CP Series
Electrocardiographs

CP 100

CP 200

Update to Directions for Use

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Update Through Software Version 2.6

This update describes changes in operation through software version 2.6 of the CP 100™ and CP 200™ electrocardiographs and the CP 200 spirometry option. This document supplements information in the following manuals:

- CP 100 12-Lead Resting Electrocardiograph Directions for Use
- CP 200 12-Lead Resting Electrocardiograph Directions for Use
- CP 200 Spirometry Option Directions for Use

Updated USB drivers for Windows 7 32-bit and 64-bit operating systems

Enables connectivity to CardioPerfect Workstation (CPWS).

Support for lithium ion battery

- The lithium ion battery features include:

  - Increased operating capacity
  - Long battery life

This software release includes all the previous software improvements.

Updated Battery Information for the CP 100/CP 200

WARNING Lithium ion battery. Risk of fire, explosion, and burns. Do not short-circuit, crush, incinerate, or disassemble the battery pack. Never dispose of batteries in refuse containers. Always recycle batteries according to local regulations.

Caution If you only install the 2.6 software without upgrading to a lithium ion battery an incorrect battery charging status will result. To continue using your Lead-Acid battery choose **System Settings > Device Configuration** and then choose the **Battery Type > Lead-Acid**.

Symbols

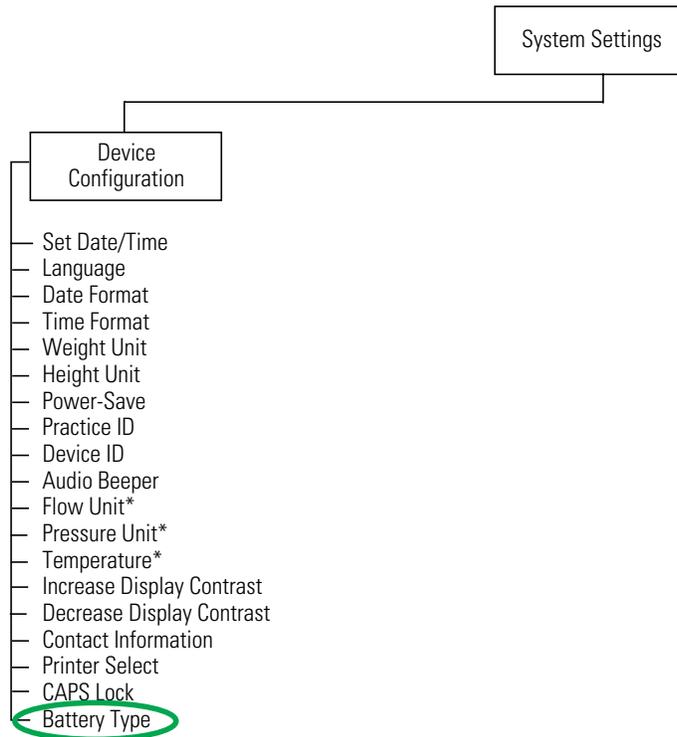|			
Li-ion	Rechargeable lithium ion battery	5	China RoHS (restriction of hazardous substances) symbols for control of pollution caused by electronic information products. 5-year environment-friendly use period (EFUP) for batteries.
	Separate the battery from other disposables for recycling.		Recycle

Updated "System Settings" Menu Tree

```
                                          ┌─────────────────┐
                                          │ System Settings │
                                          └─────────────────┘
                                                   │
                       ┌──────────────────┐
                       │     Device       │
                       │  Configuration   │
                       └──────────────────┘

                       ─ Set Date/Time
                       ─ Language
                       ─ Date Format
                       ─ Time Format
                       ─ Weight Unit
                       ─ Height Unit
                       ─ Power-Save
                       ─ Practice ID
                       ─ Device ID
                       ─ Audio Beeper
                       ─ Flow Unit*
                       ─ Pressure Unit*
                       ─ Temperature*
                       ─ Increase Display Contrast
                       ─ Decrease Display Contrast
                       ─ Contact Information
                       ─ Printer Select
                       ─ CAPS Lock
                       ─ Battery Type
```
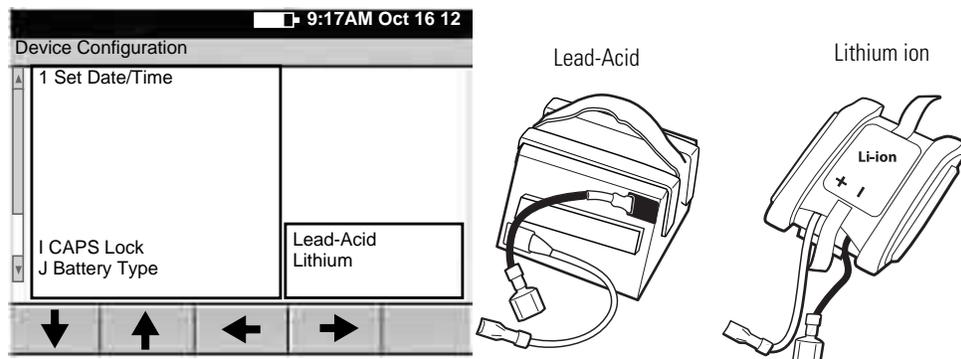
Applicable for spirometry only.

Selecting the Battery Type in the Device Configuration settings

1. Press the Menu key [⊞].

2. Choose **System Settings** > **Device Configuration**.

   The following screen appears.

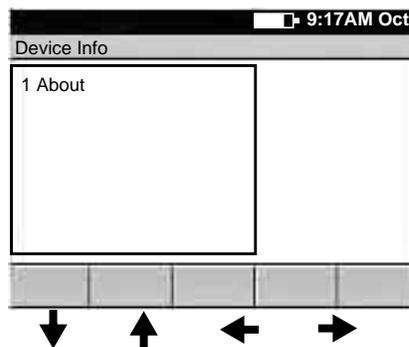**"Device Configuration" Screen**

3. Choose the **Battery Type** settings.

   - Lead-Acid
   - Lithium

4. Press the Enter key [⏎] .

5. Choose the **Previous Menu**.

Reviewing the Device Information

1. Press the Menu key [⊞].

2. Choose **System Settings** > **Device Info**.

   The following screen appears.

"Device Info" Screen

3. Select **About**.

Scroll to the bottom of the list to view your battery type (either Lead-Acid or Lithium).

Item	Description
About	Displays the following information about the electrocardiograph: • serial number • modules configured • version numbers • battery voltage • battery current • battery type

Battery Specifications

Rechargeable Battery	Specification
Lithium ion	Lithium iron phosphate, 6 volt, 6 AH Prints up to 100 continuous ECGs per charge 12-hour recharging
Lead-Acid	Lead-Acid gel, 6 volt, 5 AH Prints up to 100 continuous ECGs per charge 12-hour recharging

Feature updates prior to the 2.6 software release

If your CP 100 electrocardiograph has a serial number of 10020000, or greater, or your CP 200 electrocardiograph has a serial number 20020000, or greater, this update describes the changes in the operation of your electrocardiograph.

If your electrocardiograph has a serial number that is lower than 1002000 or 2002000, and your device was recently serviced, it may contain some or all of these new features depending on the scope of the services performed.

This document supplements information in the following manuals:

- CP 100 12-Lead Resting Electrocardiograph Directions for Use (mat. 708794)
- CP 200 12-Lead Resting Electrocardiograph Directions for Use (mat. 708793)
- CP 200 Spirometry Option Directions for Use (mat. 708795)

Battery Deep-Discharge Disconnect Added

A battery deep-discharge disconnect has been added to reduce the likelihood that your CP 100 or CP 200 electrocardiograph will operate on a deeply discharged battery. The disconnect prevents permanent damage to the battery when the battery is left uncharged for long periods of time.

This functions automatically when the electrocardiograph battery voltage is less than 5.25V in sleep mode. Once a battery disconnect has occurred, the electrocardiograph will not operate on battery power until it is charged to 6.2V or higher. This also protects the electrocardiograph from operating on a malfunctioning battery that cannot be charged to 6.2V or higher.

Reset Button

If the electrocardiograph stops functioning, you can press and hold the Power On/Off key for approximately 7 seconds to restart the electrocardiograph. Release the key once the restart begins. The key is located on the upper left of the electrocardiograph keyboard.
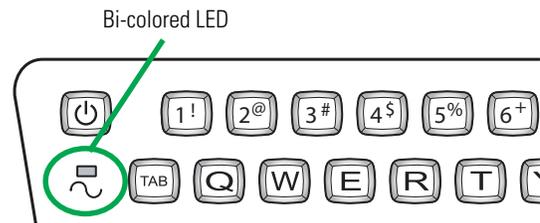
Figure 1. Reset Button

The previous method of resetting the electrocardiograph is still available. Reset the electrocardiograph by pressing the reset button located on the right side. To press the

reset button, insert a small object, such as small paper clip, into the hole next to the Spirometry port.

Bi-Colored Keyboard LED

Figure 2. Keyboard LED

The bi-colored LED on the keyboard indicates the battery status. When green, the LED indicates that AC power is present. When yellow, the LED indicates a low battery that should be charged. The LED is located below the Power On/Off key on the upper left of the electrocardiograph keyboard.


Alternate Patient Cable and Leads

The Lead configuration has changed so that all individually replaceable lead wires extend from the same end of the patient cable. This new configuration is intended to make the connection of the lead wires easier for you. It is different now than it has been in previous models where the LL (F) and RL (N) leads attached to the opposite end of the patient cable with respect to the other leads. See Figure 3"Patient Cable and Leads".
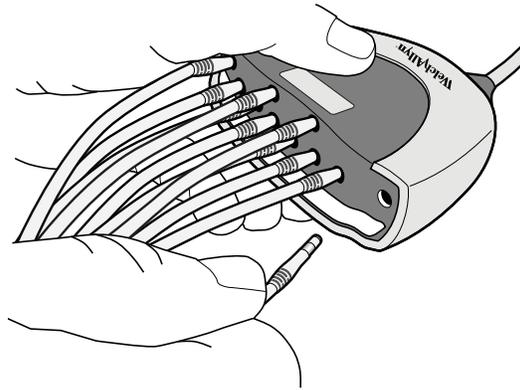
Figure 3. Patient Cable and Leads
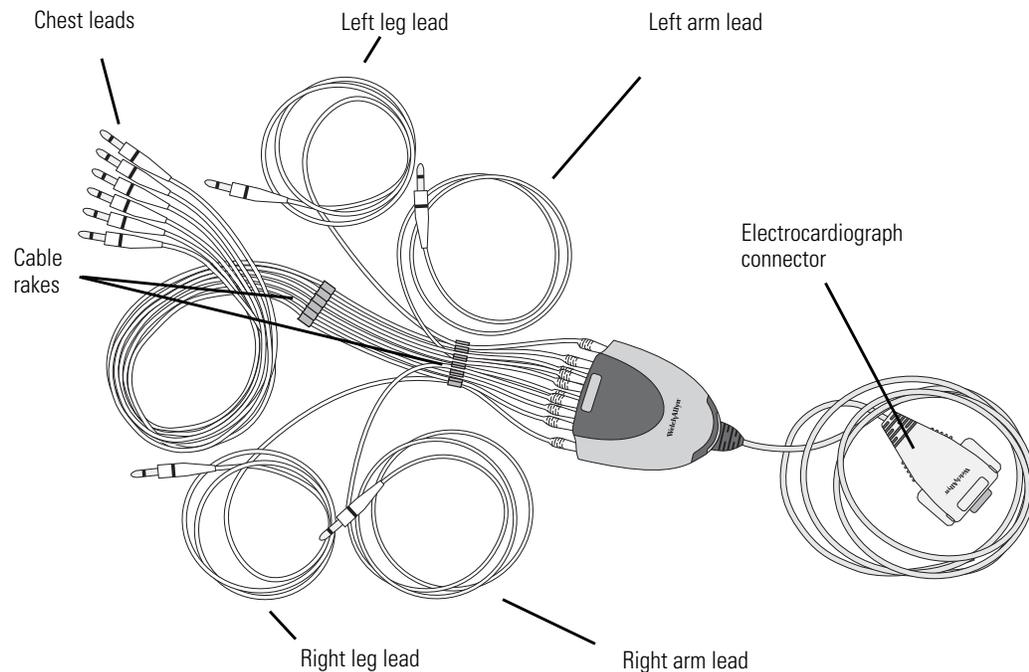
There has been no change to the replaceable lead wires. They remain compatible with previous models and are equivalent in function.

Connecting the Patient Cable

Insert all leads into their proper positions, as labeled on the connectors. See Figure 4 "Inserting the Leads".

Figure 4. Inserting the Leads

Updated Information for the CP 100/CP 200

Heart rate monitor operation

The heart rate indicated on the CP 100 or CP 200 LCD display is for reference only. Make manual measurements of the ECG intervals and magnitudes on printed ECG reports only.

The increased R wave amplitudes that are produced by some patient simulators may produce heart rate readings two times higher than normal because the R waves can be counted as T waves.

The CP 100 and CP 200 devices are not intended to be used as heart rate monitors. Heart rate monitors are covered by other standards for example: ANSI/AAMI standard EC13: Cardiac monitors, heart rate meters and alarms.

Artifact

A combination of abnormally large R wave amplitude and waveform shapes delivered by some patient simulators can trigger artifact warnings. These warnings are not consistent with actual patient morphologies. The noise warning is designed as a guide to limit low quality ECGs.

The CP 100 and CP 200 devices are compliant to all applicable standards specified in the device manual for diagnostic electrocardiographs including: IEC/EN 60601-2-51 and ANSI/AAMI EC11.

Reducing Artifact

- Use only resting tab electrodes that have not past their product expiration date. Store only in an air tight pouch within the product recommended environmental conditions.
- When using the reusable bulbs, limb plates, or clamp electrodes, always replace expired or dried up electrode gel.
- When using the reusable bulbs, limb plates, or clamp electrodes, use only an ECG conductive gel to obtain optimum conductivity. Do not use ultrasound gel.
- Orient the adapter (alligator) clips so that the metal from the clip is able to make contact with the conductive area of the resting tab electrode.
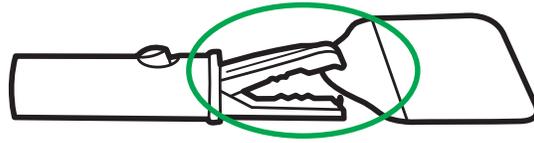
- Replace the patient lead if the banana spring at the end of the lead is broken or damaged.
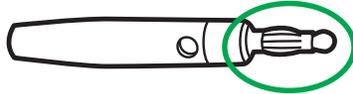
Updated Battery Information for the CP 100/CP 200

Electrocardiograph Battery - Preparation and Operation
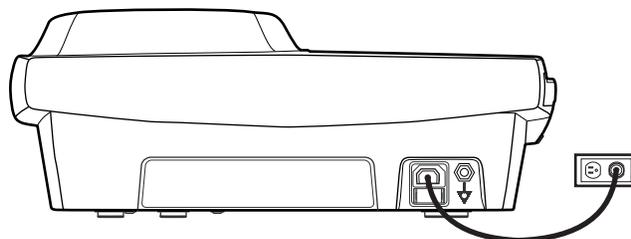
Battery performance:

The sealed lead-acid battery provides 200 to 300 discharge/charge cycles under normal operating conditions before it should be replaced. Typical battery usage will require battery replacement approximately once per year. Reduced battery performance and longevity will result if the recommendations for maximum battery performance are not followed.

The electrocardiograph uses a single, rechargeable Sealed Lead Acid (SLA) battery pack. It is designed to print up to 100 continuous rhythm ECG pages or to print 25 AUTO ECG tests per full charge. The typical charge time of the sealed lead-acid battery is 12-16 hours, but can take up to 36 hours for a highly discharged battery.

Prior to using your new electrocardiograph in battery mode:

⚠ **Caution**   Charge the Battery. Upon receipt of your new electrocardiograph, it is important to charge the electrocardiograph's battery for at least 12 hours before using it in battery mode.

Note   The electrocardiograph is fully functional when connected to AC power, regardless of the battery charge state. Using the electrocardiograph while charging the battery does not affect the charge time.

For maximum battery performance and longevity:

- Charge the battery whenever possible by connecting the electrocardiograph to AC
  power after each use.
    The CP 100/CP 200 provides a trickle charge to keep the battery fully charged.
    Continuous charging will maximize the battery performance and longevity and will
    not overcharge or degrade the battery.

- Fully recharge the battery immediately after it becomes fully discharged. A fully
  discharged battery without an immediate recharge may require an extended charge
  time (up to 36 hours) and permanently degrade battery performance and longevity.

- Use only the CP 100/CP 200 electrocardiograph's integral charger to recharge the
  battery.

- Use only a Welch Allyn CP 100/CP 200 approved replacement battery (REF 100660).

- Avoid using or storing your electrocardiograph in hot locations or in direct sunlight.

**To check the battery charge status:**

To fully charge the battery, leave the electrocardiograph plugged into AC power until you
see the fully charged indication on the display. A battery status symbol appears in the top
portion of the electrocardiograph display:

Battery is charging

Electrocardiograph
Display

Battery fully charged (symbol will
appear solid white on the
electrocardiograph display)
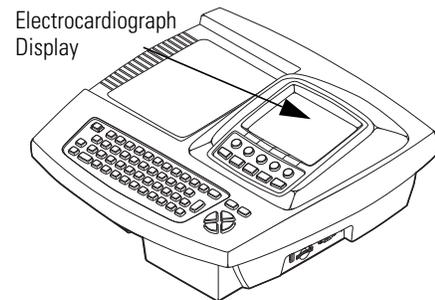
Note   Replace your battery if you are unable to perform your expected number of ECGs
per day after a full charge cycle. (12 hour minimum, up to 36 hours if deeply-
discharged).

Update Through Software Version 2.5

This update describes changes in operation through software version 2.5 of the CP 100™ and CP 200™ electrocardiographs and the CP 200 spirometry option. This document supplements information in the following manuals:

- CP 100 12-Lead Resting Electrocardiograph Directions for Use (mat. 708794)
- CP 200 12-Lead Resting Electrocardiograph Directions for Use (mat. 708793)
- CP 200 Spirometry Option Directions for Use (mat. 708795)

Lead Quality Feedback

CP 100, CP 200
Lead quality messages, which appear on various screens, now include both lead-off and artifact information.

For good quality recordings, leads must be connected and artifact free. If you print an Auto ECG despite lead-off or artifact conditions (by overriding the "Waiting for 10 seconds of quality data" message), the report reflects those conditions. In the case of lead-off signals, the report shows square waves. In the case of artifact, the report might include a warning to use the interpretation (if any) with caution.

To eliminate artifact, you might need to re-prep the patient, use fresh electrodes, or minimize patient motion during the recording.

For additional feedback on lead quality, you can now enable an artifact report. This report, a 12x1 format with all filters disabled, shows the leads with artifact so that you can remedy the problem. (The normal Auto ECG report with filters enabled might mask some of the artifact issues.) When enabled, the artifact report prints automatically with the Auto ECG report whenever artifact is detected and you override the "Waiting for 10 seconds of quality data" message.

To enable the artifact report, press the Menu key ⊞ . Choose **ECG Settings** > **Auto Report Settings** > **Artifact Report** > **On**.

Heart Rate

CP 100, CP 200
A four-beat average heart rate (HR) now appears in real time on the screen.

Body Mass Index

CP 100, CP 200
The patient's body mass index (BMI) now appears on the Enter New Patient screen and on ECG and spirometry reports when height and weight are entered.

Compliance With 60601-2-51

CP 100, CP 200
The electrocardiograph is in compliance with regulatory standards CAN/CSA C22.2 No. 60601.2.51 and IEC/EN 60601-2-51. For manufacturer's disclosures regarding 60601-2-51, please contact Welch Allyn Customer Service at the phone number listed in the Directions for Use.

Pacemaker Detection Prompt

CP 100, CP 200

If the software detects the possible presence of a pacemaker, it now asks you whether the patient has a pacemaker. If you say no, interpretation (if purchased) is included in the report. If you say yes, interpretation is not included in the report. This prompt was added to prevent false pacemaker pulses caused by environmental interference.

Symbols and International Characters

CP 100, CP 200

You can now enter symbols and international characters using the keyboard.

To enter a symbol, hold the Shift key while pressing a number key. To enter an international character, hold the Ctrl key while pressing a key with an international character above it on the keyboard label. To capitalize an international character, hold Shift + Ctrl while pressing the key.

CAPS Lock

CP 100, CP 200

You can now turn CAPS Lock on and off in the software. This feature works just like a standard Caps Lock key.

To turn CAPS Lock on or off, press the Menu key ⊞.

Choose **System Settings** > **Device Configuration** > **CAPS Lock** > **On** or **Off**.

Swedish, Danish, and Finnish Patient ID Processing

CP 100, CP 200

When you enter a valid Swedish, Danish, or Finnish patient ID, the patient's date of birth/age, gender, and race are now automatically filled in.

"Repeat Test" Softkey

CP 200

The ECG post-print screen now includes a Repeat Test softkey to let you more efficiently repeat a test.

Test Directory Usability

- **CP 200**
  More convenient searching
  When searching the test directory, you can now enter partial search criteria in the
  Patient ID or Last Name fields. For example, to find all patient IDs starting with 12
  (including 129374, 12579-125, and 12049-7564), you would enter 12 in the Patient ID
  field. To find all patients with last names starting with Jo (including Jones, Johnson,
  and Johnston) you would enter Jo in the Last Name field.

  Note: Searching is case-insensitive.

- **Flexibility in selecting tests from search results**
  You can now select tests from test directory search results in various ways instead of
  all tests being automatically selected.

  To select a contiguous group of tests, press and hold Shift while pressing an arrow
  key. To select an individual test, press an arrow key. To select all tests, press Ctrl-A.

- **Ability to delete saved tests**
  To delete tests, press the Menu key 〔▤〕. Choose **Test Directory**. Fill in the criteria,
  and press **Search**. In the Search Results screen, choose the tests that you want to
  delete. Press the **Delete** softkey.

External Printer

CP 100, CP 200
You can now connect an external printer. It must be a USB inkjet or laser printer that
supports PCL (printer control language), such as the following:

Vendor	Model	PCL Version
HP	Deskjet 995c	PCL 3
HP	Deskjet 5650	PCL 3 enhanced
HP	Laser 1022	PCL 5E
Dell	Laser 1710	PCL 5E & PCL 6
Lexmark	Laser E240	PCL 6

Printouts are always black and white.

When the external printer is selected in the Device Configuration screen and is powered
on and connected to the electrocardiograph, it prints the following:

- Auto ECG reports
- Spirometry reports (CP 200 spirometry option only)
- Device settings
- Audit trails (CP 200 only)
- Help pages

Rhythm ECGs always print to the internal printer.

To connect a printer, simply connect one end of a USB cable to the printer's USB
connector, and connect the other end to the electrocardiograph's USB connector.
No special software is required.

To select a printer, press the Menu key ⊞.

Choose **System Settings** > **Device Configuration** > **Printer Select** > **Internal** or **External**.

⚠️ **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.

Removable USB Storage Devices

CP 100, CP 200

You can now send tests to removable USB storage devices. If both an SD memory card and a USB storage device are connected, files are sent to the SD card. The capacity of an SD card must be $\geq$ 64 MB, $\leq$ 2 GB.

Note   The CP 100 and CP 200 do not support SD card capacities greater than 2 GB including SDHC and SDXC high capacity SD card formats, or other USB storage devices that have software applications pre-installed such as SanDisk U3 Smart technology.

Contact Information for Accessories
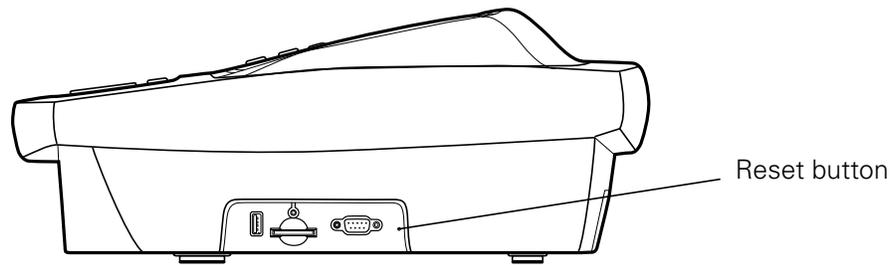
CP 100, CP 200

It is now possible to enter contact information that will appear on the accessories Help page.

To enter or review the contact information, press the Menu key ⊞. Choose **System Settings** > **Device Configuration** > **Contact Information**.

Reset Button

CP 100, CP 200

If the electrocardiograph is unresponsive for an extended time, it might be "frozen." If this occurs, reset the electrocardiograph by pressing the reset button located on the right side. To press the reset button, insert a small object, such as small paper clip, into the hole.

Reset button

Improved Battery Status Feedback

CP 100, CP 200
Whenever the battery is charging and is not yet fully charged, this icon appears: [icon].

For maximum battery performance, as often as possible leave the electrocardiograph plugged in until you see the "fully charged" icon: [icon] .

New Auto ECG Report Format

CP 100, CP 200
There is a new Auto ECG report format: 2x6 +1R (2 rows x 6 columns + 1 rhythm lead).

Configurable Default Rhythm Speed

CP 200
You can now change the default rhythm speed: 10, 25, or 50 mm/s.

To change this default, press the Menu key [icon]. Choose **ECG Settings** >
Rhythm Report Settings > **Default Rhythm Speed**.

Transferable Configurations

CP 100, CP 200
You can now transfer the configuration of one electrocardiograph to another (CP 200 to
CP 200, or CP 100 to CP 100). If you have the spirometry option, its configuration is
included in the transfer.

To transfer a configuration, follow these steps:

1. Insert a storage device (SD memory card or USB flash drive) into an
    electrocardiograph that is configured as desired.

2. Press the Menu key [icon].

3. Choose **System Settings** > **Device Info** > **Manage Settings** > **Export Files** >
    Export Configuration Files.

4. The files are copied to the storage device.

5. Remove the storage device, and insert it into another electrocardiograph of the
    same model.

6. Choose **System Settings** > **Device Info** > **Manage Settings** > **Import Files** >
    Import Configuration Files.

7. The files are copied to the electrocardiograph, and then it reboots.
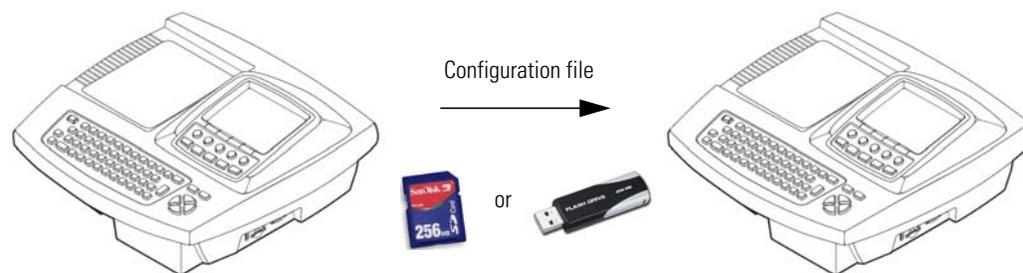
Spirometry Improvements

- **CP 200 Spirometry Option**
  Quicker access to spirometry settings
  When the electrocardiograph is in spirometry mode, the Menu key [≣] now immediately opens the Spirometry Settings menu.

- **PCP mode adjustments**
  In PCP mode, the V/T scaling was changed to AUTO, so the PCP printout now fits on a single page.

- **Physician's comments page**
  You can now choose whether spirometry reports include an additional blank page (with patient information at the top) for physician to write comments on.

  To determine whether this page prints with your reports, while in spirometry mode press the Menu key [≣]. Choose **Print Settings** > **Physician's Comments** > **Yes** or **No**.

- **Correction in Viljanen profile**
  The CP 200 Spirometry Option Directions for Use (mat. number 703411) indicates that the Viljanen norm supports FEF25. It does not. It supports FEF75.

- **Protocol settings disabled**
  When a spirometry protocol is selected (PCP, NIOSH, OSHA, or SSD), its settings are now disabled in the settings menus. This change avoids confusion during setup.

- **ATS/ERS 2005 compliance**
  The software is now compliant with ATS/ERS 2005 guidelines.

- **Effort automatic stop**
  The device now stops automatically after meeting the ATS end-of-test criteria. You do not have to press the Stop softkey.

- **Ability to turn off "Smoke Years" and "Packs Per Day"**
  You can now choose whether the fields "Smoke Years" and "Packs Per Day" will display and print. To turn these fields on or off, while in spirometry mode press the Menu key [≣]. Choose **Patient Data Settings** > **Smoke Years** or **Packs Per Day** > **On** or **Off**.

- **More norms supported**
  The software now supports these additional predictive norms: Roca 1986, Hedenström 1986 - females, Falaschetti 2004, Gore 1995, Forche II, Paoletti 1986, Hibbert 1989, Wang 1993. For details on these norms, see the updated chart on the following page.

Note For spirometry tests, the temperature and atmospheric pressure that you enter must be within these ranges:
Temperature: 10°–40° C, 50°–104° F
Pressure: 600–1100 mbar, 450–825 mmHg, 18–32 inHg, 60–110 kPa

Updated norm profiles

Norm Name (Abbrev.)	FVC	FEV1	FEV1%	FEV0.5	FEV3	FEV3/FVC	FEV6	FEV1/FEV6	PEF	FEF25-75	FEF75	FEF50	FEF25	FEF0.2-1.2	FEV0.5%	Male	Female	Pediatric	Adult	Height (cm)	Weight (kg)	Smoke Years	Caucasian	Black	Hispanic	Asian
Berglund 1963 (be)	X	X	X													X	X	≥ 7	≤ 70				X			
Crapo 1981 (cr)	X	X	X	X	X	X				X						X	X	No	M:15–91 F:17–84				X			
Dockery 1983 (do)	X	X														X	X	6–11	No	110–160			X	X		
ECCS/Quanjer 1993 (qu)	X	X	X						X	X	X	X	X			X	X	No	18–70	M:155–195 F:145–180			X	X		X
Falaschetti 2004 (fa)	X	X	X													X	X	No	16–94				X			
Forche II (fo)	X	X	X						X		X	X	X			X	X	5–17	18–90				X			
Gore 1995 (go)	X	X	X						X	X						X	X	No	18–78				X			
Gulsvik 2001 (gu)	X	X	X						X	X						X	X	No	M:15–91 F:17–84	M:157–194 F:146–178			X			
Hedenström 1986 (he)	X	X	X						X		X	X	X			X	X	No	20–70	M:160–196 F:148–183	M:55–109 F:45–94	M:15–55 F:2–53	X			
Hibbert 1989 (hi)	X	X	X						X		X	X	X			X	X	6–18	No	M:120–190 F:120–176			X			
Hsu 1979 (hs)	X	X							X	X						X	X	7–20	No	M:111–200 F:111–180			X	X	X	
Knudson 1976 (k)	X	X	X							X	X	X				X	X	≥ 8	≤ 90				X			
Knudson 1983 (kn)	X	X	X							X	X	X				X	X	≥ 6	M:≤ 85 F:≤ 88	M:111.8–195.6 F:106.7–182.9			X			
Koillinen 1998 (kl)	X	X	X	X					X			X			X	X	X	6–16	No				X			
Kory 1961 (ko)	X	X		X												X	No	No	18–66				X			
Morris 1971 (mo)	X	X								X				X		X	X	No	20–84				X			
NHANES III (nh)	X	X	X				X	X	X	X						X	X	≥ 8	≤ 80				X	X	X	
Paoletti 1986 (pa)	X	X	X						X	X						X	X	8–17	18–64				X			
Polgar 1971 (po)	X	X					X		X							X	X	3–19	No	110–170			X			
Roca 1986 (ro)	X	X	X						X	X		X				X	X	No	20–70				X			
Schoenberg 1978 (sc)	X	X	X						X		X	X				X	X	≥ 7	≥ 18		11.7–137.2		X	X		
Solymar 1980 (so)	X	X							X		X	X	X			X	X	7–18	No				X			
Viljanen 1981 (vi)	X	X	X						X		X	X				X	X	No	18–65				X			
Wang 1993 (wa)	X	X	X							X						X	X	6–18	No				X	X		
Zapletal 1969 (za)	X	X							X		X	X	X			X	X	6–18	No	M:118–181 F:107–173			X			

"Intended use" statement expanded

CP 100, CP 200

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

- Acquiring, viewing (CP 200), storing (CP 200), 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.

- Using the optional CP 200 spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function including, but not limited to, maximal volume and flow of air that can be moved in and out of the patient's lungs. These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases. The spirometer should only be used with patients able to understand the instructions for performing the test.

"Indications for use" statement expanded

CP 100, CP 200

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.

The optional CP 200 spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

Spirometry is indicated for use in various common clinical situations:

- Assessing health status before a patient begins strenuous physical activity.

- Evaluating the following symptoms, signs, or abnormal laboratory tests:

  Symptoms — dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain

  Signs — diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles, shortness of breath

  Abnormal laboratory tests — hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs

Enhanced pediatric support

CP 100, CP 200
An augmented lead set supports an alternate placement of the precordial leads on pediatric patients. This lead placement is easier to use on the small chests of infants and young children. A pediatric algorithm (PEDMEANS) is also provided for automatic ECG interpretation.The optional CP 200 spirometry module, which previously supported patients as young as six, now supports patients as young as three.

Configurable rhythm leads

CP 200
You can now configure the order in which leads appear during rhythm printing.

Bar code scanner

CP 200
A bar code scanner is available for easy entry of patient ID numbers.

Practice ID setting

CP 100, CP 200
You can now enter the name (ID) of your practice, clinic, or hospital. This ID prints on all ECG reports.

New report format

CP 100, CP 200
There is a new Auto ECG report format: 6x2 + 1R (6 rows x 2 columns + 1 rhythm lead).

Choice of QTc computation method

CP 100, CP 200
You can now choose the computation method of correcting the waveform's QT interval based on the heart rate: Bazett or Hodges.

More races added

CP 100, CP 200
Four more races are now available for entering patient data: Polynesian, Indian, Aboriginal, Native American.

New Features With Software Version 2.5

Location of printed date and time changed
The date and time on the ECG printout has been moved from the footer to the header on the ECG printout to make it easier to see and prevent confusion with other information printed in the footer.

Support of external memory devices
Drivers have been updated to support USB storage device with memory sizes greater than 2 GB.

> **Note**   The CP100 and CP200 do not support SD card capacities greater than 2 GB including SDHC and SDXC high capacity SD card formats, or other USB storage devices that have software applications pre-installed such as SanDisk U3 Smart technology.
>
> The larger the capacity of the USB storage device, the more time is needed to transfer files. Several minutes may be required to transfer files using large capacity USB storage devices. Please be patient.

Work flow changes to limit misidentified ECGS
For STAT or Auto ECGs without patient ID or name, the report Print Copy option will not be available - this is intended to prevent multiple copies of printed ECG reports without patient identification.

Appendix A – Specifications

CP100, CP200
Standard Connectivity

Com port for USB cables or removable USB storage devices (>64 MB)

SD memory card slot (for use with SD cards $\geq$ 64 MB, $\leq$ 2 GB)

> **Note**   The CP100 and CP200 do not support SD card capacities greater than 2 GB including SDHC and SDXC high capacity SD card formats, or other USB storage devices that have software applications pre-installed such as SanDisk U3 Smart technology.

Symbols

**CP100, CP200
Operation Symbols**

5134   Electrostatic sensitive devices
                      To indicate packages containing electrostatic sensitive devices, or to identify
                      a device or connector that has not been tested for immunity to electrostatic
                      discharge.
                      NOTE: For further information, see IEC 60747-1.

General Warnings

**CP100, CP200
Warnings related to Using the Electrocardiograph**

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

General Cautions

CP100, CP200

⚠ **Caution**   The Electrostatic sensitive devices symbol marked on the device indicates devices or connectors that are sensitive to electrostatic discharge which may result in an interruption of normal operation or damage to the device. Prior to connecting or disconnecting accessories from the device, touch the Equipotential stud located on the back of the device for 2 seconds or more to remove static electricity from your body.

CP100 and CP200 Directions for Use Chapter 5 updates

The following pages replace the applicable Chapter 5 pages in the previous versions of the CP 100 and CP 200 Directions For Use.

CP 100 12-Lead Resting Electrocardiograph Directions for Use (mat. 708794)

CP 200 12-Lead Resting Electrocardiograph Directions for Use (mat. 708793)

If your CP 100 electrocardiograph has a serial number of 10020000, or greater, or your CP 200 electrocardiograph has a serial number 20020000, or greater, this update describes the changes in the operation of your electrocardiograph.

If your electrocardiograph has a serial number that is lower than 1002000 or 2002000, and your device was recently serviced, it may contain some or all of these new features depending on the scope of the services performed.

Recording an Auto ECG

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

An Auto ECG is a report typically showing a 10-second acquisition of 12 leads of ECG information combined with patient data, interpretation, and measurements matrix. Two user-defined formats are available: Auto Report 1 or Auto Report 2. To learn how to set up the Auto ECG report format, see "About Auto ECG Reports" in the Directions for Use.

As shown in the following diagram, there are the two types of Auto ECG: normal and stat. For details, see these procedures:

- "Recording a Normal Auto ECG" on page 49
- "Recording a Stat Auto ECG" on page 53

Figure 31. Auto ECG Testing, Process Diagram
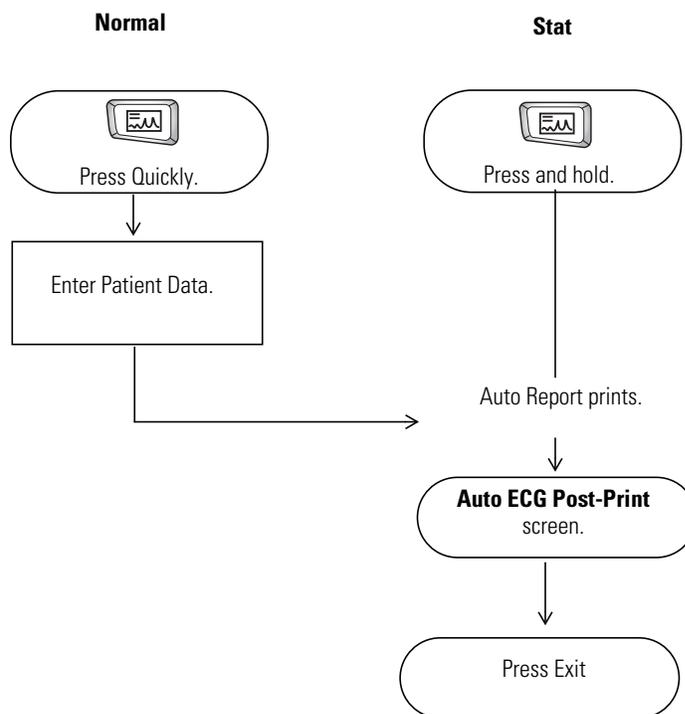
Recording a Normal Auto ECG

For a normal Auto ECG, you enter patient data and do other optional tasks before printing, as shown in Figure 31on page 48.

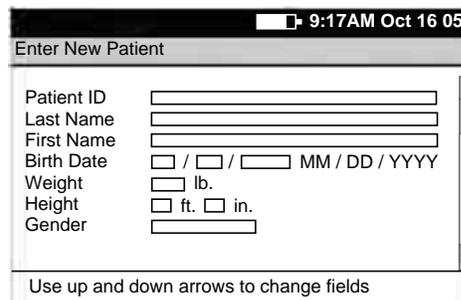**To Record a Normal Auto ECG**

1. Press the **Auto ECG** key [▣] quickly.

   Do not hold it down, or a stat ECG would begin.
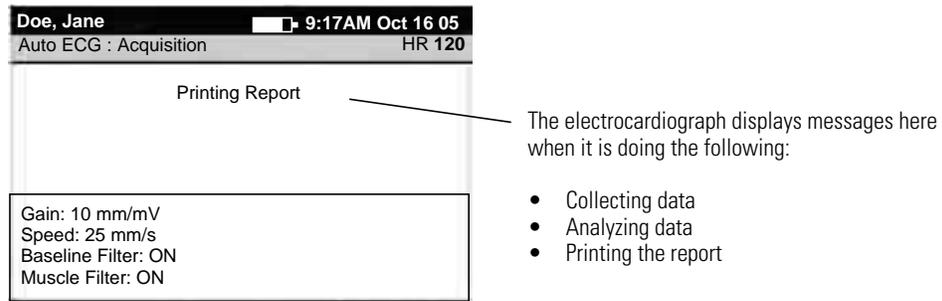
   The following screen appears.

   Figure 32. "Enter New Patient" Screen


   ```
                                   ▭▸ 9:17AM Oct 16 05
   Enter New Patient

   Patient ID      [              ]  ▲
   Last Name       [              ]
   First Name      [              ]
   Birth Date      [  ] / [  ] / [    ]  MM / DD / YYYY
   Weight          [    ] lb.
   Height          [  ] ft. [  ] in.
   Gender          [        ]         ▼

   Use up and down arrows to change fields
   ```

   For details about these data fields—including how to choose which fields display and print—see "Reviewing the Patient Data Fields Available" on page 37.

2. Enter the patient data.

3. When finished, select **Done** (at the end of the list).

   The **Auto ECG Acquisition** screen appears. See Figure 33 on page 50.

Figure 33. Auto ECG Acquisition" Screen

The electrocardiograph displays messages here when it is doing the following:

- Collecting data
- Analyzing data
- Printing the report

4. If prompted, choose whether to wait for the electrocardiograph to acquire 10 seconds of filtered, processed data before printing.

    If you override the wait time and print the available data immediately, be aware that the printed data will be insufficient in quality or quantity or both.
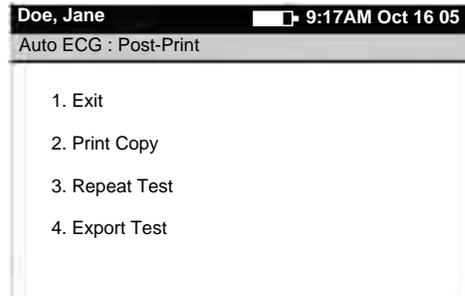
    The report prints.

Note   If you do not enter the patient data, write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

ECG report Print Copy feature will not be available if no Patient Name or ID are entered.

If a red stripe appears along the edge of your report, replace the paper. See "Loading the Thermal Chart Paper" on page 21.

After printing, the **Auto ECG Post-Print** screen appears. Figure 34 on page 51.

Figure 34. "Auto ECG Post-Print" Screen

Doe, Jane	▭▯ 9:17AM Oct 16 05
Auto ECG : Post-Print	
1. Exit	
2. Print Copy	
3. Repeat Test	
4. Export Test	

5. Select the desired item.

Item	Effect
Exit	The **Ready** screen appears if all leads are connected to the patient.
Print Copy	A copy of the test prints.
	Note Print Copy is not available for Stat Auto ECG, or if there is no Patient Name or ID entered for Auto
	To learn how to print multiple copies of all tests automatically, see "Reviewing the Interpretation and Copy Settings for Auto Reports" on page 36.
Repeat Test	The following screen appears.

Figure 35. "Auto ECG Repeat Test" Screen
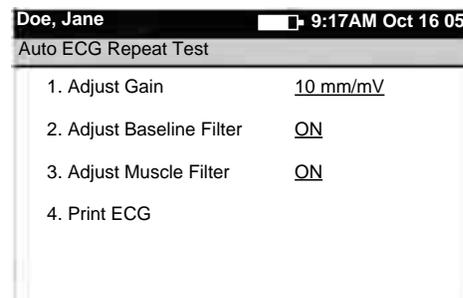
Doe, Jane	▭▯ 9:17AM Oct 16 05
Auto ECG Repeat Test	
1. Adjust Gain	10 mm/mV
2. Adjust Baseline Filter	ON
3. Adjust Muscle Filter	ON
4. Print ECG	

1. (Optional) Adjust the waveforms.
    See "Adjusting the ECG Waveforms" on page 55.

2. Choose **Print ECG**.
    A new report prints.

Note   If you do not enter the patient data, write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

Export Test	Sends the test to the memory card. An SD memory card or removable USB storage device must be in place.

6. Press Exit to complete patient testing.

⚠ **WARNING**   Failure to follow these instructions could incorrectly associate an ECG test with the wrong patient.

⚠ **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 requirements are unaffected by any other combination of filters turned on or off. Measurements performed by the optional interpretation algorithm are unaffected by any filter selections.
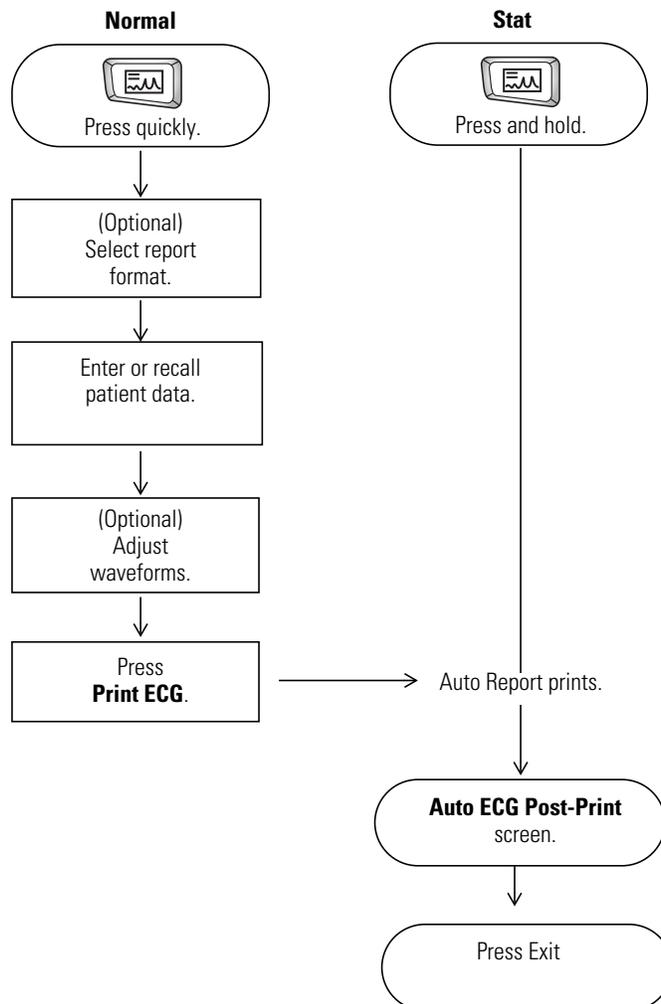
Recording a Stat Auto ECG

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

A stat Auto ECG is an immediate printout.

Stat mode bypasses patient data entry, as shown in Figure 31 on page 48 in Directions for Use. A temporary ID number is assigned to the patient to identify stat tests.

To Record a Stat Auto ECG

1. Press and <u>hold</u> the **Auto ECG** key 〔▧〕.

    The electrocardiograph begins acquiring ECG data. After it has acquired 10 seconds of quality data, it prints a report.

Note Write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

        ECG report Print Copy feature will not be available if no Patient Name or ID are entered.

2. Go to Step 4 on page 50.

Recording a Rhythm ECG

A Rhythm ECG is a continuous, real-time printout of three leads at a time.

Rhythm ECGs are printouts only. They cannot be sent to an SD memory card or removable USB storage device.

Figure 36. Rhythm ECG Testing, Process Diagram
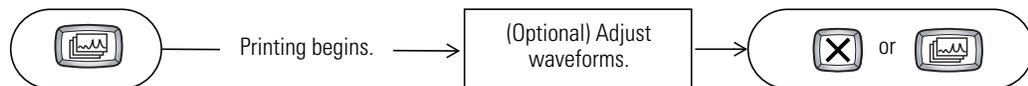
To Record a Rhythm ECG

1. Press the **Rhythm ECG** key [icon].

    Printing begins, and the following screen appears.

    Figure 37. "Rhythm ECG" Screen

2. (Optional) Adjust the waveforms.

    See "Adjusting the ECG Waveforms" on page 55.

3. Press [X] or [icon] to stop printing.

    The **Ready** screen appears if all leads are connected to the patient.

Note   Write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

Recording an Auto ECG

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

An Auto ECG is a report typically showing a 10-second acquisition of 12 leads of ECG information combined with patient data, interpretation, and measurements matrix. To learn how to set up the Auto ECG report format, see "About Auto ECG Reports" on page 39.

As shown in the following diagram, there are the two types of Auto ECG: normal and stat. For details, see these procedures:

- "Recording a Normal Auto ECG" on page 57
- "Recording a Stat Auto ECG" on page 62

Figure 36. **Auto ECG Testing, Process Diagram**

Recording a Normal Auto ECG

For a normal Auto ECG, you enter patient data and do other optional tasks before printing, as shown in Figure 36 on page 56.

To Record a Normal Auto ECG

1. Press the **Auto ECG** key 〖 🔲 〗 quickly.

    Do not hold it down, or a stat ECG would begin.

2. If prompted, choose **Auto Report 1** or **Auto Report 2**.

    The following screen appears.

    Figure 37. "Enter New Patient" Screen
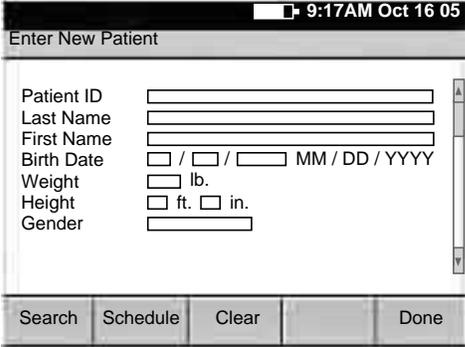
For details about these data fields— including how to choose which fields display and print—see "Reviewing the Patient Data Fields Available for Auto Reports" on page 44.

3. Enter or recall the patient data.

    •   If you are using a bar code scanner, scan the patient's bar code. The patient ID appears on the screen.

   •   If you want to enter the patient data, fill in the fields.

Note   If you do not enter the patient data, write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

    ECG report Print Copy feature will not be available if no Patient Name or ID are entered.

    •   If you want to recall saved patient data, go to "Recalling Saved Patient Data" on page 64.

        When finished, press the desired softkey:

            Clear deletes the entered data and returns to the **Patient ID** field.

            Done accepts the entered data and goes to the **Auto ECG Acquisition** screen. See Figure 38 on page 58.

Figure 38. Auto ECG Acquisition" Screen
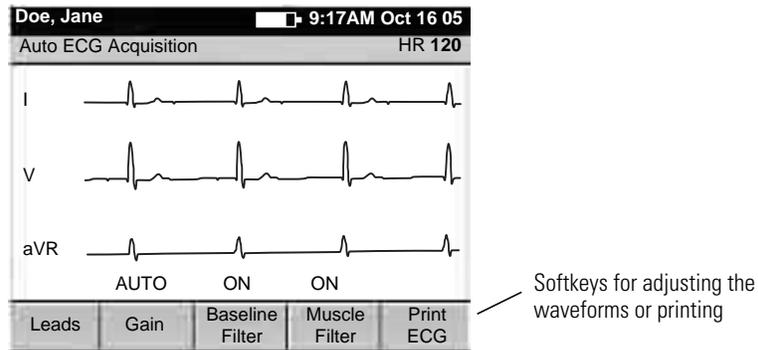
4. Verify ECG quality on the screen.

    ⚠️ **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.

5. (Optional) Adjust the waveforms.

    See "Adjusting the ECG Waveforms" on page 68.

6. Press **Print ECG**.

7. If prompted, choose whether to wait for the electrocardiograph to acquire 10 seconds of filtered, processed data before printing.
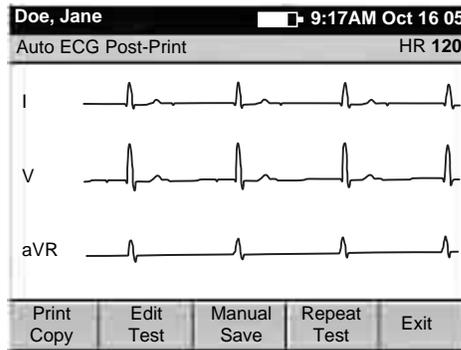
    If you override the wait time and print the available data immediately, be aware that the printed data will be insufficient in quality or quantity or both.

    The report prints.

    Note   If you do not enter the patient data, write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

    If a red stripe appears along the edge of your report, replace the paper. See "Loading the Thermal Chart Paper" on page 23.

    After printing, the **Auto ECG Post-Print** screen appears. Figure 39 on page 59.

Figure 39. "Auto ECG Post-Print" Screen

Softkeys for choosing
post-printing options

8. Press the desired softkey.

Softkey	Effect
Print Copy	Prints a copy of the test.
	Note Print Copy is not available for Stat Auto ECG, or if there is no Patient Name or ID entered for Auto
	To learn how to print multiple copies of all tests automatically, see "Reviewing the Interpretation and Copy Settings for Auto Reports" on page 43.
Edit Test	Brings up the **Edit Test – Patient Data** screen. From here you can edit or confirm the patient data and interpretation statements. See "To Edit or Confirm a Test Directly After Printing" on page 61.
Manual Save	Saves the test to the electrocardiograph's test directory. See "Managing Saved Tests In the Test Directory" on page 70.
	This **Manual Save** softkey appears only when Auto Save is disabled. For more on Auto Save, see "Reviewing the Miscellaneous ECG Settings" on page 48.
Manual Send	(May appear in place of Manual Save in Figure 4 on page 14.) Displays two softkey options:
	• **Memory Card** An SD memory card or removable USB storage device must be in place.
	• **Workstation** Either wireless communications must be configured or a USB cable must connect the CardioPerfect workstation to the electrocardiograph's Com port B (**IOIOI**).
	This **Manual Send** softkey appears only when Auto Save is enabled. For more on Auto Save, see "Reviewing the Miscellaneous ECG Settings" on page 48.
Repeat Test	Lets you repeat a test for the current patient.
Exit	The **ECG Preview** screen appears if all leads are connected to the patient.

9. Press Exit to complete patient testing.

⚠️ **WARNING** Failure to follow these instructions could incorrectly associate an ECG test with the wrong patient.

⚠️ **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 requirements are unaffected by any other combination of filters turned on or off. Measurements performed by the optional interpretation algorithm are unaffected by any filter selections.

To Edit or Confirm a Test Directly After Printing

Note A qualified physician must review and confirm all tests before patients are treated. If changes are needed for any saved test, you can edit two types of data:

- patient data
- interpretation statements

1. From the **Auto ECG Post-Print** screen (Figure 39 on page 59), press **Edit Test**.

    The **Edit Test – Patient Data** screen appears.

2. (Optional) Edit the patient data.

3. Press the desired softkey.

Softkey	Effect
Interp	Saves any changes, and displays the **Edit Test – Interpretation** screen. 1. (Optional) Edit the interpretation statements to be saved with the test. 2. Press the desired softkey: • **Patient Data** saves any changes, and returns to the **Edit Test – Patient Data** screen. • **Confirm** saves any changes, sets the test status to "confirmed," and returns to the **Auto ECG Post-Print** screen. • **Cancel** discards any changes, and returns to the **Auto ECG Post-Print** screen. • **Done** saves any changes, and returns to the **Auto ECG Post-Print** screen. For details on interpretation, see "Automatic ECG interpretation" on page 5.
Cancel	Discards any changes, and returns to the **Auto ECG Post-Print** screen.
Done	Saves any changes, and returns to the **Auto ECG Post-Print** screen.

Recording a Stat Auto ECG

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

A stat Auto ECG is an immediate printout in Auto Report 1 format.

Stat mode bypasses patient data entry, as shown in . A temporary ID number is assigned to the patient to identify stat tests. After printing, you may enter the patient data by editing the test.

In stat mode, Auto Send and Auto Save are always disabled, even if they are enabled in the ECG settings. If you want to send or save a stat Auto ECG, you may do so manually after you print.

To Record a Stat Auto ECG

1.   Press and <u>hold</u> the **Auto ECG** key [📟] .

     The electrocardiograph begins acquiring ECG data. After it has acquired 10 seconds of quality data, it prints a report.

Note   Write the patient identification information on the printed report immediately after the ECG test to avoid associating the ECG report with the wrong patient.

     ECG report Print Copy feature will not be available if no Patient Name or ID are entered.

2.   Go to .

     Continue the procedure as if you have just pressed the **Print ECG** softkey.

Recording a Rhythm ECG

A Rhythm ECG is a continuous, real-time printout of a rhythm strip with a user-defined lead arrangement. For details on reviewing or changing the lead arrangement in your reports, see "Reviewing the Rhythm Report Settings" on page 47.

Rhythm ECGs are printouts only. They cannot be saved or sent electronically.

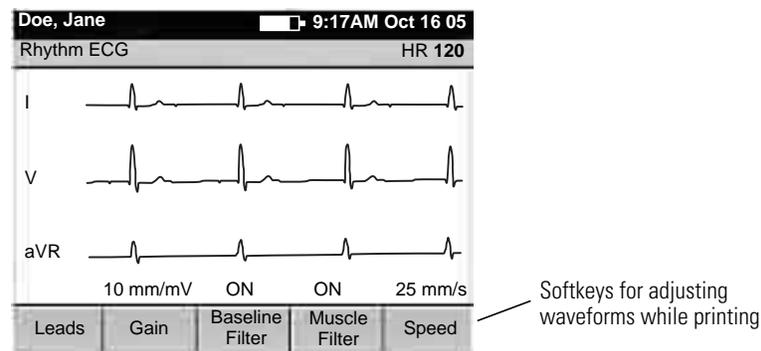**Figure 40. Rhythm ECG Testing, Process Diagram**
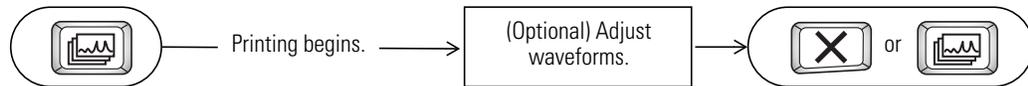
To Record a Rhythm ECG

1. Press the **Rhythm ECG** key .

    Printing begins.

    The screen displays 3 leads at a time from the leads currently printing. The printout includes either 3, 6, or 12 leads at a time. To find out how to change this number, see "Reviewing the Rhythm Report Settings" on page 47.

Figure 41. "Rhythm ECG" Screen

2. (Optional) Press the softkeys to adjust the waveforms.

    See "Adjusting the ECG Waveforms" on page 68.

3. Press or to stop printing.

    The **ECG Preview** screen appears if all leads are connected to the patient.

Welch Allyn®

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