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**Caution** US Federal law restricts this device to sale by or on the order of a physician.

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The information contained in this manual is subject to change without notice. All changes will be in compliance with regulations governing manufacture of medical equipment.

## User responsibility

This product is designed to perform in conformity with the description thereof contained in this manual and accompanying labels and inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. A defective product should not be used. Parts that are broken, plainly worn, missing or incomplete, distorted or contaminated should be replaced immediately. Should any repair or replacement become necessary, we recommend that service be performed at the nearest approved service center. The user of the product shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Welch Allyn or their authorized service personnel.

## Accessories

The Welch Allyn warranty can only be honored if you use Welch Allyn approved accessories and replacement parts.



**Caution** Use of accessories other than those recommended by Welch Allyn may compromise product performance.

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## Safety and Precautions



### Caution

Radio Frequency (RF) interference between the PRO ECG Recorder or cardiograph and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, in close proximity to the cardiograph should be evaluated before the equipment is operated as they may seriously degrade performance.

The CardioPerfect Cardiograph is susceptible to interference from RF energy sources (lowered RF immunity) which exceed the IEC 60601-1-2 limits, such as power line bursts, other medical devices, cellular products, information technology equipment and radio/television transmission.

To reduce EMC interference the cardiograph shall be separated from the emitting source as much as possible. If assistance is needed, call your local Welch Allyn service representative.

Artifact on the ECG caused by electromagnetic interference should be evaluated by a physician or physician authorized personnel to determine if it will negatively impact patient diagnosis or treatment.


Like all electronic devices, this cardiograph is susceptible to electrostatic discharge (ESD). Electrostatic discharge typically occurs when electrostatic energy is transferred to the patient, the electrodes, or the cardiograph. ESD may result in ECG artifact that may appear as narrow spikes on the cardiograph display or on the printed report. When ESD occurs, the cardiograph's ECG interpretation may be inconsistent with the physician's interpretation.

Welch Allyn assumes no liability for failures resulting from RF interference between Welch Allyn medical electronics and any radio frequency generating equipment when these levels exceed those established by applicable standards.

Patient cables and PC connection cables are intended to be inserted and removed from the Pro-Recorder in a push / pull motion. Do not twist the cables. Damage to the cables and the Pro-Recorder will occur.

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## Medical Device Directive

The CardioPerfect Pro cardiograph complies with the requirements of the Medical Device Directive 93/42/EEC and carries the  0297 mark accordingly.

 **Warnings**

CardioPerfect devices are an integral part of a personal computer based diagnostic system. The user shall adhere to warnings in order to ensure safe and reliable performance of the system.

The personal computer, computer peripheral and all accessories (non-medical electrical equipment) connected to the ECG shall be situated outside the patient environment and the system shall meet the requirements of IEC 60601-1-1.

- The personal computer used should be approved to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants). Also, the use of an additional protective earth ground or an isolation transformer is required for the electric power circuit to which the CardioPerfect system is connected in order to satisfy the IEC 60601-1-1 safety standard.
- Power strips (multiple portable socket outlets) are not allowed for use in connecting the medical electrical equipment or any accessories to ground unless used in concert with a medical approved isolation transformer.
- Additional equipment that is added to the system may pose a safety hazard. Use of an additional protective earth ground or an isolation transformer is required to meet IEC 60601-1-1.

During defibrillation, the ECG signals displayed may show waveform artifacts and cannot be relied on as a true indication of the patient's physical condition.

Accessible metal parts, such as electrode terminations, should not come in contact with other electrically conductive parts, including earth ground.

Welch Allyn provides a number of high quality patient leads in varying termination styles. Use of these approved patient leads is required for electrical protection of the patient during cardiac defibrillation.

CardioPerfect devices are not intended for direct cardiac application.

An inoperable or damaged electrocardiograph can be identified by abnormal signals on the ECG waveforms. Abnormal signals are characterized by flat lines, excess noise, square waves or other non typical anomalies that appear on the ECG waveform. The electrocardiograph can be periodically tested by connecting the CardioPerfect to an ECG simulator. Follow manufacturer's instructions.

If there is a requirement for equipment to be connected to a personal computer or other non-medical rated equipment, it is the responsibility of the user to ensure that the electric power circuit to which the CardioPerfect system is connected includes an additional protective earth ground or an isolation transformer in order to satisfy the IEC 60601-1-1 safety standard.

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

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devices may disturb the electrocardiograph signal.

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

Ensure the location of the electrode and associated cables provides maximum separation away from all sources of high-frequency energy. The best way to ensure patient safety is to completely remove all electrodes and cables from the patient when exposed to high-frequency energy.

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## Patient and Operational Safety

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. To ensure the patient's safety and your own please observe the following:

When integrating CardioPerfect devices with non-medical rated equipment, such as a computer, the addition of an additional protective earth ground or the use of a medically approved isolation transformer is required for compliance to the IEC 60601-1-1 Medical System Safety Standard.

Any system components (e.g. treadmill, personal computer, ergo meter) that require to be connected to an outlet socket shall use only grounded power cords (three-wire power cords with grounded plugs). Also make sure the outlet accepts the plug and is grounded. Never adapt a grounded plug to fit an ungrounded outlet by removing the ground prong or ground clip.

Do not connect Multiple Portable Socket Outlets (MPSO's) or extension cords to the system. Do not connect items which are not part of the system. The use of multiple portable socket outlets and other non-medical electrical equipment poses a safety hazard. Refer to the Medical System Safety Standard IEC 60601-1 for the requirements of such attachments.

Multiple portable outlet sockets shall not be placed on the floor. Multiple portable outlet sockets or extension cord shall not be connected to the system. Do not connect items which are not part of the system. The use of multiple (non-) medical electrical equipment connected to the same patient may pose a safety hazard due to the summation of leakage currents from each instrument. Any combination of (non-) medical electrical equipment should be evaluated by local safety personnel before put into service. Multiple portable outlet sockets use without an isolation transformer is disapproved unless casual access for additional equipment is impeded or prevented.

## Accessories

Use of accessories other than those recommended by Welch Allyn may compromise product performance. The Welch Allyn warranty can only be honored if you use Welch Allyn approved accessories and replacement parts.

## Warranty, Service, and Spare Parts

### Warranty

All repairs on products under warranty must be performed or approved by Welch Allyn. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Welch Allyn certified service personnel.

### Assistance and Parts

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

USA	1-800-535-6663	Canada	1-800-561-8797
Latin America	(+1) 305-669-9003	South Africa	(+27) 11-777-7555
European Call Center	(+353) 46-90-67790	Australia	(+61) 2-9638-3000
United Kingdom	(+44) 207-365-6780	Singapore	(+65) 6419-8100
France	(+33) 1-55-69-58-49	Japan	(+81) 42-703-6084
Germany	(+49) 695-098-5132	China	(+86) 21-6327-9631
Netherlands	(+31) 202-061-360	Sweden	(+46) 85-853-65-51

Before contacting Welch Allyn it is helpful to attempt to duplicate the problem and to check all accessories to ensure that they are not the cause of the problem.

### When calling, please be prepared to provide:

- Product name and model number and complete description of the problem
- The serial number of your product (if applicable)
- The 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 order, the required spare or replacement part number(s)

### Repairs

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.

In case the 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. A Return Material Authorization (RMA) number must be obtained prior to any return.

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### Note

Welch Allyn does not accept returned products without an RMA.

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### Packing Instructions

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

- Remove all hoses, cables, sensors, power cords, and ancillary products (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.

**Limited Warranty Statement**

Welch Allyn, Inc. warrants that the Welch Allyn CardioPerfect Workstation computer based product you have purchased meets the labeled specifications of the Product and will be free from defects in materials and workmanship that occur within 1 year after the date of purchase. Accessories used with the Product are warranted for 90 days after the date of purchase.

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, 120 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.

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.

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.



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**Conventions**

	<p>A safety symbol used on the device to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the device label. A <b>WARNING</b> in this manual indicates conditions or practices that, if not corrected immediately, could lead to illness, injury or death. A <b>CAUTION</b> in this manual indicates conditions or practices that, if continued or not corrected immediately, could damage the equipment.</p>
<p><b>NOTE</b></p>	<p>A <b>NOTE</b> in this manual contains additional information on cardiograph usage.</p>
	<p>Ingress Protection - Not protected against the ingress of water</p>
	<p>Serial Number</p>
	<p>Reference Number</p>
	<p>Defibrillation-Proof Type BF Applied Part</p>
	<p>Manufacture Date</p>
	<p>CE Mark (according to MDD93/42/EEC)</p>
	<p>Temperature Range</p>
	<p>Direct Current</p>

**Electromagnetic Compatibility**

When using the CardioPerfect Pro cardiograph, electromagnetic compatibility with surrounding devices should be considered and evaluated. The CardioPerfect Pro cardiograph complies with IEC 60601-1-2 limits for EMC.

## 1. About the CardioPerfect Pro Cardiograph

The Welch Allyn CardioPerfect Pro Cardiograph is specifically intended for the recording of standard 12-lead electrocardiograms of patients. The device is not suitable for direct cardiac application.



A CardioPerfect Pro system typically comes with the following components:

- CardioPerfect Pro Cardiograph (SE-PRO-600, -1200)
- Patient Cable (RE-PC or SE-PC)
- PC Interface Cable Prolink (PRO-60023, -24, -25)
- Battery Pack (PRO-60019)
- CardioPerfect Workstation Software (CPWS-SW)

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### **Caution**

The patient cable supplied with the CardioPerfect cardiograph is an integral part of the cardiograph's safety features. Using any other patient cable may compromise defibrillation protection as well as cardiograph performance. The patient cable should be routed 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.

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### **Warning**

Do not touch the patient, patient cable, PC interface cable (Prolink) or cardiograph during defibrillation. Death or injury may occur from the electrical shock delivered by the defibrillator. It is recommended to check the patient cable and PC interface cable (Prolink) for damage prior to the use of the system. If damage exists do not use the cable, contact your local Welch Allyn Sales Office or your authorized Welch Allyn dealer or distributor to have the cable replaced.

## 1.1 Accessories

Your CardioPerfect Pro cardiograph allows the use of a broad range of accessories; contact your local Welch Allyn Sales Office or your authorized Welch Allyn Dealer or Distributor.

**NOTE** All part numbers may not be available in all countries.

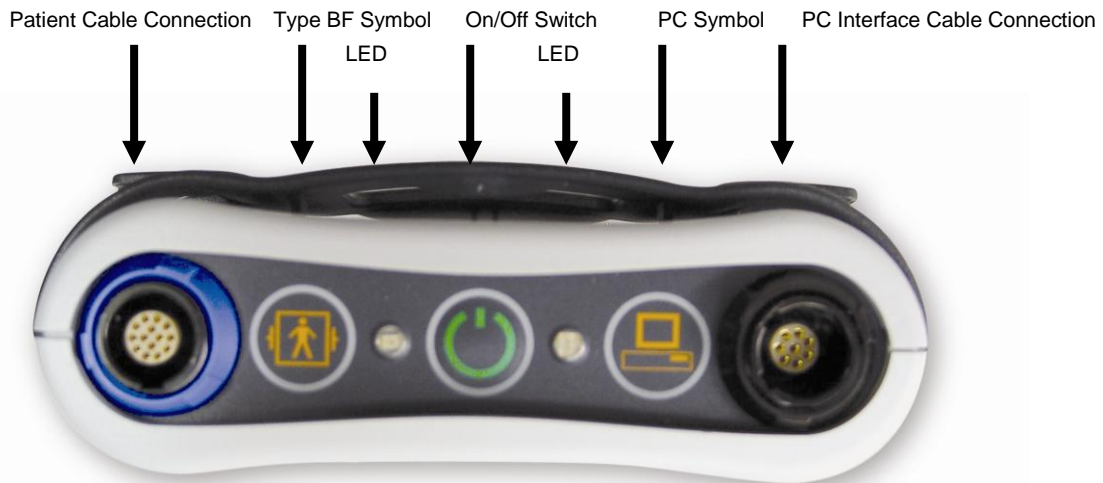
REF	Component Description	Purpose	
CPR-UN-UB-D	PC Based Resting ECG; non interpretive software	The Welch Allyn CardioPerfect Pro Cardiograph is specifically intended for the recording of standard 12-lead electro-cardiograms of patients. The device is not suitable for direct cardiac application.	
CPR-UI-UB-D	PC Based Resting ECG; interpretive software		
CPRL-UN	PC Based Resting ECG; Excludes patient cables		
CPR-UN	PC Based Resting ECG; Excludes patient cables		
CPR-UN5	PC Based Resting ECG; Excludes patient cables; 5 meter USB cable		
CPR-UN-EB	PC Based Resting ECG		
CPR-UN-EB-D	PC Based Resting ECG; includes patient cables and electrode set		
CPR-UI-EB-D	PC Based Resting ECG; Adult interpretive software		
CPR-UN-UB	PC Based Resting ECG		
CPR-UI-UB	PC Based Resting ECG; Adult interpretive software, USB cable		
CPR-SN	PC Based Resting ECG; Adult interpretive software, Serial cable		
RE-SW-MEANS	CPWS software disk; with interpretation		Software upgrade from normal resting algorithm to include indicated data analysis options. These options allow data analysis by different methods. Software enables user to view and save electro-cardiograms of patients on a PC.
RE-SW-ECG	CPWS software disk		
RE-SW-PEDIA	CPWS software disk; pediatric version with interpretation		
RE-SW-QT	CPWS software disk; dispersion option		
RE-SW-VCG	CPWS software disk; vector option		
RE-SW-RR	CPWS software disk; interval option		
RE-SW-HRV	CPWS software disk; heart rate variability option		
UPG-UN-UC-D-T	CPWS software disk; upgrade from resting to stress	Software upgrade from originally purchased CPWS. Software enables user to view and save electro-cardiograms of patients on a PC.	
CCW-UPCPWR	CPWS software disk; upgrade from DOS Windows		
UPDT-WACPW-CD	CPWS software disk, update from older CPWS versions		
UPDT-WACPW-OW	CPWS software disk; update from older versions, out of warranty only		
CPR-UPG-LTU	CPWS software disk; upgrade from resting "lite" resting ECG to normal ECG functionality		
CPR-UPG-POR-1	CPWS software disk; upgrade from POR to normal resting functionality		
CPR-UPG-MD-1	CPWS software disk and cover, upgrade from MDR to normal resting functionality		
45008-0000	Alligator clips attachment (1k box)	Clips allow user to connect banana jack terminated patient leads to electrode tabs needing alligator clip attachment.	
58581-0000	Alligator clips attachment (10 pack)		
PRO-60023	PROLINK USB CABLE ASSEMBLY (2M)	Cable allows connection of the Pro-Recorder to the PC USB connector.	
PRO-60024	PROLINK USB CABLE ASSEMBLY (3M)		
PRO-60025	PROLINK USB CABLE ASSEMBLY (5M)		
RE-PROLINK-SER	SERIAL PRO RECORDER CABLE W/9P SUB D CONN	Cable allows connection of the Pro-Recorder to the PC serial connector.	
RE-LINK-SER	UNILINK,RS232 FOR RESTING ECG		
SE-PC-IEC-PUSH	Patient Cables; PUSH style connector, ½ meter	Cable allows connection of the Pro-Recorder to the electrode	

**PRO ECG Recorder - User Manual**

REF	Component Description	Purpose
SE-PC-IEC-PSHL SE-PC-AHA-PSHL	PUSH style connector, 1.3 meters PUSH style connector, 1.3 meters	leads, which adhere to the patient for detection of cardiac signals.
SE-PC-IEC-CLIP SE-PC-IEC-CLPL SE-PC-AHA-CLIP SE-PC-AHA-CLPL	Patient Cables; CLIP style connector, 1 meter, CLIP style connector, 1.3 meters CLIP style connector, 1 meter CLIP style connector, 1.3 meters	
RE-PC-IEC-BAN RE-PC-IEC-BANL RE-PC-AHA-BAN RE-PC-AHA-BANL	Patient Cables; Banana style connector, ½ meter Banana style connector, 2 meters Banana style connector, ½ meter Banana style connector, 2 meters	
SE-PRO-600-R	CARDIO PERFECT PRO RECORDER 600HZ, refurbished	Pro-Recorder as sold with normal resting system, refurbished model.
08265-0000	UTILITY CART	Plastic cart that the PC and associated hardware can sit upon.
RE-SIM	ECG SIMULATOR	Simulator of ECG signals that allows the user to confirm operation of the Pro-Recorder and CPWS system.
RE-ELEC-SET	ELECTRODE SET (6 CUPS,4 CLAMPS,GEL), suction cups used versus the stick on tabs	Electrodes and accessories allow connection of the patient cables to the patient in a variety of attachment methods.
RE-GEL	ONE BOTTLE OF ELECTRODES GEL (260G)	
RE-GEL-12	BOX OF ELECTRODES GEL (12 BOTTLES)	
RE-ELEC-CUP	WELCH CUP (individual suction cup)	
RE-ELEC-KID	PEDIATRIC WELCH CUP ELECTRODS (pediatric version of the cup)	
RE-ELEC-CLP	LIMB LEAD CLAMPS (IEC)	
RE-ELEC	DISP ELECTRODES 50X BANANA CABLE	
RE-ELEC-20	DISPOSABLE ELECTRODES FOR BANANA CABLE	
RE-BAN-ADP	ADAPTER SET FOR BANANA TO PUSH STYLE CLIPS	
PRO-60019	BATTERY PACK FOR CP PRO RECORDER; Output 2.85 – 4.5VDC, 700mA	
PRO-60039	BATTERY CHARGER. Friwo P/N FW7400/12; Output 12VDC /1A	
PRO-60040	POWER CORD FOR BATTERY CHARGER,USA	
PRO-60041	POWER CORD FOR BATTERY CHARGER,EUROPE	
PRO-60042	POWER CORD FOR BATTERY CHARGER,UK	
102992	ADDITIONAL PROTECTIVE EARTH GROUNDING KIT FOR PC AND TREADMILL	Kit allows the CPWS system with PC and Treadmill to be compliant with IEC 60601-1-1 from a system perspective.
08281-0000	LASER PRINTER, CARDIOPERFECT	Printer that is approved for use with CPWS.
08282-0000	CPU W/MONITOR, CARDIOPERFECT	PC and Monitor that is approved for use with CPWS.
404008	CPWS FLEX ARM OPTION	Mechanical holder for the Pro-Recorder. Allows better cable management and support of the recorder while it is in use.

## 2. Installation

Before using the system, the CardioPerfect Pro cardiograph needs to be connected to the computer and the software must be properly configured.



**Figure 1 Front view CardioPerfect Pro Cardiograph**

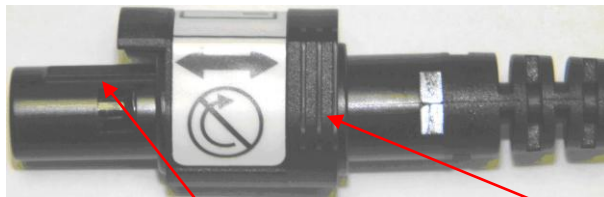
Figure 1 is a front view of the CardioPerfect Pro. A description of the items indicated is given in table 1.

**Table 1 Description of CardioPerfect Pro Cardiograph front panel.**

DESCRIPTION	EXPLANATION
Patent Cable Connection	Connection for the patient cable
Type BF Symbol	IEC symbol, type BF equipment, defibrillator proof
On/Off Switch	Manual switch to switch on cardiograph
LED	Power indicator, red indicates battery is low and needs to be recharged immediately, green indicates that sufficient battery power exists to record an ECG, no LED indicates ECG recording is not possible.
PC Symbol	Input for computer cable
PC Interface Cable Connection	Connection for the PC interface cable (Prolink)

**Before you can start recording ECG's with the CardioPerfect Pro cardiograph, you need to:**

1. Install the applicable software (refer to the Welch Allyn CardioPerfect Workstation Installation User Manual)
2. Install the hardware, including the required drivers. (Please refer to the Rest manual chapters 11 & 12 or Stress manual chapters 10 & 11)
3. Configure the software (Please refer to the Rest manual chapters 11 & 12 or Stress manual chapters 10 & 11)



**Figure 2 PC interface cable (Prolink)**

**Latch release**

**alignment key**



**Figure 3 Patient cable**

The Prolink cable has 2 alignment keys and the Patient cable has 1 alignment key.

**To connect the cables to the Pro recorder:**

1. Hold the Pro recorder in one hand; hold the Cable connector with your other hand.
2. Align the alignment keys with the notches in the corresponding Pro recorder receptacle.
3. Push the cable gently into the Pro recorder receptacle until it latches.

**To disconnect the cables from the Pro recorder:**

1. Hold the Pro recorder in one hand; hold the Cable connector with your other hand.
2. Gently pull the latch release away from the Pro recorder.



**Warning**

The Pro ECG recorder including connectors and cables should be handled with care. Improper use could result in inoperable ECG and or compromising patient safety.

Do not drop the Pro ECG recorder; this may result in mechanical failure.

Make sure the connectors are properly aligned before mating with the pro recorder.

Do not use force to insert the cables into the Pro ECG recorder receptacles.

Never pull the cables, only the latch release.


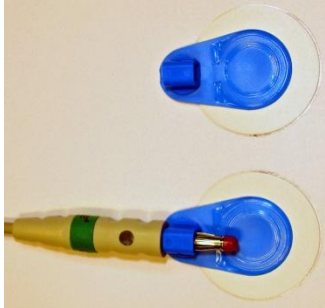
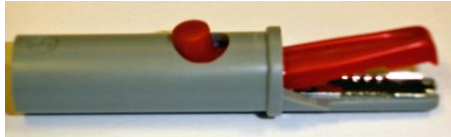
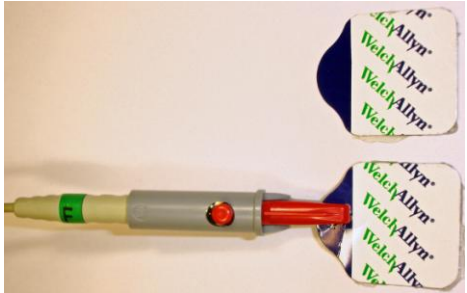




**Caution**





Patient cables and PC connection cables are intended to be inserted and removed from the Pro-Recorder in a push / pull motion. Do not twist the cables. Damage to the cables and the Pro-Recorder will occur.

**2.1 Connecting the patient cable to the electrode**

Please refer to the table below for information on connecting the patient cable to the electrodes.

	Type of connection	Connection to electrode
<b>Resting ECG</b>	<b>Banana</b>	 
	<b>Alligator clamp</b>	 
	<p><b>⚠ Caution:</b></p> <p><i>Make sure the metal part of the patient cable connector makes contact with the skin side of the electrode tab.</i></p>	
<b>Exercise ECG or Resting ECG</b>	<b>Push</b>	 



			
<p><b>Exercise ECG or Resting ECG</b></p>	<p><b>Clip</b></p>		 

### 3. Maintenance

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#### NOTE

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It is recommended to check the performance of the cardiograph regularly. Contact your local Welch Allyn Sales Office or your authorized Welch Allyn dealer or distributor. Only qualified personnel may service the cardiograph.

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#### Cleaning the CardioPerfect Cardiograph and Battery Pack

Clean the cardiograph and battery pack with a soft cloth moistened with a recommended disinfectant or cleaning agent. It is advisable to clean the battery pack and ECG recorder using moist cloth. Never clean the recorder excessively with water or other substance so that components inside or connectors on front side of the recorder can be damaged, this may ultimately lead to decreased performance.

#### Cleaning the Patient and PC interface Cables

Clean the cables with a soft cloth moistened with a recommended disinfectant or cleaning agent.

Cleaning cables: patient cables, plugs and power cords should be kept clean using lukewarm soapy water or a neutral cleaner.

Disinfecting the cables: use chemical disinfectants containing ethanol (70%-80%), propanol (70%-80%) or aldehydes (2%-4%).



**Do not** clean the patient cable with alcohol. Alcohol can cause the plastic to become brittle and may cause the cable to fail prematurely.

**Do not** autoclave the cable or use ultrasonic cleaners.

**Do not** immerse the patient cable.

**Do not** use abrasive materials to clean metal surfaces—scratches on them can cause artifacts on the ECG.

**Do not** wet the connectors.

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**NOTE**

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The CardioPerfect Pro cardiograph can be powered by a USB connection or through a battery pack. If you are using a USB connection (dummy battery pack) you do not have to charge the battery pack. If a battery pack is used with a RS232 connection, you have to charge the battery pack with a battery charger supplied by Welch Allyn.

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**Battery LED Indicator**

The battery pack is provided with a (green) LED indicator that indicates the performance status of the battery pack, the following applies:

LED Intermittent – battery pack is charging after complete discharge, it is recommended to not use the battery pack for use with the cardiograph for diagnostic purpose.

LED On – battery pack is charging and not completely charged but can be used with the cardiograph for diagnostic purpose.

LED Off – battery pack is completely charged and ready to be used with the cardiograph for diagnostic purpose.

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**Battery Care**

A fully charged battery will provide a minimum of 8 hours of operation.

The CardioPerfect Pro cardiograph can be powered by a battery pack. This battery pack contains rechargeable batteries. Battery performance is maintained when recharging takes place when the battery is almost empty. This can be seen on the recorder when the LED on the front lights up in red. This is the best time for recharging the battery pack. After the light has turned red you have still enough power for about ten minutes of recording.

Both the internal gauge measurement and the percentage of battery capacity shown in Welch Allyn CardioPerfect Workstation become less accurate.

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**Battery Charging**

1. Pull the battery compartment from the recorder by holding the recorder with one hand and pressing on both sides off the battery compartment with your other hand.
  2. Connect the battery to an electrical outlet using the power adapter by inserting the charger cable into the top of the battery compartment and charge your battery.
  3. Click the battery compartment back into place after the battery is recharged.
- 



**Warning** Charging must be done outside of the patient environment.

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**Storing the Battery**

If the cardiograph will not be used for more than three months, remove the battery pack from the unit and place it into storage. While in storage, charge the battery to retain the battery life and capacity. This ensures that the battery does not completely discharge while in storage.

**Caution**

If the battery pack is discharged to a very low level, the "Battery Time Left" on-screen timer of the CPWS software will not be accurate.

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The system must perform a "learning cycle" before accuracy is regained. This "learning cycle" is achieved by fully charging a battery, fully discharging it through use, and recharging before the next use.

**Caution**

Repeated undercharging of the battery will damage the battery and reduce battery life.

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## 4. Technical Specifications

**Table 2 CardioPerfect Pro Cardiograph**

PRO CARDIOGRAPH	SPECIFICATION
SE-PRO-600 Signal bandwidth Sampling Rate	0.05 to 150Hz 600 samples/sec
SE-PRO-1200 Signal bandwidth Sampling Rate	0.05 to 250Hz 1200 samples/sec
Pacemaker Bandwidth	2KHz
Amplitude Quantization	3.75 $\mu$ V
Skew	72.9uSec
Input impedance	>5MOhms
Gain accuracy	5% RTI
DC dynamic span	$\pm$ 300 mV (95% gain accuracy)
AC dynamic span	$\pm$ 5mV
CMMR	83 dB
Recovery time after defibrillation	80% gain accuracy after 5s
Setup time after power-on	80% gain accuracy after 5s (all leads connected)
Power consumption	<750mW
Enclosure protection against ingress of water	None - IPX0
Degree of protection against electrical shock	BF

**Table 3 CardioPerfect Pro Battery Pack**

PRO BATTERY PACK	SPECIFICATION
Battery output voltage	2.85V - 4.5V
Battery type	Nickel Metal Hydride (NIMH)
Maximum recommended output current	700mA
Battery Capacity	1650mAh nominal
Lifetime battery charge cycles	500 charge-discharge cycles
Supply voltage	9 – 18 VDC
Charger supply rating	4W
Operating temperature	+10°C to +40°C, 30% to 70% RH
Charging temperature	0°C - 35°C
Storage temperature	-20°C to + 40°C

**Table 4 Safety, EMC, and regulatory compliance**

STANDARD	STANDARD
ANSI/AAMI EC11	UL60601-1
CAN/CSA C22.2 No. 601.1	IEC/EN 60601-1
CAN/CSA C22.2 No. 601.1.1	IEC/EN 60601-1-1
CAN/CSA C22.2 No. 601.1.2	IEC/EN 60601-1-2
CAN/CSA C22.2 No. 601.1.4	IEC/EN 60601-1-4
CAN/CSA C22.2 No. 601.2.25	IEC/EN 60601-2-25
	IEC/EN 60601-2-51: 2003

**Discarding the Equipment**

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Discard the old battery appropriately

- In the USA, call 1800-SAV-LEAD for instructions on recycling it.
- International users, contact your local authorities concerning recycling.

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. See [www.welchallyn.com/weee](http://www.welchallyn.com/weee) or contact Welch Allyn Customer Service.

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**5. Guidance and Manufacturer’s Declarations**



The Welch Allyn CardioPerfect Pro Cardiograph needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided.


Portable and mobile RF communications equipment can affect the Welch Allyn CardioPerfect Pro Cardiograph.

<b>Electromagnetic Emissions</b>		
The Welch Allyn CardioPerfect Pro Cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn CardioPerfect Pro Cardiograph should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RF emissions CISPR 11	Group 1	The Welch Allyn CardioPerfect Pro Cardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Welch Allyn CardioPerfect Pro Cardiograph is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Welch Allyn CardioPerfect Pro Cardiograph or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**PRO ECG Recorder - User Manual**

<b>Electromagnetic Immunity</b>			
The Welch Allyn CardioPerfect Pro Cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn CardioPerfect Pro 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 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.
Surge  IEC 61000-4-5	±1 kV differential mode  ±2 kV common mode	±1 kV differential mode  ±2 kV common mode	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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Welch Allyn CardioPerfect Pro Cardiograph requires continued operation during power mains interruptions, it is recommended that the Welch Allyn CardioPerfect Pro Cardiograph be powered from an uninterruptible 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 AC mains voltage prior to application of the test level.		



<b>Electromagnetic Immunity</b>			
The Welch Allyn CardioPerfect Pro Cardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn CardioPerfect Pro 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn CardioPerfect Pro Cardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p style="text-align: center;"><b>Recommended separation distance</b></p> $d = \left[ \frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m	$d = \left[ \frac{3,5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 to 800 MHz</p> $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">800 MHz to 2,5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  </p>
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 structures, 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 Welch Allyn CardioPerfect Pro Cardiograph is used exceeds the applicable RF compliance level above, the Welch Allyn CardioPerfect Pro Cardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Welch Allyn CardioPerfect Pro Cardiograph.		
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

<b>Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn CardioPerfect Pro Cardiograph</b>			
The Welch Allyn CardioPerfect Pro Cardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn CardioPerfect Pro Cardiograph can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn CardioPerfect Pro 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		
	150 KHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
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 absorption and reflection from structures, objects and people.		