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Welch Allyn Ltd.
Navan, Co.Meath
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Date:

URGENT: FIELD SAFETY NOTICE

This is a Field Safety Notice containing important information regarding the safe operation of the Welch Allyn CP200 (Electrocardiograph with optional Spirometry)

DISCLAIMER: Welch Allyn has determined that there is no deficiency with this device. Welch Allyn is availing of this opportunity to assist our customers in the correct use of the device.

Dear Welch Allyn CP 200™ user:

Before the CP 200 generates an electrocardiograph (ECG) report in the Normal Auto ECG mode, the CP 200 requires entering the patient identification. The print of the ECG report will then display the patient identification. This is to avoid associating a report with a wrong patient.

However, the CP 200 has an **Auto ECG mode** where the user can override the required patient identifier. Moreover, the **Stat ECG mode** generates an ECG report without an associated patient identifier. The ECG report will then not display patient identification. Such reports without associated patient identifiers may be also intentionally printed for another time by the use of the “print copy” soft key. If you choose to routinely operate in Stat ECG mode or Auto ECG mode without patient identification:

Always write the patient identification information on the printed report and also on any print copy immediately after the ECG test to avoid associating the report with the wrong patient. You will find this instruction several times in the Directions for Use.

Where - after printing a **Stat ECG** for a patient - the user does not exit the Auto ECG Post-Print screen, connects the CP 200 to a new patient, and by mistake presses the “print copy” soft key instead of the Auto ECG button, the user will erroneously print a duplicate of the previous patient’s ECG report. The user may then believe the print copy belongs to the new patient. In order to avoid any such associating of a report with a wrong patient, please always follow the Directions for Use. In particular, if you choose to operate in Stat ECG mode or to omit the patient identifier in Auto ECG mode:

1. **Always** exit the Auto ECG Post-Print screen by pressing the Exit button after printing an ECG report.
2. **Always** press the Auto ECG button to obtain an ECG report for the next patient.

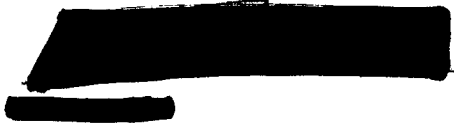
These two basic steps are explained in Chapter 5 of the CP 200 Directions for Use. The CP 200 also has “quick reference” instructions printed on the blue printer paper door, which include a picture of the Auto ECG button.

As an alternative to the “print copy” function, the user may choose to remove this by installing the enclosed software upgrade. It will limit printing of ECG reports without associated patient identifiers to a single copy only. This software-imposed printing limit will help prevent print copies from being associated with wrong patients.

If you have questions, please contact your local sales representative or Welch Allyn Technical Support:

Canada 1-800-561-8797	European Call Center +353-46-906-7790	Germany +49-747-792-7186	Latin America +1-305-669-9003	Singapore +65-6419-8100
United Kingdom +44-207-365-6780 (press Option 2)	Australia +61-29-638-3000	China +86-216-327-9631	France +33-1-6009-3366 (press Option 2)	Japan +81-33-219-0071
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Yours sincerely,



Director, International Quality Assurance & Regulatory Affairs