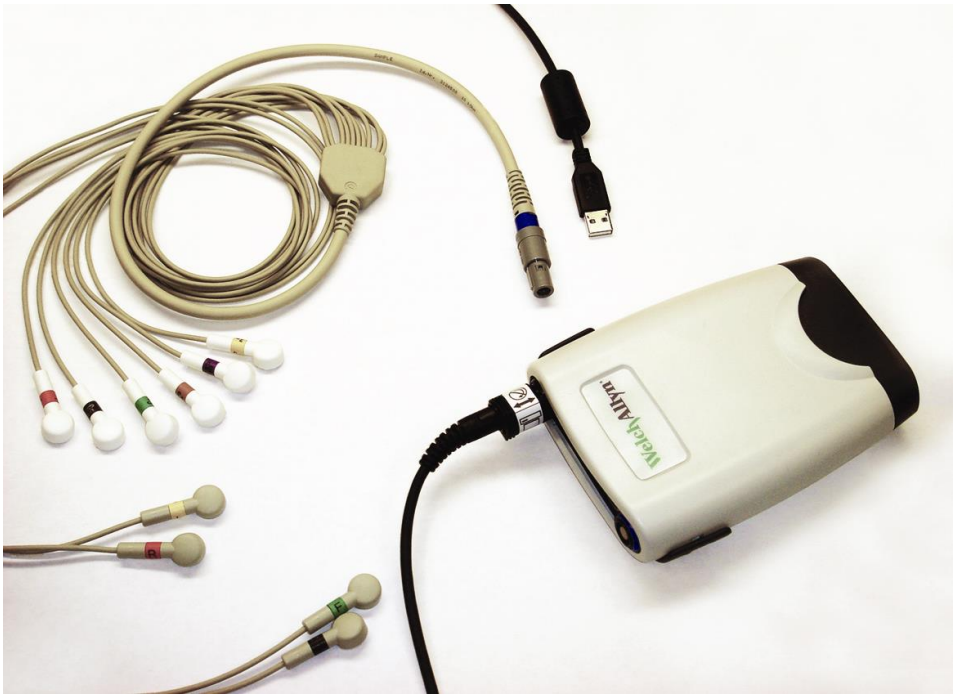
# PRO ECG Recorder - User Manual



**EC REP**

**Regulatory Affairs Representative**
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**REF** 901047 CARDIOPULMONARY ECG SYSTEM

**REF** 901095 ECG RECORDER

CE **0297**

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

## Copyright



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.

## 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 ECG Recorder in a push / pull motion. Do not twist the cables. Damage to the cables and the PRO ECG Recorder will occur.

## Warnings

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.

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 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 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.

Fire and explosion hazard. Do not operate the electrocardiograph in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment.

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.
- Consult your facility's equipment cleaning procedures when performing ECG testing on patients with open, infectious sores.

| | |
|---|---|
| | 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.<br><br>No modification of this equipment is allowed. |

## 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 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.

| **Note** | Welch Allyn does not accept returned products without an RMA. |
|---|---|

### 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.

You assume all responsibility for use of the Product with any hardware or software that does not meet the system requirements described in the Product documentation.

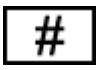
If a Product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Welch Allyn will, at its discretion, repair or replace the defective Product or accessory 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.

# Table of contents

## Conventions

| | |
|---|---|
|  | **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.<br>A WARNING in this manual indicates conditions or practices that, if not corrected immediately, could lead to illness, injury or death.<br>A CAUTION in this manual indicates conditions or practices that, if continued or not corrected immediately, could damage the equipment.** |
| **NOTE** | **A NOTE in this manual contains additional information on cardiograph usage.** |
|  | **Ingress Protection - Not protected against the ingress of water** |
|  | **Serial Number** |
|  | **Product Identifier** |
|  | **Defibrillation-Proof Type CF applied part** |
|  | **Manufacture Date<br>YYYY-MM-DD** |
|  | **CE Mark for Class Is, Im, IIa, IIb & III** |
|  | **Temperature Range** |
|  | **Reorder Number** |

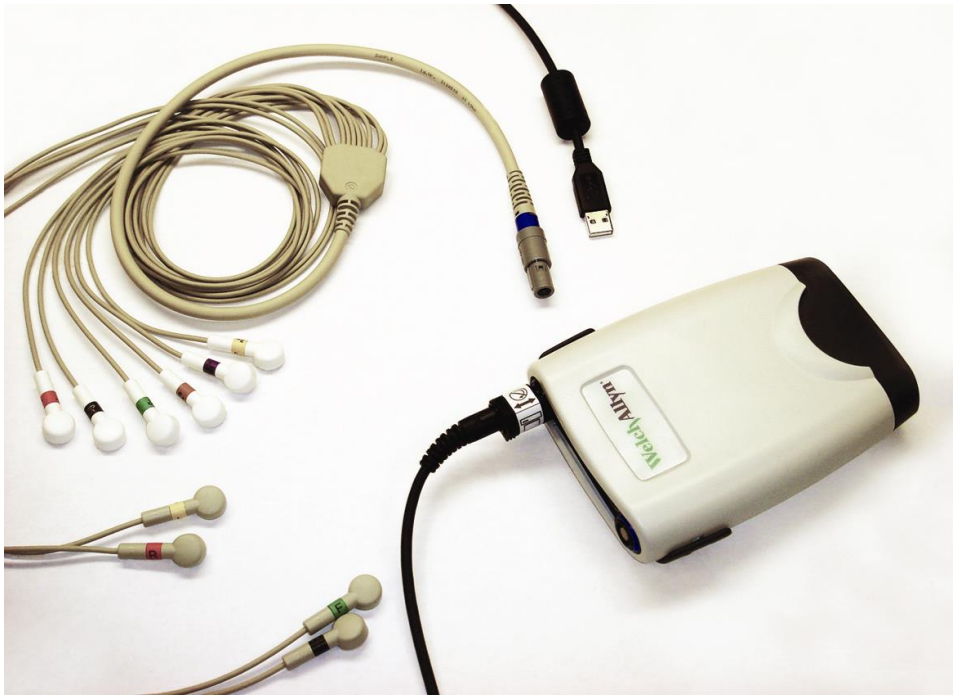
| | |
|---|---|
|  | **Do not dispose of in trash, for devices** |
|   | **Consult operating instructions/directions for use (DFU). A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.** |
|   | **Global Trade Item Number** |

## 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)
- CardioPerfect Workstation Software (CPWS-SW)

**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.

**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 | |
| 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 | |
| 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-QT | CPWS software disk; dispersion option | |
| RE-SW-VCG | CPWS software disk; vector option | |
| RE-SW-RR | CPWS software disk; interval 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 | |
| 45003-0000 | Stress kit electrodes (10 pack) | Clips allow user to connect banana jack terminated patient leads to electrode tabs needing alligator clip attachment. |
| 45008-0000 | Alligator clips attachment (1k box) | |
| 58549-0000 | Universal snap electrodes (10 pack) | |
| 715006 | 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) | |
| SE-PC-IEC-PUSH<br>SE-PC-IEC-PSHL | Patient Cables;<br>PUSH style connector, ½ meter<br>PUSH style connector,1.3 meters | Cable allows connection of the PRO-Recorder to the electrode leads, which adhere to the patient for detection of cardiac |

| REF | Component Description | Purpose |
|---|---|---|
| SE-PC-IEC-CLIP<br>SE-PC-IEC-CLPL<br>SE-PC-AHA-CLIP<br>SE-PC-AHA-CLPL | Patient Cables;<br>CLIP style connector, 1 meter, CLIP style connector, 1.3 meters<br>CLIP style connector, 1 meter<br>CLIP style connector, 1.3 meters | signals. |
| RE-PC-IEC-BAN<br>RE-PC-IEC-BANL<br>RE-PC-AHA-BAN | Patient Cables;<br>Banana style connector, ½ meter<br>Banana style connector, 2 meters<br>Banana style connector, ½ meter | |
| 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 | DISP ELECTRODES 50X BANANA CABLE | |
| RE-ELEC-20 | DISPOSABLE ELECTRODES FOR BANANA CABLE | |
| 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- from a system perspective. |
| 08281-0000 | LASER PRINTER, CARDIOPERFECT | Printer 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**

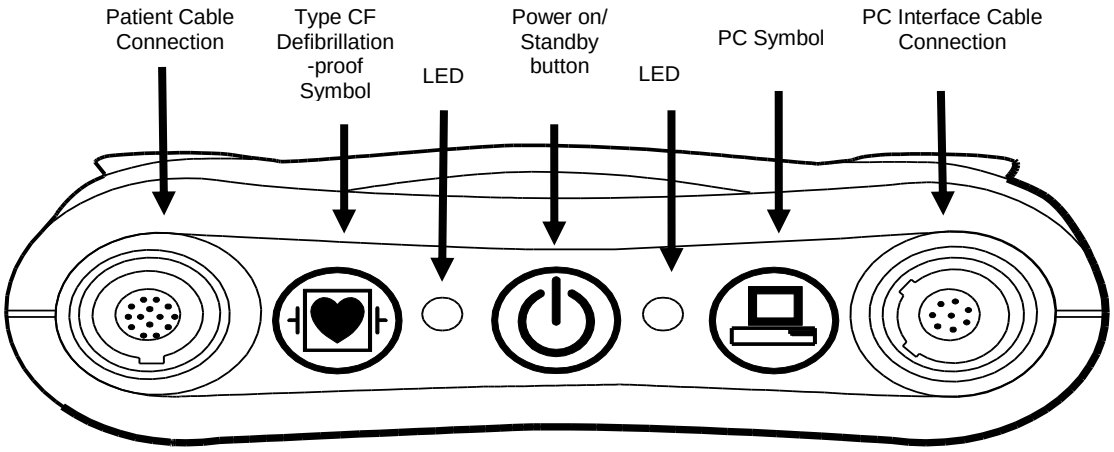



Figure 1 is a front view of the CardioPerfect PRO cardiograph. A description of the items indicated is given in table 1.

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

| DESCRIPTION | EXPLANATION |
|---|---|
| Patent Cable Connection | Connection for the patient cable |
| Type CF Symbol Defibrillation-proof | IEC symbol, type CF equipment, defibrillation-proof |
| Power on/Standby button | The Power on/Standby button only applies to older devices. Do not use this button. |
| LED | • No LED: a disconnected device that cannot record an ECG.<br>• Green: a good USB connection and sufficient power to record an ECG. |
| 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 Resting ECG manual chapters 11 & 12 or Stress manual chapters 10 & 11.)
3. Configure the software (Please refer to the Resting ECG manual chapters 11 &12 or Stress manual chapters 10 & 11.)

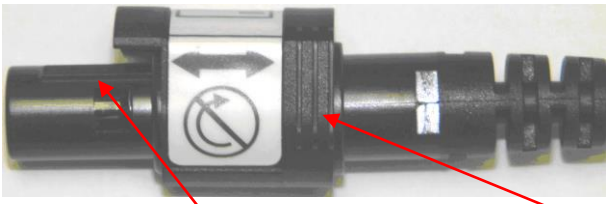


Figure 2 PC interface cable (Prolink)

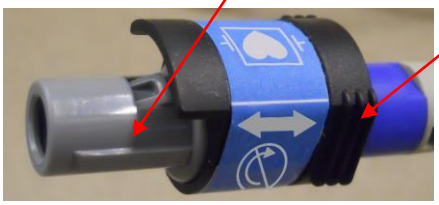



**Figure 3 Patient cable**

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

**To connect the cables to the PRO ECG Recorder:**

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

**To disconnect the cables from the PRO ECG Recorder:**

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

Do not use force to insert the cables into the PRO ECG Recorder receptacles.

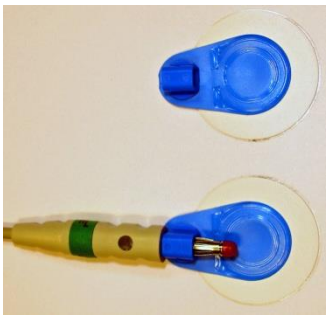
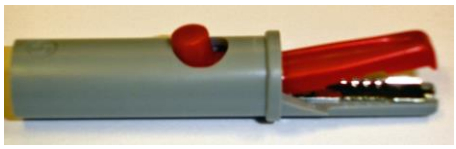
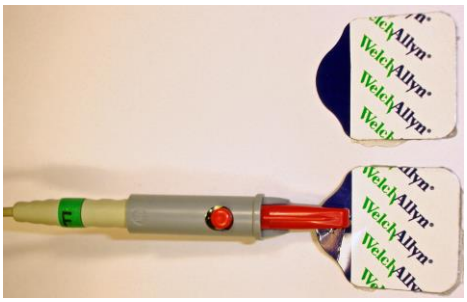
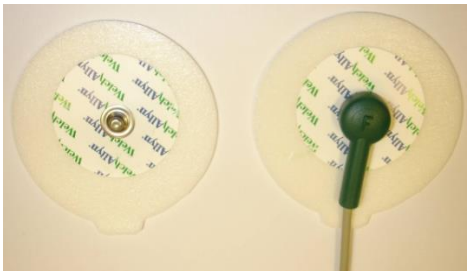
Never pull the cables, only the latch release.

**Caution**

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

<table>
<tr><th></th><th colspan="2">Type of connection</th><th>Connection to electrode</th></tr>
<tr><td rowspan="3">Resting ECG</td><td>Banana</td><td>  </td><td>  </td></tr>
<tr><td>Alligator clamp</td><td>  </td><td>  <br>⚠ Caution:<br>Make sure the metal part of the patient cable connector makes contact with the skin side of the electrode tab.</td></tr>
<tr><td>Exercise ECG or Resting ECG</td><td>Push</td><td>  </td><td>  </td></tr>
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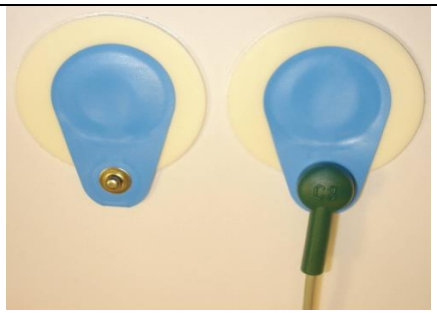
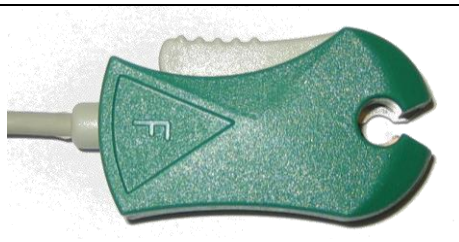
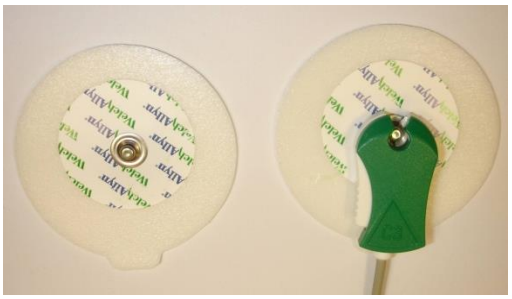
| | | |  |
| **Exercise ECG or Resting ECG** | **Clip** |  |  <br>  |

# 3. Maintenance

**Clean the equipment**

**Warning**

Keep the PRO ECG Recorder, reusable electrodes, and the patient cable clean. Patient contact with contaminated equipment can spread infection.

The patient cables should be cleaned after each use and disinfected as needed.

**Caution**

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

**Clean the PRO ECG Recorder**

Unless the PRO ECG Recorder (the device itself rather than the cables and electrodes) comes in direct contact with a patient, it is acceptable to clean the device on a routine basis according to your facility's protocols and standards or local regulations. Patient contact with the device might require immediate cleaning.
The following agents are compatible with the PRO ECG Recorder:

- 70 percent isopropyl alcohol
- 10 percent chlorine bleach solution

**Caution**

When cleaning the device, avoid using cloths or solutions that include quaternary ammonium compounds (ammonium chlorides) or glutaraldehyde-based disinfectants**.**

1. Slightly dampen a soft, clean cloth with an acceptable cleaning solution, or use a 70 percent alcohol pad to wipe the exterior of the PRO ECG Recorder. Dry all components with a clean, soft cloth or paper towel.

2. Before you power on the PRO ECG Recorder again, wait at least 10 minutes for all traces of liquid to evaporate.

**Clean the cables**

1. Slightly dampen a soft, clean cloth with lukewarm, soapy water or a neutral cleaner and clean the patient cable and PC USB interface cable.
2. Dry all cables with a clean, soft cloth or paper towel.
3. Wait at least 10 minutes before powering on the PRO ECG Recorder again.

**Disinfect the cables**

When disinfection is required, use chemical disinfectants containing ethanol (70%–80%), propanol (70%–80%), or aldehydes (2%–4%). Disinfect according to your facility's protocols and standards or local regulations.

**Caution** Do not use these agents for routine cleaning of the cables. Alcohol can cause the plastic to become brittle and may cause the cable to fail prematurely.

**Inspecting the equipment**

Perform the following inspections daily:

- Check for cracks or breaks in the PC USB interface cable, the patient cable, the patient electrodes, and the PRO ECG Recorder.
- 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.
Whenever the electrocardiograph is serviced or whenever problems are suspected, verify continued electrical safety of the device using IEC 60601-1 or ANSI/AAMI ES 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

# 4. Technical Specifications

**Table 2 CardioPerfect PRO Cardiograph**

| PRO CARDIOGRAPH | SPECIFICATION |
|---|---|
| SE-PRO-600<br>Signal bandwidth<br>Sampling Rate | <br>0.05 to 150Hz<br>600 samples/sec |
| SE-PRO-1200<br>Signal bandwidth<br>Sampling Rate | <br>0.05 to 250Hz<br>1200 samples/sec |
| Internal Sampling Rate | 9600Hz |
| Pacemaker Bandwidth | 2KHz |
| Amplitude Quantization | 3.75 µV |
| Skew | 72.9 µSec |
| Input impedance | >5M Ω |
| Gain accuracy | 5% RTI |
| DC dynamic span | ±300 mV (95% gain accuracy) |
| AC dynamic span | ±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 | CF |
| Mode of operation | Continuous |
| Storage and transport temperatures | -20° to +50° C (-4° to +122° F) |
| Relative humidity | 15 to 90% non-condensing |
| Operating altitude | -170 to +4877 m (-557 to +16000 ft) |

**Safety, EMC, and regulatory compliance**

Complies with ANSI/AAMI EC11 and multi-country versions of:
IEC 60601-1, 60601-1-2, 60601-1-6, 60601-2-25, 62304, 62366.

**Medical Device Directive**

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

Declaration of Conformity available upon request.

## Discarding the Equipment

Dispose of this product and its accessories according to local regulations. Do not dispose of as unsorted municipal waste. For more specific disposal or compliance information, go to www.welchallyn.com/weee or contact Welch Allyn Technical Support at www.welchallyn.com/about/company/locations.htm.

# 5. Guidance and Manufacturer's Declarations

| | |
|---|---|
| **Caution** | 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.<br><br>Portable and mobile RF communications equipment can affect the Welch Allyn CardioPerfect PRO Cardiograph. |

| **Electromagnetic Emissions** | | |
|---|---|---|
| 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. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions<br><br>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<br><br>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:<br>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<br><br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br><br>IEC 61000-3-3 | Complies | |

## Electromagnetic Immunity

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)<br><br>IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±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<br><br>IEC 61000-4-4 | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | ±2 kV for power supply lines<br><br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | ±1 kV differential mode<br><br>±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<br><br>IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 sec | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>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.

## Electromagnetic Immunity

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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | 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.<br><br>Recommended separation distance<br>$d = [\frac{3,5}{V_1}]\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 1 GHz | 3 V/m | $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 to 800 MHz<br><br>$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz<br><br>where *P* is the maximum output power rating of the transmitter in watts (W) and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |

| | |
|---|---|
| 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. |

## Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn CardioPerfect PRO Cardiograph

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 $d = [\frac{3,5}{V_1}]\sqrt{P}$ | 80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ | 800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ |
| 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. |