrode, or any terminal intended for connection to an external conductor for protection against electric shock. **NOTE:** *Symbol is located inside the TC10 cardiograph*	IEC 60417† 5019
	Contains a 1.6 amp (250V) time-delay fuse.	IEC 60417† 5016
	Indicates a high risk of exposure to HIGH VOLTAGE from the AC/DC module after the top cover is removed. To reduce the risk, see "Servicing the Cardiograph" on page xxx **NOTE:** *Symbol is located inside the TC10 cardiograph*	ISO 7010¥, W012
	SGS North America Certification Mark to indicate product fulfills relevant and applicable safety requirements for the US and Canada.	—

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

† IEC 60417 Graphical symbols for use on equipment

¥ ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs

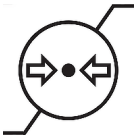
Safety and Regulatory Symbols Marked on the Packaging

Symbol	Description	Standard/Reference
	Keep dry.	ISO 15223-1* 5.3.4

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols

Safety and Regulatory Symbols Marked on the Packaging (continued)

Symbol	Description	Standard/Reference
	Ambient temperature range (non-condensing) for transport and storage (see Appendix C, "Specifications"). **Note:** *The batteries will discharge at a rapid rate if the cardiograph is stored at a high temperature.*	ISO 15223-1* 5.3.5
	Atmospheric pressure range for transport and storage (see Appendix C, "Specifications").	ISO 15223-1* 5.3.9
	Relative humidity range (non-condensing) for transport and storage. (see Appendix C, "Specifications")	ISO 15223-1* 5.3.8
	Made from recycled materials.	ISO 7000¥1135
	Fragile.	ISO 15223-1* 5.3.1
	Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials or hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information. It is advisable to contact your service personnel before disposing of this product.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
	CAUTION: In the U.S., Federal law restricts this device to sale on or by the order of a physician.	21 CFR 801.109

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols

Safety and Regulatory Symbols Marked on the Packaging (continued)

Symbol	Description	Standard/Reference
	Packaging unit, indicates the number of pieces in the package.	ISO 7000¥ 2794
	Correct upright position of the distribution package for transport and/or storage.	ISO 7000¥ 0623
	Device contains a lithium-ion battery.	—
	Indicates that the Instructions for Use is available in electronic form at www.philips.com/IFU	ISO 7000:3500 with EU MDR Article 23.1
	Identifies the manufacturer of the product., including name and address.	ISO 15223-1* 5.1.1
	Identifies the country and the date of manufacture. Two-letter code indicates country of origin in compliance with ISO 3166-1.	IEC 60417† 6049
	The number next to this symbol is the serial number of the cardiograph.	ISO 15223-1* 5.1.7
	The number next to this symbol is the catalogue number of the cardiograph.	ISO 15223-1* 5.1.6
	Medical Device.	Medical Devices Regulation 2017/745/ EU, Annex 1, 23, q.

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols

Safety and Regulatory Symbols Marked on the Packaging (continued)

Symbol	Description	Standard/Reference
UDI	Universal Device Identification information	US 21 USC 321 (h) Direction 2017/745 Article 2(1) of the European Parliament
CE 0123	CE marking accompanied by the Notified Body identification number 0123. Indicates that the product complies with the EU Regulation 2017/745.	European Medical Devices Directive 2014/53/EU
	Indicates that in the Member States or geographical area, there are restrictions on putting into service, or requirements for authorization of use for the radio equipment.	Commission implementing regulation (EU) 2017/1534 of 20 July 2017
* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements ¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols		

Safety and Regulatory Symbols Marked on the Battery

Symbol	Description	Standard/Reference
	Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials or hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information. It is advisable to contact your service personnel before disposing of this product.	Waste Electrical and Electronic Equipment directive 2012/19/EU, Article 14.4
	Identifies the manufacturer of the product .	ISO 15223-1* 5.1.1
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1* 5.4.4
* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements ¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols		

Safety and Regulatory Symbols Marked on the Battery (continued)

Symbol	Description	Standard/Reference
	The number next to this symbol is the serial number of the cardiograph.	ISO 15223-1* 5.1.7
	The number next to this symbol is the catalogue number of the cardiograph.	ISO 15223-1* 5.1.6
	The number next to this symbol is the catalogue number of the cardiograph.	—
	UL Recognized Components have been evaluated by UL for factory installation within equipment where the component's limitations of use are known and investigated by UL.	UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements, 5.1
	This product contains certain hazardous substances, and can be safely used during its environmental protection use period of 5 years, and should enter into the recycling system after its environmental protection use period.	Administrative Measure on the Control of Pollution Caused by Electronic Information Products, Chinese Ministry of Information Industry, 2006-02-28, Decree No. 39
	Ensure collection rates meet the directive. Recycling efficiency of batteries collected shall be: 65% for lead acid batteries; 75% for nickel cadmium batteries; and 50% for all other types	Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators
	Indicates that the lithium ion battery is certified by the Bureau of Indian Standards (BIS) for India market	IS 16046 (Part 2):2018 / IEC 62133-2:2017

* ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

¥ ISO 7000 Graphical symbols for use on equipment - Registered symbols

Important Patient and Safety Information

The cardiograph isolates all connections to the patient from electrical ground and all other conductive circuits in the cardiograph. This reduces the possibility of hazardous currents passing from the cardiograph through the patient's heart to ground.

WARNING

Failure to follow these warnings could affect both patient and operator safety.

Notice

Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the European Economic Area (EEA) countries, including Switzerland and Turkey, in which the user and/or patient is established.

Accessories and Supplies

WARNING

The Welsh bulb electrodes (available as an accessory for the cardiograph) do not meet the requirements of IEC 60601-2-25 for defibrillation recovery time, and cannot be reliably used for patient diagnosis immediately following defibrillation.

WARNING

When using additional peripheral equipment powered from an electrical source other than the cardiograph, the combination is considered to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1 and test the medical system according to the requirements. For additional information contact Philips Medical Systems.

WARNING

Do not use non-medical peripherals within 6 feet of a patient.

WARNING

Do not plug patient cable connectors into the Mains socket or other outlets of the cardiograph.

Caution

- **The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results.**
- **Only use Philips Medical Systems replacement parts and supplies with the cardiograph. The use of non-approved replacement parts and supplies with the cardiograph is strictly prohibited. Cardiograph safety and performance are not guaranteed when non-approved replacement parts and supplies are used with the cardiograph. For a list of approved parts and supplies, see Appendix D, "Parts and Supplies".**

- Using accessories, peripherals, or cables that are not supplied with the cardiograph or that are not recommended by Philips Medical Systems can result in increased leakage current, emissions or decreased immunity of the cardiograph.
- Connect other equipment in accordance with IEC 60601-1 Medical Electrical Systems Standard or IEC 60601-1: 2005 +A1:2012 (edition 3.1) Medical Electrical Equipment Standard Clause 16 Medical Electrical Systems.
- When connecting the cardiograph to other AC powered equipment, only connect equipment approved to IEC 60601-1 Medical Electrical Equipment.
- Only use patient electrodes that are approved by Philips Medical Systems. The use of non-approved patient electrodes may degrade cardiograph performance.
- Do not use dissimilar metal electrodes which could develop polarized potential and result in the cardiograph not getting an ECG signal.

AC Power Cord

WARNING

Whenever the AC power cord is connected to a live power outlet, ensure that it is also securely attached to the cardiograph. Always disconnect the AC power cord from the power outlet when it is not connected to the cardiograph.

WARNING

Only use grounded power cords (three-wire power cords with grounded plugs) and grounded electrical outlets that are labeled as *Hospital Only* ***or*** *Hospital Grade.* NEVER ***adapt a grounded plug to fit an ungrounded outlet by removing the ground prong. Use the equipotential post when redundant earth ground is necessary according to IEC 60601-1.***

WARNING

To avoid the risk of electric shock, this equipment must be connected only to a supply mains with protective earth.

WARNING

Real-time clock information within the cardiograph may be lost if both the external AC power source and internal battery are disconnected for more than thirty (30) minutes.

Caution

The surface of the cardiograph case above the internal power supply could feel warm to the touch.

- To disconnect the cardiograph from AC power, unplug the cardiograph AC power cord from the mains power supply. Do not place the cardiograph in a location that would make it difficult to disconnect from AC power.
- This equipment complies with the earth leakage current limits as specified in IEC 60601-1 Medical Electrical Equipment - General Requirements for Safety.
- Periodically inspect the patient cable and AC power cord for any worn or cracked insulation. Ensure that no exposed wires are visible on the AC power cord.
- Only use the Philips AC power cord supplied with the cardiograph. Use of any other power supply has not been verified and may lead to operator or patient harm, including electrical shock. Periodically inspect the AC power cord and AC power connector to ensure that both are in a safe and operable condition. If the AC power cord or AC power connector is not in a safe or operable condition, operate the cardiograph on battery power and contact Philips Medical Systems for service.

Applied Parts

WARNING

Do not touch accessible live parts and the patient simultaneously.

Applied parts for the cardiograph include the patient cable and electrodes.

Battery

Caution

- **Do not remove the battery during a patient session if the unit is not plugged into AC power or patient data may be lost.**
- **Before removing and replacing the battery from the cardiograph, unplug the AC power cord from the mains power supply and then press down and hold the On/Standby button (located on the front of the cardiograph) for at least two seconds to shut down the cardiograph. Ensure that the cardiograph is shut down. When the cardiograph is fully shut down, the screen is black, and the On/Standby button is not illuminated. Once the cardiograph is shut down, proceed to remove and replace the battery.**
- **When removing the battery from the cardiograph, it is normal for the battery to feel warm to the touch, but it will not cause a burn.**
- **Follow the battery manufacturer's guidelines for battery charging and storage. See "Battery Maintenance and Care" on page 100.**

- The TC10 only operates with a single lithium ion battery, part number 989803185291.
- Battery charge time from depletion to 90% in normal use is maximum four (4) hours.

Defibrillation

WARNING

Do not touch the patient, patient cable, leads, or the cardiograph during defibrillation. Death or injury may occur from the electrical shock delivered by the defibrillator. Do not leave any lead wires dangling.

Defibrillation recovery time is within 5 seconds when the cardiograph is operated using approved Philips applied parts.

ECG Interpretation

Caution

- **Always enter accurate patient information (including age and gender) if using the Philips DXL ECG Algorithm or Philips 12-Lead Algorithm for ECG interpretation.**
- **Before acquiring an ECG, ensure that the cardiograph screen does not show the DEMO MODE watermark on the waveform screen or report, and the Patient ID does not display the text, *Simulated data*. If these elements are present, the cardiograph is in Simulation mode and is not acquiring patient data! Restart the cardiograph to exit Simulation mode. For details, see "Working with Simulated Data" on page 18.**

Electrodes

- Philips recommends the use of disposable electrodes at all times for all patient applications. Choose either adult or pediatric disposable electrodes based on the age and size of the patient.
- For information on ordering disposable electrodes, see the *PageWriter TC10 Cardiograph Service Manual*, available on the *PageWriter TC User Documentation DVD* and on InCenter.

General Cardiograph Use

The TC10 Cardiograph is suitable for use in the patient environment. The cardiograph should be placed where the patient cannot access the enclosure and signal input/output ports during normal use.

WARNING

The operator should not contact the patient and any live parts in the patient environment at the same time.

WARNING

The cardiograph and the USB memory stick contain patient IDs and patient data. Ensure that printed or exported data is handled according to your facility's electronic protected health information (ePHI) guidelines.

Only authorized personnel should be allowed to view, handle, store, or transmit patient data.

WARNING

Electrical shock hazard. Keep the cardiograph and all cardiograph accessories away from liquids. Do not immerse the cardiograph or other accessories in any liquids. Do not touch accessible connector pins and the patient simultaneously.

WARNING

Do not connect additional Multiple Portable Socket-Outlets (MPSOs) or extension cords to the system.

WARNING

Do not plug the lead post into the mains socket or any socket or connector of the PageWriter cardiograph.

WARNING

Do not use this cardiograph near flammable anesthetics. It is not intended for use in explosive environments, in operating rooms, or during electrosurgery. The disconnection or connection of AC power, or electrostatic discharge (ESD) may result in an electrical spark.

WARNING

Defibrillator protection requires the use of Philips-specified accessories including electrodes, lead wires, and patient cables.

WARNING

The use of non-Philips equipment connected to, or operating with, the PageWriter cardiograph is not tested or supported, and may produce undesired results.

WARNING

Do not connect to the system any items which are not specified as part of the system.

WARNING

Ensure that components are installed securely and that no items are placed on the cardiograph that could cause the unit to become unstable.

WARNING

Connecting multiple cardiographs to the same patient may pose a safety hazard due to the summation of leakage currents. Any combination of instruments should be evaluated by local safety personnel before being put into service.

WARNING

Do not load or download to the cardiograph any software, security patches, or updates not authorized by Philips. Unauthorized software may compromise the operation of the cardiograph and is strictly prohibited.

WARNING

The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results.

WARNING

Do not modify the PageWriter cardiograph without authorization from Philips.

WARNING

If the PageWriter cardiograph has been modified or repaired, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TC10 cardiograph, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

Caution

- To avoid the possibility of the cardiograph shutting down due to momentary mains voltage dips/interruption during printing, it is recommended that you install the cardiograph battery before printing.
- The cardiograph may generate electromagnetic interference (EMI) that may cause nearby equipment to fail.

- The use of non-Philips equipment connected to, or operating with, the PageWriter cardiograph is not tested or supported, and may produce undesired results.

- Connecting multiple cardiographs to the same patient may pose a safety hazard due to the summation of leakage currents. Any combination of instruments should be evaluated by local safety personnel before being put into service.
- The cardiograph is suitable for use in the patient environment. The cardiograph should be located so that the operator cannot contact the patient and any live parts (including Mains power) in the patient environment at the same time. The cardiograph should be located so that the patient cannot access the enclosure and signal input/output ports of the cardiograph in normal use.
- The TC10 Cardiograph is inoperable when ECG channels are marked as “Lead Off” and red, dashed lines are shown on the screen.
- Philips will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.
- The cardiograph can resume normal operation in the previous operating mode, without loss of any user settings or stored data, and continue to perform its intended function within 5s after exposure to the defibrillation voltage.
- The cardiograph has been safety tested with the recommended accessories, peripherals, and leads, and no hazard was found when the cardiograph is operated with cardiac pacemakers or other stimulators.

IEC 60601 Standards

For information on the IEC 60601-2-25:2011 standard, please go to the Philips InCenter web site (https://philips.mizecx.com). For information on using the Philips InCenter site, see page xiii.

Main Waveform Display Screen

Manual measurements of ECG intervals and magnitudes should be performed on printed ECG reports only. Do not make manual measurements of ECG intervals and magnitudes on the main waveform display screen since these ECG representations are scaled.

Pacemaker

Pace pulses may not be visible on a printed ECG report that uses simultaneous acquisition.

Patient Cable

WARNING

The Philips patient cable (supplied with cardiograph) is an integral part of the cardiograph safety features. Use of any other patient cable may lead to the distortion or corruption of patient ECG data, may compromise defibrillation protection and degrade cardiograph performance, and overall cardiograph safety may be seriously degraded. For a list of qualified cables, see Table 1-1, "Qualified Patient Cables," on page 5.

- Keep the patient cable away from power cords and any other electrical equipment. Failure to do so can result in AC power line frequency interference on the ECG trace.
- Periodically inspect the patient cable for any cracks or breaks in the cable insulation. If the integrity of the patient cable is not assured, replace the patient cable. Contact Philips Medical Systems or your certified dealer for further assistance.

Printer

Caution

- **Do not pull on the paper while an ECG report is being printed. This can cause distortion of the waveform and can lead to potential misdiagnosis.**
- **Do not use the printer in high humidity conditions, as paper jams may result.**

- If a paper jam occurs, remove and reinstall the roll of printer paper. Refer to "Printer Paper" on page 98 for information on installing printer paper.

REACH

The EU REACH Regulation 1907/2006 requires Philips to provide chemical content information for Substances of Very High Concern (SVHC), if they are present in the relevant article above a concentration of 0.1% weight by weight. Information on substances contained in the Philips products can be found on the Philips REACH website (www.philips.com/REACH).

Servicing the Cardiograph

- Only qualified personnel may service the cardiograph or may open the cardiograph housing to access internal cardiograph components. Do not open any covers on the cardiograph. There are no internal cardiograph components that are serviced by the operator.
- The Philips Medical Systems warranty is applicable only if you use Philips Medical Systems approved accessories and replacement parts. See Appendix D, "Parts and Supplies" for more information.

Software

WARNING

Only install Philips Medical Systems software on the cardiograph. The installation or use of software not approved by Philips Medical Systems is strictly prohibited and cardiograph safety and performance are not guaranteed.

Touch Screen

WARNING

Do not use sharp objects with the touch screen or apply excessive force to the touch screen. Applying excessive force to the touch screen may result in breaking the touch screen display and can cause sharp, jagged parts to expel to persons nearby.

Manual measurements of ECG intervals and magnitudes should be performed on printed ECG reports only. Do not make manual measurements of ECG intervals and magnitudes on the touchscreen display since these ECG representations are scaled.

USB Memory Stick

WARNING

The cardiograph does not support ECG import from a USB memory stick. Do not use a USB memory stick that has been used with other cardiographs or other non-Philips devices.

Caution

- **Do not insert a USB memory stick into the cardiograph, or remove a USB memory stick from the cardiograph when the cardiograph is acquiring ECG data from the patient.**
- **Only use a USB memory stick to transfer data between the cardiograph and a computer. Do not use a USB memory stick with other devices.**
- **Keep all USB memory sticks that contain patient data in a secure location where they cannot be accessed by unauthorized personnel. Always delete patient data from a USB memory stick promptly after use.**
- **Affix a label to all USB memory sticks that contain patient data notifying users that unauthorized access of patient data on the USB memory stick is punishable by law.**
- **Philips does not guarantee that all USB memory sticks are compatible with the PageWriter TC10 cardiograph.**

- **Philips does not supply and verify any specific USB memory sticks and does not guarantee that the EMC compliance is met when the USB memory stick is connected to the PageWriter TC10 cardiograph.**

Periodically inspect the USB connectors for any cracks or breaks. If the integrity of a USB connector is not assured, do not use the USB connector, and contact Philips Medical Systems or your certified dealer for further assistance. See “Contacting Philips Response Center” on page 150.

Security Recommendations

As more patient health information is collected, stored, and transmitted electronically on a global basis, the concern for patient privacy grows. We consider the security and confidentiality of patient data to be of paramount importance. We adhere to the highest professional standards, focused on providing you with resources aimed at your regulatory compliance needs and allowing you to fully manage the safety, effectiveness, and security risks of medical devices, including your PageWriter TC10 cardiograph.

The cardiograph offers several security features which may be enabled and configured in accordance with your facility’s IT policies and procedures before deploying the cardiograph to active use.

Protecting Personal Information

It is essential that policies and procedures for the proper handling of personal or sensitive data, consider the confidentiality, integrity, and the availability of these types of data. Each organization using this product must provide the protective means necessary to safeguard personal information consistent with each country law, code and regulation, and consistent with the company policies for managing this information. While handling personal information is outside the scope of this document, in general, each organization is responsible for identifying:

- Who has access to personal data and under what conditions an individual has authorization to use that data;
- How data is stored and the conditions by which it is stored;
- How data is transmitted and the conditions under which data is transmitted.

Philips strongly recommends that your site not use patient identification numbers that are related to any other forms of identity, such as social security number or driver's license number. Using unique patient identification numbers is part of best practices for any information technology system as a way to help healthcare providers and patients avoid identity theft.

The US Department of Veterans Affairs has developed a widely used Medical Device Isolation Architecture to minimize the risk of a security breach when medical devices are connected to information networks. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy. Additional security and privacy information can be found on the Philips product security

website. Visit www.healthcare.philips.com, choose your country and language, navigate to the Customer Care page, and locate the Product Security link.

About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, please visit www.hhs.gov/ocr/privacy/.

Security Controls and Safety Measures

- Install the cardiograph in a secure location and use a privacy filter on the cardiograph monitor that shields the visibility of the screen contents from angled viewing.
- Store the cardiograph in a secure location when not in use.
- Implement “best practices” security measures to minimize unauthorized system access. These measures include short auto logout intervals when the system is idle, and training your users to lock the screen when they leave the cardiograph unattended.
- Strong password policies are recommended. The system administrator on site should establish password management policies that include rules for minimum password length and complexity. The following are recommended for consideration when creating passwords:
  - Create passwords of at least 12 characters.
  - Passwords should not contain a user name, or any part of a user’s actual name (e.g., first name).
  - Passwords should contain at least three of the following elements:
    - uppercase letter;
    - lowercase letter;
    - number;
    - symbol character (e.g., #, $, &, -).
- In case of a power supply disruption, backup options should be handled by an appropriate power fail-over system.
- Apply Windows-recommended network security and user privilege policies to prevent:
  - The installation of any software other than Philips-approved software intended for installation on the cardiograph.
  - The transmission of viruses via removable storage devices (for example, USB sticks).
- Do not load or download to the cardiograph any software, security patches, or updates not authorized by Philips. Unauthorized software may compromise the operation of the system and is strictly prohibited.

- Remember that the cardiograph contains confidential patient health information (PHI) that should be safeguarded. Avoid copying PHI to removable media. If you do, maintain physical security of the media at all times. Deleting data from rewritable/erasable media does not make the data inaccessible to a determined individual. Dispose of removable media containing patient health information in accordance with your institution's policies.
- Communication of unencrypted PHI should only occur across a secured intranet.
- Upon returning the equipment to Philips, eliminate all PHI or other confidential data, unless otherwise directed by Philips for problem investigation. Retain only the information necessary for the investigation with full agreement from both parties.
- Set up a system administrator password to prevent unauthorized access to the cardiograph settings.
- Perform regular backups of system data and store in a secure location as part of your disaster recovery plan. The cardiograph allows you to back up the stored ECG report and the configuration setting. Users with administrator accounts can back up and restore ECG reports from the Archive screen; administrators can also back up the configuration setting on the Save/Load screen.
- The exported configuration setting can be imported on the Save/Load screen to restore the cardiograph configuration.
- User must maintain physical security of the media that stores the backup files at all times.
- You risk losing ePHI if you transfer it to unsupported and/or obsolete backup media.
- For the latest security updates from Philips, visit www.healthcare.philips.com, choose your country and language, navigate to the Customer Care page, and locate the Product Security link.

The PageWriter TC10 Cardiograph

This Philips product is intended to be used and operated only in accordance with the safety procedures and operating instructions provided in this *Instructions for Use*, and for the purposes for which it was designed. The purposes for which the product are intended are provided below. However, nothing stated in this *Instructions for Use* reduces the responsibility of the user for sound clinical judgment and best clinical procedures.

The PageWriter TC10 cardiograph can be used for multiple patients.

Intended Purpose / Intended Use

The device is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze, and store these ECG signals for review by the user.

Indication for Use

The PageWriter TC10 Cardiograph is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes, and to record, display, analyze, and store these ECG signals for review by the user. It is to be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over-read and validate (or change) the computer-generated ECG interpretation.

Operating Principle

The PageWriter TC10 cardiograph collects multi-channel ECG signals of adult and pediatric patients from body surface ECG electrodes. These electrical ECG signals are amplified, digitized and processed in the digital domain. The PageWriter TC10 cardiograph records, displays, analyzes and prints the processed ECG signals for review by the clinical operator.

User Profile

PageWriter TC Cardiographs are intended to be used by trained health care professionals. Depending on local regulations and/or hospital policies, these are medical doctors, registered nurses, and health care assistants. The users of the PageWriter TC cardiographs can come from a wide variety of departments in the hospital and clinician office environments. These range from the specialist ECG Technician who is a dedicated DECG individual, to the physician intern who has used other cardiographs in the past but has only been with their current hospital a few weeks. Among these users, the primary users are technician level individuals, including ECG Technician, Cardio/Respiratory Technician, ER Technician, and Healthcare Assistants.

Intended Patient Population

The intended patient population is adult and pediatric patients in a wide variety of departments in the hospital and physician office environments. The pediatric patient is a patient whose age is under 16 years. To the intended patient population, there is no limit to patient’s stature, weight and health situation.

Medical Conditions

Electrocardiography serves as a noninvasive diagnosis tool of arrhythmias and conduction disturbances. The ECG may reflect changes associated with primary or secondary myocardial processes (e.g. those associated with coronary artery disease, hypertension, cardiomyopathy, or infiltrative disorders), metabolic and electrolyte abnormalities, and therapeutic or toxic effects of drugs or devices.

Contraindications

None.

1

Getting Started

Welcome to the PageWriter TC10 cardiograph, a versatile and powerful addition to your cardiac care patient workflow. The PageWriter TC10 cardiograph helps to simplify patient cardiac care through easy-to-use 1-2-3 touch screen operation, color-coded signal quality indicators, and integrated connectivity with a Philips ECG Management System for one touch patient order download and ECG transmission.

The cardiograph also supports integrated connectivity with an ADT Order Update system. Powerful clinical features include the Philips DXL ECG Algorithm that provides comprehensive measurement and interpretive analysis, and includes full pediatric interpretation, enhanced pacemaker pulse detection, lead reversal detection notification, and the *Critical Values* feature that provides an alert to caregivers of a silent MI or other conditions that require immediate treatment, an integral tool for acute care environments.

Other time-sensitive clinical tools include ST Map reports that indicate ST elevation, along with optional culprit artery identification that locates the probable anatomical site of a coronary artery occlusion responsible for an ischemia.

PageWriter TC10 Cardiograph Documentation

This *PageWriter TC10 Cardiograph Instructions for Use* describes all aspects of setting up, using, and maintaining your cardiograph. You can print the electronic version of this *PageWriter TC10 Cardiograph Instructions for Use* to keep with your cardiograph. You can access the electronic version of this *PageWriter TC10 Cardiograph Instructions for Use* via the on-screen help file accessed by touching **Help** on the cardiograph's touch screen (see figure 1-8 on page 15). You can also find this document on the *PageWriter TC10 User Documentation* DVD, or download the PDF from www.philips.com/IFU.

The *PageWriter TC10 User Documentation* DVD also includes the following:

- *User Skills Checklist (available in English only)*

  This checklist provides a comprehensive list of all of the tasks associated with patient preparation, taking an ECG, and using the cardiograph features. It provides the basis for all critical tasks recommended for inclusion in a clinical training program. This checklist can be printed and copied as necessary and retained as an official record of clinical training at your facility. Also available for download from Philips InCenter (https://philips.mizecx.com).

- *Philips DXL ECG Algorithm Physician's Guide*

  This Physician's Guide provides a comprehensive description of the Philips DXL ECG Algorithm versions PH100B and PH110C, and lists all of the interpretive statements included in the 0B and 0C criteria (see page 82). Also available for download from www.philips.com/IFU.

- *PageWriter TC Cardiograph Network Configuration Guide (available in English only)*

  This Network Configuration Guide provides detailed instructions on installing and configuring wireless network connectivity between the cardiograph and a Philips ECG Management System (including the OrderVue order handling option), or other third-party ECG management system. Also vailable for download from Philips InCenter (https://philips.mizecx.com).

- *PageWriter TC Cardiograph Service Manual (available in English only)*

  This document provides comprehensive information on product troubleshooting, performance verification and safety tests, using the Service Utilities accessed from the Setup menu, and installing software upgrades. Also vailable for download from Philips InCenter (https://philips.mizecx.com).

- Installing and Testing the DECG Barcode Scanner (available in English only)

  This document provides detailed instructions on installing and testing the barcode scanner for use with the PageWriter TC10 Cardiograph. Also available for download from Philips InCenter (https://philips.mizecx.com).

To open the User Documentation DVD:

1. Insert the DVD into a DVD-compatible drive on a standard PC. The main menu opens automatically. Click on a blue button or on the file name to open a file.
2. If the main menu does not automatically appear, open the DVD in Windows Explorer.
3. Double-click the file menu.pdf on the DVD. The main menu appears. Any of the files on the DVD may be printed or saved to a PC hard drive.

Note:

If you save PDF files from the DVD to a PC hard drive, Acrobat Reader 9.0 or later will need to be installed on the PC in order to view the files. For a free install, go to www.adobe.com*.*

PageWriter TC10 Cardiograph Components

The following sections include a description of all of the components of the PageWriter TC10 cardiograph, including the connection ports on the cardiograph, the patient cable, and optional accessories available with the cardiograph.

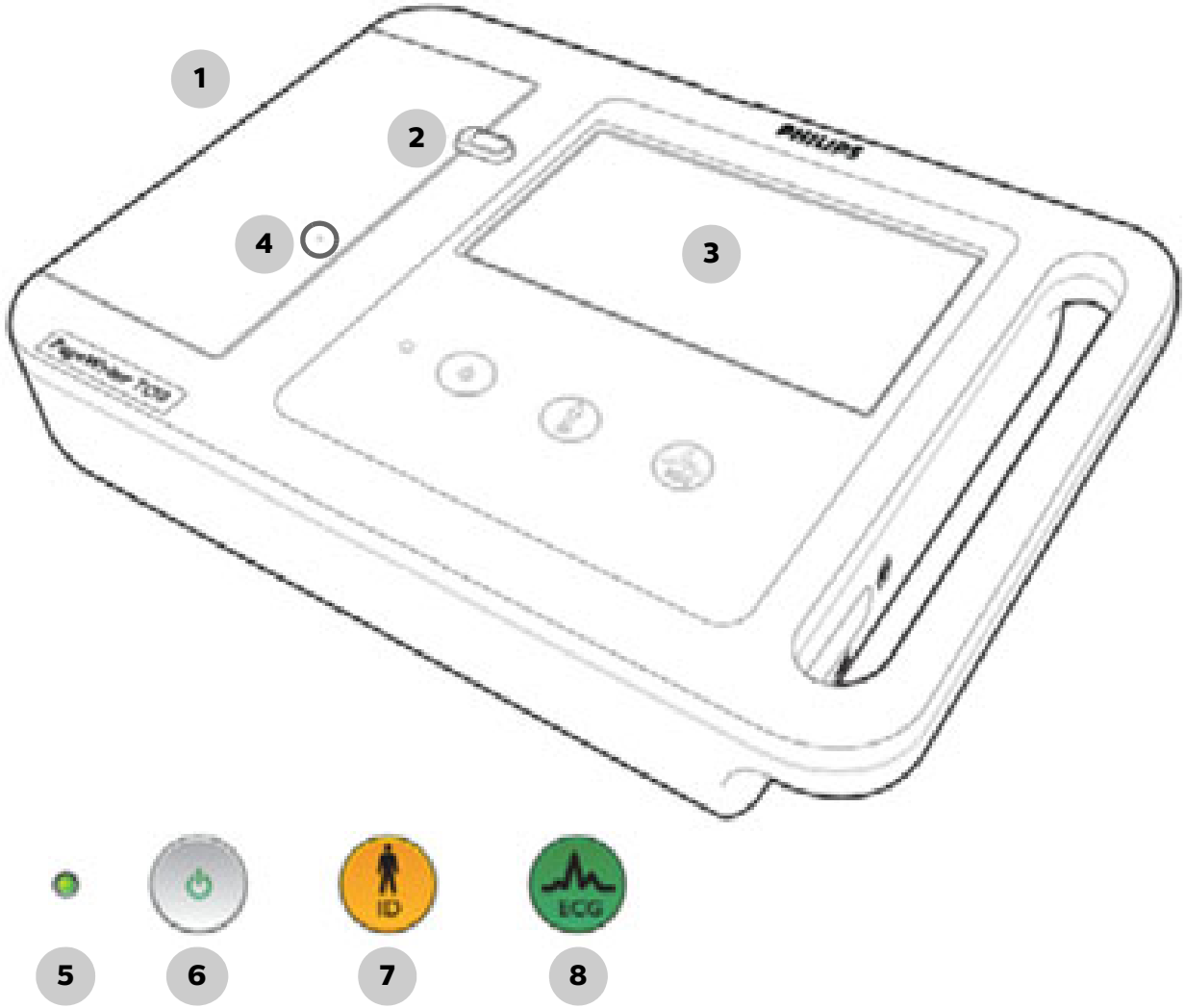
For more information on using the cardiograph features, see Chapter 3, "." For information on ordering any of the optional accessories for the cardiograph, see the *PageWriter TC10 Cardiograph Service Manual*, available on the *PageWriter TC10 User*

Documentation DVD and on InCenter. For information on ordering options and upgrades, see “Contacting Philips Response Center” on page 150.

TC10 Cardiograph

The following figures illustrate the front and back of the cardiograph.

Figure 1-1 PageWriter TC10 Cardiograph (right front view)



1 Paper compartment
2 Paper compartment release button
3 Touch screen
4 Raised dot (press here to close paper door)
5 AC power indicator light
6 On/Standby button
7 ID button
8 ECG button

Note:

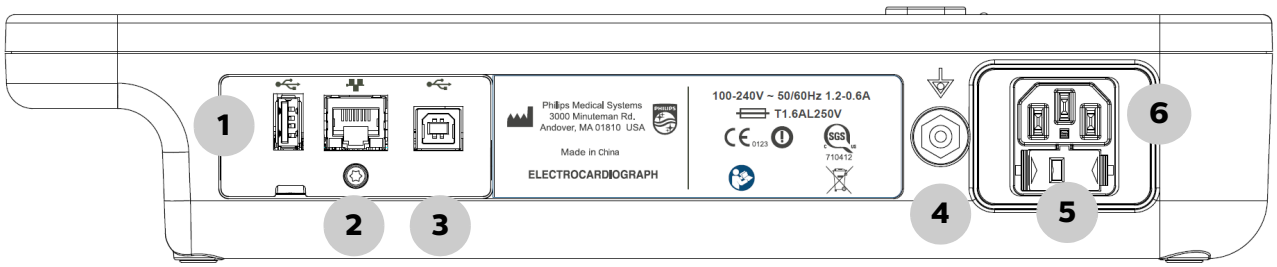
*The AC power indicator light (**5**) is illuminated in green when AC power is applied to the unit. The LED is not illuminated when power is disconnected.*

*The On/Standby button (**6**) will be illuminated in green if the unit is On. In Standby mode, the button will be illuminated in amber. When the unit is off, the LED will not be illuminated.*

The **ID** *button (**7**) will be illuminated in amber if the signal from any lead is detected and required patient information is missing.*

The **ECG** *button (**8**) will be illuminated in green only if 1) there are 12 ECG traces detected, 2) the overall signal quality level is greater than the ECG Quality Threshold, and, 3) if no required patient information is missing. Otherwise, the ECG button will not be illuminated.*

Figure 1-2 PageWriter TC10 Cardiograph (rear view)



1 USB host port

2 LAN connector

3 USB slave port (for future use)

4 Equipotential grounding post

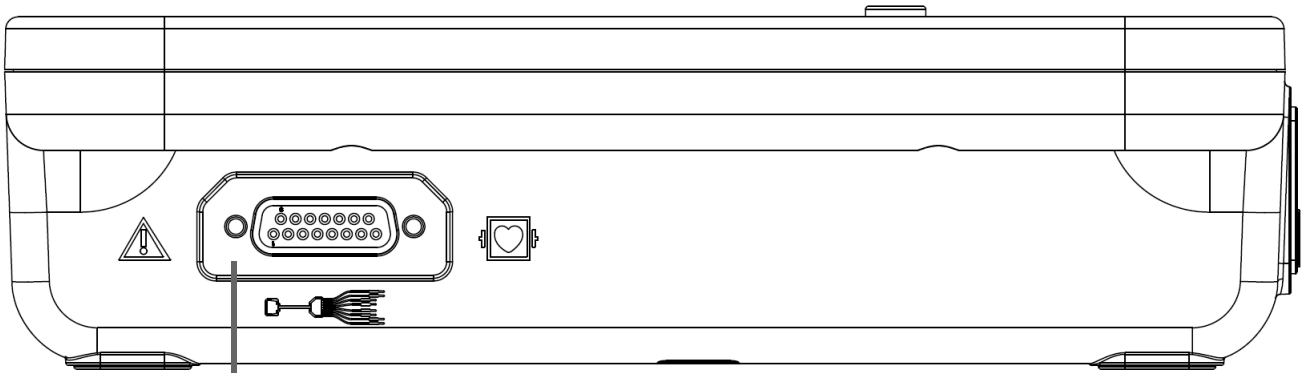
5 Fuse

6 AC power cord connector

Caution

- **Do not insert a USB memory stick into the cardiograph, or remove a USB memory stick from the cardiograph when the cardiograph is acquiring ECG data from a patient.**
- **Only use grounded power cords (three-wire power cords with grounded plugs) and grounded electrical outlets that are labeled as *Hospital Only* or *Hospital Grade*. Never adapt a grounded plug to fit an ungrounded outlet by removing the ground prong. Use the equipotential post when redundant earth ground is necessary according to IEC 60601-1.**

Figure 1-3 PageWriter TC10 Cardiograph (right side view)



About the Patient Cable

The patient cable provides an integrated leadset and connects directly to the side of the cardiograph. For details on lead placement and checking signal quality, see Chapter 3, "."

Figure 1-4 Patient Cable

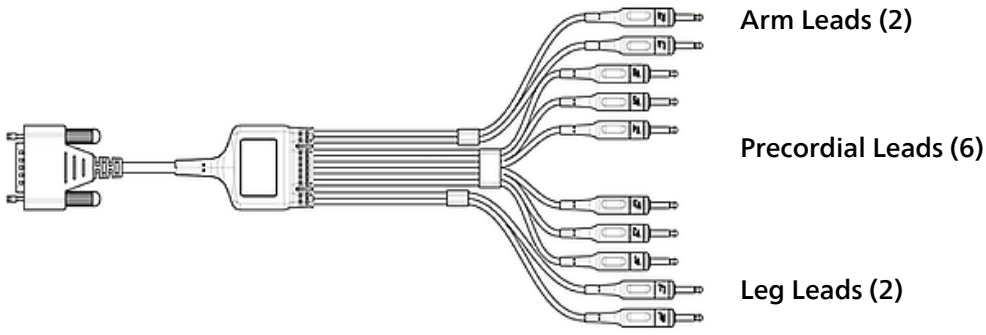


Table 1-1 Qualified Patient Cables

Part Number	Description
989803184921	12-Lead Patient Cable (IEC), Standard Length
989803184931	12-Lead Patient Cable (AAMI), Standard Length
989803184941	12-Lead Patient Cable (IEC), Long
989803184951	12-Lead Patient Cable (AAMI), Long

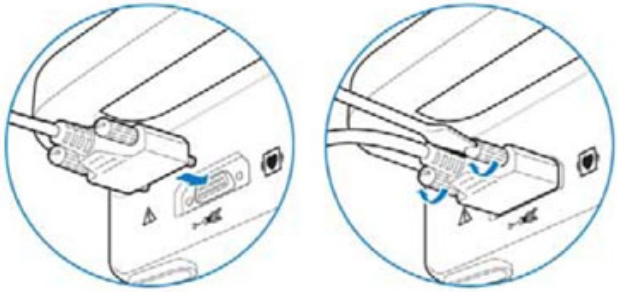
The patient cable is attached to the cardiograph through the patient data connector on the side of the cardiograph.

WARNING

The Philips patient cable (supplied with cardiograph) is an integral part of the cardiograph safety features. Use of any other patient cable may lead to the distortion or corruption of patient ECG data, may compromise defibrillation protection and degrade cardiograph performance, and overall cardiograph safety may be seriously degraded.

To attach the patient cable to the cardiograph:

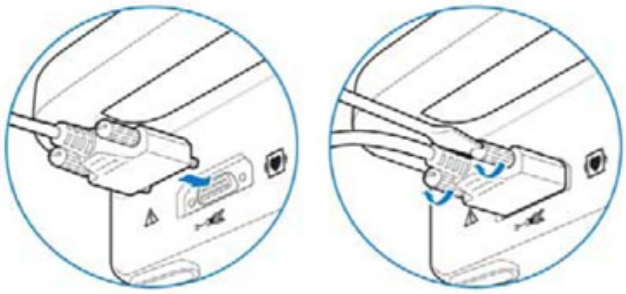
1. Connect the 15-pin connector on the patient cable to the leadset connector port ( ) located on the side panel of the cardiograph.



2. Tighten the screws on each side of the connector.

To detach the patient cable to the cardiograph:

1. Loosen the connecting screws on each side of the connector.



2. Gently pull the connector out.

Caution

Do not pull on the cable to disconnect. Grab the cable connector and pull.

Working with the Battery

WARNING

Use only Philips-approved battery.

WARNING

Do not short-circuit the battery.

WARNING

Do not force-discharge the battery.

WARNING

Do not heat the battery.

WARNING

Do not dispose of battery in fire.

Caution

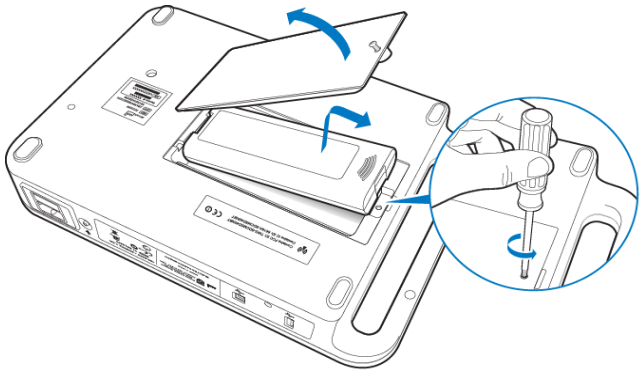
Insert the battery into the cardiograph before plugging the cardiograph into AC power.

The PageWriter TC10 uses one removable lithium ion battery, part number 989803185291. that supplies power to the cardiograph during mobile use, and powers the cardiograph printer while it is plugged into AC power.

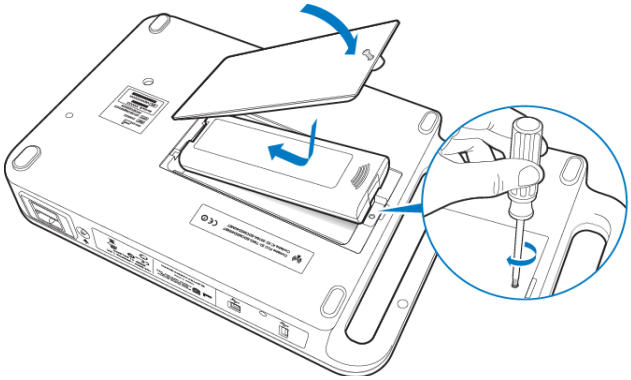
Installing the Battery

To install the battery:

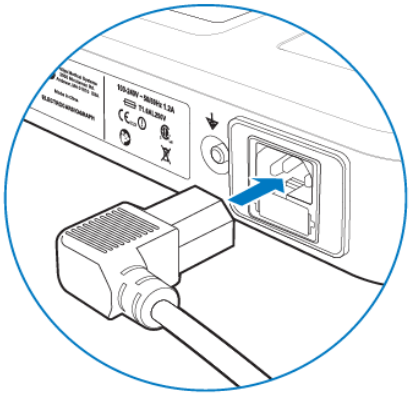
1. Carefully place unit face down on a smooth surface.
2. Use a Phillips head #1 screwdriver to loosen the screw in the battery door.
3. Remove the battery door.



4. If you are replacing a battery, remove the old battery from the compartment.
5. Insert the new battery.
6. Insert the battery door.
7. Use a Phillips head #1 screwdriver to tighten the screw for the battery compartment door.



8. Connect the AC power cord to the cardiograph. Charge the battery for five hours before operating the cardiograph on battery power only.



Caution

- **Do not remove the battery during a patient session if the unit is not plugged into AC power or patient data may be lost.**
- **Before removing and replacing the battery from the cardiograph, unplug the AC power cord from the mains power supply and then press down and hold the On/Standby button (located on the front of the cardiograph) for at least two seconds to shut down the cardiograph. Ensure that the cardiograph is shut down. When the cardiograph is fully shut down, the screen is black, and the On/Standby button is not illuminated. Once the cardiograph is shut down, proceed to remove and replace the battery.**
- **When removing the battery from the cardiograph, the battery could feel warm to the touch, but it will not cause a burn.**
- **Operate the cardiograph, charge the battery, and store the battery at a room temperature of 25°C (77°F) or lower. Exposure to higher temperatures may reduce battery life, damage the battery, and degrade overall cardiograph performance.**

Charging the Battery

Charge the battery for five hours prior to initial use. After initial charging, plug the cardiograph into AC power whenever possible, and ensure that the battery is fully recharged. The cardiograph can operate on AC power while the battery is charging, but the battery will charge at a slower rate. Proper battery maintenance and care, including frequent and full recharging of the battery, will help to prolong battery life. Refer to "Battery Maintenance and Care" on page 100 for tips on achieving optimal battery performance.

Caution

Charging the battery at temperatures greater than 45° C (113° F) can damage the battery.

Note:

- *If the cardiograph is being used regularly, fully charge the battery regularly to prolong battery life.*
- *When the battery is stored in the system, but the cardiograph is off and not in use, a full charge can last two (2) months. After two months, a full recharge is necessary to prevent battery damage.*

The TC10 cardiograph also includes configurable power-saving features to help prolong overall battery life, and to optimize battery power use between battery charges. See "Power Save Features" on page 10.

For optimal battery performance:

- Proper battery maintenance and care, including frequent and full recharging of the battery, will help to prolong battery life.
- After initial charging, plug the cardiograph into AC power whenever possible, and ensure that the battery is fully recharged. The cardiograph can operate on AC power while the battery is charging, but the battery will charge at a slower rate.

How often the battery needs to be replaced depends on how well the battery is maintained and how much it is used. If the battery is fully charged but loses significant power after only a few ECGs, consider replacement. If battery discharge cannot cover normal usage (new battery supports up to 300 reports when fully charged), the recommendation is to order a new battery.

The TC10 cardiograph also includes configurable power-saving features to help prolong overall battery life, and to optimize battery power use between battery charges. See "Power Save Features" on page 10 for an explanation of the P*ower Save* features.

Replacing the Battery

WARNING

Properly dispose of or recycle depleted batteries according to local regulations. Do not disassemble, puncture, or incinerate the disposed batteries.

WARNING

Carefully follow the instructions for installing the new battery. Only use batteries with Philips part number 989803185291.

Caution

- **When removing the battery from the cardiograph, the battery could feel warm to the touch, but it will not burn.**
- **Do not remove the battery during a patient session if the unit is not plugged into AC power or patient data may be lost.**
- **Before removing and replacing the battery from the cardiograph, press down and hold the On/Standby button (located on the front of the cardiograph) for at least two seconds to shut down the cardiograph. Ensure that the cardiograph is shut down.**
- **When the cardiograph is fully shut down, the screen is black, and the On/Standby button is not illuminated. Once the cardiograph is shut down, proceed to remove and replace the battery.**
- **Follow the battery manufacturer's guidelines for battery charging and storage. See "Battery Maintenance and Care" on page 100.**

To order a replacement battery, see *"Ordering Customer Replacement Parts and Accessories" on page 147* in this manual.

Power Save Features

There are configurable power-saving features available on the cardiograph. These features are used to help prolong overall battery life, and to optimize battery power use between battery charges.

To configure Power Save features:

1. From **Setup** on the Toolbar, go to *Configure Cardiograph Default Settings.*
2. Touch **System** to display the *Power Save Features*
   - Default for *Standby* is **ON** → set Minutes of No Activity [insert time]
   - Default for
   - *Shut Down* is **ON** → set Minutes of No Activity [insert time]

Default for Standby Battery Alert is **ON** → set Display [Low, Medium, Max]

Battery Power Indicator

The battery power indicator appears on the Status Bar and is always visible.

Figure 1-5 Battery Power Indicator on the Status Bar



The indicator displays the current battery status. The appearance of the battery power indicator depends on whether or not the TC10 cardiograph is plugged into AC power.

Table 1-2 Battery Power Indicator when plugged into AC power

Icon on Status Bar	Battery Power Level
	The battery is fully charged.
	These four indicators display in a repeating loop to indicate that the battery is charging.

Table 1-3 Battery Power Indicator when not plugged into AC power

Icon on Status Bar	Battery Power Level	
	The battery is fully charged.	
	The battery is at 75% power.	At these three power levels, when the TC10 is in Standby mode and the "Standby Battery Alert" feature is enabled, the system emits an audible alert every 30 seconds to notify the user that the unit is not plugged into AC power and is in Standby mode.
	The battery is at 50% power.	
	The battery is at 25% power.	
	Battery Low. When in Standby mode, the system emits an audible alert every 5 seconds.	
	The battery is removed or cannot be detected.	

Using the Wireless Connection

The TC10 cardiograph supports the Summit SDC-MSD40NBT wireless option.

The wireless option allows the transfer of ECG and order/patient demographic data between the cardiograph and a Philips ECG Management System or IntelliBridge Enterprise server. The cardiograph can also be configured to transfer ECG data using a wireless connection to a third- party ECG management system. For information on configuring cardiograph connectivity, see the *PageWriter TC Cardiograph Network Configuration Guide* available on the *PageWriter TC10 User Documentation* DVD, or the file can be downloaded from the Philips InCenter site.

Caution

Only use appropriate wireless LAN devices with the cardiograph that have been purchased from Philips. The use of non-approved wireless LAN devices with the cardiograph is not tested or supported, and Philips does not guarantee cardiograph operation or wireless LAN connectivity.

For information on installing the option and configuring the cardiograph for wireless transmission, see the *PageWriter TC Cardiograph Wireless LAN Installation and Configuration Instructions.* The file is provided with the Wireless kit, and is also available for download from the Philips InCenter site (https://philips.mizecx.com).

For information on ordering the wireless option, see “Ordering Options and Upgrades” on page 145.

Using a USB Memory Stick

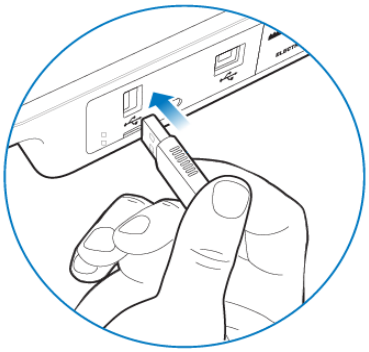
The TC10 Cardiograph can be configured to allow or deny the exchange of data between the cardiograph and a USB memory stick. For details, see “Enabling and Disabling USB Data Exchange” on page 27.

If the cardiograph is configured to allow USB data exchange, a USB memory stick can be used to transfer orders to the cardiograph from a computer that has the WebSelect Utility installed, and can also be used to transfer completed ECGs from the cardiograph as either XML files or as PDF files. A USB memory stick can also be used to save custom settings specified on the Setup screens as a *Custom Settings* file. This Custom Settings file can then be transferred to additional cardiographs to help speed up the configuration process.

For information on using the WebSelect Utility, see the *Using OrderVue with PageWriter Cardiographs* guide. This guide is available for download from the Philips InCenter site. For details, see “PageWriter TC10 Cardiograph Components” on page 2.

A USB memory stick can store up to 200 ECGs. Ensure that the USB memory stick is firmly inserted into the USB connector.

Figure 1-6 USB Memory Stick Inserted Into USB Connector



WARNING

The cardiograph does not support ECG import from a USB memory stick. Do not use a USB memory stick that has been used with other cardiographs or other non-Philips devices.

Caution

- **Do not insert a USB memory stick into the cardiograph, or remove a memory stick from the cardiograph when the cardiograph is acquiring ECG data from a patient.**
- **Only use a USB memory stick to transfer data between a PageWriter cardiograph and a computer. Do not use the memory stick with other devices.**
- **Philips does not guarantee that all USB memory sticks are compatible with the PageWriter TC10 cardiograph. Philips does not supply and verify any specific USB memory sticks and does not guarantee that the EMC compliance is met when the USB memory stick is connected to the PageWriter TC10 cardiograph.**

Using the USB Barcode Reader

The barcode reader is an optional accessory that is used to quickly enter ID information by scanning a barcode. A linear barcode reader is offered. A 2D barcode reader is also supported.

Note:

The linear barcode reader is shipped in Manual Activation Mode to ensure conducted EMI compliance. If you configure the scanner into another operation mode, then EMI compliance is not guaranteed.

The barcode reader attaches to the barcode reader connector or USB host port on the side of the cardiograph. Attach the barcode reader to the cardiograph before turning on AC power. For information on ordering the barcode reader, see “Ordering Customer Replacement Parts and Accessories” on page 147.

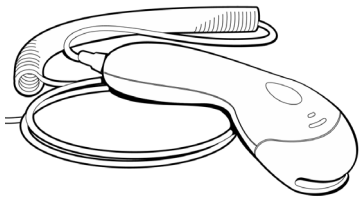
Note:

Both the linear and 2D barcode readers should be configured to use a <TAB> as the suffix of barcode input. The PageWriter TC10 User Documentation DVD includes the following documents that describe how to configure the <TAB> suffix:

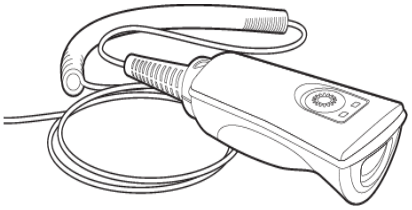
- MetroSelect® Single-Line Scanner Configuration Guide – linear barcode reader
- flexpoint™ HS-1M User's Guide – 2D barcode reader

For a list of supported symbologies, refer to the *Installing and Testing the DECG Barcode Scanner* document.

Figure 1-7 Barcode Readers



Linear Barcode Reader



2D Barcode Reader

The linear barcode reader can scan only a single line item. The 2D barcode scanner can be used to input multiple fields with a single scan on the **New Patient** or **Find Patient** screen:

- Last Name
- First Name
- Additional Name
- Date of Birth
- Gender
- Patient ID
- Physician Name
- Age
- Room
- Race
- Account Number

For more information on configuring and using a barcode scanner with a TC Cardiograph, see the configuration guides located on the *PageWriter TC Cardiograph Documentation DVD*.

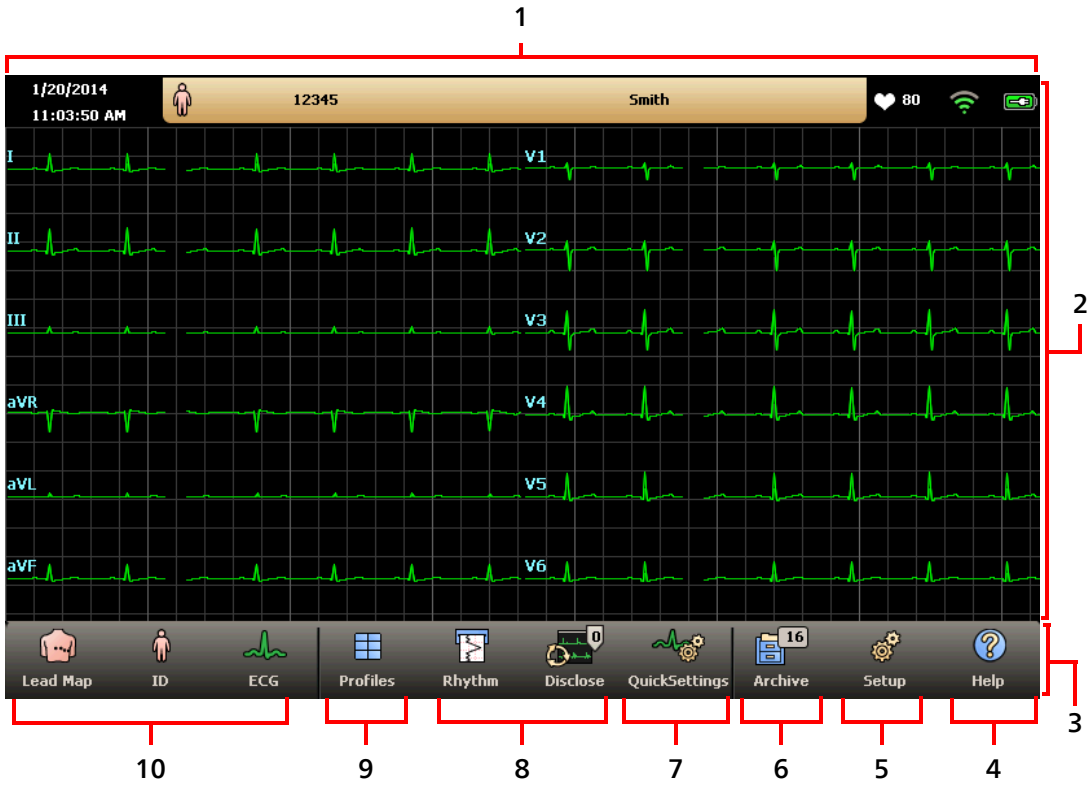
Using the Cardiograph Touch Screen

The touch screen provides access to all of the cardiograph features. Simply touch the buttons on the screen to open the different screens and to perform different functions.

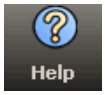
Touch Screen Overview

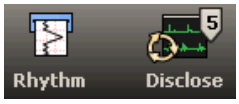
The touch screen is organized into different areas that are grouped by function. The following sections provide an overview of each area of the touch screen.

Figure 1-8 Touch Screen Overview (with 6x2 lead format)



	Feature	Description
1	Status Bar	Displays information about the current cardiograph settings, including current patient name, network connectivity status, heart rate, system power status, and the current date and time.

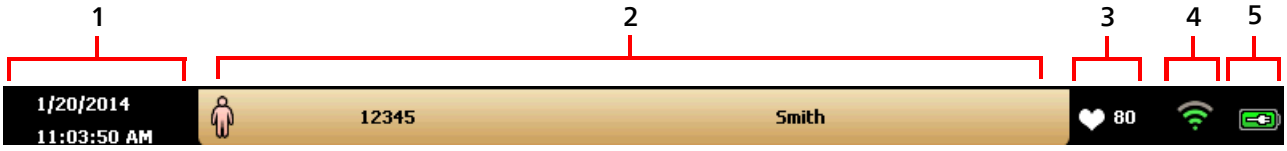
	Feature	Description
2	Waveform Display	• Display area for ECG waveforms. Lead connection quality is indicated by the color of the waveform. • Set the displayed lead format by configuring the Default Display Format in **Quicksettings > Format**, or press the up arrow (↑) or the down arrow (↓) key (on external keyboard) to change the displayed lead format.
3	Toolbar	All cardiograph ECG acquisition modes and ECG management features.
4	Help 	Provides information on how to use the cardiograph. Also provides access to the electronic version of this PageWriter TC10 Cardiograph Instructions for Use.
5	Setup 	The settings underneath this button are used to configure or change cardiograph settings, or to access the service utilities. Access to these screens may require entering a password.
6	ECG Storage and Management Features 	• Provides access to the ECG Archive, which is used as temporary storage for all ECGs acquired on the cardiograph. • From the Archive, ECGs may be transferred to a Philips ECG Management System, or a third-party ECG management system. • From the Archive, a Philips ECG Management System server may be searched for previous ECGs to view and print on the cardiograph. • The number on the button (**10**) displays the number of ECGs currently stored in the Archive.
7	Quicksettings 	Provides access to the Quick Settings toolbar:  The Quick Settings toolbar can be used to change: • Current operating settings • Report format • Interpretation level **Note:** *If a Timed ECG profile has been selected, the* Timed ECG *tab is displayed to the right of the Analysis tab. Use the Timed ECG tab to change the number of ECGs to record and the time interval between ECGs.*

	Feature	Description
8	Rhythm and Disclose Features 	• The Rhythm feature is used to print continuous rhythm strips of up to 12 selected leads until the **Stop** button is touched. • The Disclose feature is used to review captured Events, to view continuous data from one selected lead, or to print ECG reports in a variety of formats. • The number on the **Disclose** button (**5**) displays the number of Events currently stored in Disclose for the current patient session.
9	Profiles 	Provides access to change the selected exam type.

The Status Bar

The Status Bar (top of the screen) provides information about the current cardiograph settings. The Status Bar is always visible.

Figure 1-9 The Status Bar



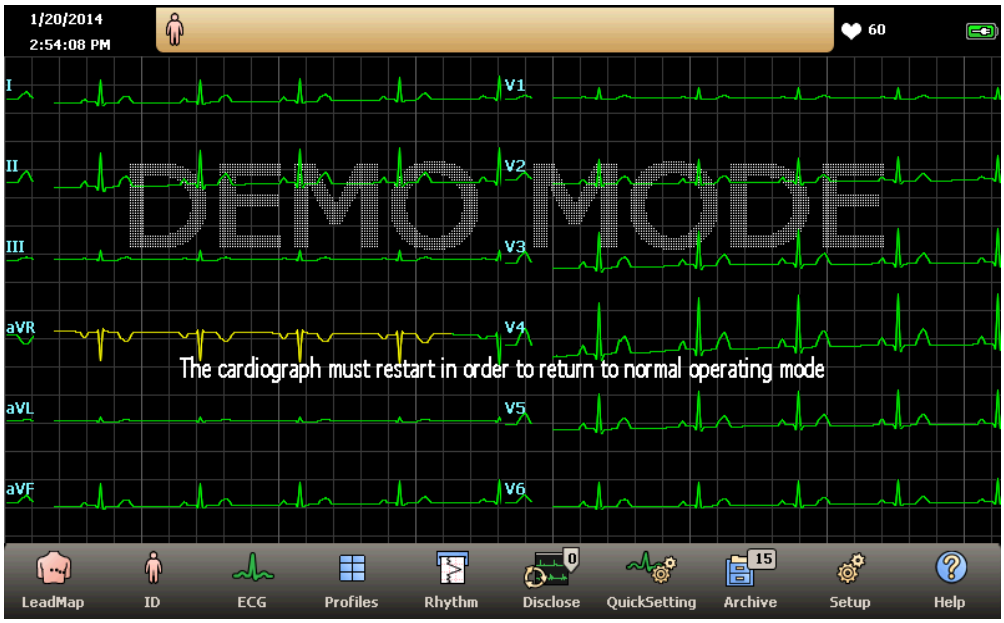
	Feature	Description
1	**Date and Time** 	• Displays the current date and time. • The date and time can be set manually, or the cardiograph can be configured to automatically synchronize the date and time with a Philips ECG Management server. • Go to the **Archive** or **Setup** screens to manually change the date and time (accessing these screens may require entering a password). Tap the displayed date and time to edit the settings.

	Feature	Description
2	**Patient ID Number and Name** 	Displays the patient ID number and patient last name for the current patient session.
3	**Heart Rate Indicator** 	• Displays the patient heart rate in beats per minute. • The icon appears in white when no patient is attached to the cardiograph. **Note:** *The heart rate indicator measurement has been verified with a simulator that can generate ECG waveforms up to 240 bpm (beats per minute). Accuracy of this measurement beyond 240 bpm has not been verified.*
4	**Wireless LAN Connectivity** 	Indicates the signal strength of the wireless LAN connection.  **No signal**  **Low strength**  **Half strength**  **Full strength**
5	**LAN Connectivity**  **Connected**  **No connection**	• Indicates if the cardiograph is connected to a live Ethernet connection through the LAN connector () on the rear of the cardiograph. • If no LAN connection is detected, a red “x” mark appears on the icon.
6	**Battery Power Indicator** 	Displays the available battery power. For more information, see “Battery Power Indicator” on page 11.

Working with Simulated Data

The cardiograph offers a simulation mode in which cardiograph displays simulated waveforms on every screen, as well as on printed reports. This mode may be useful when training users on cardiograph operation.

Figure 1-10 Simulation Mode



When simulated waveforms are enabled:

- No data is acquired from the patient
- A large watermark with the text *Demo Mode* appears on the screen and on printed reports
- Returning from standby keeps the cardiograph in Simulation mode
- After it is initially enabled, restarting the cardiograph ends simulation mode; after a restart, the cardiograph is in real-data acquisition mode.

  To return to simulation mode, you must re-enable it in the settings.

For configuration details, see “Enabling and Disabling Simulation Mode” on page 27.

Keyboards

The cardiograph includes a default, on-screen software keyboard for user input. However, the cardiograph also supports the use of a USB-connected external keyboard.

Philips ECG XML Information

The PageWriter TC10 cardiograph exports ECG data in XML (Extensible Markup Language) format. There are four available XML schema versions on the cardiograph: version 1.03, version 1.04, version 1.04.01, and version 1.04.02.

For information about the Philips ECG XML schema, see the *Data Dictionary and XML Schema Reference*, available under Philips ECG Management product lines in InCenter. For information on using Philips InCenter, see “Using the Philips InCenter Site” on page xiii.

Note:

The default XML version setting on the cardiograph must be coordinated with the XML version compatibility of the Philips ECG Management System, or other third party ECG management system used by your facility. For more information on configuring your cardiograph for use with an external ECG management system, see the PageWriter TC Cardiograph Network Configuration Guide included on the PageWriter TC10 User Documentation DVD, or download the file from the Philips InCenter site.

2

Configuring Default Clinical Settings

All of the settings on the PageWriter TC10 cardiograph may be customized to meet the needs of a specific clinical environment. The cardiograph is shipped with factory default settings, and any of these settings may be changed. All configuration of the cardiograph is completed on the **Setup** screens.

Configuring the Wireless Option

For information on configuring the wireless LAN option, see the *PageWriter TC Cardiograph Wireless LAN Installation and Configuration Instructions* provided with the wireless adapter, or download the file from the Philips InCenter web site (https://philips.mizecx.com). For information on using the Philips InCenter web site, see page xiii.

Password Access

Access to all functions that are used to configure the cardiograph may be set to be password access controlled. It is recommended to change passwords periodically and to change all default passwords to secure passwords.

Note:

Philips strongly recommends enabling password access control when the TC10 cardiograph is used for the first time, and also recommends changing the password periodically.

Tips for Creating Secure Passwords

Use the following guidelines when creating passwords used on the cardiograph:

- Include at least one upper case character
- Include at least one number
- Create passwords at least eight characters in length
- Do not use common words, names, or other easily identified terms

Configuration with a Philips ECG Management System

For information on configuring networking and other settings on the cardiograph that are used with a Philips ECG Management System (including the IntelliBridge Enterprise order handling option), see the *PageWriter TC35 Network Configuration Guide* (only available in English) included on the *PageWriter TC10 User Documentation* DVD, or download the file from the Philips InCenter web site (https://philips.mizecx.com). For information on the Philips InCenter site, see page xiii.

It is recommended that SSL (Secure Sockets Layer) be enabled when transferring ECG reports to a Philips ECG Management System.

Configuration with a Third-Party ECG Management System

For information on configuring networking and other settings on the cardiograph that are used with a third-party ECG management system, see the *PageWriter TC Cardiograph Network Configuration Guide* (only available in English) included on the User Documentation DVD, or download the file from the Philips InCenter web site (https://philips.mizecx.com). For information on the Philips InCenter site, see page xiii.

Restoring Custom Configuration Settings

After configuring the cardiograph, save the settings to a USB memory stick, or to a configured shared remote computer in case of system failure. If the cardiograph loses custom settings, the settings may be quickly and easily restored by loading them onto the cardiograph from a USB memory stick, or from a configured shared remote computer. For information on configuring a shared remote computer, see the *PageWriter TC35 Network Configuration Guide*.

To save custom settings, touch **Setup > Configure Cardiograph Default Settings > Save/Load** (top of screen). Instructions on how to save custom settings is provided directly on this screen. For information on using the Setup Help, see “Using Setup Help” on page 24.

Configuring Multiple Cardiographs

When configuring multiple cardiographs with the same Philips ECG Management System and IntelliBridge Enterprise settings, you can save all settings to a USB memory stick, or to a remote shared computer, and then upload them to additional TC cardiographs.

Note:

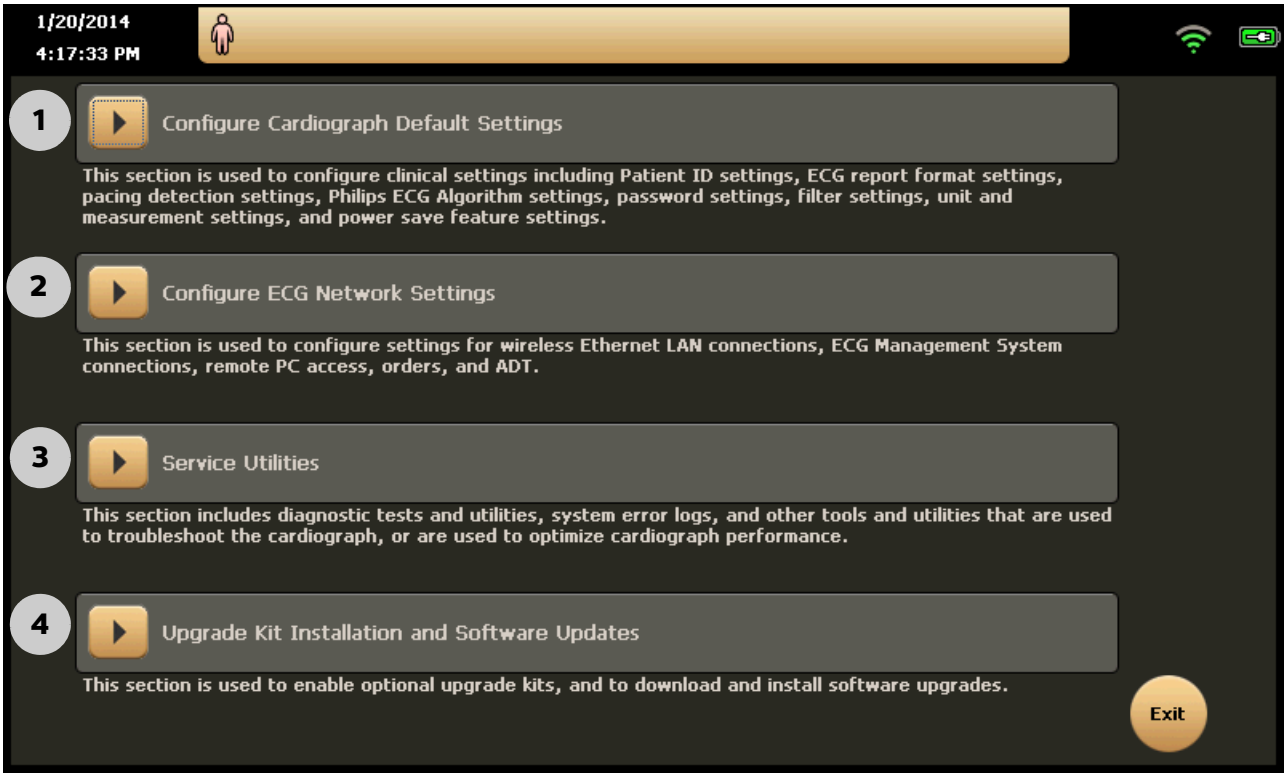
Wireless LAN settings are saved with the network settings.DAT file.

Opening the Setup Screens



To open the setup screens, touch the **Setup** button on the toolbar. The Setup menu appears.

Figure 2-1 The Setup and Service Utilities Menu



	Feature	Description
1	Configure Cardiograph Default Settings	• Touch to configure all clinical settings used on the cardiograph, including Simulation mode. • Touch to configure password and power save features. • Includes Maintenance Tests that can be used to troubleshoot or to optimize cardiograph performance. For more information, see Chapter 5, "Cardiograph Care and Maintenance."
2	Configure ECG Network Settings	• Touch to configure Philips ECG Management System, IntelliBridge Enterprise, Inbox, or third-party ECG management system settings. • Touch to configure LAN and wireless LAN connectivity. • For more information, see the *PageWriter TC35 Network Configuration Guide* (only available in English).

	Feature	Description
3	Service Utilities	• Touch to access the Service Utilities, including all maintenance and performance tests. • For more information on using the Service Utilities, see the *Service Manual* (only available in English).
4	Upgrade Kit Installation and Software Updates	• Touch to access software updates and to add options. • See the *Service Manual* (only available in English)

Using Setup Help

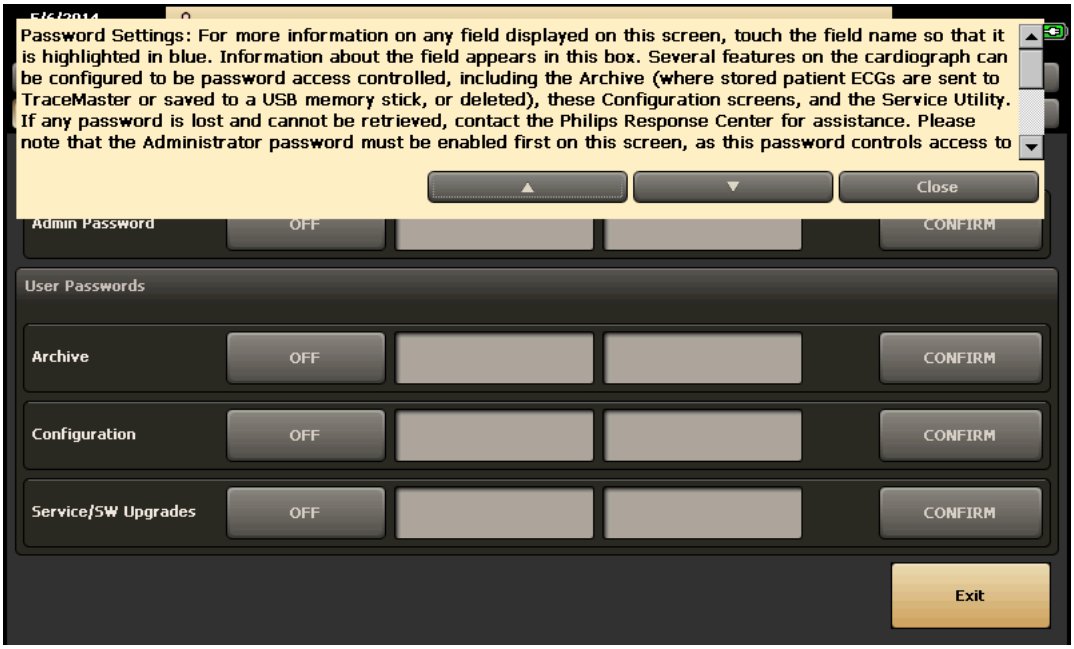
Each Setup screen within the cardiograph software application provides Help that describes the currently selected option or field. Use the Help when configuring cardiograph settings, or to learn more about a specific feature or item.

When a Setup screen is opened, Help displays in a yellow *Information box* that appears on the screen. Touch the **Close** button when done. Touch a tab, or touch the name of any field or option displayed on the screen to display Help for that specific item.

To view help for a tab or field:

1. Touch a tab or touch the name of the field or option so that it is highlighted in blue. Help for the selected item displays in the yellow Information box on the screen (see Figure 2-2 on page 24).
2. Touch **Close** when done.

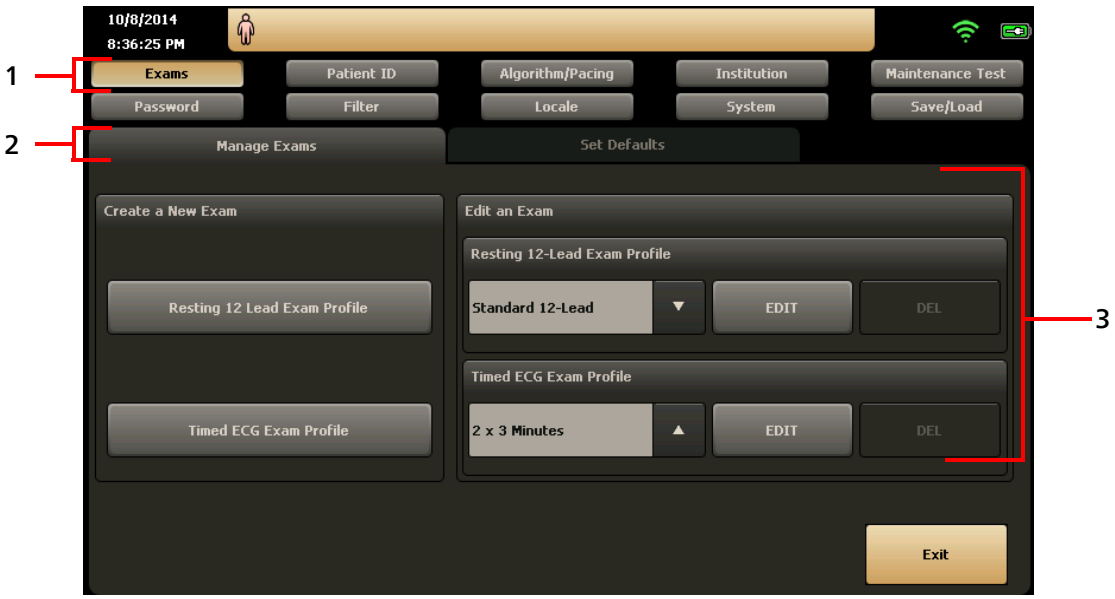
Figure 2-2 Help Displayed on a Setup Screen



Configuring 12-Lead Exam Settings

The Exam setup screen is used to specify ECG operating settings and 12-lead ECG report settings. Each set of defined settings is saved as an individual *Exam Profile* that is given a unique name. This Exam Profile can then be selected during a patient session.

Figure 2-3 The Exams Setup Screen



1 **Exams** button selected

2 **Manage Exams** tab selected

3 **Edit an Exam** drop-downs

To configure Exams settings:

1. Touch **Exams** (top left of screen) on the Default Cardiograph Settings screen.
2. The Exams setup screens appear. The **Manage Exam** tab is selected.
3. Touch a button under **Create a New Exam** to begin creating a new Exam for Resting 12-lead or Timed ECG.
4. On the following screen select a lead sequence (**Standard** or **Cabrera**). Touch **Next** (bottom right of screen) to continue.
5. On the following screen, select a report format to specify for this Exam. Select the Rhythm leads for the selected report format (if necessary). Touch **Next** to continue.
6. Select the settings for the selected report format; these settings include the waveform scale and size settings, and if the ECG data shown on the report is captured simultaneously, or time sequentially. On the right side of the screen,

select an interpretation level for the Philips 12-lead or DXL ECG algorithm. Touch **Next** to continue.

7. The following screen specifies the Rhythm leads and the waveform speed and scale settings for all Rhythm reports printed using this Exam Profile.
8. Touch **Back** to return to any previous screen and make edits. Touch **SAVE** when complete.
9. The Create New Exam profile window appears. Enter a name for the Exam Profile. Touch **OK**. The Exam Profile is now saved and may be selected during a patient session. The new Exam Profile settings may also be edited. Select the Exam Profile from the **Edit an Exam** drop-down menus on the main Exams Setup screen. See Figure 2-3, “The Exams Setup Screen,” on page 25.

Note:

- *The Print Severity setting enables the printing of the ECG severity on the ECG report. For more information on the Severity setting, see “Interpretive, Reason, and Severity Statements” on page 70.*
- *The Extended Measurements setting enables the printing of the full Extended Measurements Report with each ECG. For details, see “Extended Measurements Report” on page 93.*

Configuring 30 or 60 second reports

To configure for 30 or 60 second reports:

1. Touch **Setup > Configure Cardiograph Default Settings > Exams.**
2. Touch **Resting 12-Lead Exam Profile** or **Resting Extended Lead Exam Profile.**
3. Create a new exam profile and touch **Next**.
4. Select a report format and rhythm lead and touch **Next**.
5. Turn on **Large Report**.



6. Select **30 seconds** or **60 seconds**.
7. Touch **Next** and save the profile.

Enabling and Disabling Simulation Mode

For details on Simulation mode, see "Working with Simulated Data" on page 18.

To enable or disable Simulation mode:

1. On the Default Cardiograph Settings screen, touch **System**.
2. In the **Simulation Mode** field, touch the **OFF/ON** button. If the button is set to **OFF**, simulation mode is disabled. If the button is set to **ON**, simulation mode is enabled.

   To enable simulation mode, touch the button to set it to **ON**.

   To disable simulation mode, touch the button to set it to **OFF**.



3. Touch **Exit** to save the setting and exit Setup.
4. Touch **OK** to restart the cardiograph. A restart is required to change the Simulation mode setting.

Note:

After it is initially enabled, restarting the cardiograph ends simulation mode; after a restart, the cardiograph is in real-data acquisition mode.

Enabling and Disabling USB Data Exchange

The TC10 Cardiograph can be configured to permit or deny the exchange of data between the cardiograph and a USB memory stick. By default, the cardiograph is set to allow USB data exchange. This setting can be configured on the System setup screen.

To enable USB data exchange:

1. On the Default Cardiograph Settings screen, touch **System**.
2. In the **Disable USB Data Exchange** field, touch the **OFF/ON** button. When the button shows **OFF**, the exchange of data between the cardiograph and a USB memory stick is enabled.



3. Touch **Exit** to save the setting and exit Setup.

To disable USB data exchange:

1. On the Default Cardiograph Settings screen, touch **System**.

2. In the **Disable USB Data Exchange** field, touch the **OFF/ON** button. When the button shows **ON**, the exchange of data between the cardiograph and a USB memory stick is disabled.



3. Touch **Exit** to save the setting and exit Setup.

3

The Patient Session

Introduction

A patient session is the period of time when waveform data is acquired and processed from a single patient. A patient session begins by entering accurate patient information. Patient information is then linked with all waveform data acquired during the patient session.

Caution

- **Entering accurate patient information (age, gender) is highly recommended if using the Philips DXL ECG Algorithm, versions PH100B and PH110C, for ECG interpretation. For more information see the applicable** *Physician's Guide* **on the** *PageWriter TC User Documentation DVD***, or download the file from the Philips InCenter site (https://philips.mizecx.com).**
- **Before acquiring an ECG, ensure that the cardiograph screen does not show the DEMO MODE watermark on the waveform screen or report, and the Patient ID does not display the text,** *Simulated data***. If these elements are present, the cardiograph is in Simulation mode and is not acquiring patient data! Restart the cardiograph to exit Simulation mode. For details, see "Working with Simulated Data" on page 18.**

The steps in a typical patient session are described below.

The Patient Session		
Prepare the Patient		
Step	**Description**	**More Information See...**
1	Prepare the patient for the procedure.	"Patient Preparation" on page 32.

The Patient Session

Prepare the Patient

Step	Description	More Information See...
2	Prepare the electrode sites and attach the electrodes.	• "Preparing the Skin" on page 32. • "Electrode Placement" on page 33. • "Attaching Disposable Electrodes" on page 35. • "Attaching Welsh Bulb and Limb Clamp Electrodes" on page 36.
3	Attach the patient cable.	"Attaching the Patient Cable" on page 37.

Enter Patient Information or Take a STAT ECG

Step	Description	More Information See...
1	Return the cardiograph to active use.	"Using the On/Standby Button" on page 38.
2	• Take an urgent/STAT ECG • Enter patient information or select an order from the Worklist	• "Urgent (STAT) ECGs" on page 49. • "Entering Patient Information" on page 39.

Check the Signal Quality

Step	Description	More Information See...
1	When the patient is connected to the cardiograph, color-coded ECG waveforms appear on the Main screen. Check the signal quality.	"Checking Signal Quality" on page 44.
2	Touch **Lead Map**, or press the **Map** button on the cardiograph to verify electrode and lead connections.	"Leads Map" on page 45.

The Patient Session

Select an ECG Acquisition Mode

Step	Description	More Information See...
1	Do any of the following:	
	Capture Events for review on the Disclose screen	"Capturing Events from the Main or Rhythm Screens" on page 59.
	Print an Auto ECG	"Main ECG Screen" on page 50.
	Print a Rhythm report	"Rhythm ECG Acquisition" on page 55.
	Use the Disclose feature to: - Review Events captured on the Main or Rhythm screens - Print a 12-lead ECG of captured Event data - View continuous waveform data for a selected Disclose lead - Print a 1-minute report of a selected Disclose lead - View live patient waveform data for a selected Disclose lead	"Disclose ECG Acquisition" on page 58.
	Use the Timed ECG feature to take ECGs at preset intervals	"Using Timed ECG" on page 61.

View, Print, Save, and Transfer ECG(s) from the Preview Screen

Step	Description	More Information See...
1	Compare the most recent ECG from the same patient using the optional **Last ECG** feature (requires an active Philips ECG Management System connection)	• "Using the Last ECG Feature on the Preview Screen" on page 54. • "Critical Values on Preview Screen" on page 54.

End the Patient Session

Step	Description	More Information See...
1	Disconnect the patient.	

The Patient Session
The patient session ends when: • New patient information is entered or a new pending order is selected • The cardiograph enters Standby or is shut down • The patient is disconnected or leads are off for more than 10 seconds • Archive or Setup are selected

Patient Preparation

Thorough patient preparation techniques are essential for a good quality ECG. Follow the procedures listed in this section to ensure a quality ECG for each patient.

Note:

Good ECG technique is very important to achieve the best quality results.

Instructing the Patient

Before attaching the electrodes, greet the patient and explain the procedure. Explaining the procedure decreases anxiety and informs the patient about what to expect.

- Privacy is important to relaxation. When possible, take the ECG in a quiet room or area where others can't see the patient. Draw the curtains around the bed when taking the ECG in a room with other people.
- Reassure the patient that the procedure is painless.
- Make sure the patient is lying down and is comfortable. The patient's arms and hands must be relaxed. If the table is too narrow, place the patient's hands under the buttocks to prevent muscle tension in the arms.

Once the electrodes and patient cable are attached, instruct the patient to:

- Remain still and do not talk
- Breathe normally
- Try not to shiver
- Do not chew or clench teeth

The more relaxed the patient, the less the ECG will be affected by noise.

Preparing the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. There is a natural resistance on the skin surface due to dry, dead epidermal cells, oils, and dirt.

Note:

The area of the skin where the electrodes are applied must be clean and free of skin oil.

To prepare the skin:

1. Clip hair from electrode sites if necessary (excessive hair prevents a good connection).
2. Wash thoroughly with soap and water.
3. Dry the skin vigorously to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oil.

Note:

Do not use alcohol *to clean the skin because it dries the skin. If there is no time to follow the procedure above, rub the site with gauze to remove dead, dry skin and to increase capillary flow.*

Electrode Placement

Review the following lead labeling and electrode placement information to ensure a quality ECG.

AAMI Lead	IEC Lead	Electrode Position
RL	N	On the right leg (inside calf, midway between knee and ankle)
LL	F	On the left leg (inside calf, midway between knee and ankle)
RA	R	On the right arm (on the inside)
LA	L	On the left arm (on the inside)
V1	C1	Right side of the sternum in the 4th intercostal space
V2	C2	Left side of the sternum in the 4th intercostal space
V3	C3	Midway between V2/C2 and V4/C4

AAMI Lead	IEC Lead	Electrode Position
V4	C4	Left midclavicular line in the 5th intercostal space
V5	C5	Anterior axillary line at the same level as V4/C4
V6	C6	Left midaxillary line at the same level as V4/C4

Figure 3-1 Male Standard 12-Lead Electrode Placement (AAMI/IEC)

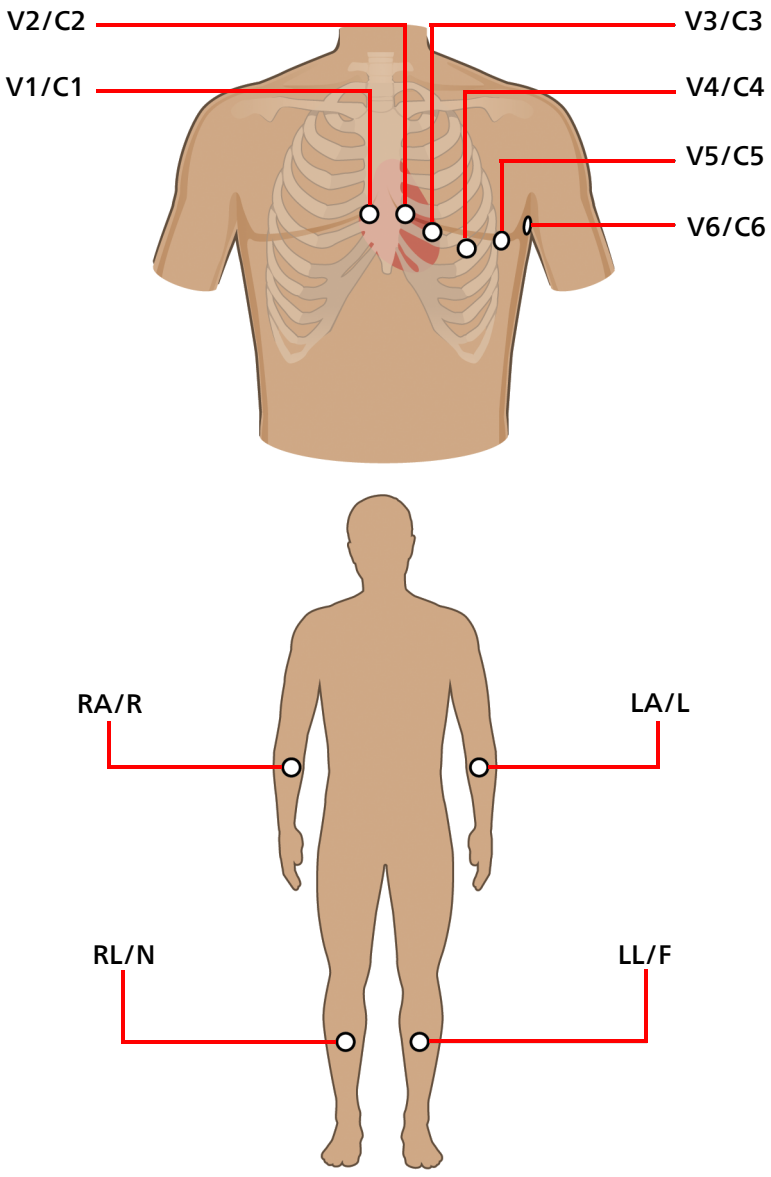
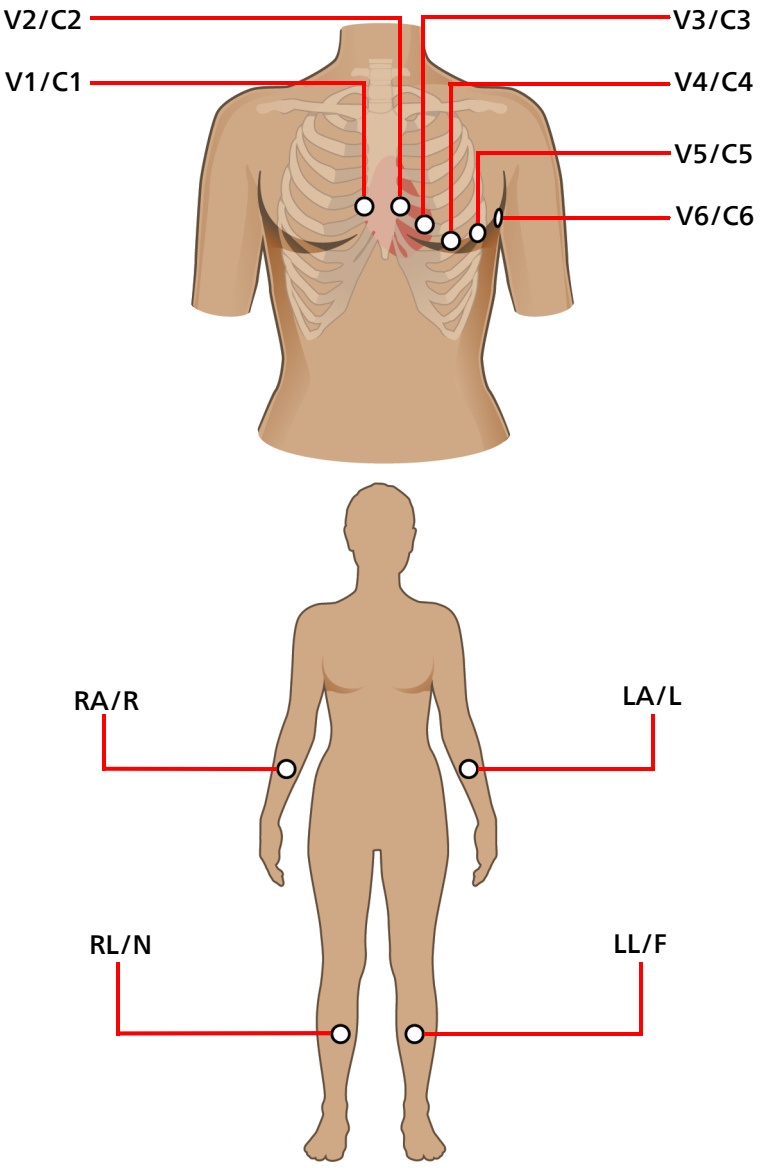


Figure 3-2 Female Standard 12-Lead Electrode Placement (AAMI/IEC)



Attaching Disposable Electrodes

For the best quality ECG, ensure that all skin preparation procedures described in “Preparing the Skin” on page 32 have been followed.

To attach disposable electrodes:

1. Expose the arms and legs of the patient (to place the limb electrodes).
2. Place the electrodes on flat, fleshy parts of the arms and legs.
3. Place the electrodes on the inside of each arm (between the wrists and elbows).
4. Place the electrodes on the inside of each calf (between the knee and the ankle).
5. Place the limb electrodes equal distance from the heart. Position the electrodes at the same place on each limb.

6. If a limb site is not available (amputation, injury) place the electrodes closer to the torso.
7. Attach the electrodes to the skin. A good test for firm electrode contact is to try to move it. If it moves easily, the electrode connection is too loose. Do not allow the electrodes to move in any way.

Attaching Welsh Bulb and Limb Clamp Electrodes

Special Note about Welsh Bulb Electrodes

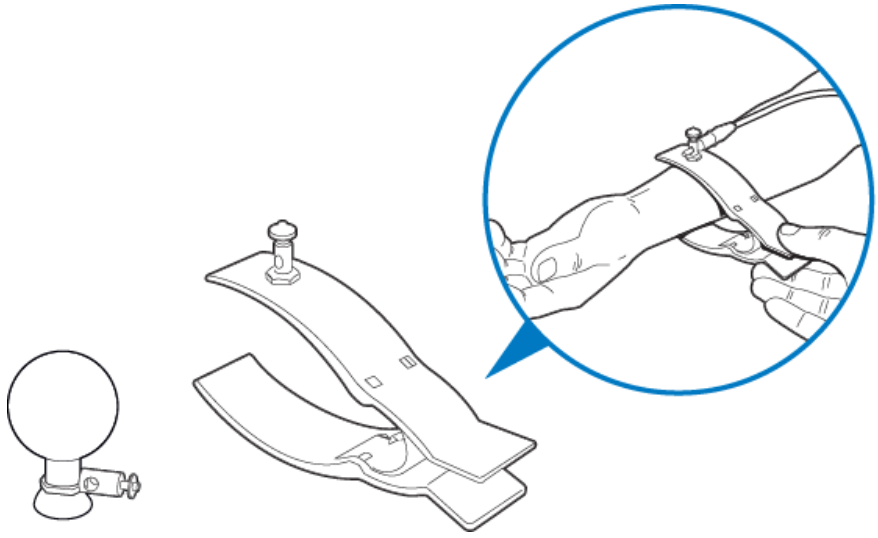
Special care is necessary when using Welsh Bulb electrodes. Pay special attention to all warning associated with these electrodes. For information on cleaning the reusable Welsh Bulb electrodes, see “Reusable Electrode Cleaning” on page 97. Philips recommends the use of disposable electrodes at all times with the PageWriter TC cardiograph.

WARNING

Always clean and disinfect reusable electrodes before patient use. See “Reusable Electrode Cleaning” on page 97 for information on cleaning and disinfecting reusable electrodes. Failure to properly clean and disinfect reusable electrodes before patient use may cause infectious materials to be transferred between patients.

The Welsh Bulb electrode is a self-restraining electrode that consists of a squeeze bulb and a metal cup. The squeeze bulb provides sufficient suction to hold the electrode firmly on the patient without causing discomfort. This electrode is used on the chest. The limb clamp electrodes are used on the arms and legs. Philips recommends the application of highly conductive multipurpose electrolyte gel to the electrode site whenever Welsh Bulb and limb clamp electrodes are used.

Figure 3-3 Welsh Bulb and Limb Clamp Electrode



For the best quality ECG, ensure that all skin preparation procedures described in "Preparing the Skin" on page 32 have been followed.

To attach disposable electrodes:

1. Expose the arms and legs of the patient (to place the limb plate electrodes).
2. Inspect both the limb clamp and the Welsh Bulb electrodes to ensure that both are clean. For information on cleaning reusable electrodes, see "Reusable Electrode Cleaning" on page 97.
3. Ensure that the patient cable and the lead wires are not twisted, and lay the patient cable flat.
4. Connect the lead wire to the corresponding electrode, this may be done one electrode at a time for convenience.
5. Apply a thin layer of electrolyte gel to the area of the skin where the electrode will be applied. The skin area covered by the electrolyte gel should not exceed the diameter of the electrode.
6. Rub the electrode on the skin with a circular motion to apply and spread the electrolyte gel to the electrode surface and skin. This is very important if the patient's skin is extremely dry. If the patient's skin is excessively hairy, follow the procedure "Preparing the Skin" on page 32 to remove hair from electrode sites.
7. Hold the electrode on the patient's skin and depress the top of the rubber bulb.
8. Release the bulb, and the electrode attaches to the patient. A good test for firm electrode contact is to try to move it. If it moves easily, the electrode connection is too loose. Do not allow the electrodes to move in any way.

Note:

- *Place the electrodes on flat, fleshy parts of the arms and legs.*
- *Place the electrodes on the inside of each arm (between the wrists and elbows).*
- *Place the electrodes on the inside of each calf (between the knee and the ankle).*
- *Place the limb electrodes equal distance from the heart. Position the electrodes at the same place on each limb.*
- *If a limb site is not available (amputation, injury) place the electrodes closer to the torso.*

To remove limb clamp and welsh bulb electrodes, detach the rubber bulb from the metal cup by pulling. Follow the procedure, "Reusable Electrode Cleaning" on page 97, to clean reusable electrodes after each use.

Attaching the Patient Cable

Each lead wire tip is labeled and color-coded for easy identification.

To attach the patient cable, attach each lead wire to the corresponding electrode.

Using the On/Standby Button

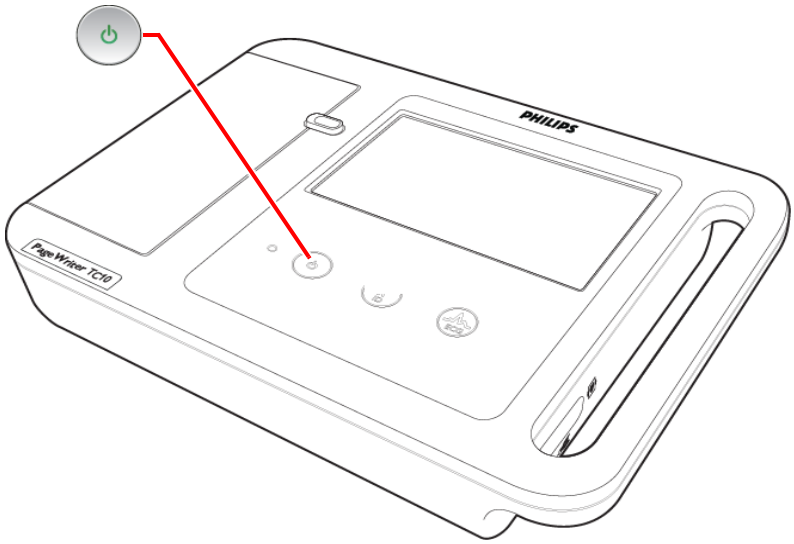
The **On/Standby** button is used to:

- Put the cardiograph into Standby when not in active use in order to conserve battery power;
- Shut down all power to the cardiograph for extended periods of inactivity;
- Return the cardiograph to active use.

Caution

- **Ensure that all patient data from an active patient session is saved before entering Standby or shutting down the cardiograph. Unsaved patient data (patient identification information, unreviewed Event Markers, unsaved ECGs) are deleted when the cardiograph enters Standby.**
- **Do not remove the battery during a patient session if the unit is not plugged into AC power, or patient data may be lost.**

Figure 3-4 PageWriter TC10 On/Standby button



To put the cardiograph into Standby (power save):

1. Press the **On/Standby** button gently to put the cardiograph into Standby. When the cardiograph is in Standby, the screen is black.
2. Press the **On/Standby** button again to return the cardiograph to active use. The screen displayed prior to entering Standby appears.

Note:

Plug the cardiograph into AC power whenever possible to recharge the battery.

Note:

- *You can pre-configure the power save time. See "Power Save Features" on page 10.*
- *If overall battery power is below 15% and the cardiograph is in Standby, when you press the On/Standby button, it will flash green five times and the cardiograph will be unable to return to active use. Plug the cardiograph into AC power to recharge the battery.*
- *If the Disclose or Rhythm screens are viewed prior to entering Standby, the Main screen will appear when the cardiograph is returned to active use.*

To shut down the cardiograph:

1. Press and hold the **On/Standby** button for 3 seconds to shut down the cardiograph. When the cardiograph is shut down, any unsaved patient data is lost.
2. Press the **On/Standby** button to return the cardiograph to active use. The cardiograph fully restarts and the Main screen appears.

Entering Patient Information

Patient information is entered by:

- Virtual keyboard
- External USB keyboard
- Selecting a pending order
- Barcode reader (optional)

Required ID Information

Required patient information is indicated in blue type on the ID screen. This information must be complete in order to transmit an ECG (as either an XML or PDF file) from the Archive to a Philips ECG Management System, or to a USB memory stick. The ID fields that are required are designated by your supervisor.

Caution

The Gender, Age, DOB, and Prescriptions(Rx) fields of patient data affect the interpretive diagnostic statements generated by the cardiograph. If any of these fields are incorrect, the cardiograph will generate incorrect interpretive statements. If patient data is incorrect, edit the patient information and take a new ECG.

Navigating on the ID Screen

- To move to the next field on the screen, press the *Tab* key (on external keyboard only).

- To move to the previous field on the screen, press and hold the *Shift* key (on external keyboard only) and then press the *Tab* key.

Entering ID Information with the Keyboard

To enter ID information with the keyboard:

1. Touch **ID** on the Toolbar. The ID screen appears. The New Patient tab (top of screen) is selected. Patient information is entered under this tab. Fields in blue are required (if configured) and must be completed



2. Enter the information. Press the ***Tab*** key (on keyboard) to scroll between the different fields.

Note:

Do not add any spaces to the **ID** *number field if you will be transferring ECGs to an IntelliSpace ECG Management System.*

---

3. Touch **OK** when done.

Note:

A message will appear if you exit the ID screen before completing the required patient information fields.

Entering ID information with the Barcode Reader

To enter ID information with the barcode reader:

1. Touch **ID** on the Toolbar. The ID screen appears. The New Patient tab (top of screen) is selected. Patient information is entered under this tab. Fields in blue are required (if configured) and must be completed



2. Scan the patient's barcode. Available data will populate the appropriate fields. You can manually enter any other data in unpopulated fields, if required or desired.

Note:

Do not add any spaces to the **ID** *number field if you will be transferring ECGs to an IntelliSpace ECG Management System.*

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3. Touch **OK** when done.

Note:

A message will appear if you exit the ID screen before completing the required patient information fields.

Selecting a Record from the Worklist

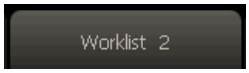
Any record contained in the Worklist may be selected for a patient session. Records are downloaded to the cardiograph from a specified Philips ECG Management System Remote Site through an inbox configured for use on the cardiograph.

To select a pending record for a patient session:

1. Touch **ID** on the Toolbar. The ID screen appears. The New Patient tab (top of screen) is selected.



2. Touch the **Worklist** tab (top of screen). The selected tab is highlighted in blue. The Worklist screen appears.



Note:

*The number displayed on the Worklist tab (**2**) indicates how many pending records are available in the Worklist.*

3. The records available in the Worklist appear on the screen. Touch a record to select it. The selected record is highlighted in blue.
4. Touch **Select** (lower right corner of screen) to select the highlighted record for the current patient session. The Main screen appears with the patient information for the selected record appearing on the Status Bar (top of screen).

Note:

Touch and hold the record for one second to display a pop-up window with additional order/ADT information.



Searching for Orders/ADT Updates

You can search for records in any inbox that is available on the cardiograph.

Or, you can search for a record during an active patient session by using data scanned from a barcode reader.

The cardiograph must be connected to the network in order to use the search feature.

To search for records:

1. Touch **ID** on the Toolbar. The ID screen appears. The New Patient tab (top of screen) is selected.

2. Touch the **Find Patient** tab (top of screen). The selected tab is highlighted in blue.

3. The **Location** drop-down list (top left of screen) contains all of the available search locations for the cardiograph. Touch the drop-down arrow button to open the list. Touch a location to select it. The selected location appears highlighted in blue and the list closes.

Note:

Worklist *is the internal cardiograph pending order and/or patient record list.*

---

4. Enter search data into the available fields including **Patient ID**, **Last Name**, **First Name**, **Date of Birth**, and **Room** (number).

   The entered information will be used to search for records. To search using data entered from an external device (barcode reader, magnetic card reader, Smart Card reader), place the cursor in the field in which the data is to be scanned. Scan the data. The data appears in the field.

Note:

*Enter the wildcard character (*) into any field to broaden the search information. For example, to search for orders for all patients with the last name of Doe, enter Doe into the Last Name field, and enter * into the First Name field.*

---

5. The selectable optional search field is located at the upper right of the screen.

   This available optional search field includes the following options: **Order Number**, **Account Number**, **Gender**, **Unit Number** or **Priority** (STAT).

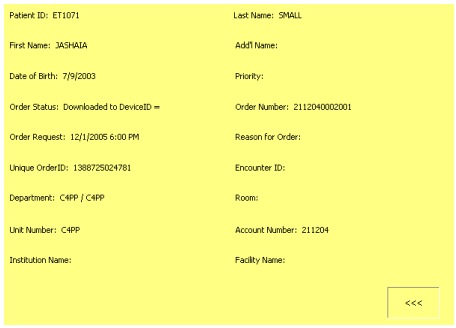
ADT patient information includes **Account Number**, **Gender**, **Unit Number**, **Encounter ID**, and **Bed Number**.



6. Touch the drop-down arrow to open the list of optional search fields. Touch an optional search field to select it. Then, enter search data into the field.
7. When all patient information to be used in the search is entered, touch **Find** (bottom of screen). The Message Bar (bottom of screen) displays the search status.
8. Touch a record to select it. The selected record appears highlighted in blue. To select the highlighted record for the current patient session, touch **Select** (bottom of screen).

Note:

- *Touch* **Cancel** *to exit the screen without saving the record.*
- *Touch and hold the record for one second to display a pop-up window with additional order/ADT information.*



Editing ID Information

Patient information may be edited at any time during a patient session, or may be edited for a single ECG on the Archive screen. A message appears if changes made to patient information could affect ECG interpretation.

Changes to patient information are applied to all ECGs taken during an active patient session, or to a single ECG stored in the Archive.

To edit ID information:

1. From Archive only, touch the saved ECG that you wish to edit. The selected item is highlighted in blue.
2. From the Main screen, or from Archive, touch **ID**. The ID screen appears.



3. From Archive, the **Edit Patient ID** tab is automatically selected, or touch this tab to select it. The selected tab is highlighted in blue.



4. Edit the ID information displayed on the screen. Press the *Tab* key (on keyboard) to scroll between the different fields.
5. Touch **OK** to save the changes.

Note:

Touch **Cancel** *to exit the screen without saving the record.*

Checking Signal Quality





The signal quality of each lead is indicated by the color of the lead as displayed on the screen. In addition to the color-coded signal quality indicators, there are additional signal quality features available on the cardiograph. If the signal quality of all leads is good, and all required patient information has been entered, the **ECG** button (front panel of cardiograph) illuminates, indicating that the ECG is ready to be taken.

In addition, touch **Lead Map** or press the **Map** button on the cardiograph to check for any loose or disconnected leads or electrodes. When you touch **Lead Map** or press the **Map** button, a lead diagram appears and any loose or disconnected leads are indicated with a red *x* mark ( ).

Finally, when using the Philips DXL ECG Algorithm, the cardiograph also detects the one of 20 lead reversals. After you press the ECG button, if detected, an alert message appears on the screen indicating one of the following conditions:

V1-V2 swapped	V1-V3 swapped	V1-V4 swapped
V1-V5 swapped	V1-V6 swapped	V2-V3 swapped
V2-V4 swapped	V2-V5 swapped	V2-V6 swapped
V3-V4 swapped	V3 V5 swapped	V3-V6 swapped
V4-V5 swapped	V4 V6 swapped	V5-V6 swapped
LA-LL swapped	LA-RA swapped	RA-LL swapped
LA-LL-RA swapped (counter-clockwise rotation)		LA-RA-LL swapped (clockwise rotation)

For information on troubleshooting signal quality issues, see “Troubleshooting Signal Quality” on page 46.

Color-Coded Waveforms

When the patient cable is attached to the patient (with the cardiograph turned on), waveforms appear on the Main ECG screen. The color of the waveform indicates the signal quality of the individual lead.

Waveform Color	Indicates...	Possible Causes
Green waveform	Good connection	
Yellow waveform	• Moderate noise level, artifact, electrical interference, or a poor electrode connection • ECG quality will be affected	• Inadequate patient preparation • Electrical interference from another device • Moderate patient movement, tense patient • Improperly gelled electrode (dried gel)
Orange waveform	• Severe artifact, electrical interference, or a poor electrode connection • One or more limb leads are disconnected (chest leads display in orange)	• Electrical interference from another device • Patient tremors, shivering patient, inadequate preparation • Very poor electrode contact, dry electrodes
Red dotted line	• Loose electrode connection • ECG waveform data that cannot be analyzed	• Inoperative electrode, electrode that has fallen off the patient • Defibrillation has been performed too recently to take ECG measurements • Broken leadset • Other cause that renders waveform data useless

Leads Map

The Leads Map is a graphical representation of a patient that shows the location of loose or inoperative electrode(s). The Leads Map is available on the Main screen only.

To open the Leads Map:

1. Touch **Lead Map** on the tool bark, or press the **Map** button on the cardiograph.



2. The location of a loose or inoperative electrode is indicated with a red *x* mark ( ).

Troubleshooting Signal Quality

Always follow good skin and patient preparation techniques prior to taking an ECG. Proper skin preparation helps to ensure a good quality ECG. Skin is a poor conductor of electricity and frequently creates artifact that distorts the ECG signal. For more information, see “Patient Preparation” on page 32. A dotted line, known as a “leads off” trace will appear on the display when there is a poor connection between the electrode and the patient.

Use the following table to identify and correct the connection:

Table 3-1 Identification of Leads Off Connections

Symptom	Check Electrode
All 12 leads show discontinuities or dashed lines	RL or N (right leg) electrode or cable wire
All leads except I show discontinuities or dashed lines	LL or F (left leg) electrode or cable wire
All leads except II show discontinuities or dashed lines	LA or L (left arm) electrode or cable wire
All leads except III show discontinuities or dashed lines	RA or R (right arm) electrode or cable wire
Any combination of chest (V) leads shows discontinuities or dashed line	Indicated chest (V) electrodes or cable wires

Identifying ECG Problems

The following table shows symptoms and solutions to problems that can occur when recording an ECG.

Table 3-2 ECG Problems and Solutions

Symptom	Cause	Possible Solutions
Power line AC Interference 	Poor electrode contact. Dry or dirty electrodes.	Abrade skin. Use new electrodes. Reapply electrodes. Check expiration date on disposable electrodes.
	Lead wires may be picking up interference from poorly grounded equipment near the patient.	Route lead wires along limbs and away from other electrical equipment. Fix or move poorly grounded equipment.
	Patient cable is too close to the cardiograph or other power cords.	Move cardiograph away from the patient. Unplug the cardiograph and operate on battery only. Move other electrical equipment away from patient. Unplug electric bed.
Wandering Baseline 	Patient movement.Electrode movement.	Reassure and relax the patient.
	Poor electrode contact and skin preparation.	Be sure that the lead wires are not pulling on the electrodes. Reapply electrodes. Enable the Wander filter (**Status Bar > QuickSettings**).
	Respiratory interference.	Move lead wires away from areas with the greatest respiratory motion.

Table 3-2 ECG Problems and Solutions *(continued)*

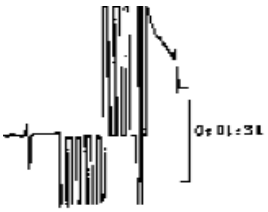
Symptom	Cause	Possible Solutions
Tremor or Muscle Artifact 	Poor electrode placement. Poor electrode contact. Patient is cold.	Clean the electrode sites. Reapply electrodes. Be sure the limb electrodes are placed on flat, non-muscular areas. Warm the patient.
	Tense, uncomfortable patient.	Reassure and relax the patient. Enable the Artifact filter (**Status Bar > QuickSettings**).
	Tremors.	Attach the limb electrodes near the trunk. Enable the Artifact filter.
Intermittent or Jittery Waveform 	Poor electrode contact. Dry electrodes.	Clean the electrode site. Reapply electrodes. Check expiration date on disposable electrodes.
	Faulty lead wires.	Replace faulty patient cable.
Poor print quality (uneven contrast or blank streaks)	Dirty print head.	Clean the print head. Use recommended paper.
Transient inoperable condition 	Transient noise in user environment appears on AC power mains or is indirectly coupled to patient cables interfering with PageWriter TC10 cardiograph ECG acquisition.	Attempt to eliminate source of transient noise or move PageWriter TC10 Cardiograph and cables away from the noise source. Operate the cardiograph on battery only. For more information, refer to “Electromagnetic Compatibility (EMC)” on page 134.

Table 3-2 ECG Problems and Solutions *(continued)*

Symptom	Cause	Possible Solutions
Dashed line	Loose electrode.	Make sure electrode contact to skin and leadset is firm.
	Broken leadset.	Replace leadset.
	Electrode polarized by defib pulses.	Use another method to detect the effectiveness of defib pulses. Certain electrodes require more time to recover from defib charges; avoid using those electrodes when defib is needed.
Solid offset line	High electrode/skin impedance.	Make sure electrode contact to skin is firm. Apply adequate ECG gel.
	Electrode polarized by defib pulses.	Use another method to detect the effectiveness of defib pulses. Certain electrodes require more time to recover from defib charges; avoid using those electrodes when defib is needed.

Urgent (STAT) ECGs

Patient information does not have to be entered in an emergency situation in order to take an ECG.

Complete all patient information after the urgent ECG is taken, but before the patient session ends. All required patient information fields must be completed in full in order to transfer an ECG to a Philips ECG Management System or to a USB memory stick (as either an XML or PDF file).

To take an emergency or STAT ECG:

1. From the Main screen, check that all leads have a good connection.
2. When all leads have a good connection, press the green **ECG** button on the front of the cardiograph twice rapidly. The ECG prints and appears on the Preview screen.



Note:

If no patient information is entered, a statement is included on the ECG that interpretation used a default age (50 years) and gender (male). The default age and gender that appear on the ECG report is specified by your supervisor.

Main ECG Screen

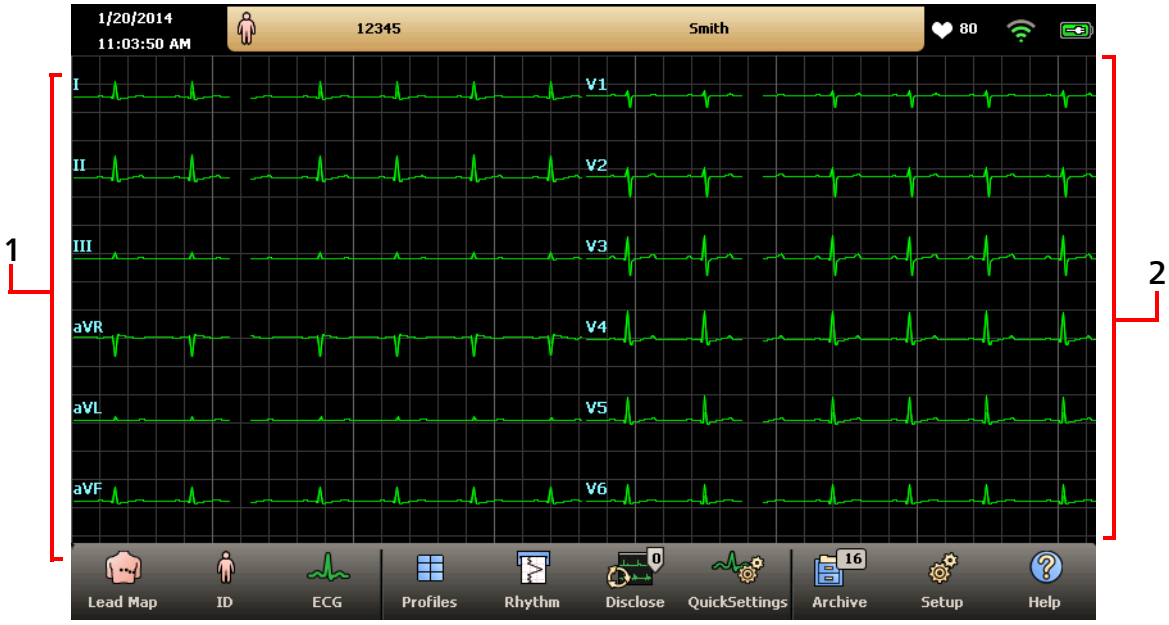
The Main ECG screen displays live patient ECG data in a variety of formats. The Main ECG screen is the default screen that appears when the cardiograph is restarted.

Changing the Lead Format on the Main ECG Screen

The format of the waveforms that display on the Main screen can be changed at any time. The available lead formats are described below.

Lead Format	Description
6x2	• This is the default lead format on the cardiograph • This view provides five seconds of continuous ECG waveform data for each lead on a split screen • In the split screen display, the limb and augmented leads on the left, and the precordial leads are on the right • See Figure 3-5 on page 50
3x4	• This view provides 2.5 seconds of waveform data for each lead, with 3 total rows with 4 leads in each row • In this view, the limb and augmented leads are on the left, and the precordial leads are on the right • See Figure 3-6 on page 51

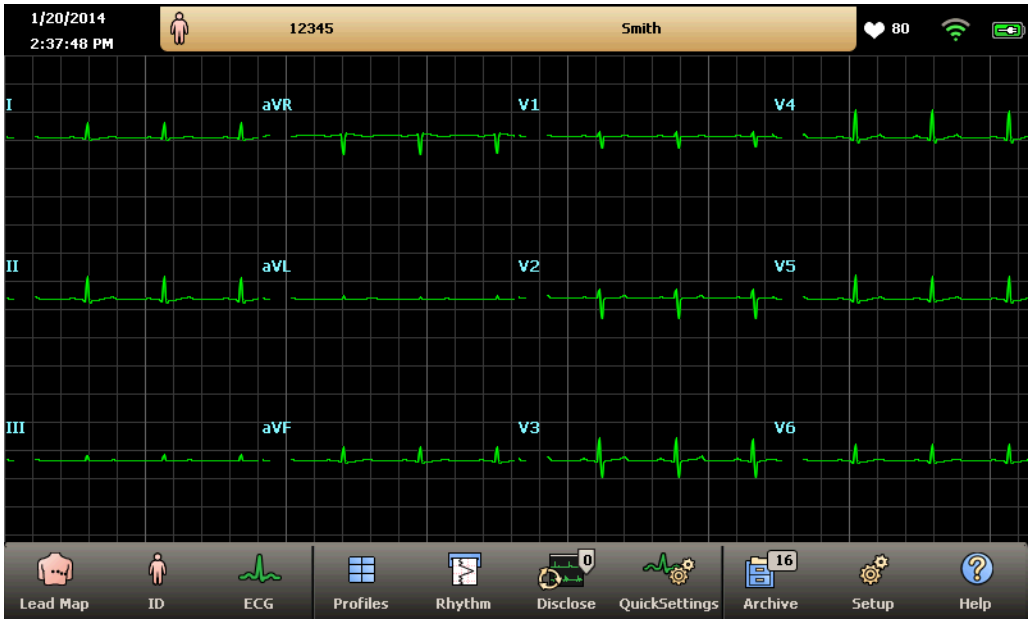
Figure 3-5 Default 6x2 Lead Format on Main Screen



1 Limb Leads

2 Precordial Leads

Figure 3-6 3x4 Lead Format on Main Screen



To change the lead display on the main screen:

1. Press the down arrow key (on keyboard) or the up arrow key to scroll through the available Main screen lead formats.
2. The lead format that displays on the Main screen when the cardiograph is shut down (by pressing and holding the On/Standby button will be retained once the cardiograph is returned to active use.

Taking an Auto ECG

Once all waveforms are of good quality, and all patient information is complete, the ECG button illuminates. When the ECG button illuminates, it means that the ECG is ready to be taken.



To take an Auto ECG, when the **ECG** button is lit, press it to take an Auto ECG.

Using the Preview Screen

The Preview screen displays the ECG exactly as it looks when printed. Touch **ECG** at any time from the Main screen to display a full-screen preview of an ECG. The ECG captures the most recent 10-seconds of waveform data.

Depending on how the Preview screen is configured to operate, once the ECG appears on the Preview screen it may automatically print, be saved to the Archive, and it may be automatically transferred to a Philips ECG Management System or other third party ECG management system. Also, the cardiograph can be configured to automatically retrieve the most recent ECG from the same patient from a specified Philips ECG Management System server for direct comparison purposes at the cardiograph.

To preview an ECG from the Main ECG screen, touch **ECG** to see a previewed ECG of the most recent 10-seconds of waveform data. If no patient information has been entered, touch **ECG** twice rapidly.

Note:

As shown in Figure 3-7, "The Preview Screen," on page 52, **Print**, **Save**, **Transfer**, *or* **Last ECG** *may not appear on your individual cardiograph, or may appear grayed out (cannot be selected), depending on how your cardiograph is configured. If the buttons are grayed out, your cardiograph is configured to automatically perform these functions. If the buttons do not appear, your cardiograph is not configured to support these functions.*

Figure 3-7 The Preview Screen

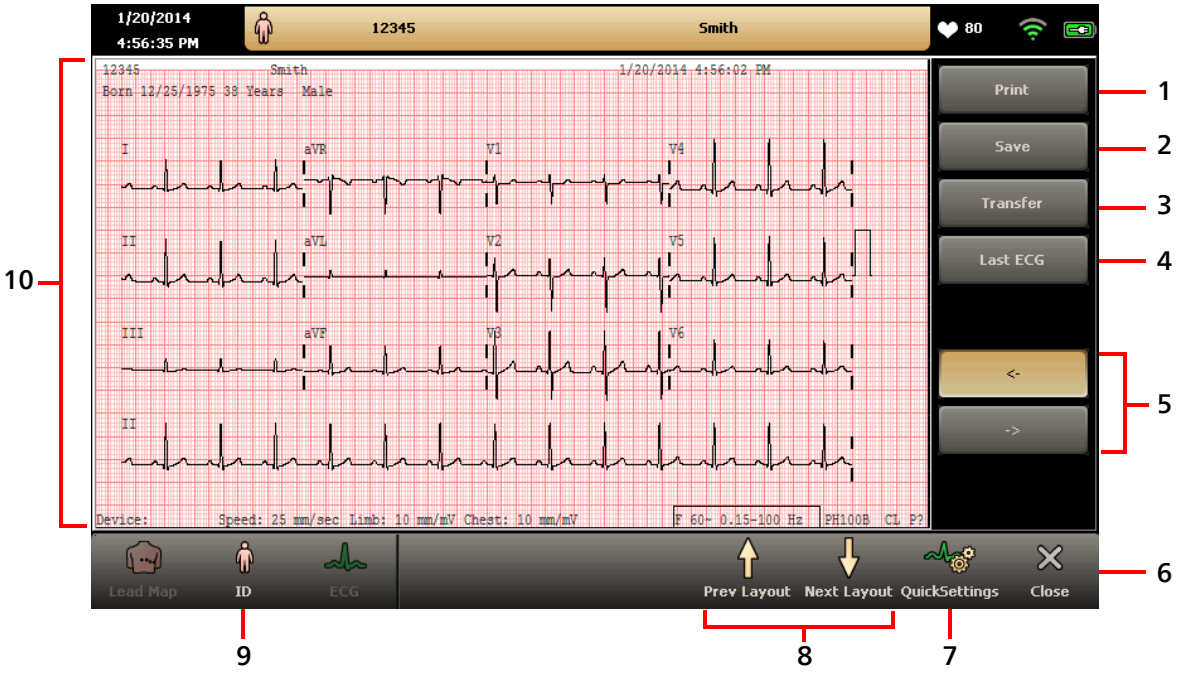


Table 3-3 Preview Screen Description

	Feature Name	Description
1	Print	Touch to print the displayed ECG.
2	Save	Touch to save the displayed ECG.
3	Transfer	Touch to send the displayed ECG to a Philips ECG Management System or to a third-party ECG management system. **Note:** *Only ECGs with complete required patient information can be transferred. Touch the* **ID** *button to complete any missing required patient information.*

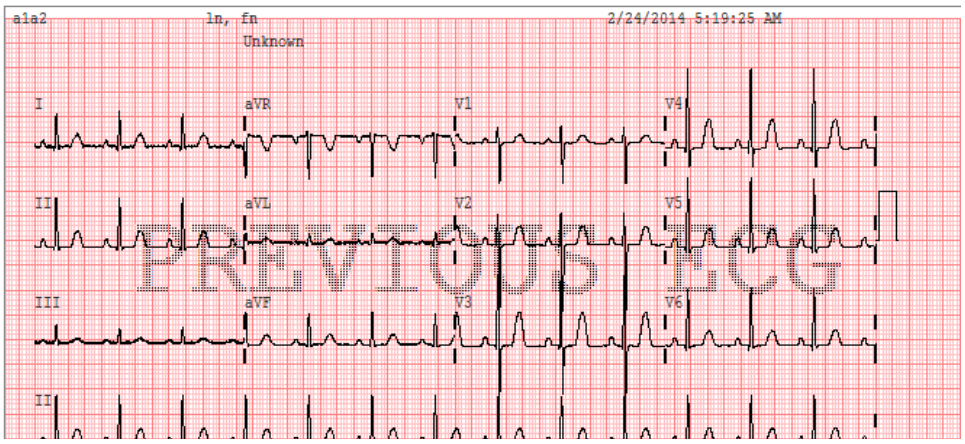
Table 3-3 Preview Screen Description *(continued)*

	Feature Name	Description
4	Last ECG	Touch to review on the Preview screen and print from the cardiograph the most recent previous ECG from the same patient. Use of this feature requires an active network connection to the specified Philips ECG Management System server. **Note:** *The* **Last ECG** *feature is only available with a Philips ECG Management System.*
5	Page Back and page Forward Buttons	Touch to view additional pages of the displayed ECG report.
6	Close	Touch to close the Preview screen and to return to the Main screen.
7	QuickSettings	Touch to: • Change the optional filter settings (Artifact, Baseline Wander). • Change pacing detection setting. • Change waveform speed and scale settings. • Change the High and Low Pass filter settings. The new settings are immediately applied.
8	Prev/Next Layout	Touch to: • Change the layout/format of the ECG report displayed on the screen. • Change the rhythm lead. The new settings are immediately applied.
9	ID	Touch to enter missing patient information for the displayed ECG (not available with the Last ECG feature). **Note:** *This feature is not used to enter patient information for a new patient.*
10	ECG Report	The displayed ECG report. Press **Prev Layout** or **Next Layout** to change the displayed report format. Touch **Print** to print out the ECG report with the new format applied. Change the level of interpretation displayed on the ECG preview in **Quicksettings > Analysis.** Touch **Print** to print out the ECG report with the new interpretation applied.

Using the Last ECG Feature on the Preview Screen

When a previous patient ECG is printed at the cardiograph using the **Last ECG** feature, a note appears on the ECG report specifying that this is a previously recorded ECG.

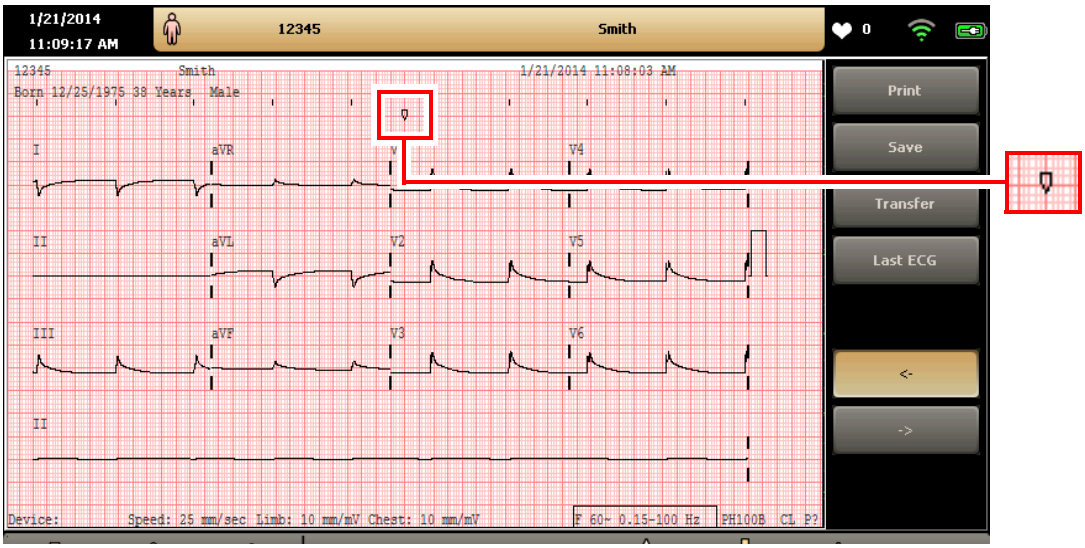
Figure 3-8 Previous ECG Watermark on ECG Report



Viewing Event Markers on the Preview Screen

If any Event Markers are captured within the 10-seconds of ECG data that appear on the Preview screen or the printed ECG report, an Event Marker symbol ( ) will appear directly above the waveform. For information on capturing Events on the Main or Rhythm screens, see “Capturing Events from the Main or Rhythm Screens” on page 59.

Figure 3-9 Event Marker Symbol on Preview Screen



Critical Values on Preview Screen

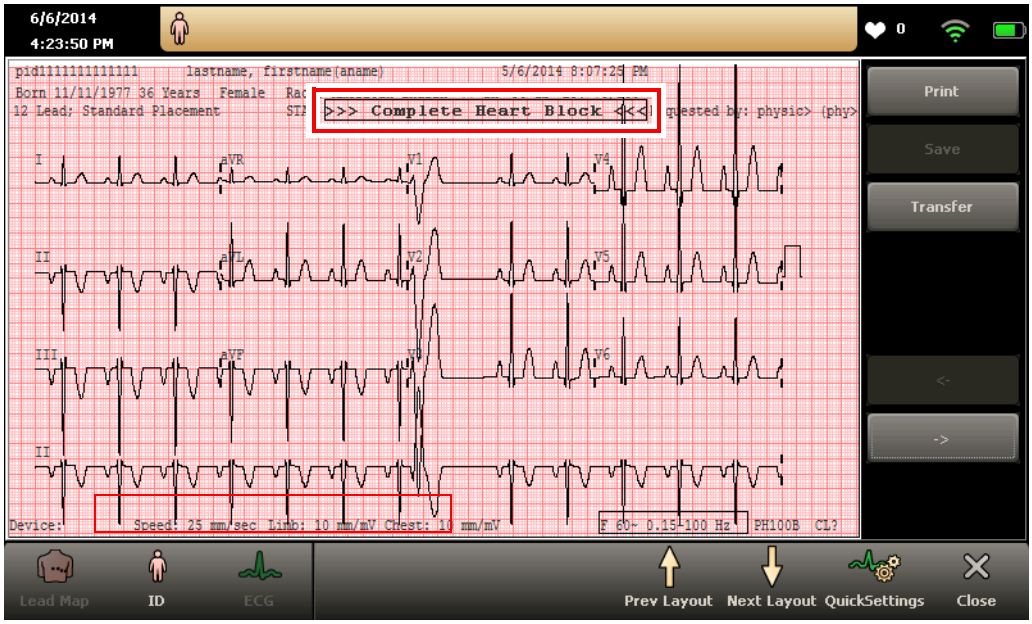
The algorithm offers a feature called *Critical Values,* that when enabled will display an ECG message on the Preview screen and print the message on the ECG report in

order to notify caregivers of an ongoing or imminent cardiac event, such as a silent MI, that requires immediate treatment. The notification statement displays prominently on the Preview screen. If any of these Critical Values appear on the Preview screen, obtain help immediately.

The messages are triggered by a defined set of interpretive statements that are listed in Appendix B, "." These warning statements include ACUTE MI, VERY HIGH HEART RATE, COMPLETE HEART BLOCK, and for the Philips DXL ECG Algorithm version PH110C, the statement ACUTE ISCHEMIA is supported.

The statement VERY HIGH HEART RATE is generated by the following formula: the measured heart rate in beats per minute, minus the patient age in years. If this value is 150 bmp or higher, the VERY HIGH HEART RATE statement will appear on the ECG.

Figure 3-10 Critical Value Message on Preview Screen



Rhythm ECG Acquisition

Rhythm ECG acquisition is used to print continuous rhythm strips of up to 6 selected leads until you touch **Stop**. The selected Rhythm leads, the size and scale of the waveforms on the printed report, pacing detection settings, and the optional Artifact filter settings may be changed at any time during the recording.

Note:

- *You do not have to stop printing the Rhythm report to change Rhythm leads.*
- *Rhythm reports are not analyzed.*

To record a rhythm ECG:

1. Touch **Rhythm** on the toolbar.



2. Touch **Stop** on the toolbar to stop printing.

To change the rhythm leads:

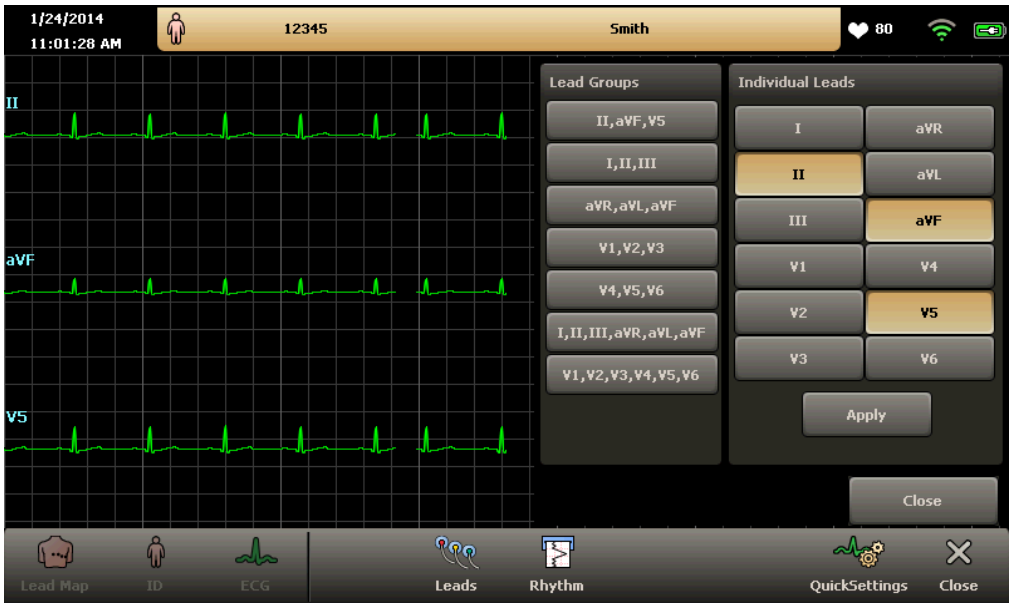
1. Touch **Leads** on the toolbar to select a predefined group of leads, or select the leads individually by touching the lead label.



2. Touch **Apply** to apply the new settings. Touch **Close** to exit the screen without changing leads.

The new rhythm lead settings are immediately applied, and the report continues to print with the selected rhythm leads.

Figure 3-11 Change Rhythm Leads



To change rhythm report settings:

1. Touch **Quick Settings** on the Status Bar (top of screen). The Settings window appears.



2. Touch the **ON**/**OFF** button next to **Artifact** to enable or to disable the Artifact filter.
3. Touch settings for waveform speed and scale as desired.

Note:

The **Chest Leads** *setting scales the precordial leads to the same size as the limb leads (***Full***) or to half the size of the limb leads (***Half***).*

4. Touch a setting next to **Pacing** to change the pacing detection setting.

Note:

The **Paced Unknown** *setting is recommended for most ECGs.*

5. Touch **Exit** . Touch **Yes** to close the window and to apply the settings. Touch **Cancel** to close the window and to discard the settings.

Special Note about Artifact Filter

The purpose of the Artifact filter is to remove skeletal muscle artifact from the ECG signal. Skeletal muscle artifact is the most difficult noise source to eliminate due to the fact that it contains the same frequencies as actual patient ECG signals. The Artifact filter will eliminate skeletal muscle artifact, but it will also reduce all high frequency components of the ECG signal. Due to this fact, use of the Artifact filter may make it impossible to detect pacemaker pulses, and may affect P waves, and the entire QRS-T complex. Only use the Artifact filter for ECGs that otherwise would be unreadable due to significant levels of muscle artifact.

Figure 3-12 The Rhythm Screen with rhythm report printing

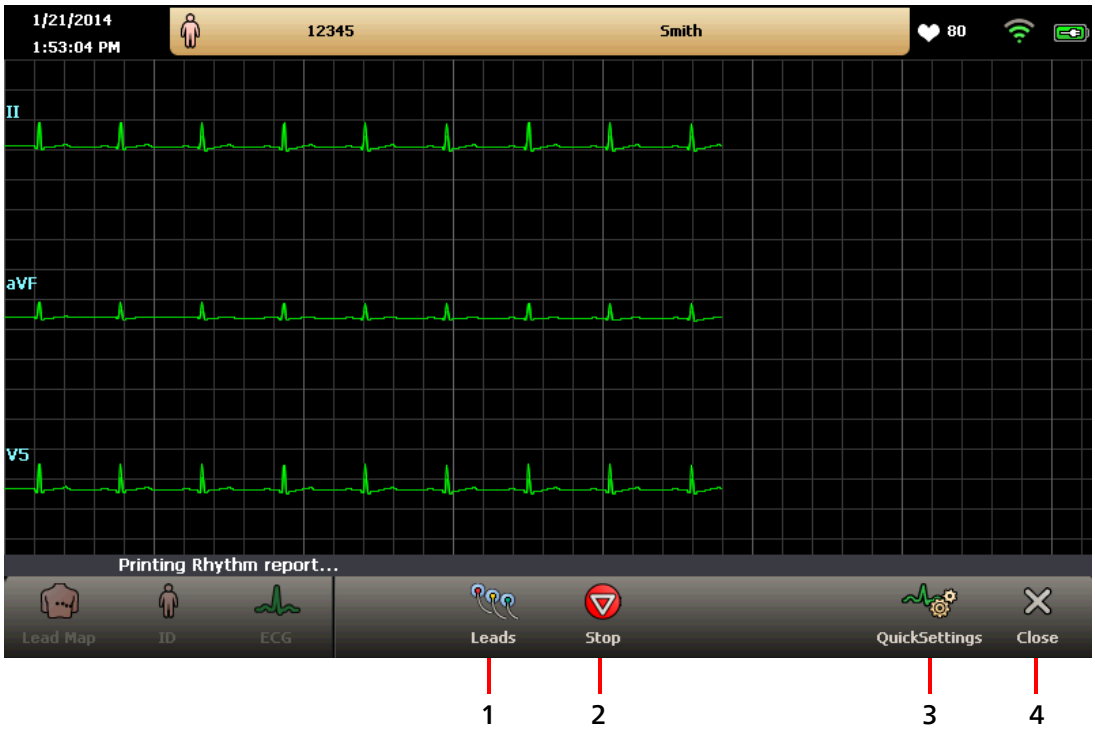


Figure 3-13 Rhythm Toolbar with no report actively printing

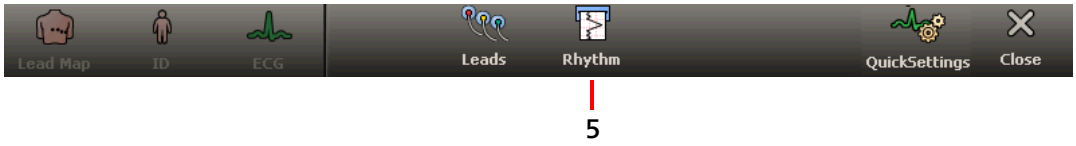


Table 3-4 Rhythm Screen

	Feature Name	Description
1	Leads	• Touch to change the rhythm leads. • This button appears whether or not a rhythm report is printing.
2	Stop	• Touch to stop printing the rhythm report. • When the rhythm report is stopped the toolbar shown in Figure 3-13 on page 58 appears.
3	QuickSettings	Touch to: • Change Artifact filter settings. • Change pacing setting. • Change waveform speed setting. • Change waveform scale setting. The new settings are immediately applied.
4	Close	• Touch to exit the Rhythm screen and return to the Main screen. • This button appears whether or not a rhythm report is printing.
5	Rhythm	• Touch this button to resume printing a rhythm report. • This button only appears when no rhythm report is printing.

Disclose ECG Acquisition

Disclose ECG acquisition is used to review Events captured on the Main or Rhythm screens, or to review up to 5 minutes of continuous ECG waveform data for a selected lead, in either a static or in a live view. The waveform data may be reviewed on the screen, and any data viewed on the screen may be selected and printed as a standard 12-lead ECG report, or as a 1-minute Disclose report of a single lead. For an example of the 1-minute Disclose report format, see “1-Minute Disclose Report” on page 92.

Capturing Events from the Main or Rhythm Screens

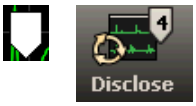
If a clinically significant event is viewed on either the Main or Rhythm screens, this clinically significant data can be captured for future review and processing on the Disclose screen. This captured data is called an *Event* and is marked on the screen with a white arrow symbol ( ). This white arrow symbol is called an *Event Marker,* and appears directly above the waveform.

The number of Events captured for the current patient session appears as a number on the **Disclose** button located on the toolbar.

As the waveform data on the screen refreshes, additional Events can be captured as necessary. Even though an Event scrolls off of the screen, it is saved for review on the Disclose screen.

To capture an Event on the Main or Rhythm screens:

1. If a clinically significant event is viewed, touch and press down on the screen directly above the waveform for two seconds in order to capture the significant data for future review and processing.
2. Once the data is captured, a white Event Marker appears above the waveform. A maximum of 6 Events can be captured for an individual patient session. After the Event is captured, the number (4) that appears on the **Disclose** button increases by 1.

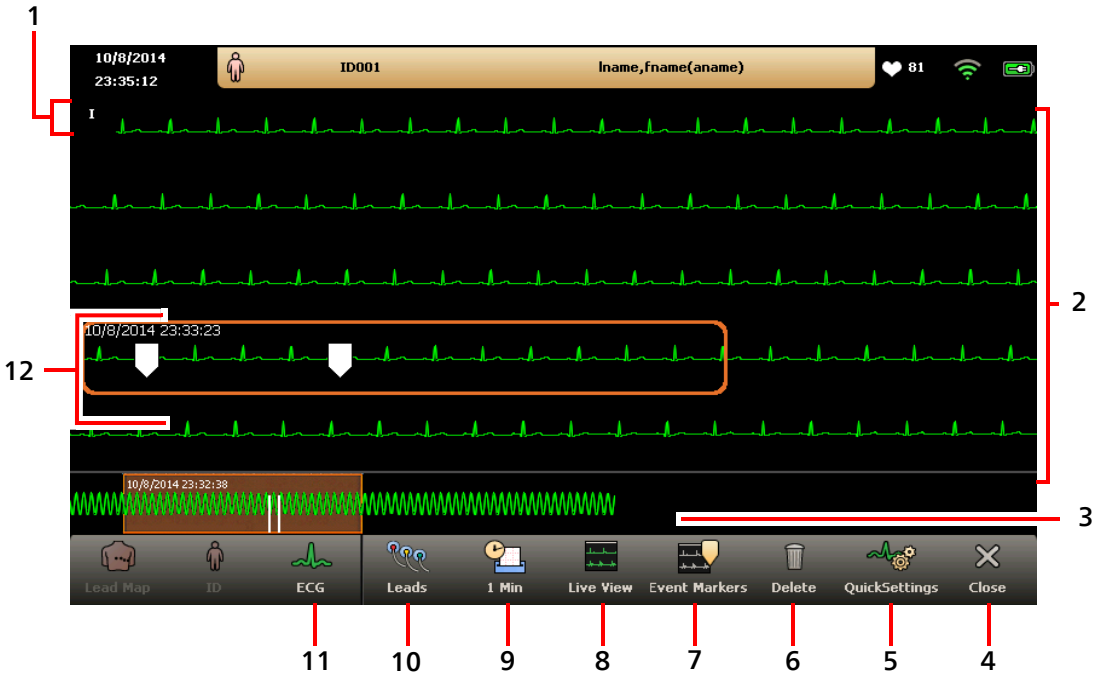


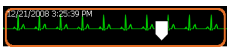
Continue to capture Events as necessary, or proceed to review Events on the Disclose screen. Even though an Event scrolls off of the screen, it is saved for future review and processing.

Reviewing Events on the Disclose Screen

Captured Events can be reviewed on the Disclose screen. When you touch **Disclose**, the Disclose screen appears in a static view.

Figure 3-14 Disclose Screen, Static View with Captured Events



	Feature Name	Description
1	Selected Disclose Lead	Only one lead may be selected as the Disclose lead.
2	Waveform Display Area	• The area where Disclose lead waveforms appear. • Touch any area on the screen to move the orange Focus box. 
3	Disclose Timeline	• This is a data timeline that displays up to 5 minutes of waveform data. • The orange shaded area in the timeline indicates the data that is displayed above in the waveform area. • Tap anywhere on the timeline to move the orange shaded area and to display different ECG waveform data on the screen. • White upright lines in the timeline are saved Events.
4	Close	Touch to exit the Disclose screen and return to the Main screen.
5	QuickSettings	Touch to: • Change Artifact filter settings. • Change pacing setting. • Change waveform speed setting. • Change waveform scale setting. The new settings are immediately applied.

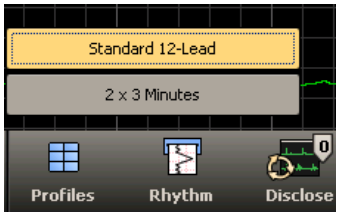
	Feature Name	Description
6	Delete	Touch this button to delete a selected event marker.
7	Event Markers	Touch this button to review all event markers (up to 6).
8	Live View	• Touch to enter Live View that displays live waveforms. • In this view, live waveforms scroll across the screen; the most recent data is seen at the top of the screen, and the oldest data is seen at the bottom of the screen.
9	1-Minute Disclose Report	• Touch this button to print a continuous 1-minute report of the selected Disclose screen. • This 1-minute Disclose report is not analyzed.
10	Leads	Touch to change the displayed Disclose lead.
11	ECG	• Touch to print a 12-lead ECG report of the data captured inside the orange Focus Box.  • Touch the ECG button on the front panel of the cardiograph to take a STAT ECG. • The ECG report appears on the Preview screen.
12	Focus Box	• The Focus Box captures 10-seconds of ECG data that can be printed as a 12-lead ECG report. • Tap anywhere on the waveform display area to move the Focus Box.  • The date and time at the upper left corner of the Focus Box is the date and the beginning time of the waveform data captured inside the Focus Box.

Using Timed ECG

The Timed ECG feature is used to take ECGs at pre-defined intervals, most commonly as part of a stress test protocol. The number of total ECGs recorded, and the interval between ECGs can be defined as a Timed ECG Exam in Setup. For more information on configuring Exams settings, see “Configuring 12-Lead Exam Settings” on page 25.

To take ECGs using the Timed ECG feature:

1. When all patient information has been entered, and all leads are of good quality, touch **Profiles** on the toolbar (bottom of screen).
2. Touch **2x3 Minutes,** the factory default Timed ECG profile.



3. Touch **ECG**. The Timed ECG protocol begins.



4. A progress bar on the bottom of the screen provides a status update on the



number of ECGs remaining, and the number of seconds remaining until the next ECG is taken. Touch **Stop** (bottom of screen) at any time to stop the Timed ECG protocol.

Transferring ECGs from the Archive

ECG reports may be transferred during a patient session from the Preview screen (if the cardiograph is configured to support this feature). Or, saved ECGs may be transferred from the Archive after the patient session ends as:

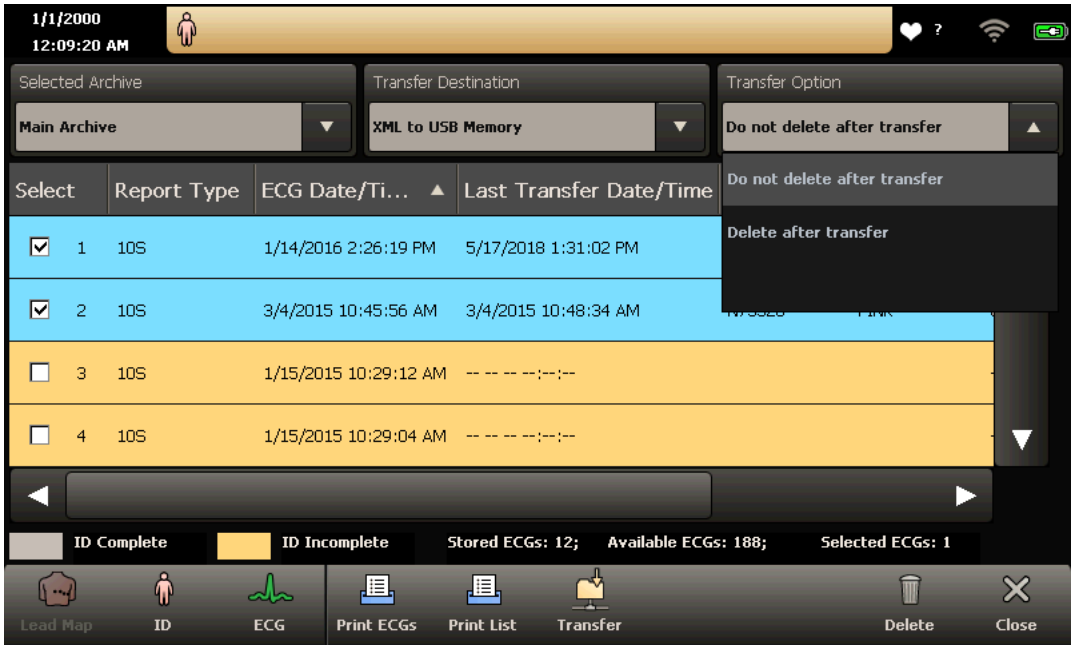
- PDF file to a USB memory stick
- XML file to a USB memory stick
- XML file to configured IntelliSpace ECG or other third party ECG management system using a network connection.

1. Touch **Archive** on the main screen.

Note:

- *Accessing the Archive screen during a study will end the patient session.*
- *Only ECGs that contain all required patient information may be transferred from the cardiograph. ECGs with incomplete ID data, highlighted in orange, cannot be transferred until the information is complete.*
- *To review ECGs that are saved as XML files to a USB memory stick (inserted into the USB connector on the cardiograph) select* **USB memory stick** *from the drop-down list.*
- *Report Type indicates the length (in seconds) of the report (10S, 30S or 60S).*
- *Before exporting the ECG reports to a USB memory stick, ensure that De-Identification is not enabled on the cardiograph. If De-Identification is enabled, all patient demographic data will be stripped from the reports on transfer.*

2. **Main Archive** is selected automatically (top left of screen). This directory contains all ECGs saved on the cardiograph.



To view only ECGs with completed ID fields, select **Main Archive - ID Complete**.

To view only ECGs with incomplete ID fields, select **Main Archive - ID Incomplete**. You then have the option to complete the missing fields.

- Highlight an incomplete ECG.
- Touch Patient ID. The ID screen for the selected ECG will open, allowing you to complete any required fields. Touch **Done** to save the information and return to the Archive screen.
- Depending on the fields you completed, you may receive a message: "Changes to patent information will cause ECG to be reinterpreted." Touch **OK**.
- The completed ECG will no longer be displayed in orange.

3. To review an ECG report, highlight it in the list and touch **ECG**. The ECG report will open in the Preview window. Touch **Close** to return to the Archive screen.
4. To delete a report, highlight it in the list and touch **Delete**. A message will appear: "Deleting selected ECGs. Touch the OK button ton continue. Touch Cancel to exit."

Note:

You can select multiple ECGs at one time by touching the checkboxes next to them in the list.

---

5. Touch **OK** to delete the selected ECGs, or **Cancel** to exit and return to the Archive screen.

Caution

Use care when deleting ECGs from the Archive screen. ECGs that have not been transferred from the archive cannot be recovered.

6. When all eligible ECGs have been selected, touch the **Transfer Destination** drop-down (top center of screen). Select an option from the drop-down list.

Note:

The options presented will depend on your cardiograph's configuration.

7. Select a transfer option, if desired. Options include:
   - **Do not delete after transfer**
   - **Delete after transfer**

   If you select **Delete**, the ECGs will be deleted from the cardiograph after transfer is successful. If transfer fails, the ECGs will remain in the list.
8. Touch **Transfer** to transfer the selected ECGs to the specified destination. A message that the transfer is in progress will appear. When the transfer is complete, the message window closes.

Note:

Depending on your security settings, you may be prompted to enter a password before transfer can begin.

9. Touch **Close** to exit the Archive screen.

Note:

ECGs saved as XML files are saved to XML schema version 1.04.01.

Transferring ECGs During and After Network Failure

If your cardiograph is disconnected from the network, the local storage may fill up. You will need to clear the local memory on the cardiograph before you can perform additional ECG studies. You can store archived cases temporarily on a USB memory stick, then transfer the stored cases when network connectivity is restored.

To transfer ECGs to a USB memory stick and clear up local storage space:

1. Insert a blank USB memory stick into the USB port on the cardiograph.
2. Touch **Archive** on the main toolbar.
3. Ensure that **Main Archive - ID Complete** is selected (top left of screen).
4. Touch the **Select** checkbox (top of column) to select all of the displayed ECGs.
5. Touch **Transfer Destination**. Select an **XML to USB Memory**.

6. Touch **Transfer Option** and select **Delete after transfer** to free up local storage space.

Note:

- *You must save the ECGs in XML format in order to transfer them to your ECG management system or DICOM server when network connectivity is restored.*
- *Before exporting the ECG reports to a USB memory stick, ensure that De-Identification is not enabled on the cardiograph. If De-Identification is enabled, all patient demographic data will be stripped from the reports on transfer.*

---

7. Touch **Transfer** to transfer the selected ECGs to the USB memory stick.

To transfer ECGs on an USB memory stick:

1. When network connectivity is restored, insert the USB memory stick used to store cases into the USB port on the cardiograph.
2. Touch **Archive** on the main toolbar.
3. Touch **Selected Archive** and select **USB memory stick**. All cases stored on the USB stick will be displayed in the archive list.
4. Touch the **Select** column header (top of screen) to select all of the displayed ECGs.
5. Touch **Transfer Destination**. Select the destination you wish to transfer to (e.g., DICOM server).

   Touch **Transfer Option** and select the desired option.
6. Touch **Transfer** (lower right corner of screen) to transfer the selected ECGs from the USB memory stick.

Note:

Import of ECGs from a different TC10 cardiograph or other device via removable media is not supported.

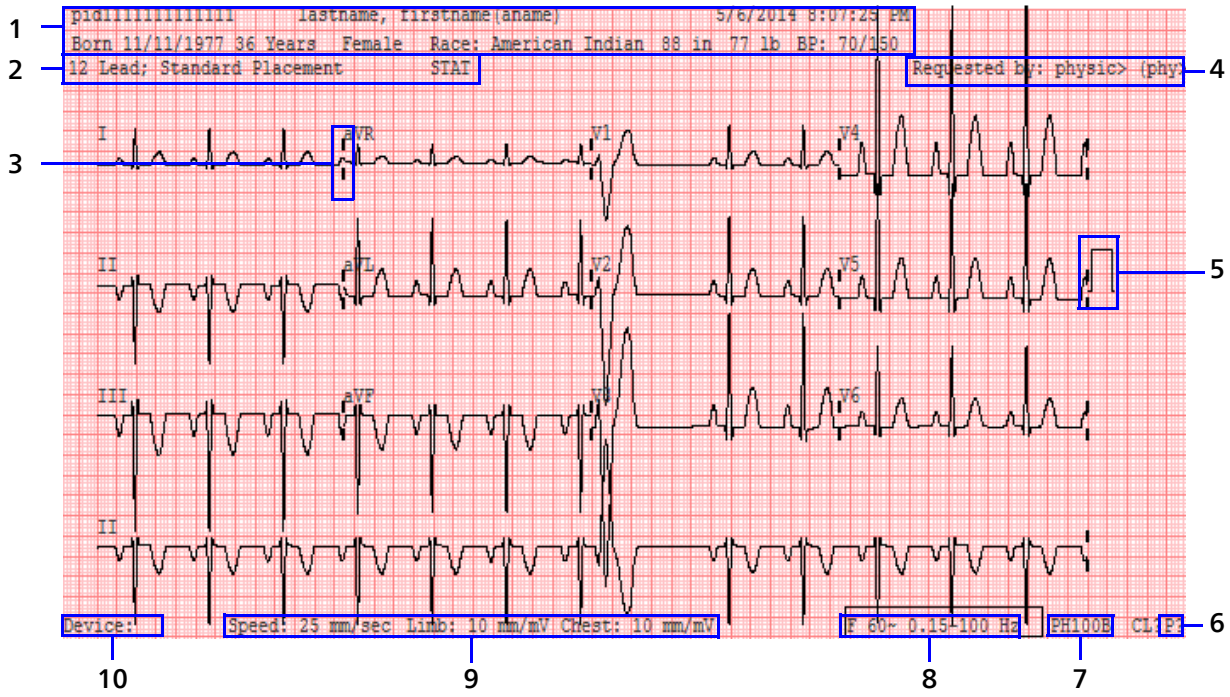
Reading the Printed ECG Report

The following table provides the nomenclature and definitions for the leads referenced on the printed ECG reports in this chapter.

LEAD Nomenclature	Definition	Name of the LEAD
I	I = L-R	Bipolar extremity LEADS (Limb LEADS Einthoven)
II	II = F-R	
III	III = F-L	
aVR	aVR = R-(L+F)/2	Augmented LEADS Goldberger
aVL	aVL = L-(R+F)/2	
aVF	aVF = F-(L+R)/2	
V1	V1 = C1-CT	Unipolar chest LEADS Wilson CT = (L+R+F)/3
V2	V2 = C2-CT	
V3	V3 = C3-CT	
V4	V4 = C4-CT	
V5	V5 = C5-CT	
V6	V6 = C6-CT	

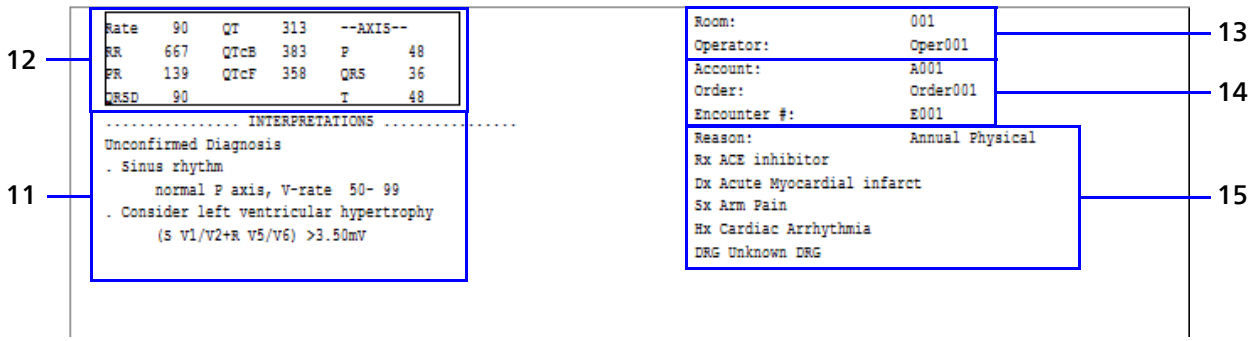
The ECG report formats described in this chapter are available on the TC10 cardiograph with installed software version A.01.00 and higher.

Figure 4-1 12-Lead 3x4, 1R Report (page one)



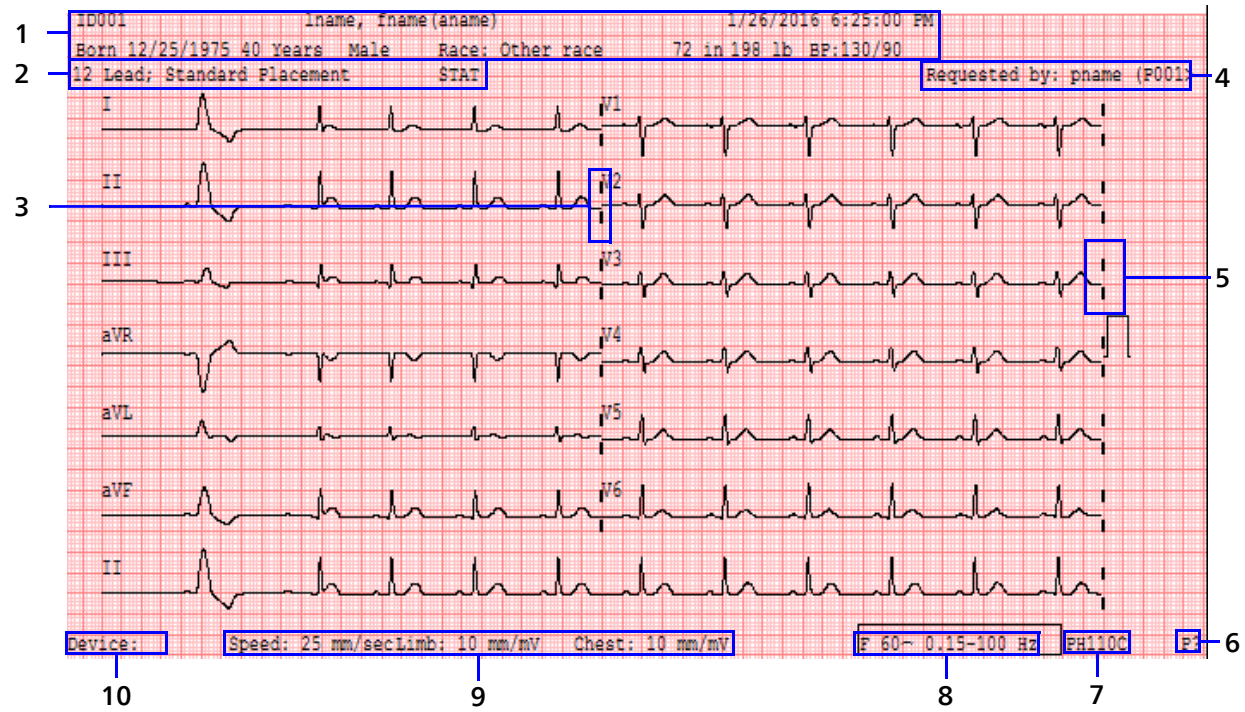
1	Patient ID Information (page 75)
2	Report Information (page 78)
3	Time Separator (page 80)
4	Physician Information (page 77)
5	Calibration Information (page 78)
6	Pacing Detection Setting (page 81)
7	Algorithm Version (page 82)
8	Filter Settings (page 83)
9	Speed and Sensitivity Settings (page 86)
10	Device Identification Number (page 86)

Figure 4-2 12-Lead 3x4, 1R Report (page two)



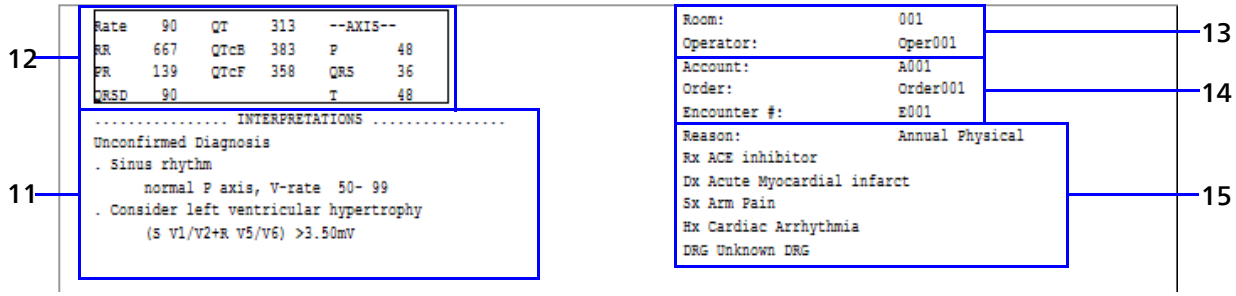
11	Interpretive, Reason, and Severity Statements (page 70)
12	Basic Measurements (page 73)
13	Institution Information (page 76)
14	ECG Order Information (page 77)
15	Patient ID Clinical Information (page 75)

Figure 4-3 12-Lead 6x2, 1R report (page one)



1	Patient ID Information (page 75)
2	Report Information (page 78)
3	Time Separator (page 80)
4	Physician Information (page 77)
5	Calibration Information (page 78)
6	Pacing Detection Setting (page 81)
7	Algorithm Version (page 82)
8	Filter Settings (page 83)
9	Speed and Sensitivity Settings (page 86)
10	Device Identification Number (page 86)

Figure 4-4 12-Lead 6x2, 1R report (page two)

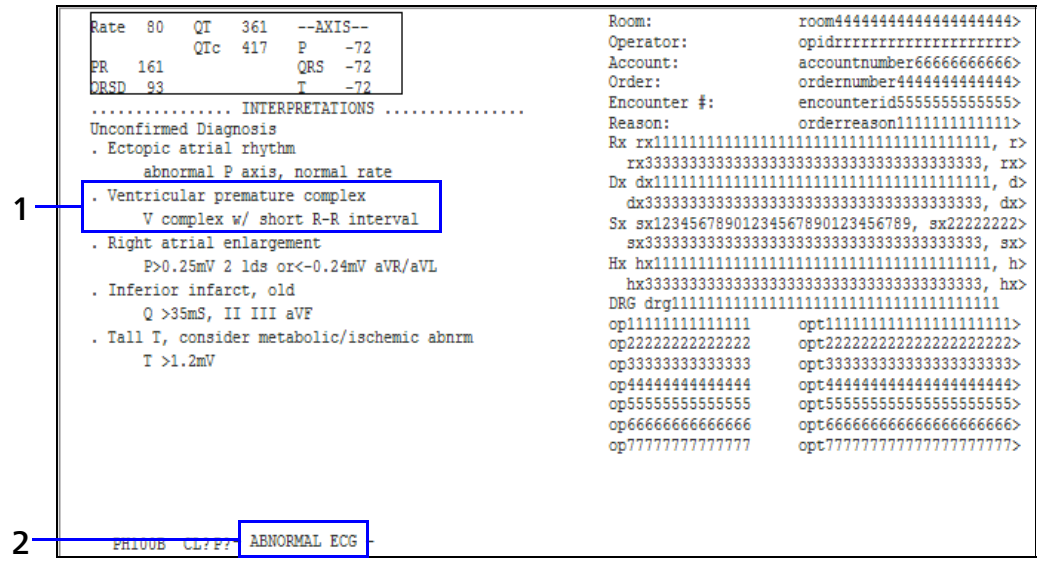


11	Interpretive, Reason, and Severity Statements (page 70)
12	Basic Measurements (page 73)
13	Institution Information (page 76)
14	ECG Order Information (page 77)
15	Patient ID Clinical Information (page 75)

Interpretive, Reason, and Severity Statements

This area of the report contains the interpretive, reason, and severity statements generated by the Philips 12-Lead, or Philips DXL ECG Algorithm.

Figure 4-5 Interpretive, Reason, and Severity Statements on the ECG Report



1	Interpretive and Reason Statements (page 70)
2	Severity Statement (page 70)

Interpretive statements may include a reason statement that summarizes the criteria that generated the interpretive statement.

Note:

The interpretive statements may include quality statements that describe a signal quality problem that occurred during recording, such as ARTIFACT IN LEAD(S) I, III, aVL.

Severity Statement

Each interpretive statement included on the ECG report has an associated severity. Severities that are more abnormal override lesser severities. The severities of all selected interpretive statements are combined to determine the overall severity of the ECG. This severity code is printed on the front page of the ECG report.

Table 4-1 Overall ECG Severity with Code

Severity	Code
No Severity	NS
Normal ECG	NO
Otherwise Normal ECG	ON

Table 4-1 Overall ECG Severity with Code (continued)

Severity	Code
Borderline ECG	BO
Abnormal ECG	AB
Defective ECG	DE

Critical Values

When the **Critical Values** setting is enabled on the acquisition equipment, statements may appear on the ECG report if specific interpretive statements are generated by the Philips DXL ECG Algorithm. These statements are intended to alert caregivers of an ongoing or imminent cardiac event, such as a silent MI, that require immediate clinical treatment. This feature is provided in part to help satisfy Section 2C of Goal 2 of the 2009 National Patient Safety Goals of the United States of America, as defined by the Joint Commission on Accreditation of Healthcare Organizations.

There are four Critical Value statements that may appear on the ECG report. These statements are shown in Figure 4-6 through Figure 4-9.

About the Extreme Tachycardia Statement

The extreme tachycardia statement Very High Heart Rate is generated by the following formula: the measured heart rate in beats per minute, minus the patient age in years. If this value is 150 bpm or higher, the measurement will generate the extreme tachycardia statement. If no patient age is specified for the ECG, the default patient age specified on the acquisition device is used.

Figure 4-6 Acute Myocardial Infarction Statement on ECG Report

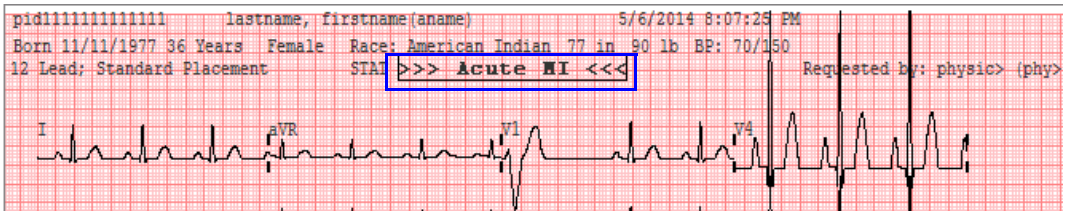


Figure 4-7 Extreme Tachycardia Statement on ECG Report

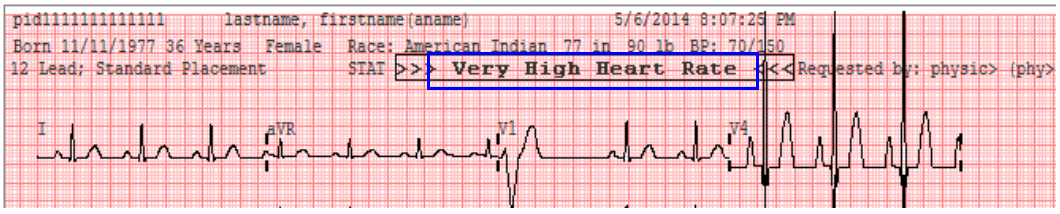


Figure 4-8 Complete Heart Block Statement on ECG Report

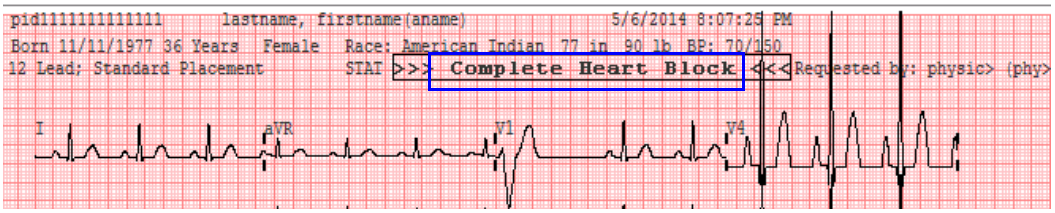
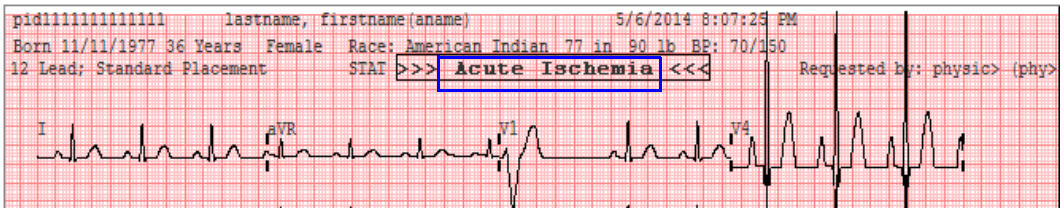


Figure 4-9 Acute Ischemia Statement on ECG Report (algorithm version PH110C only)



Basic Measurements

These measurements provide standard interval and duration measurements in milliseconds, and limb lead axis measurements in degrees. These are the values measured from the representative beat pattern in the ECG.

About Rate-Corrected QT Interval Settings

The default QT rate correction formula available on the acquisition device is Bazett's formula. The Fridericia, Hodges, and Framingham rate-corrected QT interval settings can be enabled on the acquisition device.

The QT rate correction formulas are listed below:

Bazett's

$$QTc = QT / \sqrt{RR}$$

Fridericia

$$QTc = QT / \sqrt[3]{RR}$$

Hodges

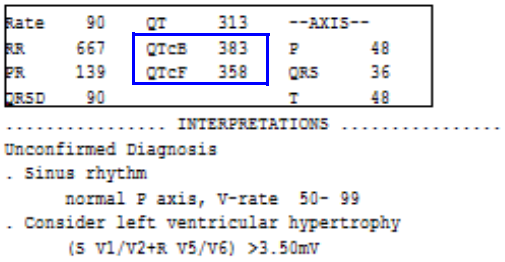
$$QTc = QT + 1.75(HR - 60)$$

Framingham

$$QTc = QT + 0.154(1 - RR)$$

For certain clinical situations, the Fridericia, Hodges, or Framingham corrected QT intervals may be preferable over Bazett's, and these additional measurements may be configured to appear in the measurements section of the printed ECG report.

Figure 4-10 The Bazett's (QTcB) and Fridericia (QTcF) Rate-Corrected QT interval on the printed ECG report



Note:

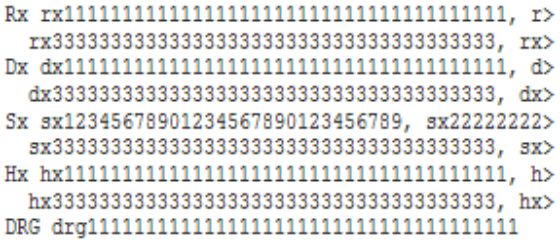
Some reports do not include the heart rate (RATE) in Basic Measurements, but do include a heart rate above the interpretive statements. This rate may be edited.

Label	Description	Units
RATE	Heart rate	beats per minute
RR	RR interval	milliseconds
PR	PR interval	milliseconds
QRSD	QRS duration	milliseconds
QT	QT interval	milliseconds
QTcB	Bazett's Rate-Corrected QT interval	milliseconds
QTcF	Fridericia Rate-Corrected QT interval	milliseconds
QTcH	Hodges' Rate-Corrected QT interval	milliseconds
QTcFm	Framingham's Rate-Corrected QT interval	milliseconds
P	Frontal P axis	degrees
QRS	Frontal QRS axis	degrees
T	Frontal T axis	degrees

Patient ID Clinical Information

This area of page two of the ECG report contains clinical patient information that is entered on the patient information entry screen, or that is contained in the order associated with the ECG. This includes information about the patient's Medications (Rx), Diagnoses (Dx), Symptoms (Sx), History (Hx), and a Diagnosis Related Group (DRG) code. The example below is for informational purposes only.

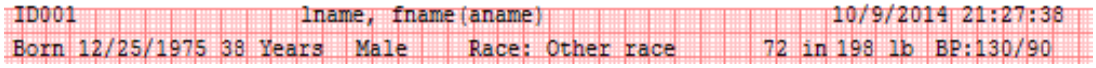
Figure 4-11 Patient ID Clinical Information on the ECG Report (page two)



Patient ID Information

This section contains patient identification information. The example below is for informational purposes only.

Figure 4-12 Patient ID Information on the ECG Report

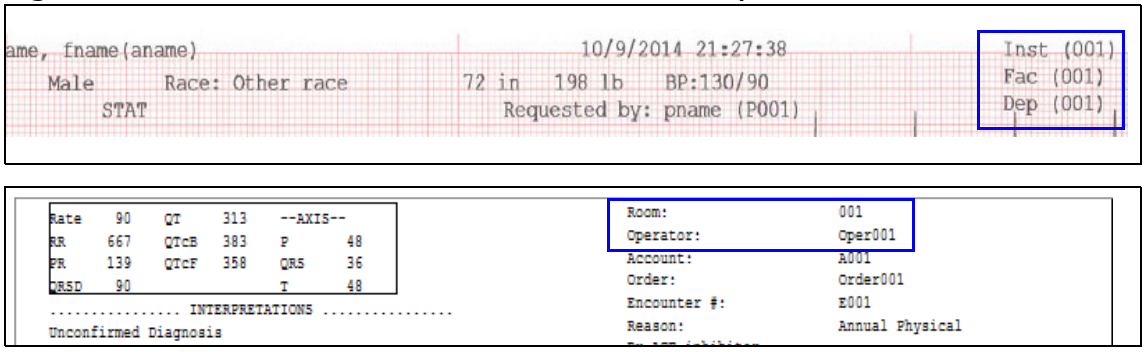


Label	Description
12345	Patient identification number (up to 32 characters)
02/26/2014; 4:53:54 PM	• Date and time of ECG acquisition • Cannot be edited
Smith, Mark	Patient name
38 Years	Patient age (may be configured to display date of birth)
Male	Patient gender
Race	Patient ethnicity
70 in 190 lbs	Patient height and weight

Institution Information

This block of identification information is optional and is fully configurable. The example below is for informational purposes only.

Figure 4-13 Institution Information on the ECG Report



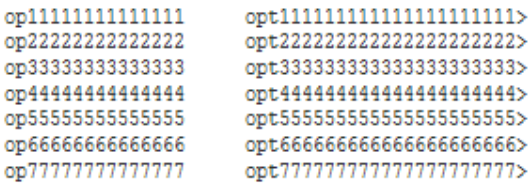
Label	Description
instname	Name and ID number of institution
facname	Name and ID number of facility or other unit within an institution
depname	Name and ID number of department
Room:	Room number of patient or room number where ECG was acquired
Operator:	Operator identification

Configurable Clinical Information

This information is configurable to fit specific clinical needs. Up to seven configurable clinical information fields may be available for use on the acquisition device.

The configurable clinical fields appear on page two of the ECG report.

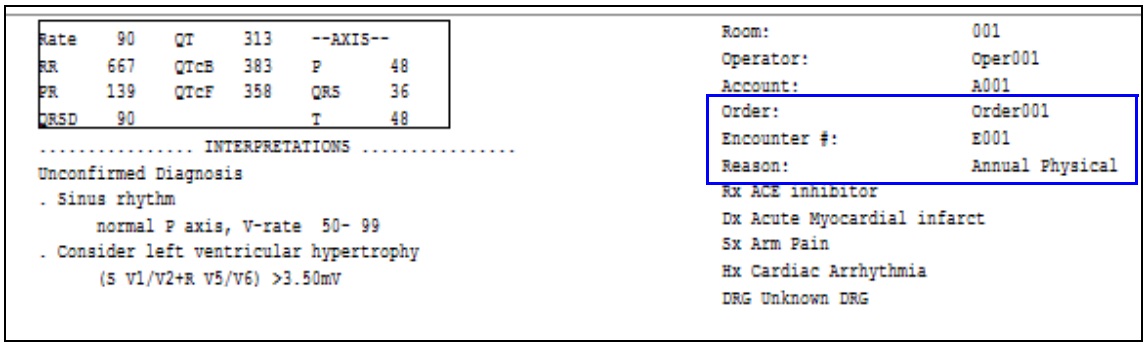
Figure 4-14 Configurable Clinical Information on the ECG Report (page two)



ECG Order Information

This area of the ECG report is optional and fully configurable, and is intended to meet the requirements of an order management system.

Figure 4-15 ECG Order Information on the ECG Report

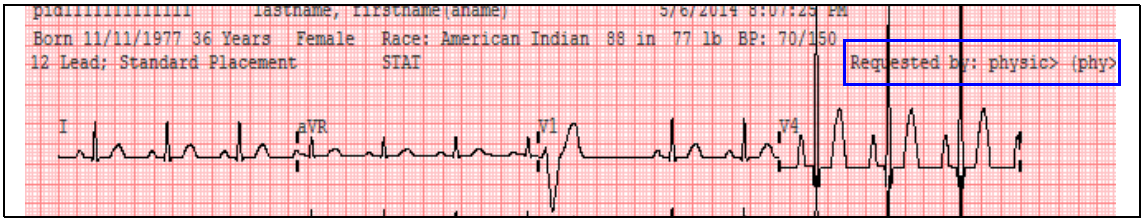


Label	Description
Order	Institution-defined order number, part of order management system.
Encounter #	Institution-defined encounter number, part of order management system.
Reason	The reason for acquiring the ECG, may be part of an order management system.

Physician Information

This information block is optional, and contains physician identification information, including the name of the ordering physician, and may include the NPI (National Provider Identifier) number in parenthesis. The NPI is only applicable to providers inside the United States.

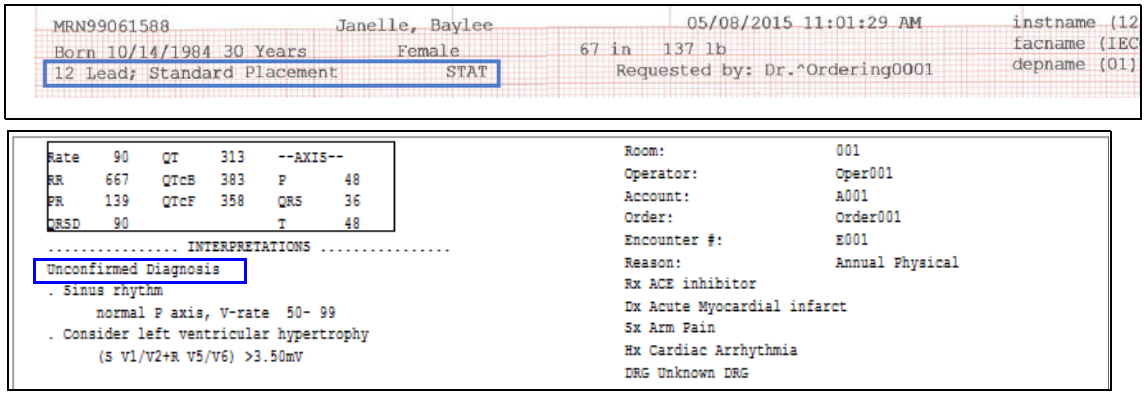
Figure 4-16 Physician Information on the ECG report



Report Information

Information about the status of the ECG report is included in this section, and may include a statement indicating that the ECG report has not yet been overread by a qualified physician.

Figure 4-17 Report Information on the ECG Report

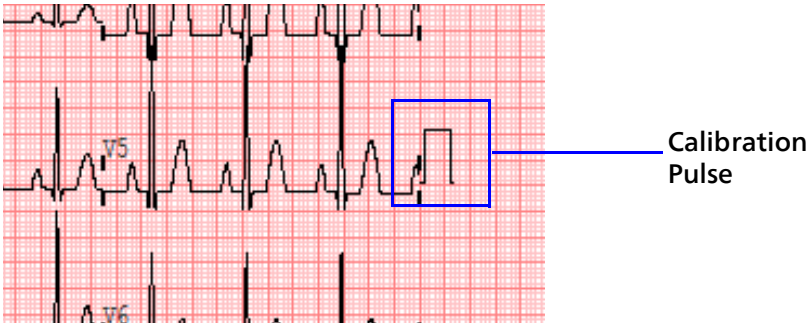


Label	Description
Report type	Identifies the report type. For example, *12 Lead; Standard Placement*
Edited flag	If one or more changes were made to interpretation statements on the Philips ECG Management System, the text Edited appears on the report.
Unconfirmed Diagnosis	• Indicates that the ECG report has not been overread by a qualified physician. • This statement may be customized by an institution.
STAT	The ECG report is designated as STAT.

Calibration Information

The calibration pulse is the rectangular waveform shown in each line of ECG trace. It shows the hypothetical deflection of the trace in response to a 1 mV calibration pulse applied to the acquisition circuitry.

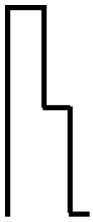
Figure 4-18 Calibration Pulse on the ECG Report



The shape of the calibration pulse reflects the scaling of the trace.

- If the calibration pulse is square ⎍ the precordial leads and limb leads were recorded at the same scale.
- If the calibration pulse is stepped ⎍ the precordial leads were recorded at half the scale of the limb leads.

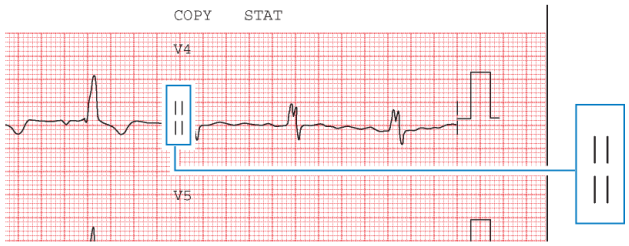
Calibration Pulse Shape	Limb (mm/mV)	Precordial (mm/mV)
	5	5
	5	2.5
	10	10
	10	5
	20	20

Calibration Pulse Shape	Limb (mm/mV)	Precordial (mm/mV)
	20	10

Time Separator

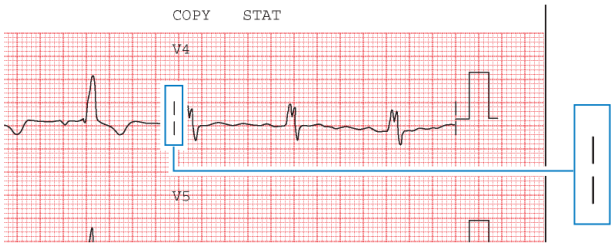
The time separator marks indicate whether the ECG data is displayed on the printed ECG report simultaneously or time-sequentially. The data for each lead is always acquired simultaneously.

Figure 4-19 Simultaneous time separator on ECG report



The double line indicates that the ECG data for each lead is displayed simultaneously. The starting point of each lead is the same time even though they may appear to start at different times on the printed ECG report.

Figure 4-20 Time sequential separator on ECG report



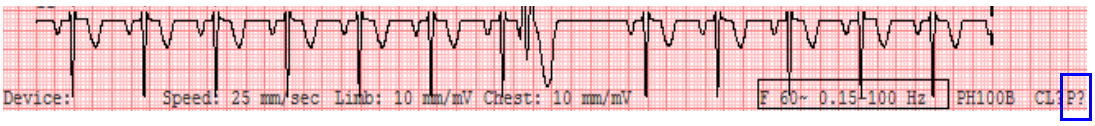
The single line indicates that the ECG data for each lead is displayed over a continuous period of time. For example, on a 3x4 grid all signals start at 0 in the first column, 2.5 seconds in the second column, 5.0 seconds in the third column, and 7.5 seconds in the fourth column.

Pacing Detection Settings

This area of the report contains information about the pacing detection settings that were selected when the ECG report was printed.

Pacemaker pulses that are detected by the acquisition device are marked on the ECG report with small vertical tick marks. These marks enable the overreader to identify false pacemaker pulse detections, or if true pulses are not being detected.

Figure 4-21 Pacing Detection Setting on the ECG report



The table below describes the possible Pacing Detection Settings available on the acquisition device, along with the setting code that appears on the printed ECG report.

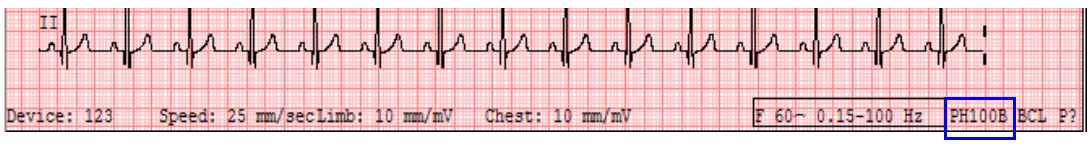
Setting	Description	ECG Report Code
Paced Unknown	• This is the default setting and normally is used for both paced and non-paced patients. • Pacemaker pulse detection is on and is at normal sensitivity. • Occasional false pacemaker pulse detections may occur in ECGs with excessive noise. • False detections may result in an incorrect interpretive statement appearing on the report. • Small amplitude pacemaker pulses may not be detected using this setting.	**P?**
Non-paced	• Pacemaker pulse detection is off. • Use this setting if there are false pacemaker pulse detections from noise, or if incorrect interpretive statements or inappropriate paced ECG complexes appear on the report.	No code appears on the ECG report if the Non-paced setting is selected.

Setting	Description	ECG Report Code
Paced	• Pacemaker pulse detection is on and is set at a higher sensitivity. • Use this setting if small amplitude pacemaker pulses are not being detected at the default (**Not Known if Paced**) setting. • False pacemaker pulse detections may occur if the ECG is noisy.	**P**
Paced (magnet)	• Use this setting if the ECG is acquired with an active pacemaker magnet or programmer in place. • Pacemaker pulse detection is on and is at a higher sensitivity. • Magnets or programmers often put the pacemaker in a fixed-rate, non-sensing mode. • The statement ECG ACQUIRED WITH MAGNET IN PLACE is printed on the ECG report. This statement notifies the overreader that a magnet or programmer was used and would explain the fixed rate behavior of the pacer.	**PM**

Algorithm Version Number

The algorithm version number is printed at the bottom of the ECG Report. The algorithm version number appears as either **PH100B** or as **PH110C** (Philips DXL ECG Algorithm). A Critical Values (**C**) lead reversal detection symbol (**L**) can also appear in this area of the ECG report if these optional features are is enabled.

Figure 4-22 Algorithm Version Number on ECG report



Label	Description
PH100B	• PH refers to Philips • 10 refers to the version of the measurement program • 0B refers to the criteria version installed on the cardiograph

Label	Description
PH110C	• PH refers to Philips • 11 refers to the version of the measurement program • 0C refers to the criteria version installed on the cardiograph
C	This symbol appears on the report if the optional Critical Values feature is enabled on the acquisition device
L	• This symbol may appear with the algorithm version number • If this symbol appears, it designates that the optional lead reversal detection feature is enabled on the acquisition device, and that the device detected a lead reversal that the operator overrode when printing the ECG
B	Borderline suppression flags indicate whether the acquiring cardiograph suppresses these statements. Options are: • No setting. Borderline suppression was disabled. • Exclude low certainty statements. Shown as **b**. • Exclude all borderline statements. Shown as **B**. See Appendix A, "."

Filter Settings

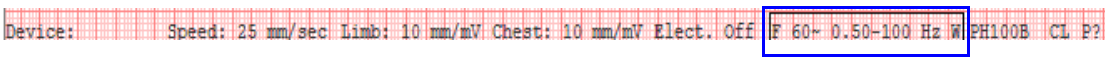
The filter settings applied to the ECG report are displayed in filter information box that is located at the bottom of the ECG report. These filters are used to optimize the displayed or printed ECG waveform.

With the exception of the AC filter, which is highly selective, there is trade off between fidelity and clarity of the ECG trace when a filter is applied. The more filtering that is applied, the greater the possibility of removing ECG signal details.

Note:

While all filters affect displayed and printed ECGs, the interpretive algorithms always receive, store, and analyze data at 0.05 to 150 Hz.

Figure 4-23 Filter Information Box on the Printed ECG Report



Artifact Filter

The Artifact filter removes skeletal muscle artifact. This noise source is the most difficult to eliminate because it possesses the same frequencies as legitimate ECG

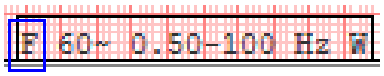
signals. While this filter eliminates skeletal muscle artifact, it also reduces all high frequency components of the ECG. This effect may make it impossible to detect pacemaker pulses, can cause visual underestimation of signal amplitudes, and can also render QRS notching invisible.

The filter removes up to 50 µV of signals in the 5 Hz to 150 Hz frequency range. This may affect P waves and the entire QRS-T complex.

Use the Artifact filter *only* for ECGs that would be unreadable due to significant levels of muscle artifact. Using the filter should provide at least rhythm information, although paced pulses may only be evident by looking at the markers that are produced on the ECG reports.

When the Artifact filter is used, the **F** symbol is included in the filter information box at the lower right corner of the printed ECG report.

Figure 4-24 Artifact Filter Symbol on Printed ECG Report

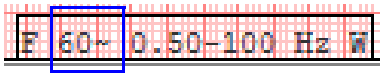


AC Filter

The AC filter removes interference created by the magnetic fields associated with electrical power interacting with the patient cable. The frequency of the AC interference is stable at 60 or 50 Hz. The AC filter removes the AC noise and leaves the ECG signal intact. The line frequency of 60 or 50 Hz is selected during the configuration of the acquisition device.

When the AC filter is used, the AC filter symbol is included in the filter information box at the lower right corner of the printed ECG report.

Figure 4-25 AC Filter Symbol on Printed ECG Report



Frequency Response Filters

These filters suppress frequencies at the high and low ends of the ECG signal spectrum. The available low frequency response filter settings are 40, 100, and 150 Hz.

In 1989, the American Heart Association recommended that frequencies up to 125 Hz be recorded for adult ECGs, and that frequencies up to 150 Hz be recorded for pediatric ECGs[1].

Changing the low-pass frequency filter to 40 or 100 Hz permits frequencies below these values to remain in the report and results in a smoother-looking ECG waveform, but eliminates some fine detail in the signal. Small deflections, notches, and slurs may be distorted or may disappear if one of these filters is applied.

1. Bailey JJ, Berson AS, Garson A, Horan LG, Macfarlane PW, Mortara DW, Zywietz C. "Recommendations for Standardization and Specifications in Automated Electrocardiography: Bandwidth and Digital Signal Processing." *Circulation* 81:730-739 (1990).

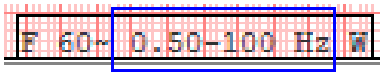
The high-pass frequency response filter settings are 0.05, 0.15, and 0.5 Hz. Using this filter permits frequencies above the selected value to appear in the ECG report. That is, this filter suppress frequencies below the selected value.

Caution

When the baseline wander filter is enabled, the high-frequency response filter is automatically set to 0.5. It is recommended that the 0.15 high frequency response filter setting be used for all other ECGs.

The frequency response of the ECG is included in the filter information box at the lower right corner of the printed ECG. The interpretive algorithms always use 0.05 to 150 Hz bandwidth for maximum fidelity. The maximum fidelity waveform is always stored in the permanent record.

Figure 4-26 Frequency Response Filter on the ECG Report

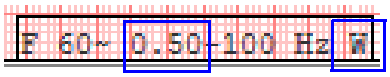


Baseline Wander Filter

Baseline wander is the slow (typically 0.1 – 0.2 Hz) drifting of the ECG baseline up or down during ECG recording. Baseline wander may result from patient respiration or from other sources. Severe baseline wander may make it difficult to determine the true wave shapes in the ECG.

Effective baseline wander suppression techniques do not distort the ST segment. While the highest frequency response limit of 0.05 Hz (recommended for normal use) eliminates baseline wander from most ECGs, additional suppression may be required. Enabling the baseline wander filter suppresses all frequencies below 0.5.

Figure 4-27 Baseline Wander Filter on the ECG Report



Caution

A 0.5 Hz baseline wander filter that may distort the ST segment is used during continuous ECG recording in Rhythm mode. *Do not* attempt to interpret the contour aspects of rhythm ECGs at this setting. If contour analysis is important in Rhythm mode, use the 0.05 Hz Rhythm high-pass frequency response setting that minimizes the ST segment distortion. Rhythm characteristics of the ECG are accurately recorded, regardless of the low-pass frequency setting in Rhythm mode.

Speed and Sensitivity Settings

This area contains information about the speed and sensitivity settings that were used for the ECG recording.

Figure 4-28 Speed and Sensitivity Settings on the ECG Report

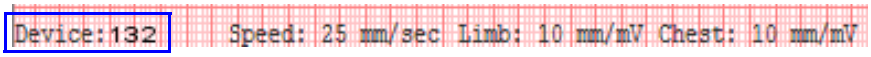


Label	Description
Speed	• The speed at which the ECG was printed • Available settings: - 25mm/sec - 50 mm/sec
Limb	• The limb lead sensitivity setting • Available settings: - 5 mm/mV - 10 mm/mV - 20 mm/mV
Chest	• Precordial lead sensitivity setting • Available settings: - 2.5 mm/mV - 5 mm/mV - 10 mm/mV - 20 mm/mV

Device Identification Number

This identification number may be entered at the acquisition device. This number is used to identify the individual device that acquired the ECG.

Figure 4-29 Device ID on the ECG Report



12-Lead ECG Report Examples

The following section includes examples of other 12-lead ECG formats.

- 3x4, 1R report with Standard Leads
- 3x4, 1R report with Cabrera Leads
- 6x2, 1R report with Cabrera Leads
- 6x2, 1R report with Standard Leads
- 6x2 report (5-second waveform segments) with Cabrera Leads
- Panoramic (Pan-12) report with Cabrera Leads. The Pan-12 report shows a one-second representative complex for each Cabrera Lead and three pre-selected rhythm strips at the bottom (aVF, V2, V5).

Figure 4-30 3x4, 1R Report with Standard Leads

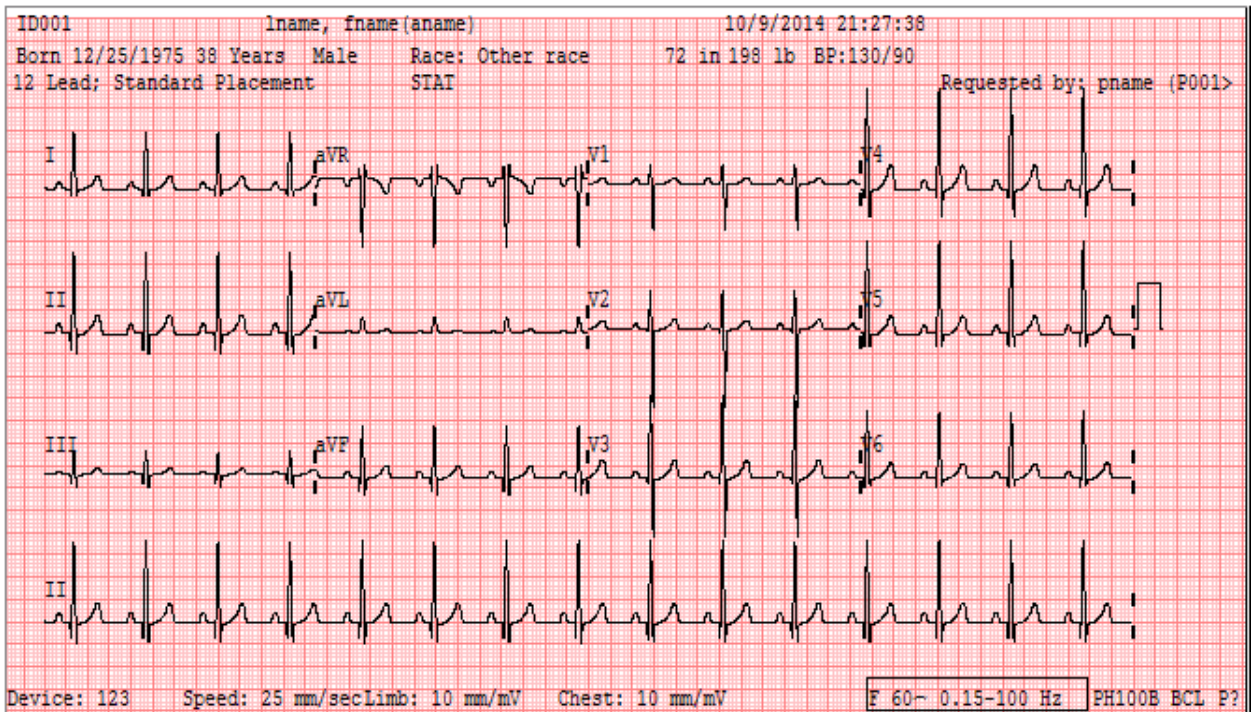


Figure 4-31 3x4, 1R Report with Cabrera Leads and Simultaneous Acquisition

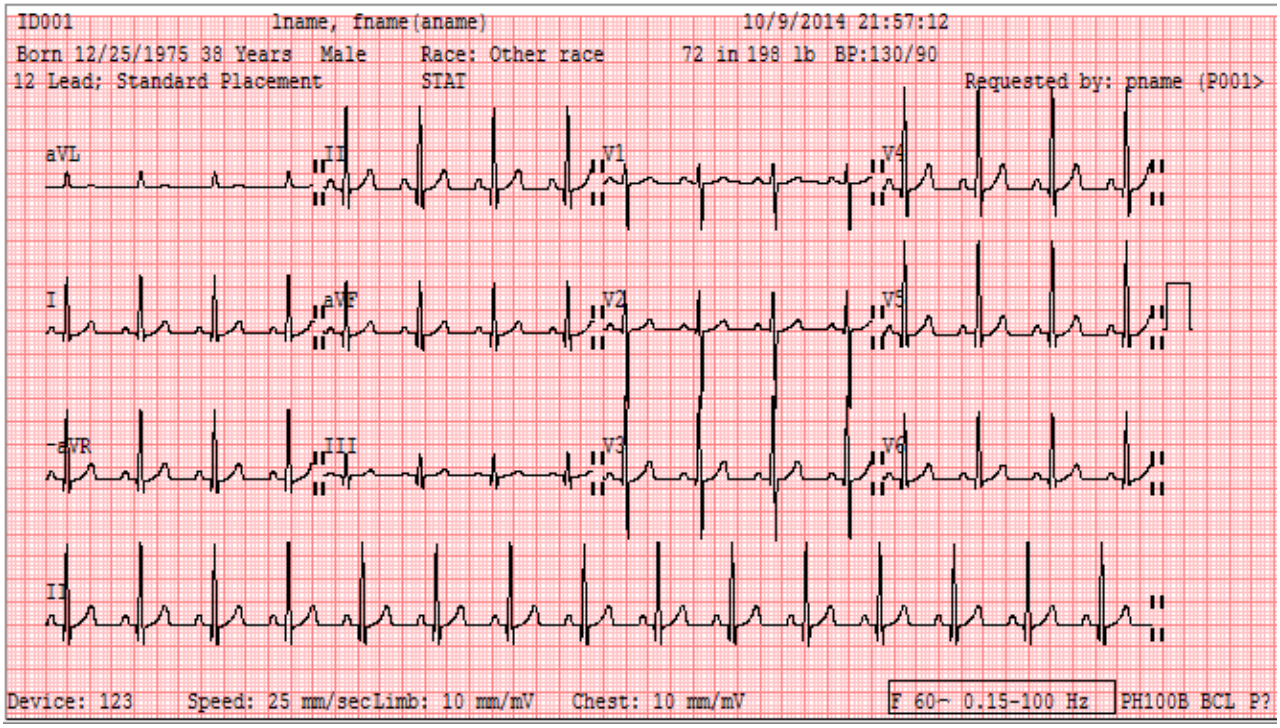


Figure 4-32 6x2, 1R Report with Cabrera Leads

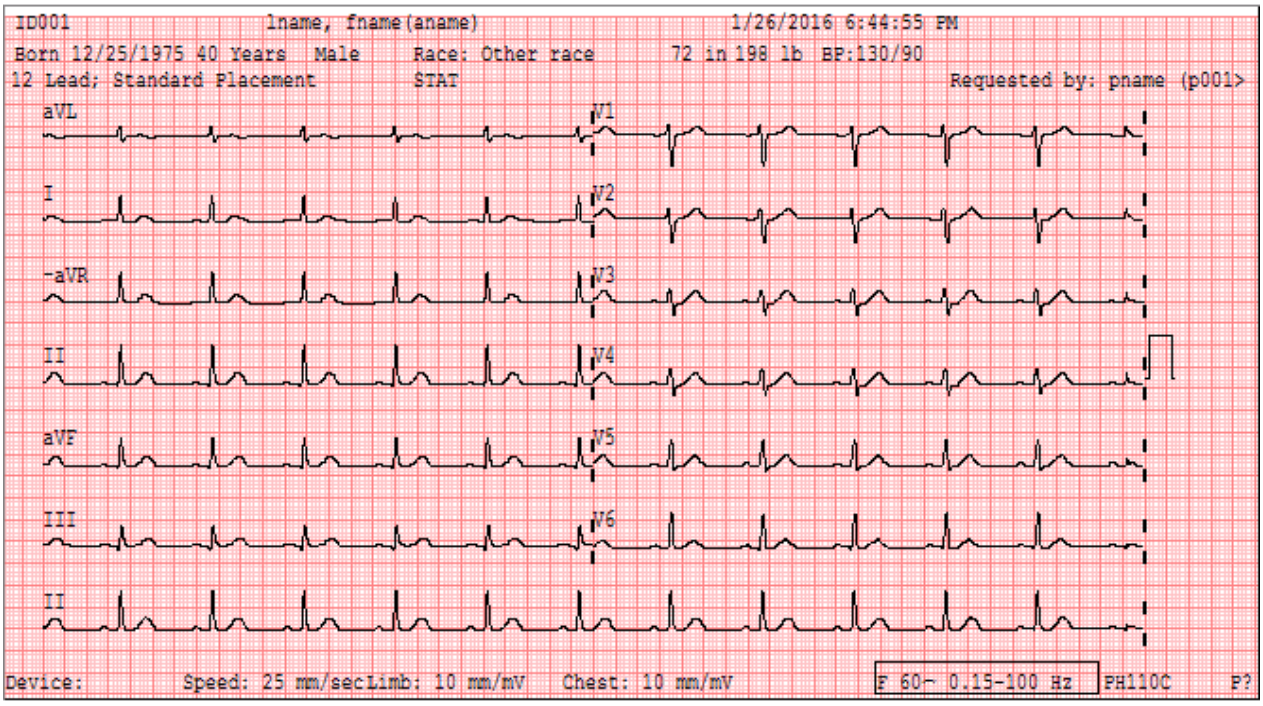


Figure 4-33 6x2, 1R Report with Standard Leads

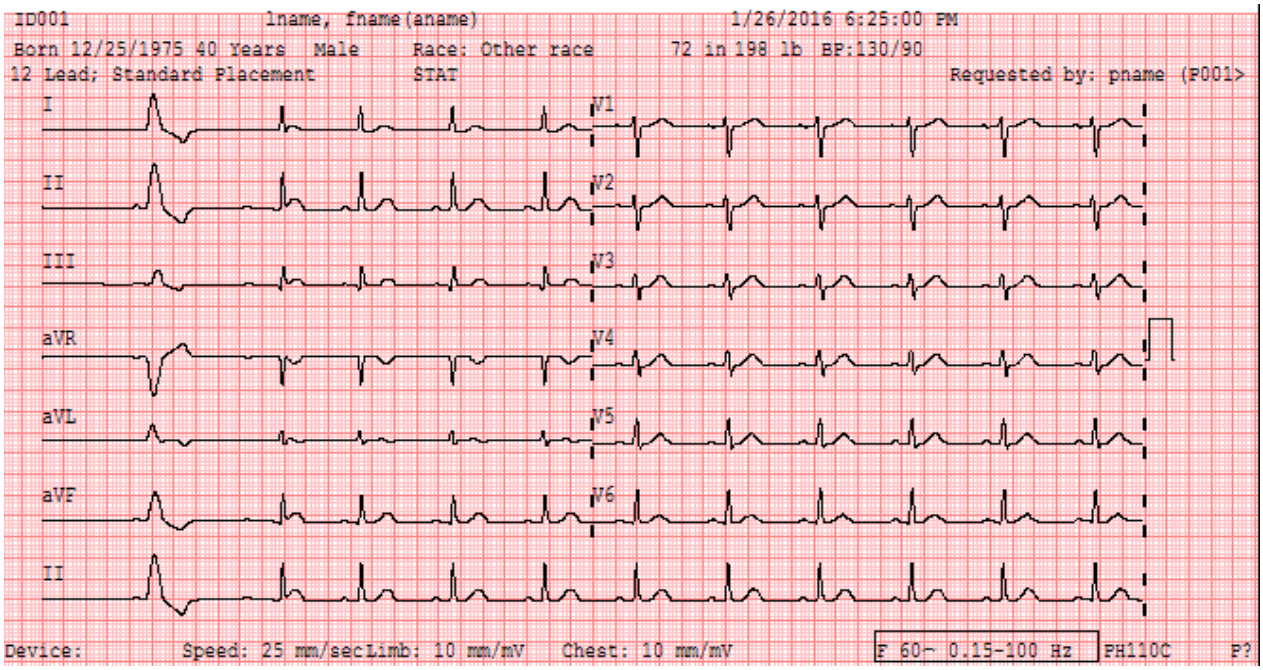


Figure 4-34 6x2 Report with Cabrera Leads

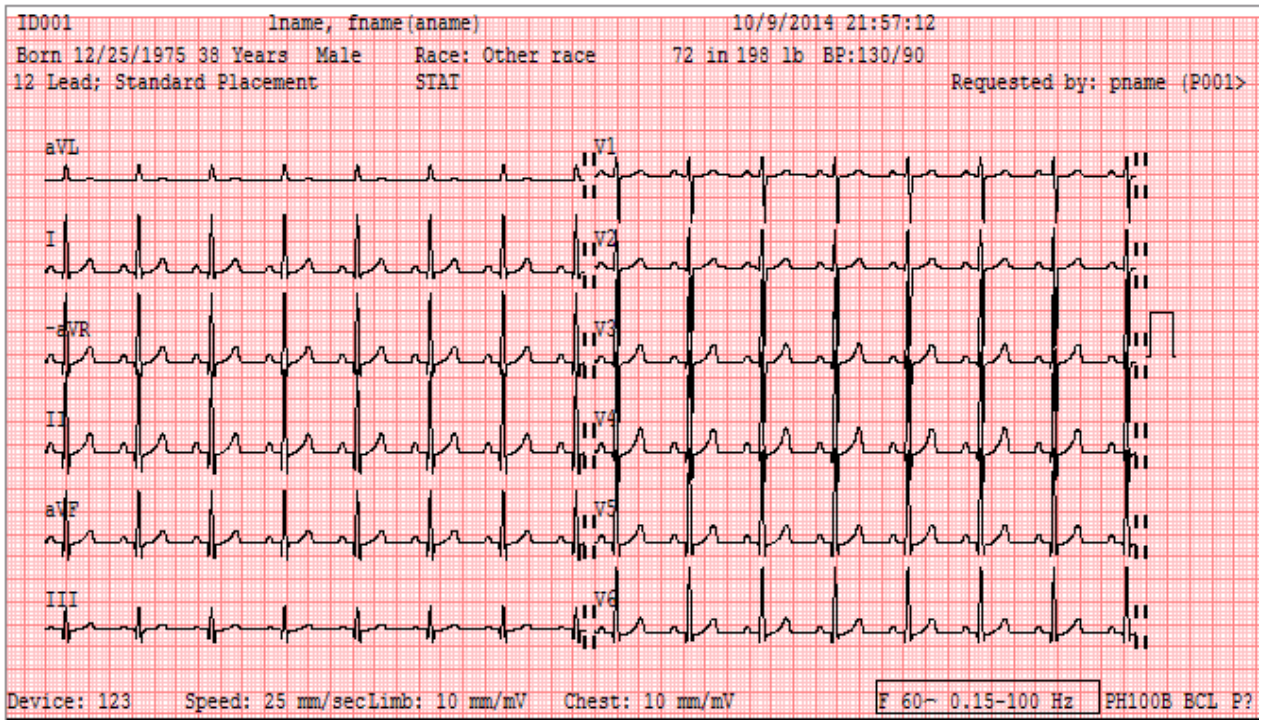
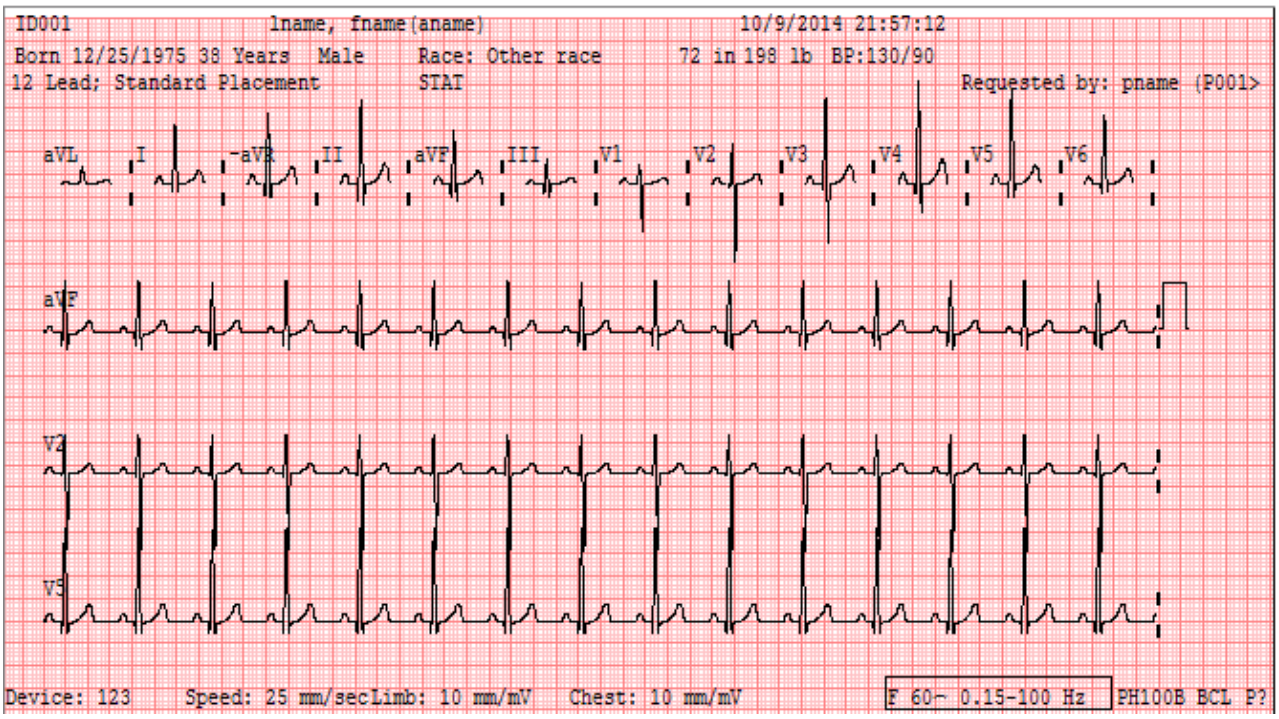


Figure 4-35 Panoramic (Pan-12) Report



Note:

Leads are displayed in Cabrera sequence on the Panoramic (Pan-12) Report regardless of the selected lead standard on the acquisition device.

ST Map Reports

ST Map reports are supported on the PageWriter TC10 cardiograph. The ST Map displays the ST values for each of the leads as derived by the interpretive algorithm (either version PH100B or version PH110C). These ST values enable the clinician to accurately detect ST elevation or ST depression, and also allow the clinician to identify the anatomical location of the ST elevation or depression. The ST segment is the portion of the ECG tracing that can indicate myocardial ischemia.

These ST values are shown graphically in two separate diagrams, or “maps.” The first diagram depicts ST values for the limb leads, and the second diagram depicts the ST values for the chest leads. Each of these diagrams depict a multi-axis orthogonal plane, and each individual axis within this plane represents the ST value at the J point for an individual lead.

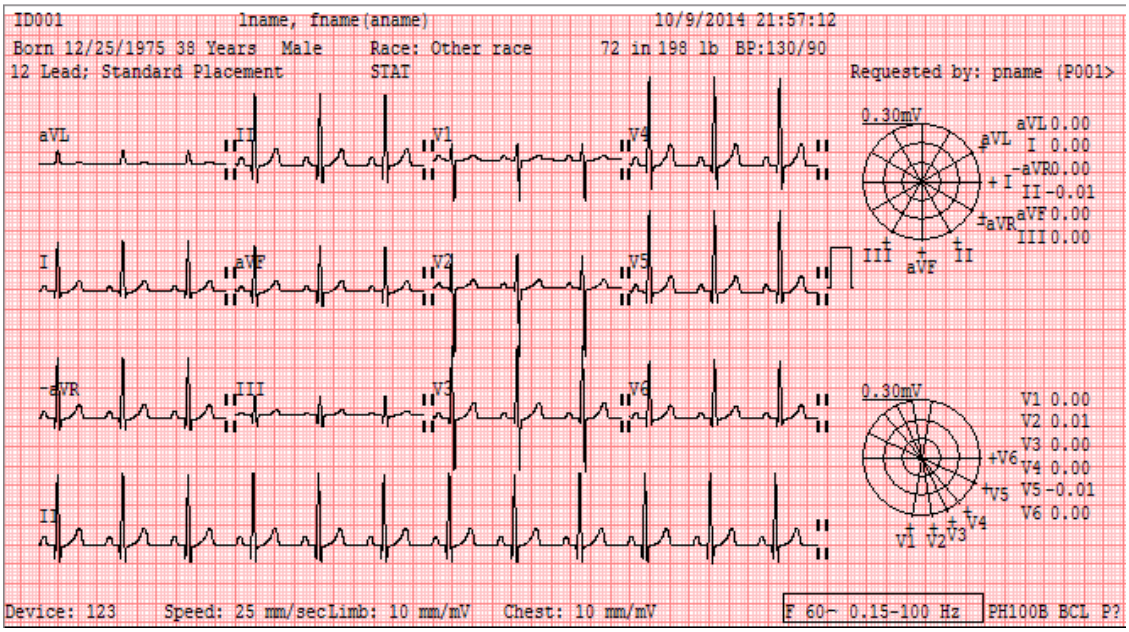
12-Lead ST Map Reports

For Standard 12 leads, the 3x4 1R 8ST report displays three rows of four 2-second waveform segments, with 1 eight-second rhythm strip at the bottom, and the ST Maps at the right side of the report.

Note:

For the 3x4 1R 8ST report, if the ST value of a lead exceeds +/-.30mV, the value displayed for leads in the ST Map will not exceed +/-.30mV, regardless of their actual value.

Figure 4-36 3x4 1R 8ST Report



Rhythm Report

Rhythm reports show up to 6 leads of continuous waveform data. The amount of report information that is included on the report is dependent upon the number of leads selected for recording. Information on the report may include:

- Patient information
- Data and time of recording
- Settings information (scale and sensitivity, filter settings)

Rhythm reports are not analyzed, so they do not provide measurement information or interpretive statements, and they are not saved to the Archive. The calibration pulse appears at the beginning of each ECG trace.

Figure 4-37 Rhythm Report with 3 Leads

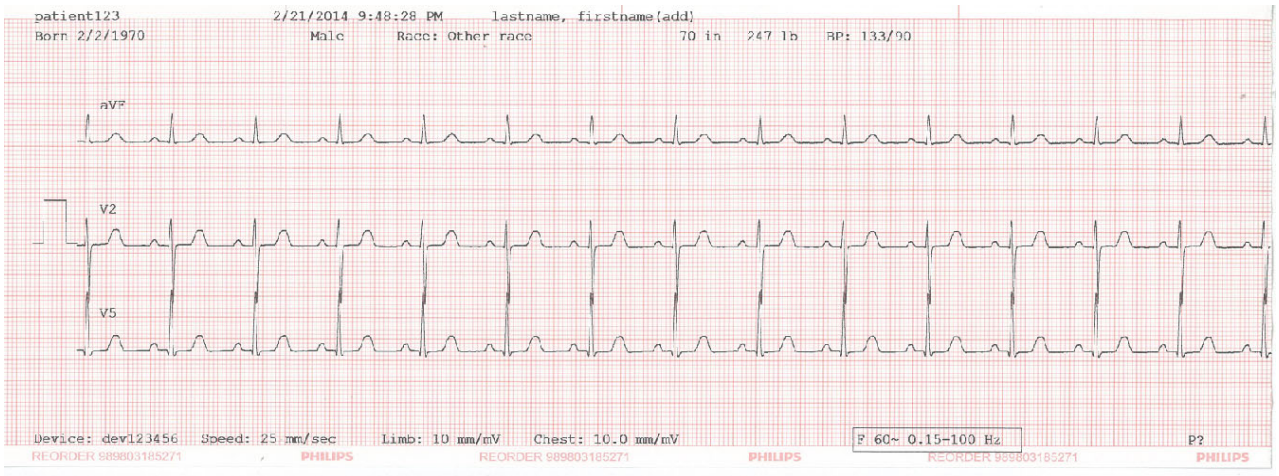
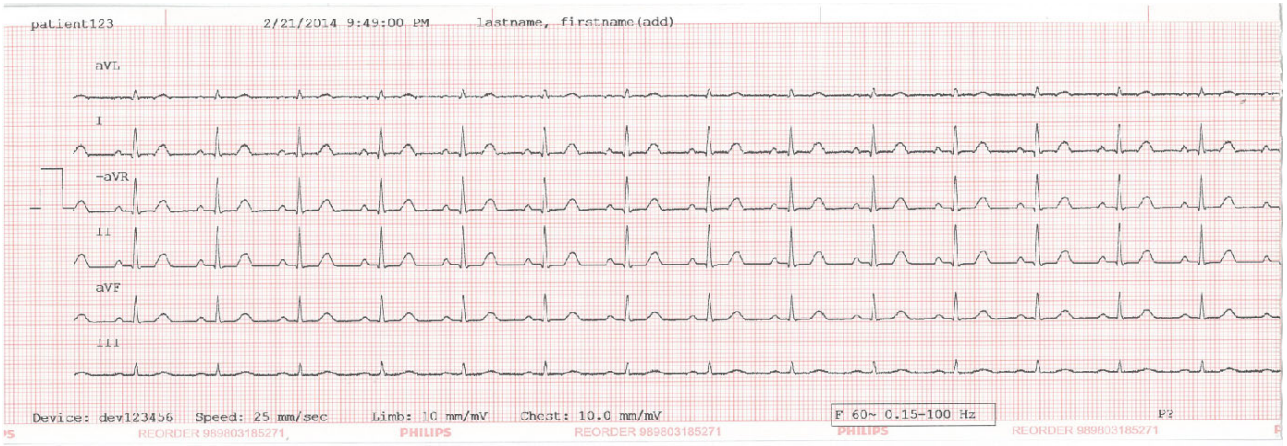


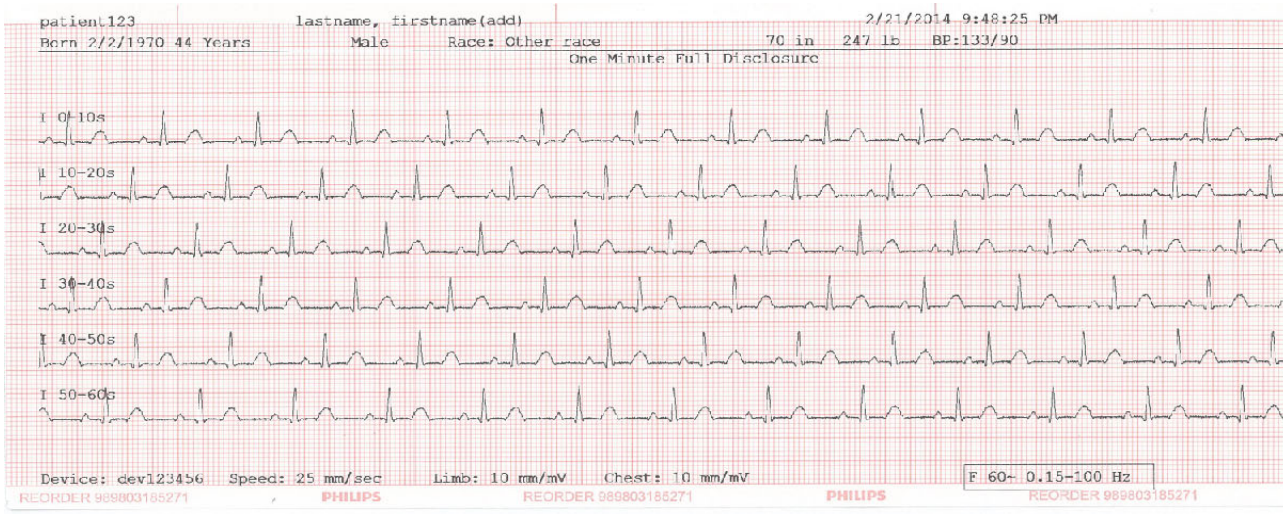
Figure 4-38 Rhythm Report with 6 Leads



1-Minute Disclose Report

The 1-Minute Disclose Report displays up to one minute of continuous ECG waveform data for the selected Disclose lead. Disclose reports are not analyzed, so they do not provide measurement information or interpretive statements, and they are not saved to the Archive. Each 10-second waveform segment on the report is labeled next to the lead name.

Figure 4-39 1-Minute Disclose Report



Extended Measurements Report

The Extended Measurements Report summarizes the output of the Philips DXL ECG Algorithm version PH100B or version PH110C. The report includes the morphology characteristics for the individual leads, and the rhythm characteristics for the rhythm groups. The algorithm uses this measurement information to generate interpretive statements. The Extended Measurements Report is especially useful if you want to examine the measurements used to generate an interpretation.

For more information on the Extended Measurements Report, see Chapter 5 of the *Philips DXL ECG Algorithm Physician's Guide* on the *PageWriter TC10 User Documentation* DVD, or download the file from the InCenter site (https://philips.mizecx.com). For information on using the InCenter site, see page xiii.

5

Cardiograph Care and Maintenance

The following chapter contains information about basic cardiograph care, and periodic cardiograph maintenance that may be required. If further technical assistance is required, contact the nearest Philips Response Center or your certified dealer.

Table 5-1 Recommended Frequency of Maintenance Tasks

Component	Recommended Frequency	Maintenance Task and page number
Cardiograph Cleaning	Weekly	"Cardiograph Cleaning" on page 96
Patient Cable Cleaning	Refer to instructions in the qualified Patient Cable's Instructions for Use	Refer to instructions in the qualified Patient Cable's Instructions for Use
Reusable Electrode Cleaning	Refer to instructions in the qualified Accessories Instructions for Use	Refer to instructions in the qualified Accessories Instructions for Use
Electrode Adapter Cleaning	Refer to instructions in the qualified Accessories Instructions for Use	Refer to instructions in the qualified Accessories Instructions for Use
Print Head Cleaning	When necessary due to uneven print quality	"Cleaning the Print Head" on page 98
Ping Test	When necessary, to confirm that the cardiograph can successfully communicate with an entered IP address	"Ping Test" on page 102
Touch screen calibration	When necessary, due to decreased touch screen performance	"Touch Screen Calibration" on page 104

Table 5-1 Recommended Frequency of Maintenance Tasks (continued)

Component	Recommended Frequency	Maintenance Task and page number
Touch screen cleaning	Weekly	"Touch Screen Cleaning" on page 104
Cardiograph Overall Sensitivity Test	Once per year	The overall sensitivity test is used to test the calibration voltage. According to *IEC 60601-2-25:2011*, this test should be run regularly. Taking an ECG using a 12-lead simulator allows you to verify areas of operation that the extended self tests cannot check, and allows you to verify the accuracy of the sensitivity settings. See the *PageWriter TC10 Cardiograph Service Manual* for detailed instructions on the performance of this test.
Replacing the Cardiograph Fuse	When the cardiograph is plugged into AC power, but the green AC power indicator light does not illuminate	"Replacing the Cardiograph Fuses" on page 106.
Battery maintenance	Bi-monthly	Discharge to empty and charge to full.

Cardiograph Cleaning

WARNING

Electrical shock hazard. Keep the cardiograph and all cardiograph accessories away from liquids. Do not immerse the cardiograph or other accessories in any liquids.

To clean the cardiograph:

1. Power off the cardiograph and unplug the AC power cord.
2. Ensure that the AC power indicator light (next to power button) is not lit.

3. Wipe the external surfaces of the cardiograph with a soft cloth dampened in any of the approved cleaning solutions listed below.

Caution

When cleaning, avoid all connectors.

Material Compatibility with Cleaners

The Cardiograph surface is made of damage-resistant materials, and is designed for easy cleaning. Philips recommends using the cleaners identified in this IFU, as these contain the most common ingredients and have been tested by Philips for compatibility. They have not been validated for efficacy.

Approved Cleaning Solutions

- Mild soap and water
- Isopropyl alcohol (consisting of 70% solution)
- Chlorine bleach (5.25% sodium hypochlorite content) mixed as 3% solution in water
- 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

Caution

- **Do not use strong solvents or abrasive cleaning materials.**
- **The cardiograph and patient cable should not be autoclaved, ultrasonically cleaned, or immersed.**

Patient Cable Cleaning

Refer to instructions in the qualified Patient Cable's Instructions for Use.

Reusable Electrode Cleaning

Refer to instructions in the qualified Accessories' Instructions for Use.

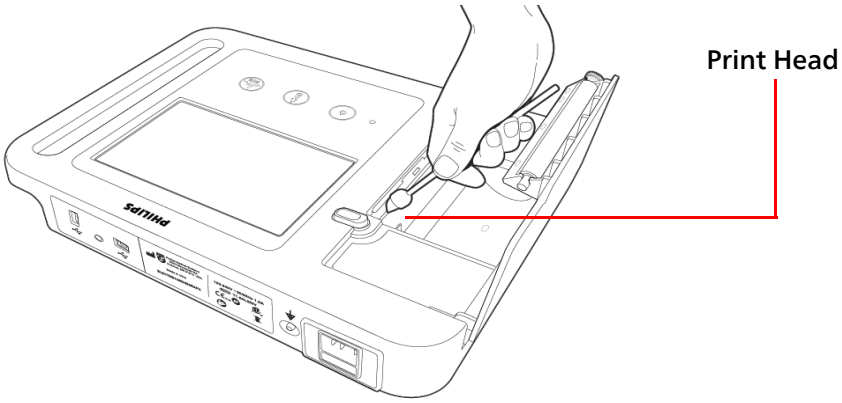
Electrode Adapter Cleaning

Refer to instructions in the qualified Accessories' Instructions for Use.

Cleaning the Print Head

Clean the print head periodically, as a dirty print head may cause poor or uneven print quality. Clean the print head more frequently when printing large volumes of ECGs.

Figure 5-1 Cleaning the Print Head



To clean the print head:

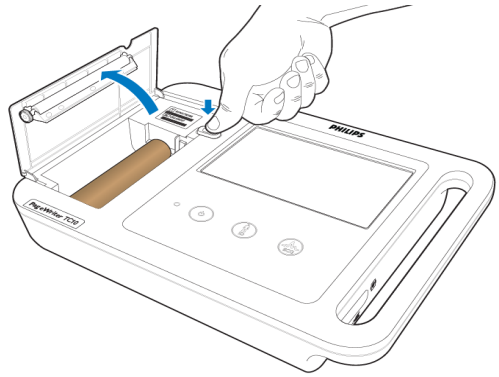
1. Unplug the cardiograph from AC power.
2. Remove the battery from the cardiograph. See “Installing the Battery” on page 7.
3. Press the paper compartment release button to open the paper compartment cover.
4. Wipe the print head lightly with a foam swab dipped in 90% alcohol.
5. Allow the print head to dry.

Printer Paper

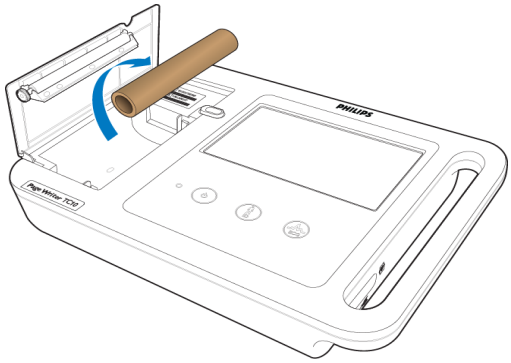
Replace the printer paper when a red stripe appears on the printed ECG report. Only use Philips replacement printer paper (part number 989803185271). For additional part ordering information, see “The cardiograph includes a default, on-screen software keyboard for user input. However, the cardiograph also supports the use of a USB-connected external keyboard.” on page 19.

To change the printer paper:

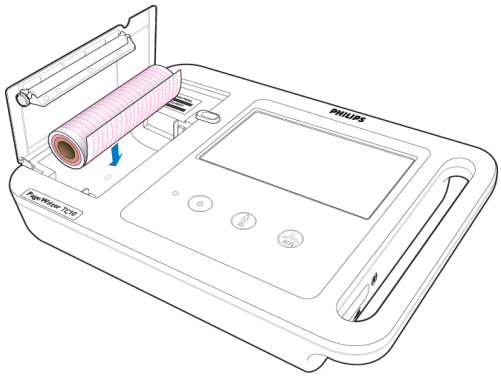
1. Press the paper compartment release button to open the paper compartment cover.



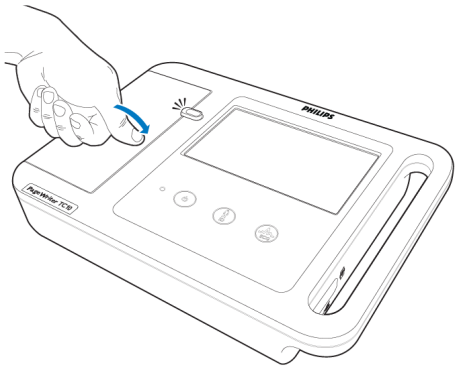
2. Remove the paper core.



3. Insert a new roll of printer paper with the printed side oriented as shown.



4. Press down on the raised dot on the paper compartment cover until the cover snaps in place (the release button pops up).



Battery Maintenance and Care

The PageWriter TC10 cardiograph uses a removable lithium ion battery that supplies power to the cardiograph during mobile use.

For optimal battery performance:

- If the cardiograph is being used regularly, fully charge the battery regularly to prolong battery life.
- When the cardiograph is not in use, always charge the battery. Plug the cardiograph into AC power. Ensure that the green AC power indicator light on the front of the cardiograph is lit. If the battery is charged while the cardiograph is in use, it will charge at a slower rate.
- If the TC10 cardiograph is not being used regularly (i.e., will be stored for more than two months without use), charge the battery to two bars (50% capacity); then remove AC power from the cardiograph, and remove the battery from the cardiograph. Store the battery in a cool, dry location. A battery stored outside the cardiograph will need to be recharged to 50% capacity every two months.
- When a battery is stored in the TC10, it will slowly discharge even if the cardiograph is powered off. If a fully charged new battery is stored in a powered-off TC10 for more than 2 months, the battery must be charged every 2 months. If not, the battery will be damaged, or the battery life will be shortened. It is recommended that the battery be removed from the cardiograph and properly charged for storage, instead of placing it in a powered off TC10 system.
- When the battery's full-charge capacity has decreased to half that of a new battery or it is not able to last 4 hours during normal usage, the battery is considered to be at the end of its life.
- Follow the battery manufacturer's guidelines for battery charging and storage:

Battery Charging	Battery Storage
Environmental temperature: Standard charge: 0 °C ~ +40 °C Discharge: -20 °C ~ +60 °C Relative humidity: <=90%	Storage temperature: Short-term (3 months): -20 ~ +35 °C Long-term (6 months): -5 ~ +35 °C Relative humidity: 45% ~ 75%

Caution

Charging the battery at temperatures greater than 45 °C (113 °F) can damage the battery.

Replacing the Battery in the TC10 Cardiograph

WARNING

Properly dispose of or recycle depleted batteries according to local regulations. Do not disassemble, puncture, or incinerate the disposed batteries.

WARNING

Carefully follow the instructions for replacing the battery. Only use batteries with Philips part number 989803185291.

WARNING

Real-time clock (RTC) information may be lost after power sources (both AC power and battery) are disconnected for longer than 30 minutes.

Caution

- Do not remove the battery during a patient session if the unit is not plugged into AC power or patient data may be lost.
- Do not heat the battery.
- Do not short-circuit the battery.
- Do not forcibly discharge the batter from the cardiograph.
- Before removing and replacing the battery from the cardiograph, unplug the AC power cord from the mains power supply and then press down and hold the On/Standby button (located on the front of the cardiograph) for at least two seconds to shut down the cardiograph. Ensure that the cardiograph is shut down. When the cardiograph is fully shut down, the screen is black, and the On/Standby button is not illuminated. Once the cardiograph is shut down, proceed to remove and replace the batteries.
- When removing the battery from the cardiograph, it is normal for the battery to feel warm to the touch, but it will not cause a burn.
- Do not dispose of the battery by burning in an incinerator or other fire.
- Follow the battery manufacturer's guidelines for battery charging and storage. See "Battery Maintenance and Care" on page 100.

- **If the battery is exhausted after prolonged storage in the cardiograph, the battery should be removed from the device and disposed of properly.**

How often the battery needs to be replaced depends on how well the battery is maintained and how much it is used. If the battery is fully charged but loses significant power after only a few ECGs, consider replacement. For information on ordering a replacement battery, see "Ordering Customer Replacement Parts and Accessories" on page 147.

To install the battery, see "Installing the Battery" on page 7.

Ping Test

The Ping Test is used with a wireless network connection to verify that the cardiograph can successfully communicate over a network connection to an entered IP address.

To perform the Ping Test:

1. Ensure that the LAN cable is securely attached to the LAN connector on the rear of the cardiograph, or that the wireless LAN connection is associated to an access point and that green bars appear on the Status bar (top of screen), indicating a live wireless connection.



2. Touch **Setup** on the bottom tool bar. The Configuration Setup and Service Utilities menu appears.
3. Touch **Configure Cardiograph Default Settings**. > **Maintenance Test** (upper right side of screen).
4. Touch **Ping Test**. The Ping Test window appears.
5. Enter the IP address to ping. Touch **Ping**.
6. The Ping Test results window appears and reports the test results.

If the test is unsuccessful, check the IP address and try again.

Cardiograph and Accessory Disposal

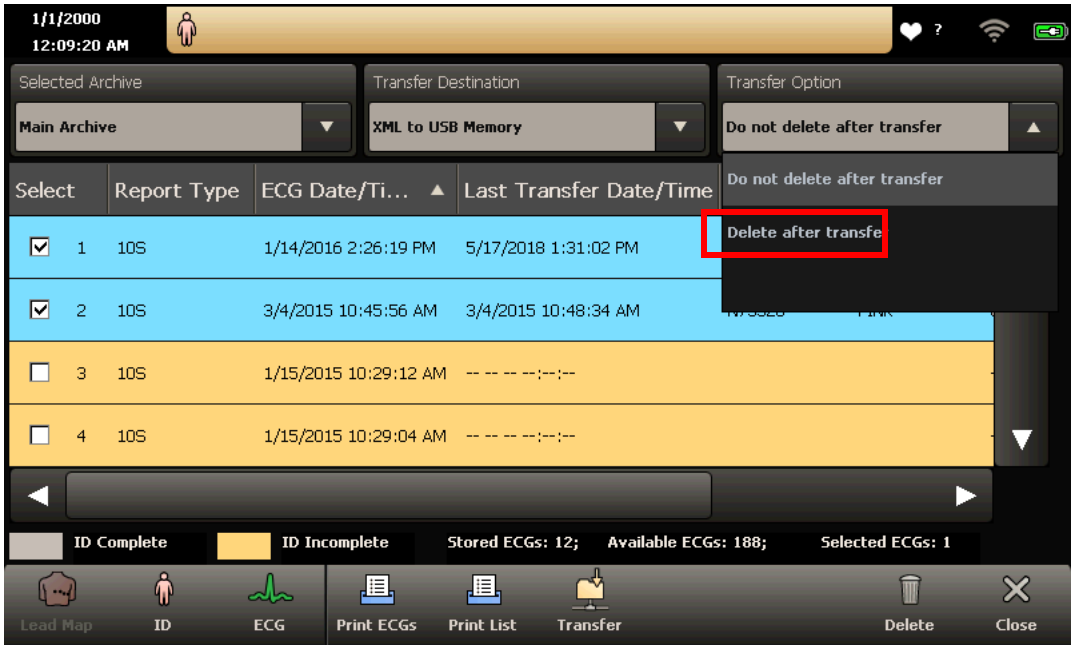
When the cardiograph has reached the end of its product life, dispose of it according to local ordinances. When any of the cardiograph accessories reach the end of their product life, dispose of these items in accordance with manufacturer instructions and local ordinances.

Deleting Patient Information Before Disposal

Philips recommends that you delete all patient health information (PHI) from a cardiograph prior to disposal.

To delete all patient information:

1. Touch **Archive** on the main screen. **Main Archive** is selected automatically (top left of screen). This directory contains all ECGs saved on the cardiograph.



2. Select multiple ECGs at one time by touching the checkboxes next to them in the list.
3. When all eligible ECGs have been selected, touch the **Transfer Destination** drop-down (top center of screen). Select an option from the drop-down list.

Note:

The options presented will depend on your cardiograph's configuration.

---

4. Select **Delete after transfer** (see image above). The ECGs will be deleted from the cardiograph after transfer is successful. If transfer fails, the ECGs will remain in the list.
5. Touch **Transfer** to transfer the selected ECGs to the specified destination. A message that the transfer is in progress will appear. When the transfer is complete, the message window closes.

Note:

Depending on your security settings, you may be prompted to enter a password before transfer can begin.

---

6. Verify that the Archive screen contains no ECGs.
7. Touch **Close** to exit the Archive screen.

Maintaining the Touch Screen

The touch screen may require occasional maintenance, including calibration and cleaning.

Touch Screen Calibration

The touch screen may be calibrated at any time. Calibration is recommended if it requires many attempts to select an item on the screen, or if selecting items on a specific area of the screen is difficult.

The touch screen may also require calibration if the cardiograph is used in different settings (seated instead of standing) or by users of significantly different height. The touch screen may need to be recalibrated to work optimally in the new setting or with the new user.

To calibrate the touch screen:

1. From any screen, touch the **Ctrl** + **Alt** + **C** (on keyboard) at the same time, or touch **Setup** on the tool bar (accessing the Setup screens may require entering a password).
2. Touch **Configure Cardiograph Default Settings** > **Maintenance Test** > **Touch Screen Calibration and Test**.
3. A white screen appears with a cross hair (center of screen). Touch the middle of the cross hair where the two lines intersect. When the cross hair is touched it moves to a new location. Continue to touch the center of the cross hair.
4. Tap the screen (when a message appears) to end the test.

Touch Screen Cleaning

The touch screen may require occasional cleaning.

To clean the touch screen:

1. Dampen a soft cloth with water or with isopropyl alcohol.
2. Wring excess moisture from the cloth.
3. Wipe the touch screen area clean. Allow the touch screen to dry completely before use.
4. Perform the Touch Screen Calibration test (see page 104) to optimize performance.

Changing the Date and Time

The date and time that displays on the cardiograph may be changed manually, or may be configured to automatically synchronize with a specified Philips ECG Management System server using the Time Synchronization feature. For more information on configuring the Time Synchronization feature on the cardiograph, see the *PageWriter TC Cardiograph Network Configuration Guide* on the User Documentation and Training DVD.

Follow the procedure below to manually set the date or time.

Note:

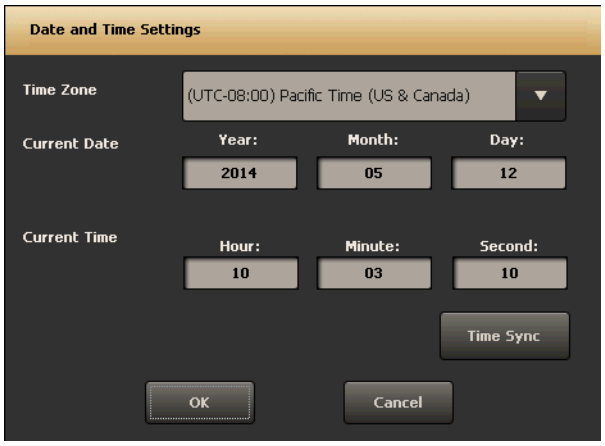
Opening the Setup screens may require entering a password. If a password is lost and cannot be retrieved, call the Philips Response Center or your certified dealer for further assistance.

To set the date and time:

1. On the Archive or Setup screen, touch the date or time setting at the top of the display.

2. The Date and Time Settings window appears with the current specified date and time displayed. To change the current date, touch the back or forward arrows next to the name of the displayed month (to change the month), or touch a date on the calendar to change the date within the displayed month.

   You can also access this same date and time dialog box on the **Edit/Delete Remote Site** tab:

   a. Go to **Setup**.
   b. Select **Configure ECG Network Settings**.
   c. Select the **Remote Sites** tab.
   d. Select the **Edit/Delete Remote Site** tab.

   Touch **Set** next to **Manual Time Set**.

3. Touch the drop-down arrow for **Time Zone** to change the selected time zone.
4. To change the **Current Date** display, touch the **Year:**, **Month:**, or **Day:** fields and type the correct value(s).
5. To change the **Current Time** display, touch the **Hour:**, **Minute:**, or **Second:** fields and type the correct value(s).
6. Touch **OK** when done. Touch **Exit** (lower right corner of screen) to exit the Setup screen. The new time and date are immediately applied.

Note:

- *The* **Hour:** *field accepts values from 0-23.*
- *The time displayed on the cardiograph automatically adjusts for Daylight Savings Time, if applicable.*
- *Touch* **Time Sync** *to manually synchronize the cardiograph date and time with a specified Philips ECG Management System server.*

Replacing the Cardiograph Fuses

If the green power on indicator light does not illuminate when the cardiograph is plugged into AC power, one or both of the AC fuses needs to be replaced.

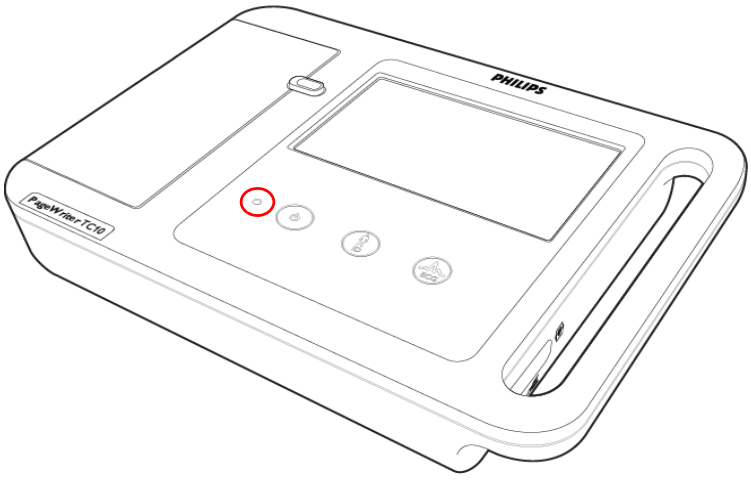
WARNING

Disconnect the AC power cord before replacing the fuse.

WARNING

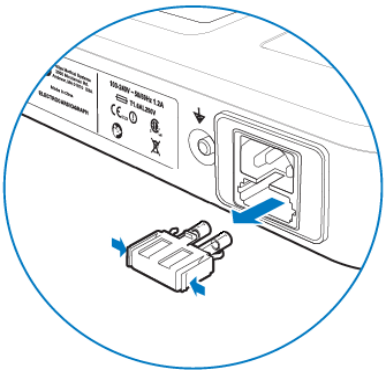
Real-time clock information within the cardiograph may be lost if both the external AC power source and internal battery are disconnected for more than five minutes.

Figure 5-2 AC Power Indicator Light on Cardiograph



Only use replacement AC fuses with Philips part number 453564131221, or use a 1.6 amp (250V) time-delay fuse the same size and configuration as the original fuse.

Figure 5-3 Replacing an AC Fuse



To replace the AC fuse:

1. Unplug the cardiograph from AC power. Pull out the AC power cord from the AC power connector on the rear of the cardiograph.
2. Locate the AC fuse, which is directly below the AC power connector.
3. Push on both ends of the fuse and pull out the fuse from the holder slot.
4. Insert the new fuse using the same orientation.
5. Push the new fuse all the way into the fuse holder slot. The fuse snaps into place.

A

Suppressed Borderline Interpretive Statements

Introduction

This Appendix includes a listing of all borderline interpretive statements that are suppressed using the *Borderline Statement Suppression* feature that is available with the Philips DXL ECG Algorithm versions PH100B and PH110C. This feature is used to exclude interpretive statements that indicate a borderline or otherwise normal condition from appearing on the ECG report. Borderline interpretive statements are generated by measurements that are above an abnormal threshold, but may in fact indicate a non-pathological condition. These statements indicate to the clinician that a condition may be present, but there is no decisive indicator. These statements often include the terms “minimal,” “consider,” or “borderline.”

For more information on the Philips DXL ECG Algorithm versions PH100B and PH110C, see the *Philips DXL ECG Algorithm Physician’s Guide,* available on the *PageWriter TC10 User Documentation* DVD, or for download from the Philips InCenter web site (https://philips.mizecx.com). For information on using the Philips InCenter web site, see page xiii.

Note:

*The symbol *** in an interpretive statement is replaced with a numeric value on the ECG report.*

Algorithm Version PH100B Exclude Low Certainty Suppressed Statements

The following interpretive statements listed in Table A-1 are suppressed when the Exclude Low Certainty setting is selected under the Algorithm/Pacing button on the Setup, Default Cardiograph Settings screen.

Table A-1 Algorithm Version PH100B Exclude Low Certainty - Suppressed Statements

Statement Code	Interpretive Statement
BAVCD	Borderline prolonged PR interval.....PR > ** , V-rate ** - **

Table A-1 Algorithm Version PH100B Exclude Low Certainty - Suppressed Statements

Statement Code	Interpretive Statement
BIVCD	Borderline intraventricular conduction delay.....QRSd > ** mS
CLAE	Consider left atrial enlargement.....wide or notched P waves
CRAE	Consider right atrial enlargement.....P >0.24mV limb lead
ET	Abnormal R-wave progression, early transition.....QRS area>0 in V2
ETRSR1	RSR' in V1 or V2, right VCD or RVH.....QRS area positive & R' V1/V2
LOWT	Borderline T wave abnormalities.....flat T
LT	Abnormal R-wave progression, late transition.....QRS area <0 in V5/V6
LVHQ	Consider left ventricular hypertrophy.....deep Q in V5-6 or II III aVF
LVOLFB	Borderline low voltage, extremity leads.....all extremity leads <0.6mV
NFAD	No further analysis attempted due to paced rhythm
NFRA	No further rhythm analysis attempted due to paced rhythm
QMAB	Artifact in lead(s) ** and baseline wander in lead(s) **
QMART	Artifact in lead(s) **
QMBW	Baseline wander in lead(s) **
REPB	Borderline repolarization abnormality....ST dep & abnormal T
RSR1	RSR' in V1 or V2, probably normal variant.....small R' only
RSRNV	RSR' in V1, normal variation.....term-vector post-rightward
SDALP	Nonspecific ST depression, anterolateral lds.....ST <-0.10mV, I aVL V2-V6
SDANP	Nonspecific ST depression, anterior leads.....ST <-0.10mV, V2-V5
SDCU	Minimal ST depression.....ST concave upward
SDINP	Nonspecific ST depression, inferior leads.....ST <-0.10mV, II III aVF
SDJ	Junctional ST depression.....ST <-0.10mV any 3 leads

Table A-1 Algorithm Version PH100B Exclude Low Certainty - Suppressed Statements

Statement Code	Interpretive Statement
SDM	Minimal ST depression.....ST <-0.05mV in 2 leads
SEALP	ST elevation, prob normal variation, ant-lat.....ST >0.15 mV, I aVL V2-V6
SEANP	ST elev, probably normal variation, ant leads.....ST>0.15mV, V2-V5
SEINP	ST elevation, probably normal variation, inf.....ST>0.15mV, II III aVF
SPRB	Borderline short PR interval.....PR int < ** mS
TAXAB	Borderline T wave abnormalities...T axis not between (-10,100)
TAXQT	Borderline T wave abnormalities.....QRS-T axis angle (91,180)
TTW1	Tall T, probably normal variant, ant-lat lds.....T >1.0mV, I aVL V2-V6

Algorithm Version PH100B Exclude All Suppressed Statements

The interpretive statements listed in Table A-1, “Algorithm Version PH100B Exclude Low Certainty - Suppressed Statements,” on page 109, and the interpretive statements listed in Table A-2, “Algorithm Version PH100B Exclude All Setting - Suppressed Statements,” on page 111, are suppressed when the Exclude All setting is selected under the Algorithm/Pacing button on the Setup, Default Cardiograph Settings screen.

Table A-2 Algorithm Version PH100B Exclude All Setting - Suppressed Statements

Statement Code	Interpretive Statement
ANTQ	Abnormal Q wave in V1.....Q >15mS in V1
AXL	Borderline left-axis deviation.....QRS axis (** , **)
AXR	Borderline right-axis deviation.....QRS axis (** , **)
BIVCDL	Borderline IVCD with LAD.....QRSd > ** mS, axis(-90,-30)
CRHPI	Consider RVH or posterior infarct.....large R in V1
CRHPIR	Consider RVH or PMI w/ sec repol abnormality....large R V1, repol abnormality

Table A-2 Algorithm Version PH100B Exclude All Setting - Suppressed Statements

Statement Code	Interpretive Statement
RPMIC	Tall R wave in V2, consider RVH or PMI.....R/S ratio >3, T >0.30mV V1 V2
CRVH	Consider right ventricular hypertrophy.....large R or R' V1/V2
INFQ	Abnormal inferior Q waves.....Qs add to 80 mS in II III aVF
IQNV	Inferior Q waves, probably normal variation.... Q >30mS, age<21 male, <30 female
IRBBRV	IRBBB, the RSR' pattern may also reflect RVH...IRBBB, R or R' >0.5mV in V1-V3
LATQ	Abnormal lateral Q waves.....Q >35mS, I aVL V5 V6
LQNV	Lateral Q waves, probably normal variation...Q >35mS, age<31 male, <40 female
LQTB	Borderline prolonged QT interval.....QTc > ** mS
LVHR56	LVH by voltage.....R >*.***mV in V5 or V6
LVHR6	LVH by voltage.....R >*.***mV in V6
LVHRS	Consider left ventricular hypertrophy.....RV6+SV1 >*.***mV
LVHRSI	LVH by voltage.....(R I+S III) >*.***mV
LVHS12	LVH by voltage.....S <*.*** in V1 or *.*** in V2
LVHTA	Consider left ventricular hypertrophy...prominent leftward forces
LVHV	LVH by voltage.....R >*.*** in aVL
MSTEA	Minimal ST elevation, anterior leads.....ST >0.10mV, V1-V4
MSTEAL	Minimal ST elevation, anterolateral leads.....ST >0.08mV, I aVL V2-V6
MSTEI	Minimal ST elevation, inferior leads....ST >0.06mV, II III aVF
MSTEL	Minimal ST elevation, lateral leads...ST >0.06mV, I aVL V5 V6
PLAE	Probable left atrial enlargement.....P >50mS, <-0.10mV V1

Table A-2 Algorithm Version PH100B Exclude All Setting - Suppressed Statements

Statement Code	Interpretive Statement
PQAL	Borderline Q wave in anterolateral leads.....Q >35mS, I aVL V3-V6
PQAN	Borderline Q wave in anterior leads.....Q >30mS in V2-V5
PQIN	Borderline Q waves in inferior leads.....Qs add to 80 mS in II III aVF
PQLA	Borderline Q waves in lateral leads...Q >35mS in I aVL V5 V6
PRAE	Probable right atrial enlargement....biphasic P >0.20 mV in V1
REPBAL	Borderline repol abnormality, ant-lat leads.....ST dep, T flat/neg, I aVL V2-V6
REPBAN	Borderline repol abnormality, ant leads.....ST dep, T flat/neg, V2-V4
REPBIL	Borderline repol abnormality, inf-lat leads.....ST dep, T flat/neg, inf/lat
REPBIN	Borderline repol abnormality, inferior leads.....ST dep, T flat/neg, II III aVF
REPBLA	Borderline repol abnormality, lateral leads.....ST dep, T flat/neg, I aVL V5 V6
RVHS5	Consider right ventricular hypertrophy.....deep S in V5
RVHS6	Consider right ventricular hypertrophy.....deep S in V6
SD0AL	Minimal ST depression, anterolateral leads.....ST <-0.04mV, I aVL V2-V6
SD0AN	Minimal ST depression, anterior leads....ST <-0.03mV, V2-V4
SD0IN	Minimal ST depression, inferior leads...ST <-0.04mV, II III aVF
SD0LA	Minimal ST depression, lateral leads.....ST <-0.04mV, I aVL V5 V6
SD0NS	Minimal ST depression.....ST <-0.04mV, T neg, any 2 leads
SPR	Short PR interval.....PR < ** mS
SQT	Short QT interval.....QTc <340mS
T0AL	Borderline T abnormalities, ant-lat leads.....T flat/neg, I aVL V2-V6
T0AN	Borderline T abnormalities, anterior leads...T flat or neg, V2-V4

Table A-2 Algorithm Version PH100B Exclude All Setting - Suppressed Statements

Statement Code	Interpretive Statement
T0IN	Borderline T abnormalities, inferior leads.....T flat/neg, II III aVF
T0LA	Borderline T abnormalities, lateral leads.....T flat/neg, I aVL V5 V6
T0NS	Borderline T wave abnormalities.....T/QRS ratio < 1/20 or flat T
TTW30	Tall T waves, probably normal variant....T >1.2mV, age 16-30

Algorithm Version PH110C Exclude Low Certainty Suppressed Statements

The following interpretive statements listed in Table A-3 are suppressed when the Exclude Low Certainty setting is selected under the Algorithm/Pacing button on the Setup, Default Cardiograph Settings screen.

Table A-3 Algorithm Version PH110C Exclude Low Certainty - Suppressed Statements

Statement Code	Interpretive Statement
BAVCD	Borderline prolonged PR interval.....PR > ** , V-rate ** - **
BIVCD	Borderline intraventricular conduction delay.....QRSd > ** mS
CLAE	Consider left atrial enlargement.....wide or notched P waves
CRAE	Consider right atrial enlargement.....P >0.24mV limb lead
ET	Abnormal R-wave progression, early transition.....QRS area>0 in V2
ETRSR1	RSR' in V1 or V2, right VCD or RVH.....QRS area positive & R' V1/V2
LOWT	Borderline T wave abnormalities.....flat T
LT	Abnormal R-wave progression, late transition.....QRS area <0 in V5/V6
LVHQ	Consider left ventricular hypertrophy.....deep Q in V5-6 or II III aVF
LVOLFB	Borderline low voltage, extremity leads.....all extremity leads <0.6mV
NFAD	No further analysis attempted due to paced rhythm

Table A-3 Algorithm Version PH110C Exclude Low Certainty – Suppressed Statements

Statement Code	Interpretive Statement
NFRA	No further rhythm analysis attempted due to paced rhythm
QMAB	Artifact in lead(s) ** and baseline wander in lead(s) **
QMART	Artifact in lead(s) **
QMBW	Baseline wander in lead(s) **
REPB	Borderline repolarization abnormality....ST dep & abnormal T
RSR1	RSR' in V1 or V2, probably normal variant.....small R' only
RSRNV	RSR' in V1, normal variation.....term-vector post-rightward
SDALP	Nonspecific ST depression, anterolateral lds.....ST <-0.10mV, I aVL V2-V6
SDANP	Nonspecific ST depression, anterior leads.....ST <-0.10mV, V2-V5
SDCU	Minimal ST depression.....ST concave upward
SDINP	Nonspecific ST depression, inferior leads.....ST <-0.10mV, II III aVF
SDJ	Junctional ST depression.....ST <-0.10mV any 3 leads
SDM	Minimal ST depression.....ST <-0.05mV in 2 leads
SEALP	ST elevation, prob normal variation, ant-lat.....ST >0.15 mV, I aVL V2-V6
SEANP	ST elev, probably normal variation, ant leads.....ST>0.15mV, V2-V5
SEINP	ST elevation, probably normal variation, inf.....ST>0.15mV, II III aVF
SPRB	Borderline short PR interval.....PR int < ** mS
TAXAB	Borderline T wave abnormalities...T axis not between (-10,100)
TAXQT	Borderline T wave abnormalities.....QRS-T axis angle (91,180)
TTW1	Tall T, probably normal variant, ant-lat lds.....T >1.0mV, I aVL V2-V6

Algorithm Version PH110C Exclude All Suppressed Statements

The interpretive statements listed in Table A-3, “Algorithm Version PH110C Exclude Low Certainty - Suppressed Statements,” on page 114, and the interpretive statements listed in Table A-4, “Algorithm Version PH110C Exclude All Setting - Suppressed Statements,” on page 116, are suppressed when the Exclude All setting is selected under the Algorithm/Pacing button on the Setup, Default Cardiograph Settings screen.

Table A-4 Algorithm Version PH110C Exclude All Setting – Suppressed Statements

Statement Code	Interpretive Statement
ANTQ	Abnormal Q wave in V1.....Q >15mS in V1
AXL	Borderline left-axis deviation.....QRS axis (** , **)
AXR	Borderline right-axis deviation.....QRS axis (** , **)
BIVCDL	Borderline IVCD with LAD.....QRSd > ** mS, axis(-90,-30)
CRHPI	Consider RVH or posterior infarct.....large R in V1
CRHPIR	Consider RVH or PMI w/ sec repol abnormality....large R V1, repol abnormality
RPMIC	Tall R wave in V2, consider RVH or PMI.....R/S ratio >3, T >0.30mV V1 V2
CRVH	Consider right ventricular hypertrophy.....large R or R' V1/V2
INFQ	Abnormal inferior Q waves.....Qs add to 80 mS in II III aVF
IQNV	Inferior Q waves, probably normal variation.... Q >30mS, age<21 male, <30 female
IRBBRV	IRBBB, the RSR' pattern may also reflect RVH...IRBBB, R or R' >0.5mV in V1-V3
LATQ	Abnormal lateral Q waves.....Q >35mS, I aVL V5 V6
LQNV	Lateral Q waves, probably normal variation...Q >35mS, age<31 male, <40 female
LQTB	Borderline prolonged QT interval.....QTc > ** mS
LVHR56	LVH by voltage.....R >*.***mV in V5 or V6

Table A-4 Algorithm Version PH110C Exclude All Setting - Suppressed Statements *(continued)*

Statement Code	Interpretive Statement
LVHR6	LVH by voltage.....R >*.***mV in V6
LVHRS	Consider left ventricular hypertrophy.....RV6+SV1 >*.***mV
LVHRSI	LVH by voltage.....(R I+S III) >*.***mV
LVHS12	LVH by voltage.....S <*.*** in V1 or *.*** in V2
LVHTA	Consider left ventricular hypertrophy...prominent leftward forces
LVHV	LVH by voltage.....R >*.*** in aVL
MSTEA	Minimal ST elevation, anterior leads.....ST >0.10mV, V1-V4
MSTEAL	Minimal ST elevation, anterolateral leads.....ST >0.08mV, I aVL V2-V6
MSTEI	Minimal ST elevation, inferior leads....ST >0.06mV, II III aVF
MSTEL	Minimal ST elevation, lateral leads...ST >0.06mV, I aVL V5 V6
PLAE	Probable left atrial enlargement.....P >50mS, <-0.10mV V1
PQAL	Borderline Q wave in anterolateral leads.....Q >35mS, I aVL V3-V6
PQAN	Borderline Q wave in anterior leads.....Q >30mS in V2-V5
PQIN	Borderline Q waves in inferior leads.....Qs add to 80 mS in II III aVF
PQLA	Borderline Q waves in lateral leads...Q >35mS in I aVL V5 V6
PRAE	Probable right atrial enlargement....biphasic P >0.20 mV in V1
REPBAL	Borderline repol abnormality, ant-lat leads.....ST dep, T flat/neg, I aVL V2-V6
REPBAN	Borderline repol abnormality, ant leads.....ST dep, T flat/neg, V2-V4
REPBIL	Borderline repol abnormality, inf-lat leads.....ST dep, T flat/neg, inf/lat
REPBIN	Borderline repol abnormality, inferior leads.....ST dep, T flat/neg, II III aVF
REPBLA	Borderline repol abnormality, lateral leads.....ST dep, T flat/neg, I aVL V5 V6

Table A-4 **Algorithm Version PH110C Exclude All Setting - Suppressed Statements *(continued)***

Statement Code	Interpretive Statement
RVHS5	Consider right ventricular hypertrophy.....deep S in V5
RVHS6	Consider right ventricular hypertrophy.....deep S in V6
SD0AL	Minimal ST depression, anterolateral leads.....ST <-0.04mV, I aVL V2-V6
SD0AN	Minimal ST depression, anterior leads....ST <-0.03mV, V2-V4
SD0IN	Minimal ST depression, inferior leads...ST <-0.04mV, II III aVF
SD0LA	Minimal ST depression, lateral leads.....ST <-0.04mV, I aVL V5 V6
SD0NS	Minimal ST depression.....ST <-0.04mV, T neg, any 2 leads
SPR	Short PR interval.....PR < ** mS
SQT	Short QT interval.....QTc <340mS
T0AL	Borderline T abnormalities, ant-lat leads.....T flat/neg, I aVL V2-V6
T0AN	Borderline T abnormalities, anterior leads...T flat or neg, V2-V4
T0IN	Borderline T abnormalities, inferior leads.....T flat/neg, II III aVF
T0LA	Borderline T abnormalities, lateral leads.....T flat/neg, I aVL V5 V6
T0NS	Borderline T wave abnormalities.....T/QRS ratio < 1/20 or flat T
TTW30	Tall T waves, probably normal variant....T >1.2mV, age 16-30

B

Critical Value Statements

Introduction

This Appendix includes a listing of all interpretive statements generated by the Philips DXL ECG Algorithm Versions PH100B and PH110C that will result in a *Critical Value* statement appearing on the ECG report. Use of the Critical Values feature makes it simple to align with the Joint Commission's National Patient Safety Goals to improve the timeliness of reporting critical test results and their receipt by a responsible licensed caregiver. The Critical Values feature is a configurable option that summarizes four critical values for ECG interpretation using simple terminology. When appropriate, the DXL Algorithm outputs an emphasized statement to advise caregivers of the need for urgent care, with the goal of reducing time from discovery of a critical cardiac event to intervention.

Thirty interpretive statements are summarized in the following four Critical Values:

- Acute Myocardial Infarction
- Complete Heart Block
- Very High Heart Rate
- Acute Ischemia

Table B-1 through Table B-8 on the following pages provide a list of all of the interpretive statements that will generate a Critical Value. Multiple interpretive statements can trigger an individual Critical Value, and this Critical Value statement appears in the interpretive statement block on the ECG report, and a second notation also appears at the bottom right of the ECG report for additional emphasis.

For more information on the Philips DXL ECG Algorithm Versions PH100B and PH110C, see the *Philips 16-Lead Algorithm Physican's Guide* on the *PageWriter TC10 User Documentation* DVD, or download the file from the Philips InCenter web site (https://philips.mizecx.com). For information on using the Philips InCenter web site, see page xiii.

Algorithm Version PH100B Acute Myocardial Infarction Critical Value Statements

If any of the interpretive statements listed in Table B-1 result from the measurements generated by an ECG, the Critical Value statement Acute MI will appear on the ECG report.

Table B-1 Philips DXL ECG Algorithm Version PH100B Acute Myocardial Infarct Critical Value Statements

Statement Code	Interpretive Statement
AMIA	Anterior infarct, acute.....ST >0.25mV, V2-V5
AMIAP	Probable anterior infarct, acute.....ST >0.15mV, upright T, V2-V5
AMIPA	Anterior infarct, possibly acute.....ST >0.15mV, upright T, V2-V5
AMIAD	Anterior infarct, acute (LAD).....ST >0.25mV, V2-V5
IMIAP	Probable inferior infarct, acute.....ST>0.10mV, II III aVF
IMIPA	Inferior infarct, possibly acute.....Q >30mS, ST >0.10mV, II III aVF
IMIA	Inferior infarct, acute.....ST>0.10mV, T upright, II III aVF
IMIAR	Inferior infarct, acute (RCA).....ST>0.10mV in III > II
IMIAX	Inferior infarct, acute (LCx).....ST>0.10mV, II III aVF, STd V1-V3
PMIA	Posterior infarct, acute.....ST<-0.1 V1-V3 or ST>.05 V7-V9
PMIAP	Probable posterior infarct, acute.....ST<-.05 V1-V3 or >.05 V7-V9
PMIAX	Posterior infarct, acute (LCx).....ST<-0.1 V1-V3 or ST>.05 V7-V9
IPMIA	Inferoposterior infarct, acute.....ST>.1 inf, <-.1 V1-3 or >.05 V7-V9
IPMIAR	Inferoposterior infarct, acute (RCA).....ST>.1 inf, <-.1 ant
IPMIAX	Inferoposterior infarct, acute (LCx).....ST>.1 inf, <-.1 V1-3 or >.05 V7-V9
LMIAP	Probable lateral infarct, acute.....Q >28mS, ST>0.10mV, V5 V6 I aVL
LMIPA	Lateral infarct, possibly acute.....Q >28mS, ST >0.10mV, V5 V6 I aVL
LMIA	Lateral infarct, acute.....ST >.10mV, V5 V6 I aVL

Table B-1 Philips DXL ECG Algorithm Version PH100B Acute Myocardial Infarct Critical Value Statements *(continued)*

Statement Code	Interpretive Statement
LMIAD	Lateral infarct, acute (LAD).....ST >.10mV, V5 V6 I aVL
ILMIA	Inferolateral infarct, acute.....ST>.10mV, inf-lat leads
ILMIAX	Inferolateral infarct, acute (LCx).....ST>.10mV, inf-lat leads
ILMIAR	Inferolateral infarct, acute (RCA).....ST>.10mV, inf-lat leads
ASMIAP	Probable anteroseptal infarct, acute.....ST>0.15mV, T upright, V1-V2
ASMIPA	Anteroseptal infarct, possibly acute.....Q>35mS, ST>0.15mV, V1-V2
ASMIA	Anteroseptal infarct, acute.....ST >0.20mV, V1-V2
ASMIAD	Anteroseptal infarct, acute (LAD).....ST >0.25mV, V1-V2
EAMIA	Extensive anterior infarct, acute.....ST >0.20mV, V1-V6
EAMIAD	Extensive anterior infarct, acute (LAD).....ST >0.20mV, V1-V6
EAMIPA	Extensive anterior infarct, possibly acute.....Q >35mS, ST >0.15mV, V1-V6
ALIAP	Probable anterolateral infarct, acute.....ST >0.15mV, V2-V6, I, aVL
ALIPA	Anterolateral infarct, possibly acute.....Q >35mS, ST >0.15mV, V2-V6, I, aVL
ALIA	Anterolateral infarct, acute.....ST >0.20mV, V2-V6, I, aVL
ALIAD	Anterolateral infarct, acute (LAD).....ST >0.20mV, V2-V6, I, aVL
RMIAP	Probable right ventricular infarct, acute...ST>.08, V3R-V5R, aVR & STd in lat
RMIA	Right ventricular infarct, acute.....ST>.10, V3R-V5R, aVR & STd in lat
RMIAR	Right ventricular infarct, acute (RCA).....ST>.08, aVR V3R-V5R & STd lat lds

Algorithm Version PH100B Tachycardia Critical Value Statements

If any of the interpretive statements listed in Table B-2 result from the measurements generated by an ECG, the Critical Value statement Very High Heart Rate will appear on the ECG report.

Table B-2 Philips DXL ECG Algorithm Version PH100B Tachycardia Critical Value Statements

Statement Code	**Interpretive Statement**
ETACH	Extreme tachycardia.....V-rate >(220-age)
TACHW	Wide-QRS tachycardia V-rate>***, QRSd>***
VTACH	Extreme tachycardia with wide complex, no further rhythm analysis attempted

Algorithm Version PH100B Complete Heart Block Critical Value Statements

If any of the interpretive statements listed in Table B-3 result from the measurements generated by an ECG, the Critical Value statement Complete Heart Block will appear on the ECG report.

Table B-3 Philips DXL ECG Algorithm Version PH100B Complete Heart Block Critical Value Statements

Statement Code	**Interpretive Statement**
3AVB	AV block, complete (third degree).....V-rate<***, AV dissociation
3AVBIR	Complete AV block with wide QRS complex.....V-rate<***, QRSd>***, AV dissoc
3AVBFF	A-flutter/fibrillation w/ complete AV block...A-rate>220, V-rate<***, AV dissoc

Algorithm Version PH100B Acute Ischemia Critical Value Statements

If the interpretive statement listed in Table B-4 is generated by the measurements from a patient ECG, the Critical Value statement Acute Ischemia will appear on the ECG report.

Table B-4 Philips DXL ECG Algorithm Version PH100B Acute Ischemia Critical Value Statements

Statement Code	Interpretive Statement
LMMVD	Repol abnrm, severe global ischemia (LM/3VD) STe aVR, STd & Tneg, ant/lat/inf

Algorithm Version PH110C Acute Myocardial Infarction Critical Value Statements

If any of the interpretive statements listed in Table B-5 result from the measurements generated by an ECG, the Critical Value statement Acute MI will appear on the ECG report.

Table B-5 Philips DXL ECG Algorithm Version PH110C Acute Myocardial Infarct Critical Value Statements

Statement Code	Interpretive Statement
AMIA	Anterior infarct, acute.....ST >0.25mV, V2-V5
AMIAP	Probable anterior infarct, acute.....ST >0.15mV, upright T, V2-V5
AMIPA	Anterior infarct, possibly acute.....ST >0.15mV, upright T, V2-V5
AMIAD	Anterior infarct, acute (LAD).....ST >0.25mV, V2-V5
AMIAPD	Anterior infarct, acute (proxLAD).....ST >0.2mV, V2-V5
IMIAP	Probable inferior infarct, acute.....ST>0.10mV, II III aVF
IMIPA	Inferior infarct, possibly acute.....Q >30mS, ST >0.10mV, II III aVF
IMIA	Inferior infarct, acute.....ST>0.10mV, T upright, II III aVF
IMIAR	Inferior infarct, acute (RCA).....ST>0.10mV in III > II
IMIAX	Inferior infarct, acute (LCx).....ST>0.10mV, II III aVF, STd V1-V3

Table B-5 Philips DXL ECG Algorithm Version PH110C Acute Myocardial Infarct Critical Value Statements *(continued)*

Statement Code	Interpretive Statement
PMIA	Posterior infarct, acute.....ST<-0.1 V1-V3 or ST>.05 V7-V9
PMIAP	Probable posterior infarct, acute.....ST<-.05 V1-V3 or >.05 V7-V9
PMIAX	Posterior infarct, acute (LCx).....ST<-0.1 V1-V3 or ST>.05 V7-V9
IPMIA	Inferoposterior infarct, acute.....ST>.1 inf, <-.1 V1-3 or >.05 V7-V9
IPMIAR	Inferoposterior infarct, acute (RCA).....ST>.1 inf, <-.1 ant
IPMIAX	Inferoposterior infarct, acute (LCx).....ST>.1 inf, <-.1 V1-3 or >.05 V7-V9
LBBMIP	Probable acute infarct and LBBB.....concordant ST
LMIAP	Probable lateral infarct, acute.....Q >28mS, ST>0.10mV, V5 V6 I aVL
LMIPA	Lateral infarct, possibly acute.....Q >28mS, ST >0.10mV, V5 V6 I aVL
LMIA	Lateral infarct, acute.....ST >.10mV, V5 V6 I aVL
LMIAD	Lateral infarct, acute (LAD).....ST >.10mV, V5 V6 I aVL
ILMIA	Inferolateral infarct, acute.....ST>.10mV, inf-lat leads
ILMIAX	Inferolateral infarct, acute (LCx).....ST>.10mV, inf-lat leads
ILMIAR	Inferolateral infarct, acute (RCA).....ST>.10mV, inf-lat leads
ASMIAP	Probable anteroseptal infarct, acute.....ST>0.15mV, T upright, V1-V2
ASMIPA	Anteroseptal infarct, possibly acute.....Q>35mS, ST>0.15mV, V1-V2
ASMIA	Anteroseptal infarct, acute.....ST >0.20mV, V1-V2
ASMIAD	Anteroseptal infarct, acute (LAD).....ST >0.25mV, V1-V2
EAMIA	Extensive anterior infarct, acute.....ST >0.20mV, V1-V6
EAMIAD	Extensive anterior infarct, acute (LAD).....ST >0.20mV, V1-V6
EAMIPA	Extensive anterior infarct, possibly acute.....Q >35mS, ST >0.15mV, V1-V6
ALIAP	Probable anterolateral infarct, acute.....ST >0.15mV, V2-V6,I,aVL

Table B-5 Philips DXL ECG Algorithm Version PH110C Acute Myocardial Infarct Critical Value Statements *(continued)*

Statement Code	Interpretive Statement
ALIPA	Anterolateral infarct, possibly acute.....Q >35mS, ST >0.15mV, V2-V6,I,aVL
ALIA	Anterolateral infarct, acute.....ST >0.20mV, V2-V6, I, aVL
ALIAD	Anterolateral infarct, acute (LAD).....ST >0.20mV, V2-V6, I, aVL
RMIAP	Probable right ventricular infarct, acute...ST>.08, V3R-V5R, aVR & STd in lat
RMIA	Right ventricular infarct, acute.....ST>.10, V3R-V5R, aVR & STd in lat
RMIAR	Right ventricular infarct, acute (RCA).....ST>.08, aVR V3R-V5R & STd lat lds

Algorithm Version PH110C Tachycardia Critical Value Statements

If any of the interpretive statements listed in Table B-6 result from the measurements generated by an ECG, the Critical Value statement Very High Heart Rate will appear on the ECG report.

Table B-6 Philips DXL ECG Algorithm Version PH110C Tachycardia Critical Value Statements

Statement Code	Interpretive Statement
ETACH	Extreme tachycardia.....V-rate >(220-age)
TACHW	Wide-QRS tachycardia V-rate>***, QRSd>***
VTACH	Extreme tachycardia with wide complex, no further rhythm analysis attempted

Algorithm Version PH110C Complete Heart Block Critical Value Statements

If any of the interpretive statements listed in Table B-7 result from the measurements generated by an ECG, the Critical Value statement Complete Heart Block will appear on the ECG report.

Table B-7 Philips DXL ECG Algorithm Version PH110C Complete Heart Block Critical Value Statements

Statement Code	Interpretive Statement
3AVB	AV block, complete (third degree).....V-rate<***, AV dissociation
3AVBIR	Complete AV block with wide QRS complex.....V-rate<***, QRSd>***, AV dissoc
3AVBFF	A-flutter/fibrillation w/ complete AV block...A-rate>220, V-rate<***, AV dissoc

Algorithm Version PH110C Acute Ischemia Critical Value Statements

If the interpretive statement listed in Table B-8 is generated by the measurements from a patient ECG, the Critical Value statement Acute Ischemia will appear on the ECG report.

Table B-8 Philips DXL ECG Algorithm Version PH110C Acute Ischemia Critical Value Statements

Statement Code	Interpretive Statement
LMMVD	Repol abnrm, severe global ischemia (LM/3VD) STe aVR, STd & Tneg, ant/lat/inf

C

Specifications

Technical Specifications

ECG Functions

- Simultaneous Lead Acquisition (12 leads)
- Rhythm Strips (up to 6 selected leads)
- Event Marking: 6 independent events can be marked for later review and analysis
- Full Disclosure: Five-minute history of up to 12 leads. Complete ECG of any 10 seconds.
- Timed ECG

Touch Screen Display

- 800 x 480 pixel resolution VGA with 16-bit/pixel color depth
- 5-wire, resistive touch screen
- 15.4 cm wide x 8.6 cm high (7-inch diagonal) color liquid crystal touch screen display with LED backlight

Display Accuracy

- The accuracy of the ECG signals are within +/- 5% (or +/- 40 µV whichever is greater), over a range of 0 to +/- 5 mV, in the presence of common mode DC offset voltages of +/- 300 mV. The cardiograph performance is tested to comply with the accuracy requirements over the dynamic ranges and frequency ranges specified in the IEC 60601-2-25:2011 standard.
- For additional details regarding accuracy and precision, refer to the *Physician's Guide* and the Manufacturer's Disclosure Statement.

Signal Processing/Acquisition

Raw Sampling Rate

- 8000 samples per seconds on each patient connection

- 24-bit A/D conversion provides down sampled 0.13µV resolution
- Simultaneous acquisition, channel skew less than 10µs

Sampling Rate

- 500 samples per second for processed ECG data
- 12-bit 5µV/LSB filtered ECG data

Auto Frequency Response

0.05-150 Hz, 0.15-150 Hz, 0.5-150 Hz
0.05-100 Hz, 0.15-100 Hz, 0.5-100 Hz
0.05-40 Hz, 0.15-40 Hz, 0.5-40 Hz

Rhythm Frequency Response

0.05-150 Hz, 0.15-150 Hz, 0.05-100 Hz,
0.15-100 Hz, 0.05-40 Hz, 0.15-40 Hz

Minimum Amplitude or Value of Patient Physiological Signal

Caution

The QRS wave must be a minimum of 100µV peak to peak or greater for the complex of the lead to be measured. The operation of the cardiograph below this value may cause incorrect ECG analysis.

Filters

- AC noise (Off, 50 Hz, 60 Hz)
- Baseline Wander (On, Off)
- Artifact (On, Off)
- Low-Pass (40 Hz, 100 Hz, 150 Hz)
- High-Pass (0.05 Hz, 0.15 Hz, 0.5 Hz)

Thermal Printer

Thermal Printer Resolution

- High-resolution, digital-array printer using a 110 mm wide x 28.5 m long roll of thermal-sensitive paper
- 200 dpi (amplitude axis) by 500 dpi (time axis) at 25 mm/sec

Report Formats

Exam Profiles

Up to 12 configured Exam Profiles can be specified

12-Lead Report Formats

- Panoramic 12 (Cabrera sequence only)
- 6x2
- 6x2 1R
- 3x4
- 3x4 1R
- 3x4 3R
- 3x4 1R 8ST
- Extended Measurements

Rhythm Report Formats

Rhythm (up to 6 selected leads)

STEMI Diagnostic Aids

- Polar ST Maps with frontal and transverse planes available on two ECG report formats
- STEMI-CA criteria
- Critical Values

Barcode Reader (optional)

The optional barcode reader offers flexible field data entry. For a list of supported symbologies, refer to the *Installing and Testing the DECG Barcode Scanner* document.

Battery Operation

Voltage	Current	Power
11.1 V@ 4800 mAh	4.8A max (continuous)	53W max (continuous)

Capacity

- 300 typical patient reports (3x4 3R format without measurement and interpretation), or
- 120 minutes 3-lead rhythm printing (10 Hz, 1mV signals), or
- 10 hours continuous operation without printing

Status Display

- Battery capacity indicator
- Low battery audio and visual alerts

Recharge Time

- Less than 4 hours to at least 90% capacity (standby/off mode)
- Less than 4 hours to at least 90% capacity (run mode without printing)

When ambient temperature is close to 40°C, it is recommended to shut down the TC10 cardiograph during battery charging.

Note:

Battery capacity and recharge time is tested under room temperature/humidity conditions. Customers may experience different behavior due to different use models and different environments. Battery capacity percentage cannot be accurately measured.

Network Connection

- 10/100 Base-T IEEE 802.3 Ethernet via RJ45 connector
- Wireless LAN connection supports 802.11 a/b/g/n standards

ECG Storage

- XML File Format in version 1.03, 1.04, 1.04.01, and 1.04.02
- Up to 200 ECGs to internal flash memory
- Up to 200 ECGs per USB Memory Stick (optional)
- Full fidelity at 500 Hz of all 10 seconds of all 12 leads

Orders and ADT

- Orders: Up to 200 pending orders can be stored on the cardiograph
- ADT: Full patient demographic information can be automatically retrieved

ECG File Formats

- XML (Schema 1.03 and 1.04, 1.04.01, 1.04.02)
- PDF

Power and Environment

Line Power: 100-240 Vac, 50/60 Hz, 1.2A - 0.6A

Cardiograph Environmental Operating Conditions

- 10° to 40 °C (50° to 104°F)
- 10% to 90% relative humidity (non-condensing)
- 1014hPa to 697hPa (0 to 3,048 m/10,000 ft.)

Cardiograph Environmental Storage and Transport Conditions

- -20° to 50 °C (-4° to 122°F)
- 10% to 90% relative humidity (non-condensing)
- 1014 hPa to 572 hPa (0 to 4,572 m/15,000 ft.)

Note:

The 1014hPa listed in the Operating and Storage Conditions is the average sea-level pressure. Due to weather and geographic factors, the actual sea-level pressure may deviate slightly, which should not be construed as limiting the operation and storage of the device.

Cardiograph Dimensions

Length	Width	Height	Weight
33.8 cm (13.3 in.)	24 cm (9.5 in.)	6.5 cm (2.6 in.)	2.5 kg (5.5 lbs.)

Note:

Dimensions do not include footpad and printer button.

Service Life

The TC10 cardiograph is expected to have a service life of seven (7) years, not including consumables, such as batteries, paper, or leadwires.

Consumables are intended for one time use (e.g., paper or single-use electrodes) or may have a a limited lifetime expectancy depending on various use loads (e.g., battery or leadwires).

Safety and Performance

Meets the following requirements for safety and performance:

- IEC 60601-1: 2005+A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.
- IEC 60601-2-25: 2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
- IEC 62366-1: 2015 Medical devices –Part 1: Application of usability engineering to medical devices.
- IEC 60601-1-6: 2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304: 2006+A1: 2015 Medical device software - Software life-cycle processes.

Essential Performance

In normal conditions of use, the PageWriter TC10 cardiograph shall provide performance that is free from unacceptable RISK. To comply to the requirements of IEC 60601-1 and IEC60601-2-25 as well as IEC60601-1-2, the ESSENTIAL PERFORMACE of the PageWriter TC10 is considered as below: .

The minimum performance when operating under normal condition and specific EMC conditions (Conducted disturbances, Electrical Fast Transients/ Bursts)	
EP1	No interruption or cessation of current operating mode (e.g. no restart).
	No spontaneous operation of controls (e.g. no activation of touch screen without user interaction).
	The accuracy of the measurements is guaranteed over the specified measurement and frequency response range.[1]
EP2	The ECG noise level caused by EMC interference is no more than 100uV peak to valley.[2]
EP3	FILTERS for line frequency interference suppression shall not introduce on the ECG REPORT more than 50 μV peak-to-valley distortion of the signal in any LEAD.[3]
The capability of automatic recovery when affected by defibrillation or electrostatic discharge:	
EP4	After defibrillation, Within 5 seconds, device shall resume normal operation in the previous operating mode without operator intervention, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function.[4]

EP5	Device may show temporary DEGRADATION during electrostatic discharges. Within 10 s, device shall resume normal operation in the previous operating mode without operator intervention, without loss of any OPERATOR settings or stored data, and shall continue to continue to perform its intended function and maintain its accuracy of amplitude measurement.[5]

1. Refer to clause 201.12.1.101 of IEC60601-2-25:2011.
2. Refer to clause 202.6.2.4.1 and clause 202.6.2.6.1 of IEC60601-2-25:2011.
3. Refer to clause 201.12.4.105.3 of IEC60601-2-25:2011.
4. Refer to clause 201.8.5.5.1 of IEC60601-2-25:2011.
5. Refer to clause 202.6.2.2.1 of IEC60601-2-25:2011.

The PageWriter TC10 Cardiograph is not intended to be used in an electrosurgery environment. Electrosurgical interference immunity is not essential performance of the TC10 cardiograph.

Optional device function, such as barcode reader, is not considered Essential Performance.

Classification (IEC 60601-1)

PageWriter TC10 Cardiograph Class I (Internally Powered)

Symbol	Meaning
	ECG physio isolation is type CF, defibrillator proof. Suitable for all patient applications including direct cardiac application. System is in continuous operation.
IPX0	Cardiograph has no protection against the entry of liquids.
IPX4	The patient cable is protected against splashing water. Water splashed against the patient cable from any direction shall have no harmful effect.
• Cardiograph is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. • System is continuous operation. • Applied parts of the TC10 cardiograph includes the patient cable and electrodes.	

WARNING

When using additional peripheral equipment powered from an electrical source other than the cardiograph, the combination is considered to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1 and test the medical system according to the requirements. For additional information contact Philips Medical Systems.

Note:

- *IEC 60601-2-25:2011 high frequency response is tested by methods A and E.*
- *The TC10 cardiograph is a digital system. Because of their sampling characteristics and the asynchronism between sample rate and signal rate, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon is not physiologic and must be understood by operators.*

Electromagnetic Compatibility (EMC)

Electronic devices can either generate or receive electromagnetic interference. The PageWriter TC10 cardiograph has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to Medical Collateral standard IEC 60601-1-2 (with exceptions noted in proceeding tables). This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2.

The cardiograph needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

WARNING

Radio frequency (RF) interference from nearby transmitting devices may degrade performance of the electronic equipment. Electromagnetic compatibility with surrounding devices should be assessed prior to using the equipment.

WARNING

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electrical equipment. The portable RF equipment (including peripherals such as antenna cables and external antennas), should be used no closer than 30 cm (12 inches) to any part of the TC10 cardiograph, including cables specified by Philips.

WARNING

The use of accessories and cables other than those specified in the Philips PageWriter TC10 cardiograph service and user documentation can result in increased emissions or decreased immunity of the system.

WARNING

The PageWriter TC10 cardiograph should not be used next to or stacked on top of other equipment. If you must stack the product, you must check that normal operation is possible in the necessary configuration before the product is used.

Reducing Electromagnetic Interference

The PageWriter TC cardiograph and accessories may become sensitive to interference from other RF energy sources including power lines. RF energy sources include other medical devices, wireless devices, information technology equipment, and radio/television transmission. Should interference be encountered, as demonstrated by artifact on the ECG trace, unintended change on operating state, or unit lockup, attempt to locate the source by assessing:

- If the interference is intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical devices?
- Does the ECG signal quality change dramatically when the AC power cord is unplugged?

Once the source of the interference is located, attempt to attenuate the EMC coupling path by distancing the cardiograph from the source of the interference as much as possible. If further assistance is needed, contact the Philips Response Center or your certified dealer.

The PageWriter TC10 cardiograph has been evaluated in the Electromagnetic Environment listed in tables C-1 to C-4 based on Medical Collateral standard IEC 60601-1-2, 2nd and 3rd Editions.

Table C-1 PageWriter TC Cardiograph Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the PageWriter TC10 cardiograph should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment: guidance**
RF Emissions CISPR 11	Group 1	The PageWriter TC10 cardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low are not likely to cause any interference in nearby electronic equipment.

Table C-1 PageWriter TC Cardiograph Guidance and Manufacturer's Declaration: Electromagnetic Emissions *(continued)*

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the PageWriter TC10 cardiograph should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment: guidance**
RF Emissions CISPR 11	Class B	The PageWriter TC10 cardiograph is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table C-2 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the PageWriter TC10 cardiograph should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be constructed of wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Table C-2 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the PageWriter TC10 cardiograph should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment: guidance**
Surge IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV lines(s) to earth	+/- 1 kV line to line +/- 2 kV lines(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the cardiograph requires continued operation during power mains interruptions, it is recommended that the cardiograph be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Table C-3 Guidance and Manufacturer's Declaration: Electromagentic Immunity

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the PageWriter TC10 cardiograph should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PageWriter TC cardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PageWriter TC cardiograph is used exceeds the applicable RF compliance level above, the PageWriter TC cardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PageWriter TC cardiograph.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table C-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the PageWriter TC10 Cardiograph: for equipment and systems that are not life-supporting

The PageWriter TC10 cardiograph is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PageWriter TC10 cardiograph can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PageWriter TC10 cardiograph as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)	
0.01	150 KHz to 800 KHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

The PageWriter TC10 cardiograph is also evaluated based on the requirements of IEC 60601-1-2:2014 4th Edition.

Table C-5 PageWriter TC10 Cardiograph: Electromagnetic Emissions

Phenomenon	Compliance	Electromagnetic Environment
RF Emissions	CISPR 11, Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 6100-3-3	Professional healthcare facility environment

Table C-6 PageWriter TC10 Cardiograph: Enclosure Port

Phenomenon	Compliance	Immunity Test Levels Professional Healthcare Facility Environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table C-7
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table C-7 PageWriter TC10 Cardiograph: Proximity fields from RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels Professional Healthcare Facility Environment
385	380 –390	Pulse modulation 18 Hz, 27 V/m
450	430 –470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m

Table C-7 PageWriter TC10 Cardiograph: Proximity fields from RF wireless communications equipment *(continued)*

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels Professional Healthcare Facility Environment
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 21 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table C-8 PageWriter TC10 Cardiograph: Input AC Port

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surges line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV

Table C-8 PageWriter TC10 Cardiograph: Input AC Port *(continued)*

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table C-9 PageWriter TC10 Cardiograph: Signal Input/Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels Professional Healthcare Facility Environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15–80 MHz 6 V in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz

Wireless LAN Option Specifications

Table C-10 Option D24 SDC-MSD40NBT Wireless LAN RF Specifications

Item	Specifications
Wi-Fi Modulation	BPSK @ 1, 6, 6.5, 7.2, and 9 Mbps QPSK @ 2, 5.5, 11, 12, 13, 14.4,18, 19.5, and 21.7 Mbps 16-QAM @ 24, 26, 28.9, 36, 39, and 43.3 Mbps 64-QAM @ 48, 52, 54, 57.8, 58.5, 65, and 72.2 Mbps
Wi-Fi 2.4 GHz Frequency Bands	ETSI: 2.4 GHz to 2.483 GHz FCC: 2.4 GHz to 2.483 GHz MIC (Japan): 2.4 GHz to 2.495 GHz KC: 2.4 GHz to 2.483 GHz
5 GHz Frequency Bands	ETSI • 5.15 GHz to 5.35 GHz • 5.47 GHz to 5.725 GHz FCC • 5.15 GHz to 5.35 GHz • 5.47 GHz to 5.725 GHz • 5.725 GHz to 5.82 GHz MIC (Japan) • 5.15 GHz to 5.35 GHz KC • 5.15 GHz to 5.35 GHz • 5.725 GHz to 5.82 GHz

Table C-10 Option D24 SDC-MSD40NBT Wireless LAN RF Specifications (continued)

Item	Specifications
Transmit Power Note: Transmit power varies according to individual country regulations. All values nominal, +/-2 dBm.	802.11a • 6 Mbps • 16 dBm (40 mW) • 54 Mbps • 14 dBm (25 mW) 802.11b • 1 Mbps • 17 dBm (50 mW) • 11 Mbps • 16 dBm (40 mW) 802.11g • 6 Mbps • 15 dBm (32 mW) • 54 Mbps • 13 dBm (20 mW) 802.11n (2.4 GHz) • 6.5 Mbps (MCS0) • 15 dBm (32 mW) • 65 Mbps (MCS7) • 11 dBm (13 mW) 802.11n (5 GHz) • 6.5 Mbps (MCS0) • 16 dBm (40 mW) • 65 Mbps (MCS7) • 13 dBm (20 mW)

For more TC10 cardiograph wireless LAN option specifications, see the *PageWriter TC Wireless LAN Installation and Configuration Guide*.

D

Parts and Supplies

Most supplies may be ordered on the web at www.philips.com/healthcarestore.

For additional assistance, contact your Philips Sales Representative or your local distributor.. If the replacement part that you need is not listed in this section, please contact Philips Response Center for further assistance. See “Contacting Philips Response Center” on page 150.

Supplies and Ordering information

Ordering Options and Upgrades

For more information on ordering any of the following cardiograph upgrades or options, contact your Philips Sales Representative or your local distributor.

For software upgrades, ensure that you have your PageWriter TC10 cardiograph’s serial number.

Table D-1 Hardware

Option Number	Description
H12	1D Barcode Scanner (linear)
H23	Long patient cable

Table D-2 Software

Option Number	Description
D01	Networked Worklists/Patient List Support **Note:** *Includes option D07. No need to order option D07 in addition to option D01.*
D02	ADT Support **Note:** *Enables query/download ADT from IBE.*

Table D-2 Software (continued)

Option Number	Description
D03	DXL 12-Lead ECG Algorithm **Note:** *Enables PH100B (Sedici) and PH110C (Ascent) algorithm versions.*
D05	5-min Disclosure and Events **Note:** *Enables event marker and disclose functions.*
D06	Archive, Last ECG, and Interactive Query **Note:** *Includes option D12 Interactive Query.*
D07	Manual Worklists/Patient List Support **Note:** *Cannot be ordered with option D01.*
D08	Native DICOM support **Note:** *Option D01 must be ordered as well to support full DICOM workflow.*
D20	Wired LAN **Note:** *Enables wired network connectivity.*
D24	Wireless 802.11 (a, b, g, n) **Note:** *Enables wireless network connectivity.*

Table D-3 Accessories

Option Number	Description
E04	Welsh Bulbs
E06	Double-sided Tab Clips, compatible with both tab and snap electrodes

Table D-4 Warranty

Option Number	Description
W03	3 year return to Philips Bench
W05	5 year parts and support by certified dealer

Ordering Customer Replacement Parts and Accessories

The following items represent the supplies available at the time of this manual's printing. Additions to and deletions from this list are likely to occur over time. Not all supplies may be available in all countries.

WARNING

When using additional peripheral equipment powered from an electrical source rather than from the cardiograph, the combination is considered a to be a medical system. It is the responsibility of the operator to comply with IEC 60601-1, and to test the medical system according to the requirements. For additional information, contact Philips Response Center.

Most supplies may be ordered on the web at www.philips.com/healthcarestore. For additional assistance, contact your Philips Sales Representative or your local distributor.

Special Note about Welsh Bulb Electrodes

Figure D-1 Welsh Bulb Electrode



Welsh Bulb electrodes are offered as an optional supply part with the PageWriter TC10 cardiograph. Special care is necessary when using these electrodes. Pay special attention to all warnings associated with these electrodes. For information on cleaning the reusable Welsh Bulb electrodes, “Reusable Electrode Cleaning” on page 97. Philips recommends the use of disposable electrodes with the PageWriter TC cardiograph.

WARNING

The Welsh bulb electrodes (available as an accessory for the cardiograph) do not meet the requirements of IEC 60601-2-25 for defibrillation recovery time, and cannot be reliably used for patient diagnosis immediately following defibrillation.

WARNING

Always clean and disinfect reusable electrodes before patient use. See "Reusable Electrode Cleaning" on page 97 for information on cleaning and disinfecting reusable electrodes. Failure to properly clean and disinfect reusable electrodes before patient use may cause infectious materials to be transferred between patients.

Table D-5 Accessories

Item(s)	Part Number	Description
Welsh Bulb Electrodes	989803185251	Reusable Welsh Bulb electrode, AHA/IEC. • Screw-in connector • 6 electrodes per box
Limb Clamp Electrodes	40494E	Limb Clamp Electrode • Screw-in connector • 4 clamps per box
Tab Electrodes	13943B	Solid Gel Tab Electrode, Resting ECG. • 1 3/8" (35 mm) (L) x 7/8" (22mm) (W) • 1000 electrodes per case • 100 electrodes per pouch • 10 electrodes per card
Snap Electrodes* * not compatible with PageWriter TC10 cardiograph in China	40420A	High-Tack Foam Wet Gel ECG Electrode Disposable, High-Tack Foam, Wet Gel Electrode for diagnostic, stress, resting, and monitoring ECG. • 28mm x 55mm (1.1" x 2.2") • 5 per strip • 30 per pouch • 300 per case
ECG Trunk Cable	989803184921	12-Lead Patient Cable (IEC) Standard Length
	989803184931	12-Lead Patient Cable (AAMI) Standard Length
	989803184941	12-Lead Patient Cable (IEC) Long
	989803184951	12-Lead Patient Cable (AAMI) Long

Table D-5 Accessories (continued)

Item(s)	Part Number	Description
Lead-to-Electrode Adapters	989803166031	Clear Tab/Snap Adapter Connects 1/8" posts and 4mm post banana plugs to tab or snap electrodes. 10 per bag.
	989803209691	Clear Tab/Snap Adapter Connects 1/8" posts and 4mm post banana plugs to tab or snap electrodes. 10 per bag.
Thermal Paper	989803185271	Thermal roll paper, 110mm wide
Replacement Battery	989803185291	PageWriter TC10 battery Replacement battery, 6 cell.
Linear Barcode reader	989803194501	USB Linear Barcode Reader

Country Power Cords		
UK	8120-1351	CBL AC POWER CORD 2 METER OPTION 900
EUROPE	8120-1689	CBL AC POWER CORD 2 METER OPTION 902
CN	8120-2961	CMS CBL EXT GND ASSY (Crocodile clip)
ZA	8120-4211	CBL AC POWER CORD 2 METER OPTION 917
AU, NZ	8120-4475	CBL AC POWER CORD 2 METER OPTION 901
IL	8120-5182	CBL AC POWER CORD 2 METER OPTION 919
US	8120-5429	CBL AC 3 WIRE POWER CORD
AR	8120-6869	CBL AC POWER CORD 2 METER OPTION 920

Table D-5 Accessories (continued)

Item(s)	Part Number	Description
CN	8120-8376	CBL AC POWER CORD 2.2 METER OPTION 922

Contacting Philips Response Center

Philips Customer Care can assist with product troubleshooting and provide technical expertise to help with any issue with the PageWriter TC cardiographs or any of its accessories.

For more information on how to contact Philips Customer Care, go to http://www.usa.philips.com/healthcare/country-selector.html. Select the link for your country or region, scroll to the bottom of the page, and click “Contact.”



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