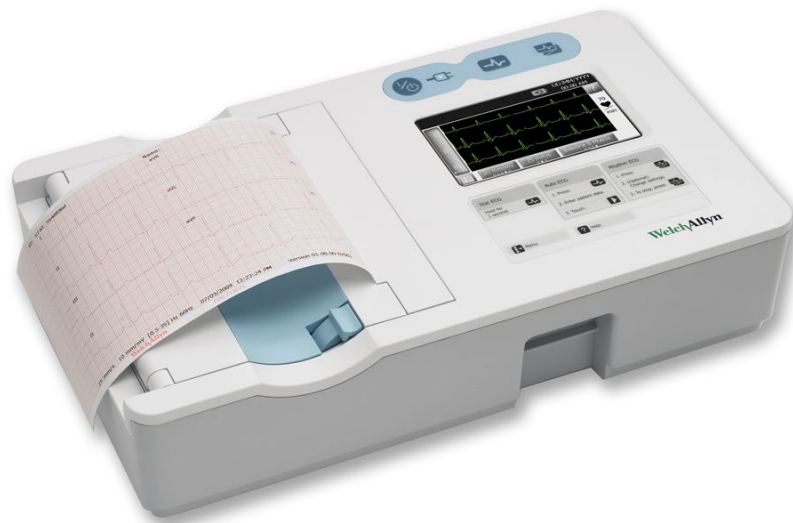


# CP 50™ and CP 50 Plus™ 12-lead resting electrocardiograph

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## Directions for use

**WelchAllyn®**

Advancing Frontline Care™

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[www.welchallyn.com/about/company/locations.htm](http://www.welchallyn.com/about/company/locations.htm).

Multilanguage CD:  105487

Printed manual:  DIR 80015344, Ver. F



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 901048 ELECTROCARDIOGRAPH



**WelchAllyn**<sup>®</sup>  
Advancing Frontline Care<sup>™</sup>

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# Introduction

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## About this document

This document is written for clinical professionals with a working knowledge of medical procedures and terminology required for monitoring cardiac patients.

Before using the electrocardiograph for clinical applications — or before setting up, configuring, troubleshooting, or servicing the electrocardiograph — you must read and understand this document and all other information that accompanies the electrocardiograph and related options or accessories.

## Intended use

The Welch Allyn electrocardiography products (subject devices) are intended for use by trained operators in health facilities. The subject devices provide the following diagnostic functions:

- Acquiring, viewing, storing, and printing ECG waveforms using ECG front-end modules (patient cables) and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional algorithms to generate measurements, data presentations, graphical presentations, and interpretative statements on an advisory basis. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the result of physical examination, the ECG tracings, and other clinical findings.

## Indications for use

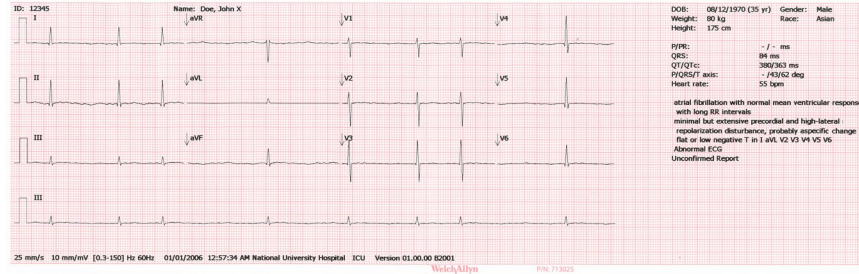
The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function.

The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities which must be confirmed by a physician with other relevant clinical information.

## About the test types

### Auto ECG

A report typically showing a 10-second acquisition of 12 leads of ECG information combined with patient data, measurements, and optional interpretation. Auto ECGs can be saved to the electrocardiograph's test directory or to a USB mass-storage device. In CP 50 Plus models, auto ECGs can also be sent to a Welch Allyn CardioPerfect workstation.



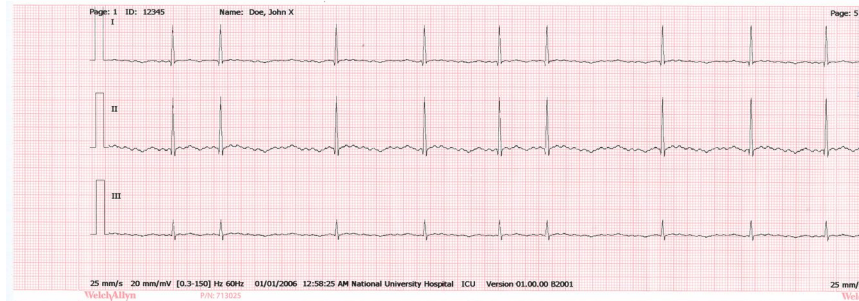
### Auto ECG report example

### Stat ECG

An auto ECG that starts instantly without waiting for you to enter patient data or adjust the waveforms.

### Rhythm ECG

A continuous, real-time printout of rhythm strips with a user-defined lead configuration. Rhythm ECGs are printouts only. They cannot be saved.



### Rhythm ECG report example

# Features

## Pacemaker detection

The software detects the possible presence of a pacemaker. If you confirm that the patient has a pacemaker, the ECG report includes no interpretation, and it indicates that a pacemaker was detected.

## Automatic ECG interpretation (optional)

The optional MEANS interpretation algorithm, developed by the University of Rotterdam in the Netherlands, provides automatic analysis of ECG tests. For more information, see the MEANS Physicians' Manual or the PEDMEANS Physicians' Manual on the CD that came with your electrocardiograph. The MEANS algorithm is used for adult patients 18 years and older. The PEDMEANS algorithm is used for pediatric patients from 1 day through 17 years old.

## CP 50 Plus (optional)

The CP 50 Plus consists of the CP 50 device and an optional connectivity feature that is enabled with a software activation code.

## Configuration options

The device is available in multiple configurations. Use the following to identify a configuration:

[Device] [Feature] - [Cable] [Language] [PowerCord]

Position	Description																																
[Device]	Four characters that indicate the device: CP50.																																
[Feature]	One or two characters that indicates the added feature: <ul style="list-style-type: none"> <li>• <b>Blank</b>: A basic feature.</li> <li>• <b>A</b>: Includes automatic ECG interpretation.</li> <li>• <b>P</b>: Includes connectivity.</li> <li>• <b>AP</b>: Includes automatic ECG interpretation and connectivity.</li> </ul>																																
[Cable]	A number that specifies the cable type included with the device: <ul style="list-style-type: none"> <li>• <b>1</b>: AHA ECG cable with disposable electrodes.</li> <li>• <b>2</b>: IEC ECG cable with disposable electrodes.</li> <li>• <b>3</b>: AHA ECG cable with reusable electrodes.</li> <li>• <b>4</b>: IEC ECG cable with reusable electrodes.</li> </ul>																																
[Language]	Two characters that indicate the language of the manual included with your device:																																
	<table border="1"> <thead> <tr> <th>Code</th> <th>Language</th> <th>Code</th> <th>Language</th> </tr> </thead> <tbody> <tr> <td>DA</td> <td>Danish</td> <td>NO</td> <td>Norwegian</td> </tr> <tr> <td>DE</td> <td>German</td> <td>PL</td> <td>Polish</td> </tr> <tr> <td>EN</td> <td>English</td> <td>PT</td> <td>Portuguese</td> </tr> <tr> <td>ES</td> <td>Spanish</td> <td>RU</td> <td>Russian</td> </tr> <tr> <td>FR</td> <td>French</td> <td>SV</td> <td>Swedish</td> </tr> <tr> <td>IT</td> <td>Italian</td> <td>VI</td> <td>Vietnamese</td> </tr> <tr> <td>NL</td> <td>Dutch</td> <td>ZH</td> <td>Simplified Chinese</td> </tr> </tbody> </table>	Code	Language	Code	Language	DA	Danish	NO	Norwegian	DE	German	PL	Polish	EN	English	PT	Portuguese	ES	Spanish	RU	Russian	FR	French	SV	Swedish	IT	Italian	VI	Vietnamese	NL	Dutch	ZH	Simplified Chinese
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[PowerCord]	One number that indicates the power cord packaged with the device.																																
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# Symbols

## Documentation symbols



**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.



**CAUTION** The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data. This definition applies to both yellow and black and white symbols.



Follow instructions/directions for use (DFU) -- mandatory action.

A copy of the DFU is available on this website.

A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.

## Operation symbols



Power on/standby



Search



Auto ECG



Rhythm ECG



Accept



Close/Cancel



Previous



Next



Help
















Menu





Backspace







## Power symbols






	(LED off) No AC power is present.		Battery absent or faulty.
	(LED green) AC power is present, and battery is charging. (LED amber) AC power is present, and battery is charging.		Battery is charged to the indicated level.
	Alternating current		Battery is charging
	Dangerous voltage		Battery door
	Fuse		Rechargeable battery
	Protective earth		Nonionizing electromagnetic radiation
	Equipotential terminal	<b>Li-ion</b>	Lithium ion

## Connectivity symbols













	USB		Ethernet (RJ-45 )
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## Shipping, storing, and environment symbols

	This end up		Keep dry.
	Fragile		Relative humidity limit
	Temperature limits		Atmospheric air-pressure limits

	Separate the battery from other disposables for recycling.		Recycle.
	Separate the device from other disposables for recycling. See <a href="http://www.welchallyn.com/weee">www.welchallyn.com/weee</a> .	 	China RoHS (restriction of hazardous substances) symbols for control of pollution caused by electronic information products. 5-year environment-friendly use period (EFUP) for batteries. 10-year EFUP for the device. For details, see the accompanying documentation.

### Miscellaneous symbols

	Heartbeats per minute		Hot surface. Do not touch.
	Manufacturer		Date of manufacture
	Defibrillation-proof Type CF applied parts		Defibrillation-proof Type BF applied parts
	Reorder number		Serial number
	Do not reuse		Batch code
	Meets essential requirements of European Medical Device Directive 93/42/EEC		Software activation code

## General warnings

Warnings indicate conditions or practices that could lead to illness, injury, or death.

### Warnings related to the environment



**WARNING** To avoid a possible explosion, do not use the electrocardiograph in the presence of flammable anesthetics: mixtures containing air, oxygen, or nitrous oxide.



**WARNING** When transporting the electrocardiograph on a cart, tuck the patient cable away from the wheels so that it does not present a hazard.

### Warnings related to accessories and other equipment



**WARNING** For operator and patient safety, peripheral equipment and accessories that can come in direct patient contact must be in compliance with all appropriate safety, EMC, and regulatory requirements.



**WARNING** All signal input and output (I/O) connectors are intended for connection of only devices complying with IEC 60601-1, or other IEC standards (for example, IEC 60950), as appropriate to the device. Connecting additional devices to the electrocardiograph might increase chassis or patient leakage currents. To maintain operator and patient safety, consider the requirements of IEC 60601-1-1. Measure the leakage currents to confirm that no electric shock hazard exists. In the case of a USB printer, the printer (non-medical electrical equipment) shall be situated outside the patient environment (reference IEC 60601-1-1). The printer used should be approved to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants), and use of an isolation transformer is recommended. If there is a requirement for the printer to be situated within the patient environment it is the responsibility of the user to ensure that the system provides a level of safety in compliance with IEC 60601-1 and 60601-1-1.



**WARNING** The electrocardiograph has not been designed for use with highfrequency (HF) surgical equipment and does not protect against hazards to the patient.

### Warnings related to using the electrocardiograph



**WARNING** This device captures and presents data reflecting a patient's physiological condition. When reviewed by a trained physician or clinician, this data can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis or prescribing treatment.



**WARNING** To avoid serious injury or death, take these precautions during patient defibrillation:

- Avoid contact with the electrocardiograph, patient cable, and patient.
- Verify that the patient leads are properly connected.
- Place defibrillator paddles properly in relation to electrodes.
- After defibrillation, pull each patient lead out of the patient cable and inspect the tips for charring (black carbon marks). If there is any charring, the patient cable and individual leads must be replaced. If there is no charring, fully reinsert the leads into the patient cable. (Charring can occur only if a lead is not fully inserted into the patient cable before defibrillation.)



**WARNING** To prevent the spread of infection, take these precautions:

- Dispose of single-use components (for example, electrodes) after using them once.
- Regularly clean all components that come in contact with patients.
- Avoid ECG testing for patients with open, infectious sores.



**WARNING** Avoid positioning any leads or cables so that they could easily trip someone or become wrapped around a patient's neck.



**WARNING** To ensure safe use of the device, follow the documented maintenance procedures.



**WARNING** Only qualified service personnel should attempt to repair the electrocardiograph. In case of a malfunction, call Technical Support.



**WARNING** Do not perform ST segment analysis on the ECG screen display, since these ECG representations are scaled. Make manual measurements of ECG intervals and magnitudes on printed ECG reports only.



**WARNING** To maintain diagnostic accuracy and to comply with IEC 60601-02-51, do not scale (re size) when sending a saved ECG to an external printer.



**WARNING** To avoid injury, do not touch the print head immediately after printing. It might be hot.

## General cautions

Cautions indicate conditions or practices that could damage the equipment or other property.



**CAUTION** Federal US law restricts sale of the device identified in this manual to, or on the order of, a licensed physician.



**CAUTION** When removing the electrocardiograph from storage, allow it to thermally stabilize to surrounding environmental conditions before using it.



**CAUTION** To prevent possible damage, do not use sharp or hard objects to press the touch screen or the buttons. Only use fingertips.



**CAUTION** Do not expose the patient cable to strong ultraviolet radiation.



**CAUTION** Do not pull or stretch the patient cable. Doing so could result in mechanical or electrical failures. Form the patient cable into a loose loop before storing.



**CAUTION** Avoid positioning the patient cable where it might get pinched, stretched, or stepped on. Otherwise, measurements might no longer be accurate, and repair might be necessary.



**CAUTION** Using the equipotential terminal for anything but grounding purposes may contribute to damage of the device.



**CAUTION** Use only parts and accessories, including thermal paper, that were supplied with the device and available through Welch Allyn. The use of accessories other than those specified may result in degraded performance or unsafe use of this device.



**CAUTION** Portable and mobile RF communications equipment can affect the performance of the electrocardiograph.



**CAUTION** The electrocardiograph meets the Class A requirements of IEC 60601-1-2 regarding incidental emission of radio frequency interference. As such it is suitable for use in commercial grade electrical environments. If the electrocardiograph is used in residential grade electrical environments and you experience incidental interference with other equipment that uses radio frequency signals to operate, minimize the interference.



**CAUTION** Other medical equipment—including but not limited to defibrillators, ultrasound machines, pacemakers, and other stimulators—may be used simultaneously with the electrocardiograph. However, such devices may disturb the electrocardiograph signal.



**CAUTION** The power cord must be disconnected from AC power before cleaning, maintaining, transporting, or servicing.

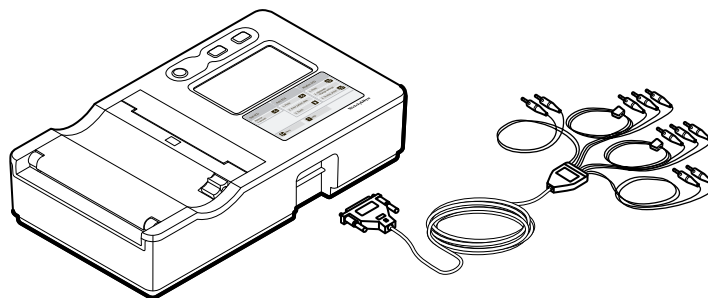


**CAUTION** The requirements of AAMI EC11, Section 3.2.7.2, Frequency and Impulse Response, for an impulse triangle waveform may be impacted by up to 5 milliseconds of small amplitude dampened ringing immediately after the impulse when the muscle filter (35 Hz) is turned on or a small amplitude offset when the baseline filter (0.5 Hz) is turned on. These filters, in any combination turned on or off, meet the AAMI requirements. Measurements performed by the optional interpretation algorithm are unaffected by any filter selections.

# Setup

---

## Connecting the patient cable



**WARNING** Do not allow the conductive parts of the patient cable, electrodes, or associated connections of defibrillation-proof applied parts, including the neutral conductor of the patient cable and electrodes, to come into contact with other conductive parts, including earth ground. Otherwise, an electrical short might result, risking electric shock to patients and damage to the device.



**WARNING** To avoid injury to the patient or damage to the device, never plug patient leads into any other device or wall outlet.

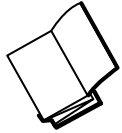


**CAUTION** Always connect the patient cable and the leads properly during defibrillation. Otherwise, the connected leads could be damaged.

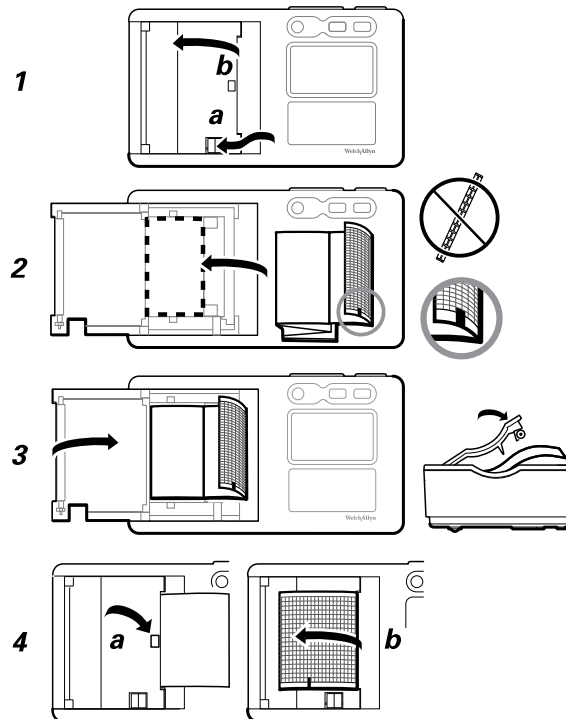
## Loading the thermal paper

The electrocardiograph prints on z-fold thermal paper or roll thermal paper.


- Store the paper in a cool, dry, dark place.
- Do not expose it to bright light or UV sources.
- Do not expose it to solvents, adhesives, or cleaning fluids.
- Do not store it with vinyls, plastics, or shrink wraps.

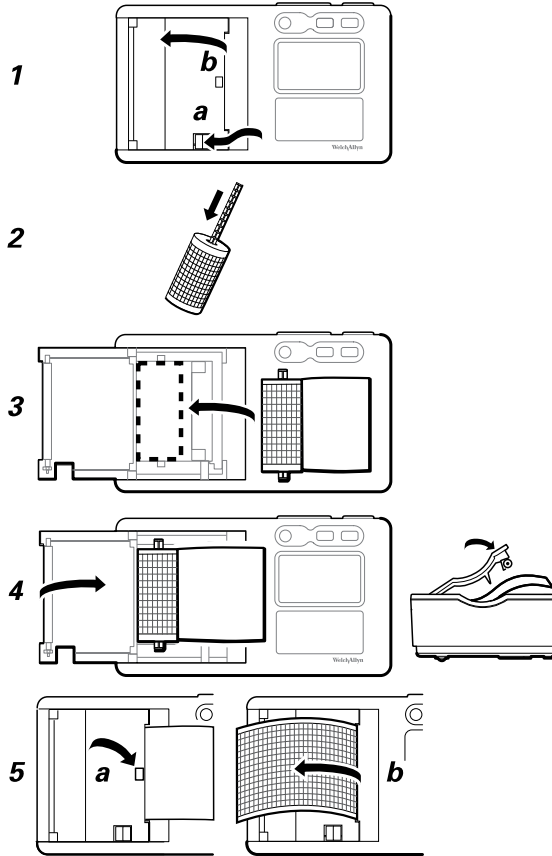


### To load z-fold thermal paper





 To load a roll of thermal paper



## Powering the electrocardiograph

The electrocardiograph runs on AC or battery power. Plug the electrocardiograph into AC power as often as possible so that the built-in charger can keep the battery charged. Regardless of the battery condition, you can use the electrocardiograph whenever it is plugged in.



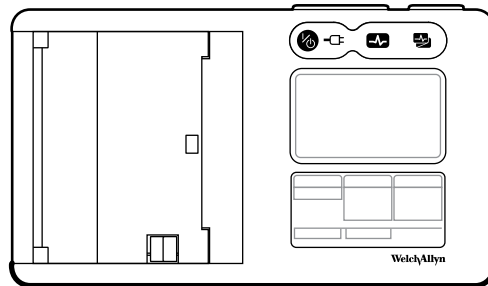
**WARNING** When you use AC power, always plug the electrocardiograph into a hospital-grade outlet to avoid the risk of shock.




**WARNING** If the integrity of the building's safety ground is in doubt, operate this device on battery power to avoid the risk of shock.

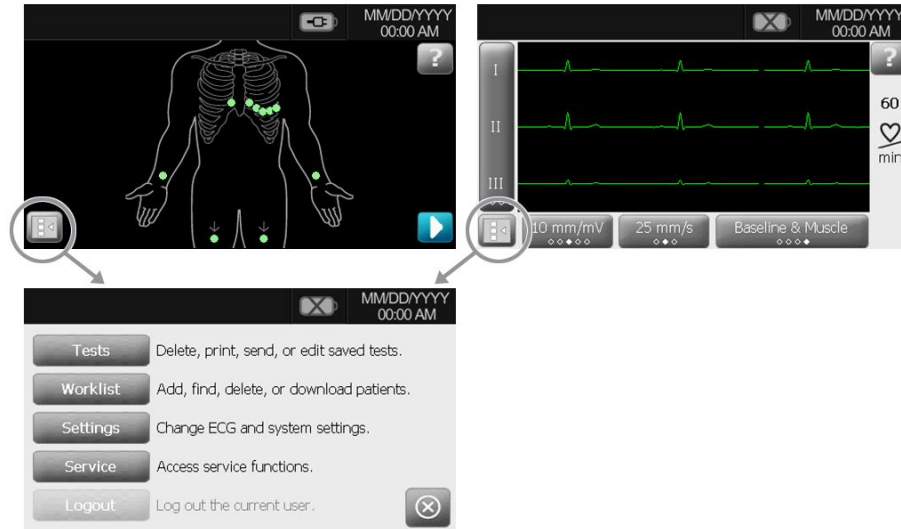
## To power up or power down

Press  .



## About the menu

The menu provides access to the saved patient tests, the settings, and the service functions. From either of the main screens, you can reach the menu by touching the menu button. 




## Viewing or changing the settings

Three setting types are available:

- The ECG settings, which control the content and format of your reports. In CP 50 Plus models, these settings include a second report format (auto report 2), customizable patient data fields, and auto save options.
- The System settings, which control the overall device.
- The Security settings, which control user login and the audit trail.

### To view or change the settings

1. Touch the menu button. 
2. Touch **Settings** > **System** > **About or Upgrade**.
3. Make changes as needed.

## Viewing the device information

You can view device information in two places:

- The **About** screen, which lists the model number, serial number, software versions, RAM usage, available NAND.
- The **Upgrade** screen, which lists the installed options.

## To view the device information

1. Touch the menu button. 
2. Touch **Settings** > **System** > **About or Upgrade**.

## Verifying proper operation

To ensure the accuracy of test data, you should verify proper operation of the electrocardiograph before it is used for the first time with patients. You should reverify proper operation once a year.

### To verify proper operation

1. Use an ECG simulator to acquire and print a standard 12-lead ECG of known amplitude and rate.
2. Look for the following indications of proper operation:
  - Printing should be dark and even across the page.
  - There should be no evidence of print-head dot failure (no printing breaks forming horizontal streaks).
  - Thermal paper should move smoothly and consistently during printing.
  - The waveforms should have no distortion or excessive noise.
  - The amplitude and rate of the waveforms should match the input value from the ECG simulator.
  - Z-fold thermal paper should stop with perforations near the tear bar, indicating proper cue-sensor operation.
3. If you see any indications of improper operation, call Welch Allyn Technical Support.

## Connecting to an external USB printer (optional - available with CP 50 Plus only)

You can connect a CP 50 Plus electrocardiograph to an external printer. The printer must be a USB inkjet or laser printer that supports PCL3 and PCL5 (printer control languages).

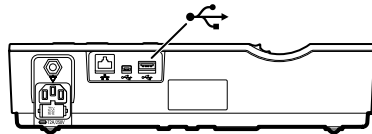
No special software is required.


The external printer prints auto ECG reports, always in black and white. (Rhythm ECGs always print to the internal printer.)

Cables longer than three meters have not been verified for use with the electrocardiograph. Do not use cables longer than three meters.

### To connect to an external USB printer

1. Connect one end of a USB cable to the printer's USB connector, and connect the other end to the electrocardiograph's USB connector.



2. Enable the external printer.
  - a. Touch the menu button. 
  - b. Touch Settings > ECG > Auto report 1 or Auto report 2.
  - c. Under Printer, select External.

## Connecting to a CardioPerfect workstation (optional, available with CP 50 Plus only)

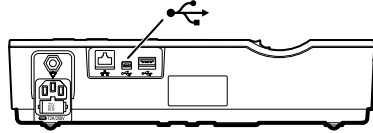
You can connect a CP 50 Plus electrocardiograph to a Welch Allyn CardioPerfect workstation via USB cable or via Ethernet cable. Software provided in the Connex Software Connectivity Kit is required to communicate with the Welch Allyn CardioPerfect workstation. After you connect, you can perform several functions from the electrocardiograph, including:

- Send ECG tests to the workstation.
- Search for patient data in the workstation database.

Cables longer than three meters have not been verified for use with the electrocardiograph. Do not use cables longer than three meters.

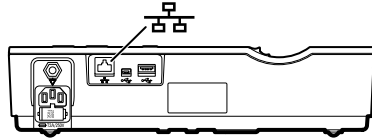
## To connect to a workstation via USB cable

Connect the electrocardiograph to any of the workstation's USB ports. No software configuration is required. The electrocardiograph is ready to communicate.




## To connect to a network-connected workstation via Ethernet cable

1. Connect the electrocardiograph to the same network as the workstation. If you need help, consult with your network administrator.



**WARNING** To reduce the risk of fire and shock hazards, connect Ethernet cables within the boundaries of a single building. Ethernet cables that span multiple buildings can introduce fire or shock hazards unless fiber optic cables or lightning arrestors are properly installed or other appropriate safety measures are taken.

2. Go to the CP 50 connectivity screen
  - a. Touch the menu button. 
  - b. Touch the **Settings** > **System** > **Network** > **Device**.
3. Fill in the screen.
  - If DHCP is enabled for the network, select the **DHCP** checkbox.
  - If DHCP is not enabled, fill in the fields: static IP address, subnet mask, and default gateway.
4. Touch the Test tab
5. Connect to the network.
  - a. In the **Host Address** field, enter the host IP address.
  - b. Touch **Ping Test**. The electrocardiograph pings the host.
6. Touch the **Server** tab.
7. Choose one of these to specify how to get server IP information:
  - **Obtain server IP information automatically**: Select this option if you want the device to get the IP address, or if you don't know the server's IP address.
  - **Server IP address**: Fill in this field if your server IP address is available.
8. Touch **Server Test**.  
The electrocardiograph connects to the server.

The electrocardiograph is ready to communicate with the workstation. (To set up the workstation, see the instructions that came with the workstation connectivity software.)





# ECG tests

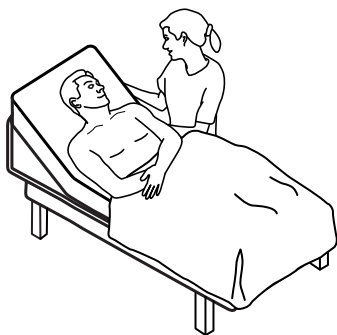
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## Attaching the leads to the patient

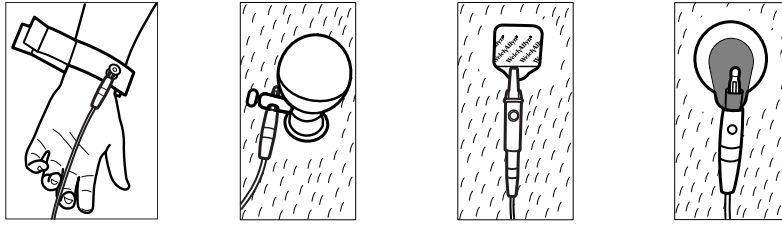
Proper lead attachment is important for a successful ECG. The most common ECG problems are caused by poor electrode contact and loose leads. Follow your local procedures for attaching the leads to the patient. Here are some common guidelines.

### To attach the leads to the patient

1. Prepare the patient.
  - Describe the procedure. Explain the importance of holding still during the test. (Movement can create artifact.)
  - Verify that the patient is comfortable, warm, and relaxed. (Shivering can create artifact.)
  - Put the patient in a reclining position with the head slightly higher than the heart and legs (the semi-Fowler's position).



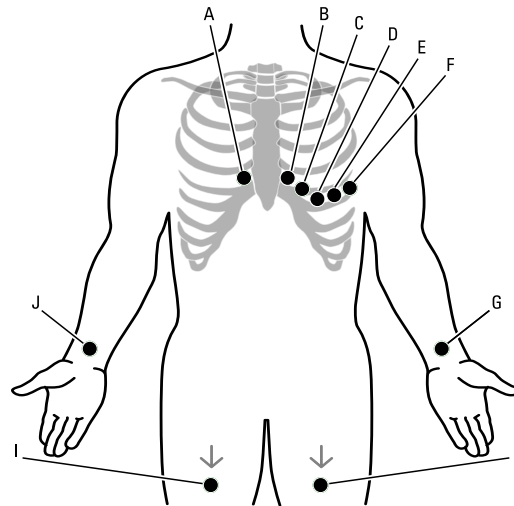
2. Select the electrode locations. (See the "Electrode locations" chart.)
  - Look for flat areas.
  - Avoid fatty areas, bony areas, and major muscles.
3. Prepare the electrode locations.
  - Shave or clip the hair.
  - Thoroughly clean the skin, and lightly rub it dry. You may use soap and water, isopropyl alcohol, or skin preparation pads.
4. Attach the lead wires to the electrodes.
5. Apply the electrodes to the patient.



Electrode examples, left to right: arm clamp (reusable), Welsh cup (reusable), tab electrode (disposable), monitoring electrode (disposable).

- **For reusable electrodes:** Use electrode paste, gel, or cream to cover an area the size of each electrode but no larger. Secure the arm and leg clamps. Apply the Welsh cups (suction electrodes) to the chest.
- **For disposable tab electrodes:** Place the electrode tab between the “jaws” of the connector. Keep the tab flat. Verify that the metal portion of the connector makes contact with the skin side of the electrode tab.
- **For all disposable electrodes:** Lightly tug on the connector to ensure that the lead is securely attached. If the electrode comes off, replace it with a new electrode. If the connector comes off, reconnect it.

## Electrode locations

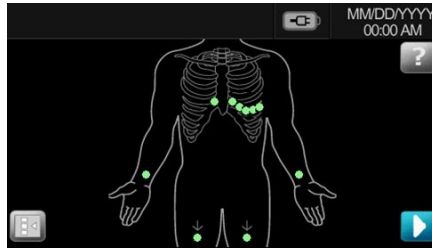


	<b>AHA</b>	<b>IEC</b>	<b>Location</b>
A	V1 (red)	C1 (red)	Fourth intercostal space at the right sternal border.
B	V2 (yellow)	C2 (yellow)	Fourth intercostal space at the left sternal border.
C	V3 (green)	C3 (green)	Midway between V2 and V4.
D	V4 (blue)	C4 (brown)	Fifth intercostal space to the left of the midclavicular line.
E	V5 (orange)	C5 (black)	Anterior axillary line at the same horizontal level as V4.
F	V6 (purple)	C6 (purple)	Mid-axillary line at the same horizontal level as V4 and V5.
G	LA (black)	L (yellow)	Just above the left wrist on the inside of the arm.
H	LL (red)	R (green)	Just above the left ankle.

	<b>AHA</b>	<b>IEC</b>	<b>Location</b>
I	RL (green)	N (black)	Just above the right ankle.
J	RA (white)	R (red)	Just above the right wrist on the inside of the arm.

# Performing an ECG test

1. Attach the leads to the patient. Any flashing dots on the lead-status screen indicate unattached or poorly attached leads.



When all leads have been attached for several seconds, the ECG preview screen appears.



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- ① Leads button

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  - ② Gain button (size)

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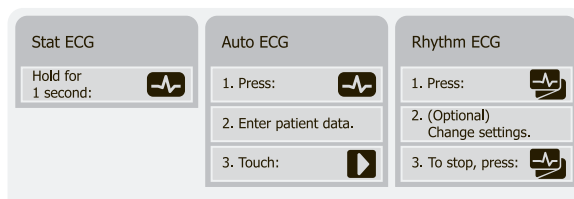
  - ③ Speed button

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  - ④ Filters button

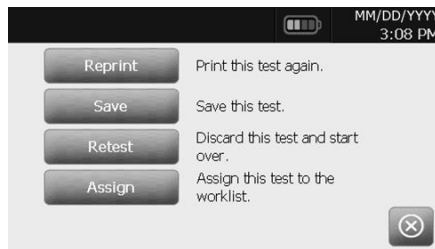
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2. If an **Artifact** message appears, minimize the artifact, as described under Troubleshooting. You might need to ensure that the patient is comfortably warm, reprepare the patient’s skin, use fresh electrodes, or minimize patient motion.
3. (Optional) Adjust the waveforms, using the buttons to cycle through the options:
  - leads displayed
  - gain (size)
  - speed
  - filters
4. Perform the desired type of test: stat ECG, auto ECG, or rhythm ECG.



For auto ECGs, you can enter patient data automatically if it is available.

- The Search button  gives you access to patient data in the test directory or in a connected database (CardioPerfect workstation or EMR).
  - The Worklist button (CP 50 Plus only) gives you access to patient data in the worklist.
5. If a **Waiting for 10 (or 20) seconds of quality data** message appears, at least 10 or 20 seconds of ECG data have been collected with excessive artifact. Time requirements in the message may vary, based upon selected print format. Minimize the artifact, as described under Troubleshooting. Then wait for the test to print. If necessary, you can override the wait time and print the available data immediately, but the result might be an incomplete or poor-quality test.
  6. After the test prints, select the desired option: **Reprint**, **Save**, **Retest**, or **Assign** (Any tests that you save to a USB mass-storage device can be retrieved only from a CardioPerfect workstation.)



**WARNING** To avoid the risk of associating reports with the wrong patients, make sure that each test identifies the patient. If any report does not identify the patient, write the patient identification information on the report immediately following the ECG test.

## Administrative tasks

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### Turning the security option on or off (optional - available with CP 50 Plus only)

The electrocardiograph incorporates security features that can keep patient data confidential. When the security option is off, user login is never required. When the security option is on, user login is required for the following tasks:

- searching for patient data
- managing the test directory
- managing the worklist
- managing the user list
- managing the audit trail

A user's level of access is either "user" or "administrator," as determined in the user list.

#### To turn the security option on or off

1. Touch the menu button. 
2. Touch **Settings** > **Security**.
3. Turn the security option on or off.

### Managing the user list (optional - available with CP 50 Plus only)


The user list, which is enabled when the security option is on, identifies all individuals who are authorized to access patient data.

The user list can hold up to 25 users. After the list reaches 25 users, you can add users only if some users are set to inactive status. New users replace inactive users. If all 25 users are active, you receive a message that the user list is full.

Two levels of access can be assigned:

- **User level:** User-level users have access to the test directory and the worklist, including searching and editing privileges.
- **Administrator level:** Administrator-level users have user-level access and can also create and administer users.

**To manage the user list**

1. Touch the menu button. 
2. Touch **Settings** > **System** > **Users**.
3. Add, edit, delete, activate, or deactivate users.


## Turning the audit trail on or off (optional - available with CP 50 Plus only)

An audit trail, a collection of information about user activity, may be helpful or even required for record-keeping. It records the user identity code and time associated with each use of the electrocardiograph, including these types of activity:

- accessing the test directory
- searching the worklist
- editing patient data
- accessing administrative functions

When the audit trail is turned on, the electrocardiograph collects this type of information in a file in its memory.

**To turn the audit trail on or off**

1. Touch the menu button. 
2. Touch **Settings** > **System**.
3. Turn the audit trail on or off.


## Managing the worklist (optional - available with CP 50 Plus only)

The worklist is a group of patients whose demographic data has been entered into the electrocardiograph memory to be recalled for a test later that day. The worklist holds up to 50 patients.

When you perform an auto ECG, you can fill in the patient's data from the worklist automatically by touching the **Worklist** button.

You can add or delete patients any time. If the electrocardiograph is connected to an EMR, you can also download a worklist.


**To manage the worklist**

1. Touch the menu button. 
2. Touch **Worklist**.
3. Add patients, delete patients, or download a worklist.



## Managing the test directory


The test directory is a group of ECG tests that have been saved in the electrocardiograph memory.

When you perform an auto ECG, you can fill in the patient's data from the test directory automatically by touching the search button. 

With all electrocardiograph models, you can delete or print saved tests. With CP 50 Plus models, you can also do the following:

- Edit the patient data in saved tests.
- Send saved tests to a USB mass-storage device or to a Welch Allyn CardioPerfect workstation. (Any tests that you send to a USB mass-storage device can be retrieved only from a CardioPerfect workstation.)

### To manage the test directory

1. Touch the menu button. 
2. Touch **Tests**.
3. Delete, edit, print, or send saved tests. (Options vary per model.)



# Maintenance

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## Cleaning the equipment



**WARNING** Keep the electrocardiograph, reusable electrodes, and the patient cable clean. Patient contact with contaminated equipment can spread infection.



**CAUTION** Never let soap or water come into contact with the electrocardiograph's internal printer, connectors, or jacks.



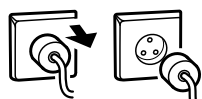
**CAUTION** Never immerse the electrocardiograph or the patient cable in liquid. Never autoclave or steam clean the electrocardiograph or the patient cable. Never pour alcohol directly on the electrocardiograph or the patient cable, and never soak any components in alcohol. If any liquid enters the electrocardiograph, remove the electrocardiograph from service, and have it inspected by a qualified service person before using it again.

Acceptable cleaning solutions:

- Mild detergent and water, ½ tsp detergent per cup of water
- Bleach and water, 1 part bleach (6.00% sodium hypochlorite) with 9 parts water
- Isopropyl alcohol and water, 70% by volume
- PDI®Sani-Cloth® Plus wipes (14.85% isopropanol)
- CaviWipes™ (17.2% isopropanol)

## To clean the equipment (monthly or more often if needed)

1.






Disconnect the power plug from the AC outlet.

2.



Turn off the electrocardiograph. (Press and hold the power button for at least six seconds until the screen goes blank.)

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3.  Dampen a cloth with any of the acceptable cleaning solutions, and wipe the exterior of the patient cable, reusable electrodes, and electrocardiograph. Dry all components with a clean, soft cloth, or paper towel.
-  **WARNING** The patient cable and reusable electrodes should be cleaned between each patient.
- 
4.  Before you turn on the electrocardiograph again, wait at least 10 minutes for all traces of liquid to evaporate.
- 

## Inspecting the equipment

Perform the following inspections daily.

- Check for cracked or broken patient cable, patient electrodes, power cord, communications cables, display, and enclosure.
- Check for bent or missing pins on all cables.
- Check all cable and cord connections; reseat if any connectors are loose.

## Testing the electrocardiograph

Welch Allyn recommends verifying proper operation of the electrocardiograph once a year to ensure reliability. See *Verifying proper operation*.

Whenever the electrocardiograph is serviced or whenever problems are suspected, verify continued electrical safety of the device using IEC 60601-1 or ANSI/AAMI ES1 methods and limits.



**WARNING** Only qualified service personnel should perform leakage current tests.

Test for the following:

- Patient leakage current
- Chassis leakage current
- Earth leakage current
- Dielectric strength (AC and patient circuits)

## Replacing the battery

Replace the battery under these circumstances:

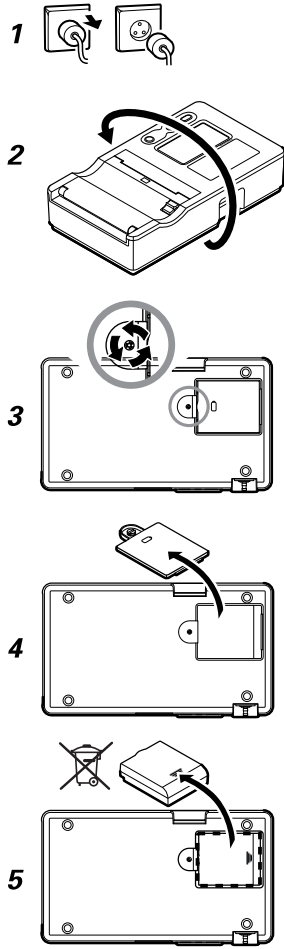
- It loses its charge quickly.
- You have charged it, and the electrocardiograph still does not turn on when unplugged.

The first time that you press the power button after installing a new battery, the electrocardiograph goes through some diagnostic tests that cause it to take longer than usual to power up.

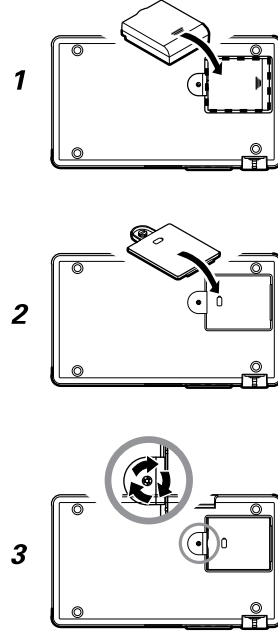
Discard the old battery appropriately. Contact your local authorities concerning recycling.

# To replace the battery

## Remove the old battery



## Insert the new battery



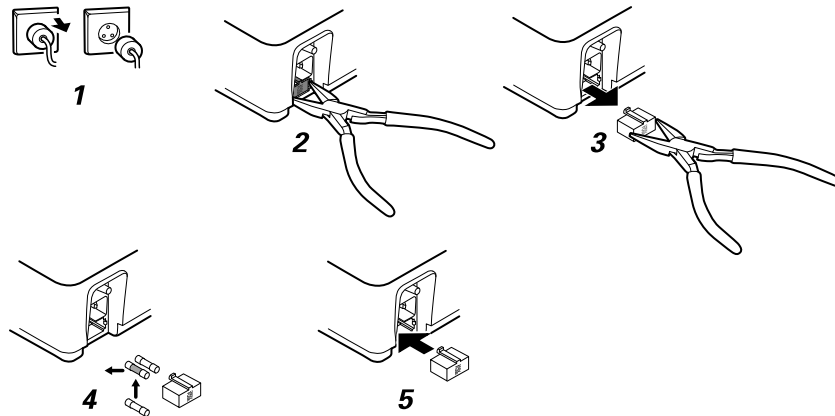
## Replacing the AC fuses

You might need to replace one or both of the AC fuses if the AC power indicator does not light up when the electrocardiograph is connected to AC power.



**WARNING** Failure to unplug could result in electrocution.

### To replace the AC fuses



If either fuse is dark or has a broken wire, replace the fuse. Line up the fuse case with the opening; it goes in only one way.

## Storing the equipment

When storing the electrocardiograph, cords, and accessories, observe the environmental storage conditions that are identified in the product specifications.

## Discarding the equipment

Discard the electrocardiograph, cords, and accessories according to local laws.



Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. For more specific disposal information, see [www.welchallyn.com/weee](http://www.welchallyn.com/weee), or contact Welch Allyn Customer Service at +44 207 365 6780.

# Troubleshooting

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## Lead-quality problems

### “Artifact” message on the screen

Artifact is signal distortion that makes it difficult to accurately discern the waveform morphology.

#### Causes

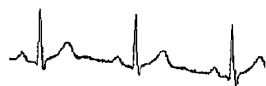
- The patient was moving.
- The patient was shivering.
- There is electrical interference.

#### Actions

See actions for wandering baseline, muscle tremor, and AC interference.

## Wandering baseline

Wandering baseline is an upward and downward fluctuation of the waveforms.



#### Causes

- Electrodes are dirty, corroded, loose, or positioned on bony areas.
- The electrode gel is insufficient or dried.
- The patient has oily skin or used body lotions.
- Rising and falling of chest during rapid or apprehensive breathing.

#### Actions

- Clean the patient's skin with alcohol or acetone.
- Reposition or replace the electrodes.
- Verify that the patient is comfortable, warm, and relaxed.
- If wandering baseline persists, turn the baseline filter on.

## Muscle tremor



### Causes

- The patient is uncomfortable, tense, nervous.
- The patient is cold and shivering.
- The exam bed is too narrow or short to comfortably support arms and legs.
- The arm or leg electrode straps are too tight.

### Actions

- Verify that the patient is comfortable, warm, and relaxed.
- Check all electrode contacts.
- If interference persists, turn the muscle-tremor filter on. If interference still persists, the problem is probably electrical in nature. See the suggestions for reducing AC interference (in a related troubleshooting tip).

## AC interference

AC interference superimposes even-peaked, regular voltage on the waveforms.



### Causes

- The patient or technician was touching an electrode during recording.
- The patient was touching a metal part of an exam table or bed.
- A lead wire, patient cable, or power cord are broken.
- Electrical devices in the immediate area, or lighting, or wiring concealed in walls or floors are interfering.
- An electrical outlet is improperly grounded.
- The AC filter is turned off or set incorrectly.

### Actions

- Verify that the patient is not touching any metal.
- Verify that the AC power cable is not touching the patient cable.
- Verify that the proper AC filter is selected.
- If interference persists, unplug the electrocardiograph from AC power and run it on the battery. If this solves the problem, you'll know that the noise was introduced through the power line.
- If interference still persists, the noise may be caused by other equipment in the room or by poorly grounded power lines. Try moving to another room.



## Lead alert or square wave



A dot might be flashing on the lead-status screen. Or one or more leads might appear as a square wave.

### Causes

- Electrode contact might be poor.
- A lead might be loose.
- A lead might be defective.

### Actions

- Replace the electrode.
- Verify that the patient's skin has been properly prepared.
- Verify that electrodes have been properly stored and handled.
- Replace the patient cable.

## System problems

### The electrocardiograph won't turn on when it is plugged in

**Causes**

- The AC power connection is faulty.
- An AC fuse is blown.
- There is no AC power.

**Actions**

- Check the AC power source.
- Check the AC fuses.

### The electrocardiograph won't turn on when it is unplugged

**Causes**

- The battery is disconnected or incorrectly connected.
- The battery is low, not charging, depleted, or bad.

**Actions**

- Check the battery connections.
- Recharge the battery.
- Replace the battery.

### The electrocardiograph shuts down during printing

**Causes**

- The battery is low or bad.

**Actions**

- Recharge the battery.
- Replace the battery.

### The electrocardiograph prints fewer than 10 reports on a full battery charge

**Causes**

- The battery is degraded.

**Actions**

- Replace the battery.

## The electrocardiograph does not respond when you press buttons or touch the screen

### Causes

- The electrocardiograph is frozen.

### Actions

- Reset the electrocardiograph by pressing and holding the power button for at least six seconds until the screen goes blank. Press the power button again. The electrocardiograph goes through some diagnostic tests that cause it to take longer than usual to power up.
- Touch the **Settings** tab. Touch the **Advanced** tab. Touch the **Power down** button. The electrocardiograph goes through some diagnostic tests that cause it to take longer than usual to power up.

**Note** For more troubleshooting guidelines, see the service manual.



**CAUTION** The service manual is for use only by qualified service personnel who understand technical English.

## Limited warranty

Welch Allyn, Inc., warrants that the CP 50 and CP 50 Plus electrocardiographs (the Products) meet the labeled specifications of the Products and will be free from defects in materials and workmanship that occur within 1 year after the date of purchase, except that accessories used with the Products are warranted for 90 days after the date of purchase. Such accessories include cables, electrodes, and battery.

The date of purchase is: 1) the date specified in our records, if you purchased the Product directly from us, 2) the date specified in the warranty registration card that we ask you to send to us, or 3) if you don't return the warranty registration card, 30 days after the date on which the Product was sold to the dealer from whom you bought the Product, as documented in our records.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

If a product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Welch Allyn will, at its discretion, repair or replace the defective Product or accessory free of charge. If your Product requires repairs covered by this warranty, upon your request Welch Allyn will loan to you, at no cost, a substitute Product for use until your repaired Product is returned.

You must obtain a return authorization from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair. Contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

## Service policy

All repairs on products under warranty must be performed by Welch Allyn or by a service provider authorized by Welch Allyn. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair should be performed exclusively by Welch Allyn or by a service provider that has been authorized by Welch Allyn.

If the product fails to function properly—or if you need assistance, service, or spare parts—contact the nearest Welch Allyn Technical Support Center.

Before contacting Welch Allyn, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name, model number, and serial number of your product.
- Complete description of the problem.
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call first the nearest Welch Allyn Technical Support Center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary return of your product.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return your product for service, follow these recommended packing instructions:

- Remove all hoses, cables, sensors, power cords, and other accessories (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Welch Allyn Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.



# Specifications

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Item	Specification
Dimensions, including rubber feet (length x height x width)	32.5 x 8 x 18.8 cm (12.8 x 3.1 x 7.4 in.)
Weight	2.0 kg (4.4 lb)
Keyboard type (power, auto ECG, and rhythm ECG buttons)	Polyester overlay
Display	
Type	TFT, 11 cm (4.3 in.) color touch screen
Resolution	WQVGA, 480 x 272
Thermal paper	
Z-fold	11.4 cm (4.5 in.) x 250 sheets
Roll	11.4 cm (4.5 in.) x 20 m
Thermal printer (internal)	Computer-controlled dot array, 8 dots/mm
Thermal-chart-paper speeds	10, 25, 50 mm/s
Gain settings	
Auto ECGs	2.5, 5, 10, 20 mm/mV, AUTO
Rhythm ECGs	2.5, 5, 10, 20 mm/mV
Lead configurations	Standard, Cabrera
Report formats, internal printer*	
Auto ECGs	3x4 @ 25 mm/s, 3x4 @ 50 mm/s, 3x4 + 1R @ 25 mm/s, 3x4 - 5.0s @ 25 mm/s, 3x4 - 5.0s @ 50 mm/s, 2x6 - 1.6s @ 25 mm/s, No print
Rhythm ECGs	3 leads
Average cycles	3x4 + 3R @ 25 mm/s, 3x4 + 3R @ 50 mm/s, 2x6 + 1R @ 25 mm/s, 2x6 + 1R @ 50 mm/s, No print

Item	Specification
Report formats, external printer*	3x4 @ 25 mm/s, 3x4 @ 50 mm/s, 3x4 + 1R @ 25 mm/s, 3x4 + 3R @ 25 mm/s,
Auto ECGs	3x4 - 5.0s @ 25 mm/s, 3x4 - 5.0s @ 50 mm/s, 6x2 - 5.0s @ 25 mm/s, 12x1 - 5.0s @ 25 mm/s, No print
Average cycles	3x4 + 3R @ 25 mm/s, 3x4 + 3R @ 50 mm/s, 2x6 + 1R @ 25 mm/s, 2x6 + 1R @ 50 mm/s, 3x4 + 2R @ 25 mm/s, 3x4 + 2R @ 50 mm/s, 6x2 + 2R @ 50 mm/s, No print
ECG storage (in test directory)	At least 25 ECG tests
Patient storage (in worklist, CP 50 Plus only)	Up to 50 patients
Frequency range	0.3 to 150 Hz
Digital sampling rate	> 1,000 samples/second/channel
Pacemaker detection	ANSI/AAMI EC11
Power requirement	Universal AC power supply 110-240 V~, 50/60 Hz ~, 1.5 A maximum
AC fuses	Time-lag type, 2.0-amp 250-V rating, Littlefuse 0218002P or equivalent
Rechargeable battery	10.8V, 1.9Ah minimum, 3-cells Li-ion "smart" battery. A fully charged battery prints up to 25 ECGs with one extra copy per test.
Filters	
High-performance baseline	0.5 Hz 35 Hz
Muscle tremor	50 Hz or 60 Hz
AC interference	
Safety, EMC, and regulatory compliance	ANSI/AAMI EC11** CAN/CSA C22.2 No. 601.1 CAN/CSA C22.2 No. 601.1.1 CAN/CSA C22.2 No. 601.1.2 CAN/CSA C22.2 No. 601.1.4 CAN/CSA C22.2 No. 601.2.25 UL60601-1 IEC/EN 60601-1 IEC/EN 60601-1-1 IEC/EN 60601-1-2 IEC/EN 60601-1-4 IEC/EN 60601-1-6 IEC/EN 60601-2-25 *** IEC/EN 60601-2-51 (2x6 lead arrangement)
Standard connectivity	Mini USB client and USB host, Ethernet (optional - available with CP 50 Plus only)
Connectivity with electronic medical records (CP 50 Plus only)	Through the Welch Allyn CardioPerfect workstation software



<b>Item</b>	<b>Specification</b>
Electrodes	Rigorously tested for conductivity, adhesion, and hypoallergenic qualities, and exceed all AAMI standards
Power cable	Meets or exceeds Type SJT.
Environmental operating conditions	+10° C to +40° C (+50° F to +104° F)
Temperature	15 - 95% noncondensing (30 - 70% for printing)
Relative humidity	700 - 1060 hPa
Atmospheric air-pressure limits	
Environmental storage conditions	-20° C to +50° C (-4° F to +122° F)
Temperature	15 - 95% noncondensing
Relative humidity	700 - 1060 hPa
Atmospheric air-pressure limits	
Protection against electric shock	Class I, internally powered Type BF
Mode of operation	Continuous

\* If you print at a high gain setting, the waveform or calibration marks might be clipped. This clipping does not comply with clause 51.103.1 of the IEC/EN 60601-2-51 standard. Use a lower gain setting to observe the full waveform.

\*\* Per AAMI EC11:1991/(R)2001 Diagnostic Electrocardiographic Devices, Section 3.1.2.1 Disclosure of cautionary information/ performance characteristics paragraph c) Accuracy of input signal reproduction, the manufacturer shall disclose the methods used to establish overall system error and frequency response. Welch Allyn has used methods A & D, as prescribed in section 3.2.7.2 and 4.2.7.2 of this same standard, to verify overall system error and frequency response. Because of the sampling characteristics and the asynchronism between sample rate and signal rate, digital ECG systems such as the CP 50 may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon is not physiologic.

\*\*\* Disposable electrodes from Welch Allyn shall be used during patient defibrillation.

Specifications are subject to change without notice.



# Guidance and manufacturer's declarations

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## EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2007.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document and the Welch Allyn website: [http://www.welchallyn.com/apps/products/product\\_category.jsp?catcode=CARDIO](http://www.welchallyn.com/apps/products/product_category.jsp?catcode=CARDIO).
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The electrocardiograph complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the electrocardiograph in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the electrocardiograph in extremely close proximity to other equipment.

## Emmissions and immunity information

For information about electromagnetic compatibility (EMC), see the Welch Allyn website.

[http://www.welchallyn.com/apps/products/product\\_category.jsp?catcode=CARDIO](http://www.welchallyn.com/apps/products/product_category.jsp?catcode=CARDIO)

