CP300

12 Channel ECG Recorder

Service handbook

Art. no.: 714095 rev.: b

WelchAllyn®

Distributed by

Welch Allyn
4341 State Street Road, PO Box 220
Skaneateles Falls, NY 13153-0220
www.welchallyn.com

Sales and Service information:
For information about any Welch Allyn product, please call Welch Allyn Technical Support:

USA	1 800 535 6663
	+ 1 315 685 4560
Australia	+ 61 29 638 3000
Canada	1 800 561 8797
China	+ 86 216 327 9631
European Call Center	+ 353 46 906 7790
France	+ 331 6009 3366
Germany	+ 49 747 792 7186
Japan	+ 81 33 219 0071
Latin America	+ 1 305 669 9003
Netherlands	+ 31 15 750 5000
Singapore	+ 65 6419 8100
South Africa	+ 27 11 777 7555
United Kingdom	+ 44 207 365 6780
Sweden	+ 46 85 853 6551

Welch Allyn LTD.
Navan Business Park
Dublin Road
Navan, County Meath, Republic of Ireland
Tel.: 353-46-90-67700
Fax: 353-46-90-67755

Produced by

SCHILLER AG
Altgasse 68
CH-6341 Baar, Switzerland

Article No: 714095 rev.: b
SAG 2.540052
Issue date: 26.01.10

Contents

Art. no.: 714095 rev.: b

Art. no.: 714095 rev.: b

Art. no.: 714095 rev.: b

Art. no.: 714095 rev.: b

1 Safety Notes

This Service Handbook is for qualified service personnel only, trained by Welch Allyn. Refer to the operating instruction manual 714250 for operation the device.

1.1 Responsibility of the User

- Specify the competencies of the personnel for operation and repair.
- Ensure that service personnel have read and understood these service instructions. In particular this section “safety notes" must be read and understood.
- Have damaged or missing components replaced immediately.
- The service personnel is responsible for compliance with all applicable accident prevention regulations and safety regulations.

1.2 Intended Use

- The CP300 is a 12-channel, ECG device used for the recording, analysis and evaluation of ECG Recordings. Recordings made with the CP300 can be used as a diagnostic aid for heart function and heart conditions. The CP300 is designed for indoor use and can be used for all patients of both sexes, all races, and all ages.
- Only operate the device in accordance with the specified technical data.
- Do **not** use or repair this unit in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.

1.3 Organizational Measures

- Before servicing the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided by Welch Allyn
- Keep these service instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- Observe the operating instructions and service instructions.
- These service instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.

Art. no.: 714095 rev.: b

1.4 Safety-conscious Operation

- ▲ Do not place any liquids on the unit. If liquid should be spilled over the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- ▲ Danger of electric shock! Do not open the device without disconnecting the device from the mains.
- ▲ Before cleaning and to isolate the mains power supply, switch the unit off and disconnect it from the mains by removing the plug.
- ▲ Do not use high temperature sterilization processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.
- ▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- ▲ Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

1.5 Safety Facilities

- ▲ Operating the device without the correctly rated fuse, or with defective cables, constitutes a danger to life. Therefore:
  - – Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
  - – Damaged cable connections and connectors must be replaced immediately.
  - – The electrical safety devices, such as fuses, must not be altered.
  - – Ruptured fuses must only be replaced with the same type and rating as the original.

1.6 Operation with other Devices

- ▲ Use only accessories and other parts recommended or supplied by Welch Allyn. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ Ancillary equipment connected to the analogue and/or digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
  - – EC/EN 60601-1-1 states that the patient must remain at least 5 feet clear of the unit. If this is not possible, a safety isolating transformer must be installed.

Art. no.: 714095 rev.: b

1.7 Safety Symbols and Pictograms

1.7.1 Symbols Used in this Document

The safety level is classified according ANSI Z535.4. The following overview shows the used safety symbols and pictograms used in this manual.

For a direct danger which could lead to severe personal injury or to death.

For a possibly dangerous situation, which could lead to heavy bodily injury or to death.

For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

For general safety notes as listed in this chapter.

Used for electrical dangers, warnings and other notes in regarding operation with electricity.

Note For possibly dangerous situations, which could lead to damages to property or system failure. **Important** or helpful user information

Reference to other guidelines

Observe precautions for handling electrostatic sensitive devices

Tools required for a procedure.

Art. no.: 714095 rev.: b

1.7.2 Symbols Used on the Device

Potential equalization

CF symbol. This unit is classified safe for internal and external use. However, It is only defibrillation protected when used with the original patient cable!

Inappropriate disposal can lead to environmental pollution.

Units/components and accessories no longer required can be returned to Welch Allyn for disposal. Alternatively, the unit should be disposed of in a municipally approved recycling center.

CE 0123

Notified body of the CE certification (TÜV P.S.)

Attention: Consult accompanying documents.

1.8 Terms of warranty

The Welch Allyn CP300 is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by him, and
- the Welch Allyn CP300 and approved attached equipment is used in accordance with the manufacturers instructions.

Art. no.: 714095 rev.: b

2 Introduction

The Welch Allyn CP300 is a diagnostic workstation designed to record, display, archive, present, and analyse ECG recordings and other measurements. 12-lead resting ECG recordings give measurements, interpretation, average cycles and rhythm sections as standard. Exercise testing includes predefined stress protocols and dedicated keys for treadmill control. All leads and measurements can be printed in the format most convenient to the physician and print formats can be predefined.

2.1 Standard Features

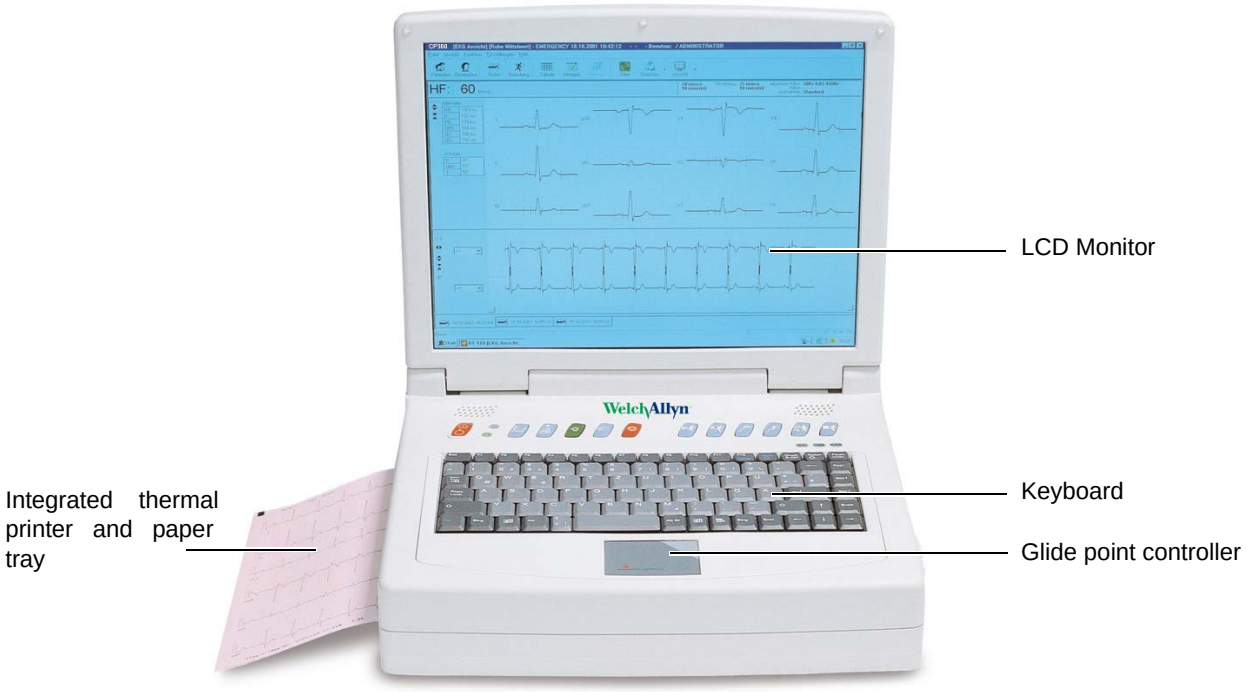
- Simple one key operation with dedicated function keys and icons
- Glide point controller for menu and function selection
- Resting ECG with measurements and average cycles
- Storage facilities for ECGs
- Interfaces for control of digital ergometers / treadmills
- Automatic and real-time manual ECG recording
- Integrated quality thermal printer

2.2 Options

- ECG interpretation
- Exercise ECG with analysis program with ST measurement, average complexes and trends
- External Printer
- External pointing control device (e.g. mouse, trackball)
- External keyboard
- SEMA-200 database

Art. no.: 714095 rev.: b

2.3 Main Components of the CP300



2.4 Operating Philosophy

The operating philosophy of the CP300 is that users are allocated user rights which allow access to specific functions. Several user levels are available. It is the system administrator / Manufacturers technician who defines the users and allocates the user level.

The levels are as follows:

Level	User Rights
Emergency	This only allows the user to carry out and view an emergency ECG. Any user can carry out an emergency ECG without login.
Medical technician	Recording (resting and exercise ECGs), patient data entry and patient data editing. Viewing of all recordings.
Physician	As above plus validation of all recordings in a defined department. Access to all user settings.
Supervising Physician	As above plus validation of all recordings in any department.
Administrator	As above without validation. Access to all system settings and defining new users.
Manufacturers Technician	Access to all system settings and defining new users. The manufacturers technician cannot make a recording (except emergency), and has no access to patient data or patient recordings.

Art. no.: 714095 rev.: b

2.5 Default Login Codes

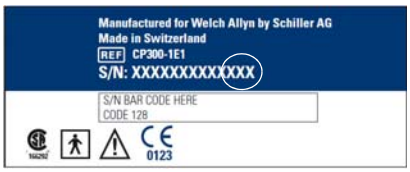
There are default login codes for **Manufacturers technician** and **Administrator** login levels. Only Manufacturers technician login level has access to unit firmware update, software option update and other menu options. The default logins are as follows:

Manufacturers technician

User Name: sysop
Password: pt160

Administrator

User Name: admin
Password: serial number of the unit



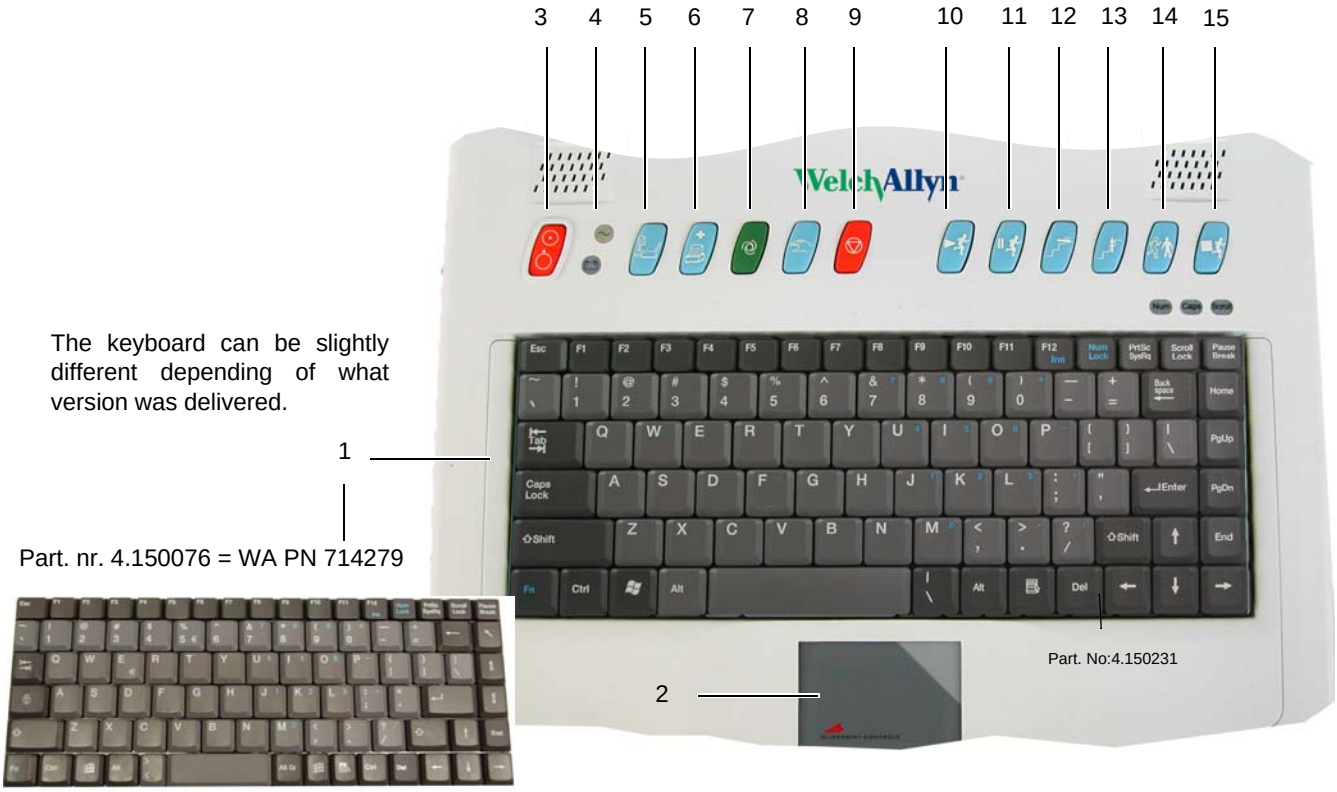
The serial number of the unit is printed on a label attached to the bottom of the unit. Use the last 3 digits of the number ignoring any preceding `0`s. In the example given, `163` is number that must be entered.

Menu options and function icons are only displayed on the screen when user rights allow. This User Guide makes no distinction for the settings available. If a menu item or function described in this book is not available, check your user level displayed at the top of the screen.

Users are defined in the **settings menu** > Login/startup, Users, Departments..... (**see page 50**).

Art. no.: 714095 rev.: b

2.6 Keypad



The keyboard can be slightly different depending of what version was delivered.

(1) Alpha-numeric keyboard. The keys F1 to F10 have varying functions depending on use (see page 18).

(2) **Glide point controller** (see page 21)

(3) **On/off** key

(4) **Power Source Indicators** - mains (upper indicator) and battery (lower indicator). The mains indicator shows that mains is connected: the battery lamp indicates that the unit is running on battery power (mains power disconnected during use - limited screen display and printout possibilities).

(5) **Paper tray open close** key for paper replacement.

(6) **Easy print (and Emergency**) Key - obtain a printout in normal use and an (emergency) printout at any time in the event of mains power failure, or screen failure.

(7) **Auto** Key - start an ECG recording (resting) in auto mode.

(8) **Manual** key - continuous printout of ECG.

(9) **Stop** key - stop printout, run paper to start position.

Dedicated Exercise Keys

Keys 10 to 15 are keys dedicated to exercise testing.

(10) **Start** test

(11) **Interrupt** test (and stop treadmill)

(12) Hold Stage

(13) Next Stage

(14) Recovery Stage

(15) Stop Test

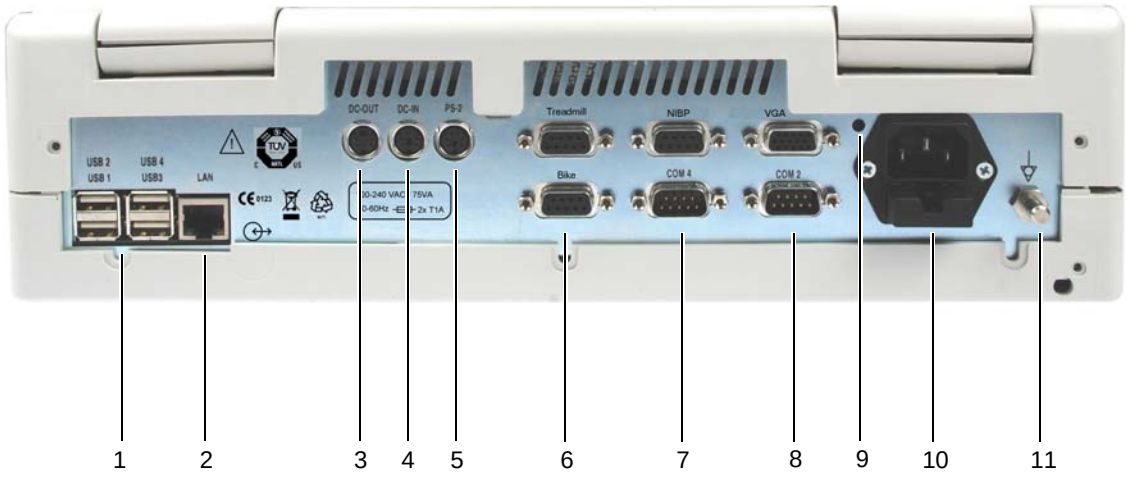
Art. no.: 714095 rev.: b

2.7 External Connections

⚠ CAUTION

▲ All externally connected hardware must be approved by Welch Allyn. Connection of any hardware not approved by Welch Allyn is at the owner's risk. The unit guarantee may also be invalid.

2.7.1 Back Panel



(1) Four **USB connectors** (Universal Serial Bus (version 1.1 protocol)). The USB connectors are used for connection of USB devices e.g. mouse, printer, bar-code reader, wireless LAN etc.

(2) **LAN** - Network connector (RJ45).

(3) **DC out connector** for the output of dc signals (range ±10 V) to, for example, another ECG device or monitor. Also used for the trigger output for the BP-200 BP unit.

(4) **DC In connector** for the input of dc (ECG) signals from another unit (range ±2.5 V).

(5) **PS-2 connector** for the connection of an external pointing device (e.g. mouse, trackball), or external keyboard. Use the Welch Allyn Y-cable, for connection of an external keyboard.

– When an external point and control device (e.g. mouse) is connected, the glide point controller is disabled. Similarly, when an external keyboard is connected, the CP300 keyboard is disabled.

(6) **Bike** connection (EXT 1, RS-232) : **Treadmill** (EXT 2, RS-232)

(7) **NIBP** connection (EXT 3 , RS-232) **COM 4** - not connected.

(8) **COM 2** (RS-232) - Connection of a spiro sensor: **VGA** - monitor connector for VGA standard monitors.

(9) **Master (Hardware) Reset**.

(10) **Mains connector**.

(11) **Potential equalization stud**. The potential equalization stud is used to equalize the ground potential of the unit to that of any nearby mains powered equipment. Use the hospital or building common ground for all mains powered units.

Art. no.: 714095 rev.: b

2.7.2 Side Panel

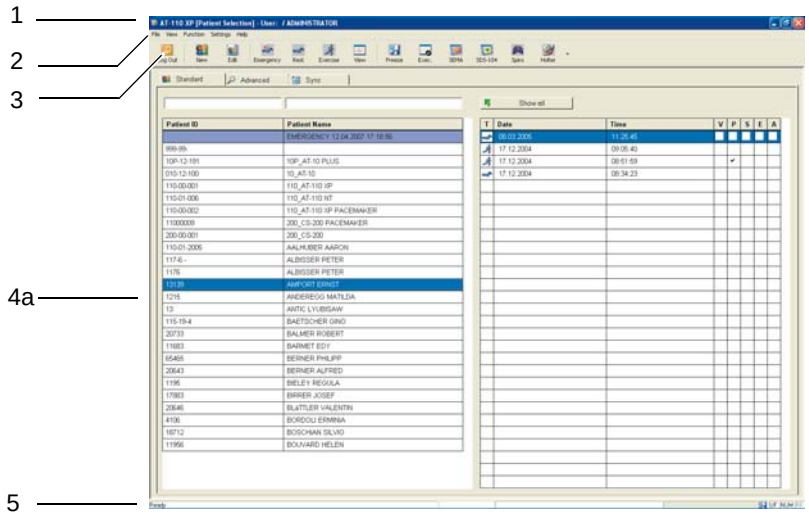
The connection for the ECG patient cable is situated on the right hand side panel of the unit.

- The patient cable and connector is CF ⊣♥⊢ rated, that is fully floating and isolated, defibrillation protected, suitable for intra-cardiac application.
- The unit is only CF rated and defibrillation protected if used with the original patient cable.

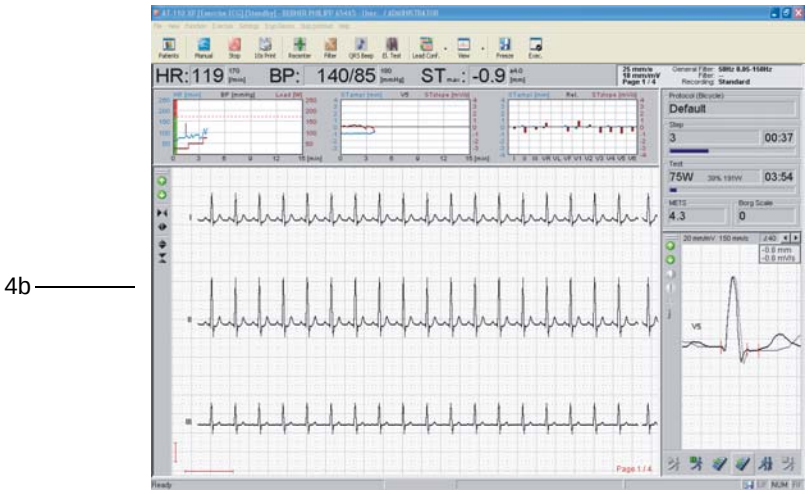
Art. no.: 714095 rev.: b

2.8 The Display

Example of the Patient Screen



Example of an aquisition Screen (exercise)



The display will vary according to the current task being carried out. In all screens however, the top, middle and bottom areas display the same information groups. The following gives examples of the patient screen and the exercise acquisition screen.

(1) **Header line** - the top line gives general information as follows:

- current screen type (resting, exercise, patient, etc.)
- patient name and number (acquisition screen only)
- the user, and the user login level.
- Menu line - below the header are the menu options.

(2) **Menu Line** - the menu options will vary according to the screen displayed and the user login level.

(3) **Function icons** - these change according to the screen displayed, system settings and the user login level.

(4) **Data area** - main data area according to the screen selected.

- in the patient screen **(4a)** this area displays the database information and includes all stored patients and associated recordings.
- In the data acquisition screens **(4b)**, this area displays the real time data.
- In the view screens (not shown), this area displays the recorded data.

(5) System Information

Art. no.: 714095 rev.: b

3 Function Keys

3.1 Function Key Table

	Patient Screen	Recording Screens		View Screens	
Function Key		**Resting ECG**	**Exercise ECG**	**Resting ECG**	**Exercise ECG**
F1					
<Ctrl> F1	→ Start Emergency Acquisition Screen				
F2					
<Shift> F2	→ Edit Patient	→ Edit Patient	→ Edit Patient	→ Edit Patient	→ Edit Patient
<Ctrl> F2	→ Start Resting Acquisition Screen (with selected patient)				
F3	→	→ Start Manual Printout	→ Start Manual Printout		
<Ctrl> F3	→ Start Exercise Acquisition Screen (with selected patient)				
F4		→ Stop Manual Print	→ Stop Manual Print		
F5		→ Autostart (Recording)	→		
F6		→ Filter	→ Filter	→ Filter	→ Filter
<Shift>F6		→ center Signal	→ center Signal		
F7			→ Start/Begin/ Recovery		
F8					
F9					
F10					
Esc					
PgDn	→ PgDn	→ Previous lead group	→ Previous lead group	→ Previous lead group	
PgUp	→ PgUp	→ Next lead group	→ Next lead group	→ Next lead group	
up (arrow)	→ up	→ Previous lead	→ Previous lead	→ Previous lead	→ Previous lead
down (arrow)	→ down	→ Next lead	→ Next lead	→ Next lead	→ Next lead
left (arrow)			→ J-point -		→ J-point - / scroll
right (arrow)			→ J-point +		→ J-point + / scroll

Art. no.: 714095 rev.: b

4 Operation

4.1 Start-up and Initial Preparation

⚠ DANGER

▲ Danger of electrical shock. Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.

4.1.1 Location

- Do not keep or operate the unit in a wet, moist, or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapors or liquids.
- The CP300 should not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

4.1.2 Connection of External Cable Assemblies and Ancillary Equipment

1. Connect the power cable at the rear of the unit. The Mains indicator lamp is lit.
2. Connect the patient cable (side panel).
3. Connect any ancillary and optional equipment (see page 15). These may include the following:
   – Ergometer (analogue or digital) for exercise testing
   – External monitor
   – Network cable
   – External printer

4.1.3 Potential equalization

The potential equalization stud at the rear of the unit is used to equalize the ground potential of the CP300 to that of all mains powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option.

To avoid possible interference from the ergometer when carrying out an exercise test, it is recommended that both the CP300 and the ergometer are connected to the same common ground.

⚠ CAUTION

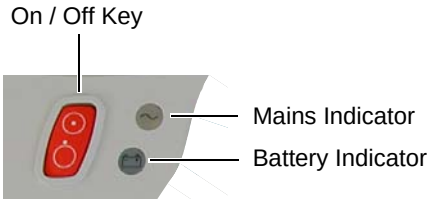
▲ To prevent the possibility of leakage current when an external printer, external monitor, or ergo device is connected, always ensure that the mains lead (with earth grounding connection), and / or the potential equalization, is attached to the CP300.

Art. no.: 714095 rev.: b

4.1.4 Switching ON and OFF

The unit is switched on and off with the **On / Off** key.

4.1.5 Power Supply and Backup Battery Operation



The unit is operated from the mains supply. When mains is connected the mains indicator is lit.

An internal backup battery is provided for emergency use in the event of a mains power failure. If a power failure occurs the screen goes blank but the processor continues to function. The backup battery provides enough power for approximately 15 minutes of use. The Battery indicator is lit when running on battery power and blinks when the battery capacity is low.

Mains and battery LED Indicators

The LED indicators on the unit casing indicate the power operation as follows:

Function	Battery LED	Mains LED
Mains Connected:		
Battery Charging	• On	• On
Battery Full	• Off	• On
Emergency Battery Working:	• On	• Off
Battery capacity limited	• Blinking	• Off

The battery LED also blinks when the unit is shutting down. This indicates that the operating system has already closed and the system board is switching off.

4.1.6 Isolating the Mains Supply

To isolate the power supply, remove the mains plug from the wall socket.

4.1.7 System and ECG Settings

- The System Settings (time, date, user ID, etc.), and other general and ECG settings (macros, ergometer, etc.), are found in the System Settings section (see page 50).

Art. no.: 714095 rev.: b

4.2 Glide Point Controller Operation

Only light pressure is required to move the cursor and select items by tapping with the finger. The glide point controller will not work correctly if excessive pressure is used. To select any menu item or to confirm a setting, select a function etc., the procedure is the same.

Selecting an Icon

1. Move finger lightly over the glide point controller to position the cursor (arrow) on the icon that you wish to select.
2. Lightly `double tap` (same as a double click with a mouse) the glide point controller to select.

Pull down menu item

1. Move finger over the glide point controller - the cursor (arrow) on the screen moves.
2. Position the cursor on the horizontal menu bar and lightly tap the glide point controller - further menu items are displayed and can be selected in the same way.

Right Click Function

The lighter area in the top right corner of the glide pad has the same function as the `right` button on a conventional mouse.

4.2.1 Connecting a Mouse or Trackball Device

The CP300 can work with an external point and control device. When a mouse or trackball etc. is connected (to the PS-2 connector on the back panel), the glide point controller operation is disabled.

Art. no.: 714095 rev.: b

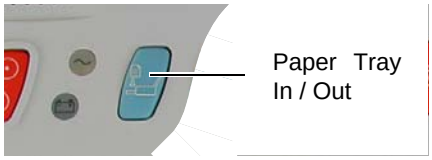
4.3 Changing the Printing Paper

Important

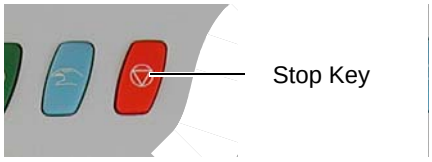
The device is delivered without printing paper installed. The thermo-paper is sensitive to heat, humidity and chemical vapors. The following points apply to both storage, and when archiving the results.

- Before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used.
- Store in a cool, dark and dry area.
- Do not store near chemicals e.g. sterilization liquids.
- In particular do not store in a plastic cover.
- Certain glues can react with the paper - do not attach the printout onto a mounting sheet with glue.

Welch Allyn can only guarantee perfect printouts when CP300 original chart paper or chart paper of the same quality is used.



1. Press the **Paper Tray** key to open the paper tray (remove any remaining paper from the paper tray if replacing paper.
2. Place a new paper pack into the paper tray with the printed (grid) side facing upwards and the black paper mark to the top of the unit.



3. Place the beginning of the paper over the black paper roller on the paper tray cover.
4. Press the **Paper Tray** key to return the paper tray in position.
5. Press the **Stop** key to transport the paper to the start position.

Art. no.: 714095 rev.: b

5 Physical and Functional Overview

5.1 Physical Overview

The CP300 unit is enclosed in a two part, medical standard, molded plastic case.

The top part contains the keyboard and the LCD screen with the base section containing all the electronics of the unit, the RS-232 interface, the thermal printer, the paper tray, the battery and mains transformer.

The electronics of the unit are contained on a single double sided printed circuit board, the main board (MK 17-1). This board is secured on spacers molded in the base section.

The battery is secured in position in a molded recess accessed from the bottom of the units, and the mains transformer is secured on spacers above the printed circuit board.

The thermal printer is mounted on spacers molded to the base and the paper tray motor mounted in a similar way.

Exploded views of the unit are given in the Construction Drawings section at the end of this book (see page 75).

5.2 Functional Overview

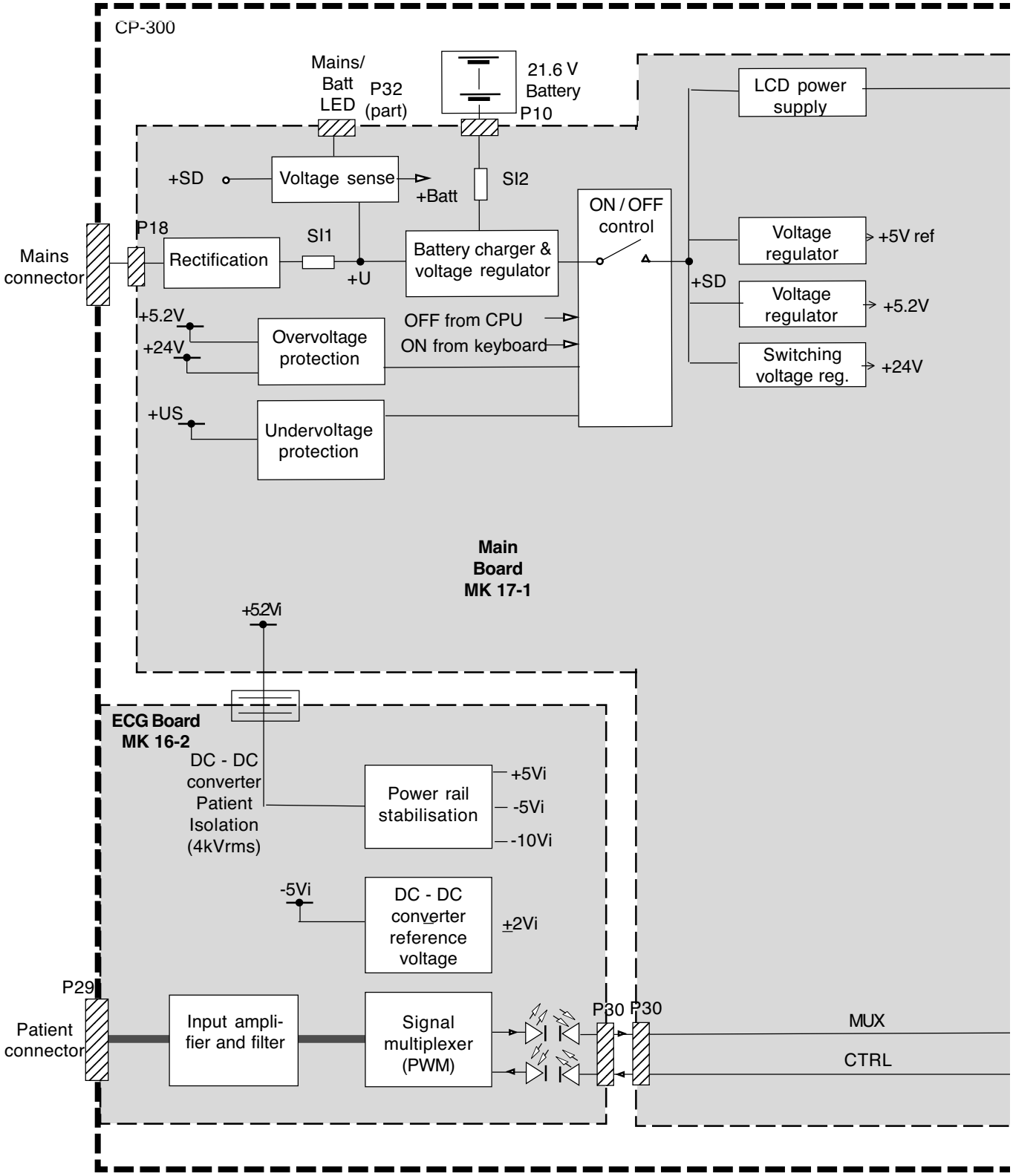
The CP300 has a PC architecture, including standard expansions like a network connection and USB ports, etc. The electronics of the CP300 including the power supply, is contained on a single Main Board (MK 17-1), which contains a ' piggy back' PC single board controller. The electronics of the CP300 are EMC shielded.

The ECG board provides isolated patient connection and initial processing of the ECG signals.

The operating system in the CP300 is Windows® NT or XP. The user interface, all settings, graphical presentations etc. are based on Windows®. The evaluation of the ECG data, control of the printer and other functions are realised on the Welch Allyn ECG processor card with its own 68331 microprocessor system. The systems communicate with each other via dual port RAMs.

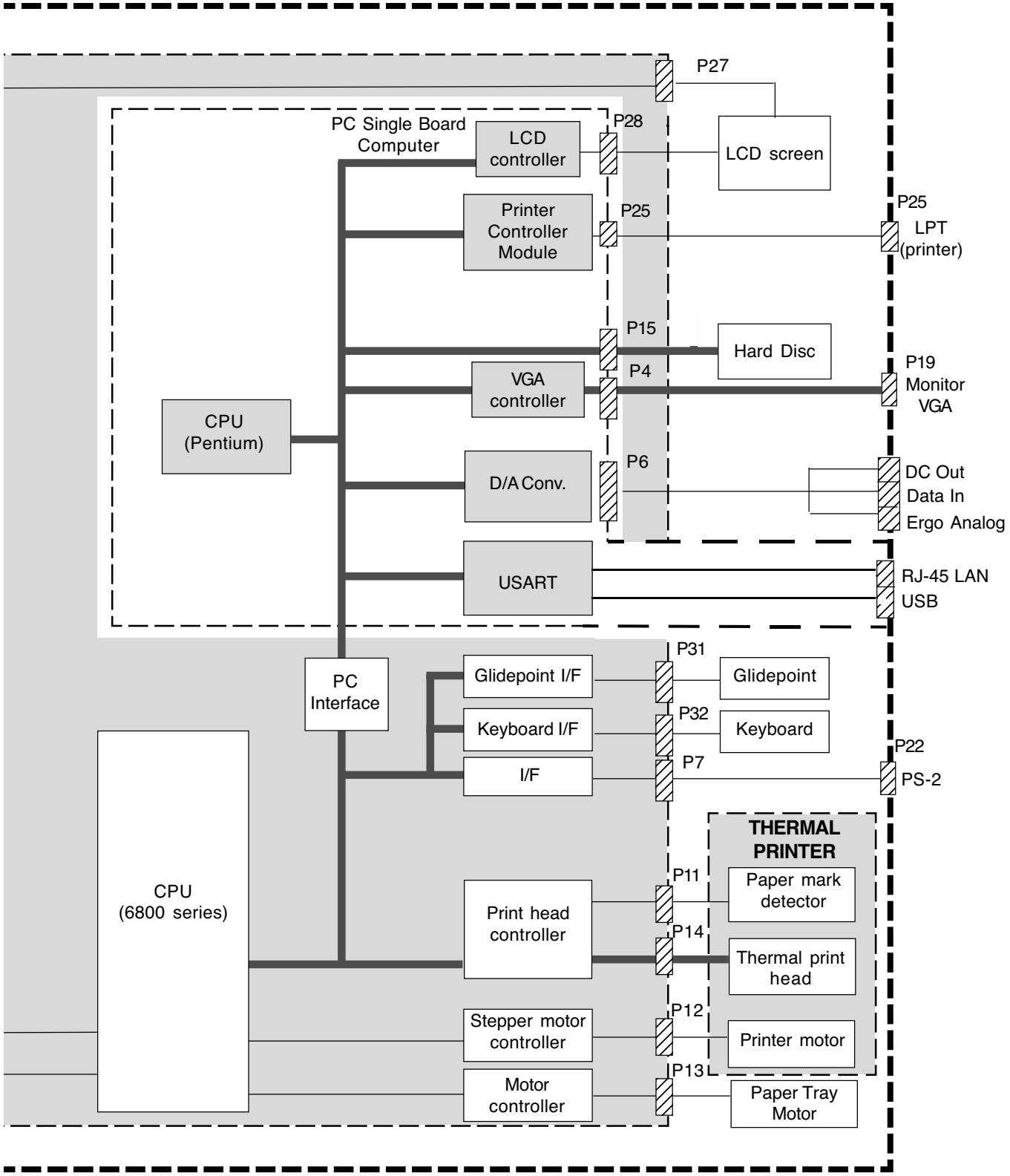
Interconnection and EMC drawings are given in the Construction Drawings section at the end of this book (see page 78).

Art. no.: 714095 rev.: b



Art. no.: 714095 rev.: b

Note: The connector designations given here are liable to change.



Art. no.: 714095 rev.: b

6 Functional Checks

6.1 Service interval

The device must be checked at regular intervals. The test results must be compared with the results following and be documented.

The following table gives information about interval and competence of maintenance which can be required.

Interval	Service		Responsible
Every 6 months	• Visual inspection of the unit and cables (see page 29). • General unit integrity check (see following).	➜	User
Every 12 months	• The visual, general, measuring and calibration tests and checks according to the checklist at the end of this book (see page 81).	➜	By Welch Allyn authorized technician
Every 12 months[a]	• Electrical safety tests according to either: – IEC 60601-1, (see page 37), or – EN 62353:2005, or – Local directives[b]	➜	By Welch Allyn authorized technician

a. The time interval for the electrical safety tests is a guideline and can vary according to local and country specific directives and according to unit use. For example when a unit is used intensively, safety checks should be carried out more often. When a unit is used less intensively, the safety check period can be longer. In addition the safety test must be carried out in the following circumstances:

-If a unit is dropped, receives any large jolt or knock or is subject to severe vibration, etc.

-If a unit has been subject to strong radiation or electrical shock, etc.

-When a unit has been repaired or serviced that requires the case to be opened.

-Additionally, a safety test can be carried out at any time if the unit isolation is suspected of being inadequate.

b. The two directives detailed here are standard specifications for reference. Local and country directives for safety testing of medical devices must be adhered to and take precedence.

Art. no.: 714095 rev.: b

6.2 General Unit Integrity Check

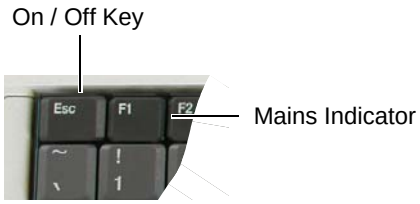
The procedure detailed here is a general confidence check of the unit if a fault is suspected. It is not a full functional test but is intended to provide a general confidence check in all the main functional areas.

Comprehensive instructions for operating the unit are provided in the CP300 User Guide. This are available from Welch Allyn on request.

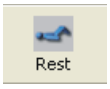
Equipment and Tools Required

- Patient simulator

6.2.1 Procedure



1. Connect mains power to the unit and ensure that the (green) mains LED lights.
2. Switch the unit on by pressing the **On** key.
3. Login at **Administrator** level.
4. Ensure that after a few moments the LCD screen lights and the patient screen is displayed.
5. Check the screen for missing pixels.
6. Using the patient cable, connect the patient simulator to the unit and switch the simulator on.



7. In the patient screen click on **New Patient** and define a new fictitious patient (that can be deleted afterwards).
8. Click on the **Resting ECG icon** to confirm the patient and the user and enter the ECG recording screen.
9. Take two automatic ECG recordings in Auto Mode as follows:

➜ Take the first auto mode recording by pressing the **Auto Start key** on the keyboard,
➜ Take the second auto mode recording by clicking the **Auto Icon** on the screen.

10. After a few seconds, a printout is given and the result displayed on the screen (dependent on setup, (see page 56).
11. Check the printout for faulty pixels.

A printout is set in system settings to be generated or disabled automatically directly after an auto mode recording. The printout can be on the internal thermal printer or on an external laser printer. If a printout is not obtained generated one manually or enabled the auto printout and take another auto mode recording

The data on the printout can also be defined by the user. Note that the auto mode format is independent of the current screen display.

Art. no.: 714095 rev.: b

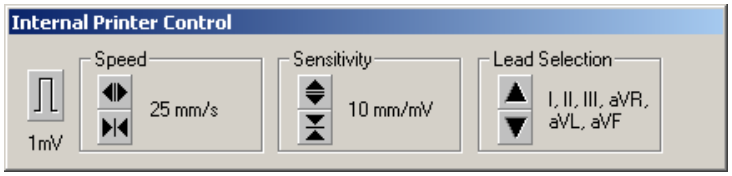
6.2.2 Continuous Printout (Internal thermal printer only)

Manual real-time printout is not available on an external printer because the data processing of inkjet and laser printers is too slow for real time print. When a continuous real-time printout of the ECG is required, it is always printed on the internal thermal printer.

1a 2a

1b 2b

1. Press the **Manual Start key (1b)** or the **Manual Start Icon (1a) to start a continuous printout.** The speed, sensitivity and lead group are changed using the pop-up control panel.



If the traces drift, click the 1 mV icon to print a 1 mV reference pulse

2. Change the Lead group, sensitivity and speed
3. Check that the printout changes when selected on the screen
4. To stop the manual printout, press the **Stop key (2b)** or the **Stop Icon (2a)**.

If any function is suspected of malfunction, calibration is not correct, or the printout is not correct for any reason etc., the full functional check must be carried out -see following.

Art. no.: 714095 rev.: b

6.3 Functional Checks and Tests

6.3.1 External Sight Control

Required equipment

- None

6-monthly

Check the following:

- Mechanical condition of the device:
  - no cracks or chips in the casing.
  - mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc.). All plugs and sockets are straight and in good condition.
  - no soiling which could hamper the safety of the device.

12-monthly

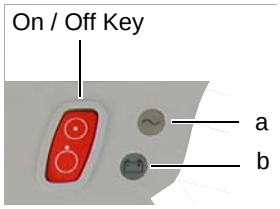
Check the following:

- Mechanical condition of the device as detailed above.
- Voltage selector is set correctly.
- Correct fuse rating according table (see page 68).
- The following safety labels are on the device and are readable:
  - Back Panel, type designation and fuse rating label.
  - Side Panel (patient connector), **CF label** and **attention** symbol.

Art. no.: 714095 rev.: b

6.3.2 Mains and Battery Indicators (LED) test

The internal battery provides power for a limited time. The length of time will depend on many factors enough including battery age, condition, charge, and temperature The battery indicator is lit when running on battery power and blinks when the battery capacity is low. The minimum time for a fully charged battery should be > 15 minutes. If the time is significantly less than this the battery should be replaced.



1. Connect the power cable at the rear of the unit.
   – Check that the mains indicator lamp is lit **(a)** when the unit is connected to the mains supply.
2. Switch the unit on.
3. Disconnect the power cable.
   – check that the mains indicator lamp switches off **(a)**
   – check that the battery lamp is lit **(b**)
   – check that the battery lamp blinks after when the battery has limited capacity.

Mains and battery LED Indicators

The LED indicators on the unit casing indicate the power operation as follows:

Function	Battery LED	Mains LED
Mains Connected:		
Battery Charging	• On	• On
Battery Full	• Off	• On
Battery Working:	• On	• Off
Battery capacity limited	• Blinking	• Off

The battery LED also blinks when the unit is shutting down. This indicates that the operating system has already closed and the system board is switching off.

6.3.3 Battery Capacity Check

1. Connect the device to the mains.
2. Charge the battery for at least 8 hours.
3. Switch the unit on.
4. Switch off the mains supply and ensure that the unit remains on for approximately >15 minutes. If the time is less than 15 minutes change the battery.

6.3.4 Keyboard Test

Check following items:

- Check the keyboard for mechanical damage and excessive wear. If any can be seen, the keyboard must be replaced.
- Check all function keys for their proper operation.
- Test the alphabetical keyboard as follows:
  – open the auto mode recording made in the general checks
  – open the interpretation screen for that recording
  – press each key in turn and check that it registers on the interpretation screen.

Art. no.: 714095 rev.: b

6.3.5 LCD Screen Test

- Visually check the screen for spots, or black fields. If many are apparent, the LCD must be replaced (a few faulty pixels is normal).
- Check that the LCD shade (contrast and brilliance) is even and the same all over. If not it indicates that the back light may be faulty and the LCD must be replaced.

Art. no.: 714095 rev.: b

6.3.6 Printer Checks

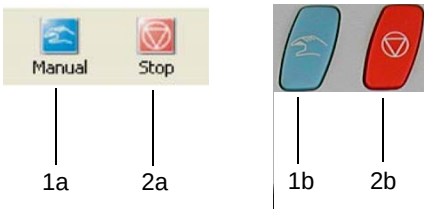
Required equipment

- Calibrated ECG Patient Simulator (e.g Müller & Sebastiani MS410 ECG Simulator)

IMPORTANT!

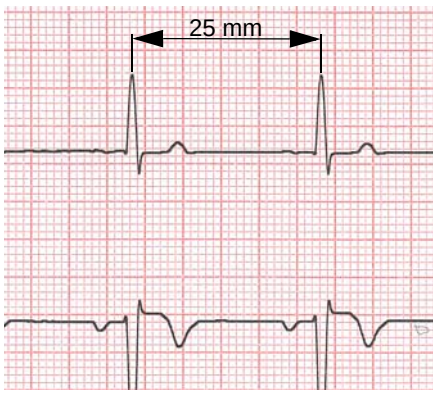
- The measurement devices listed above are subject to the instructions according to ISO Standards in regards to Test Equipment Control.

Paper Feed

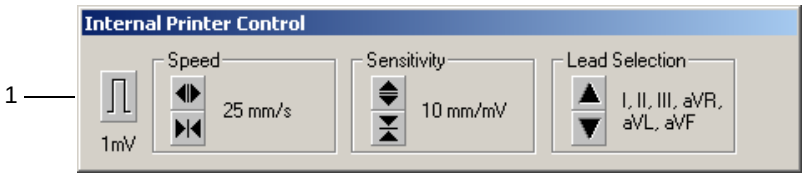


1. Press the **Manual Start key (1b)** or the **Manual Start Icon(1a).**
2. Press the **Stop key (2b)** or the **Stop Icon (2a)** twice to stop the printout and transport the paper to the paper perforation point.
3. The paper must stop exactly at the perforation. If this is not the case:
   – Check that CP300 paper is used.
   – Clean the paper detection opto window with an alcohol solution.
   – Check the paper mark detection circuit.

Printing Speed



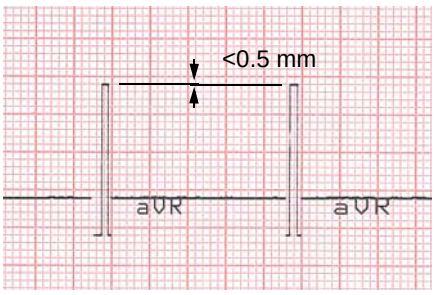
1. Connect the calibrated simulator to the ECG device using the patient cable and select a HR of 60 / min. No arrhythmias.
2. Check that the HR shows exactly 60 on the LCD.
3. The speed, sensitivity and lead group are changed using the pop-up control panel.



4. Set the printing speed to 10. 25 and 50 mm/s print one page in turn at each speed.
5. Stop the printout and check calibration waveform on the paper grid. A ruler can be used or the paper grid scale can be used to do this.
   – On the 10 mm/s printout the distance between two peaks must be 10 mm ± 0.5 mm.
   – On the 25 mm/s printout the distance between two peaks must be 25 mm ± 0.5 mm (example shown).
   – On the 50 mm/s printout the distance between two peaks must be 50 mm ± 0.75 mm

Parallelism test

This will test the mechanical adjustment of the print head to the paper grids.



1. Remove the simulator.
2. Press the **Man Start** key.
3. Click any speed key twice or the 1 mV icon **(1)**. This will generate a calibration waveform on the printout.
4. Stop printout and check the calibration waveforms on the paper grid.
   – All calibration waveforms for each lead must be lined up vertically. The maximum deviation must not be more than ± 0.5 square (0.5 mm). If the values are outside this tolerance, the mechanical adjustment of the print head has to be corrected.

Art. no.: 714095 rev.: b

6.3.7 ECG Amplifier and Patient Cable Test (Electrode/ Lead Resistance)

This gives electrode dc offset and is the voltage drop in the patient cable and electrodes. The result column gives the detected voltage for each electrode in millivolts measured between the electrode on the left leg and each of the individual electrodes. It can indicate any faults in the patient cable or patient electrode. The measured voltage value will depend on where the electrodes are connected. The voltage readings that can be expected are as follows:

With patient connected: **± 100 mV**: Good connection, low resistance. An offset of up to ±300 mV will give an acceptable recording.

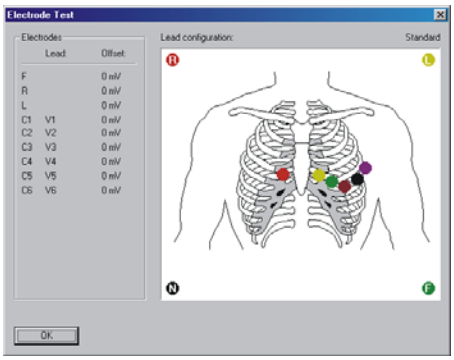
With patient simulator connected: **± 20 mV**: This will depend on the patient simulator used and must be taken as a flexible measurement.

With all electrodes shorted together: **± 20 mV**.

No patient cable connected: **-300 to -550 mV**

Procedure

1. With a patient simulator connected enter the resting ECG acquisition screen.
2. Click the **Electrode Test** menu icon



3. The Offset measurement table on the left of the screen gives an indication of the electrode/skin resistance for all the electrodes. Disconnect ECG patient simulator. Check the following:
   – device beeps
   – all lead designations highlighted
   – the mV reading for all leads is -300 mV to -550 mV
4. Connect ECG simulator and setup HR to 60 b/min, no arrhytmias.
5. Check the following:
   – all leads stops blinking
   – the mV reading for all leads is between -20 mV and +20 mV.

- When a standard 10-lead cable is connected, check RA, LA, and C1 to C6 only.
- Additionally check C7, C8, and C9 when a 13 lead patient cable is used.
- Additionally check C7, C8, C9 and C10, when a 14 lead patient cable is used.

Art. no.: 714095 rev.: b

6.3.8 ECG Printout Reference

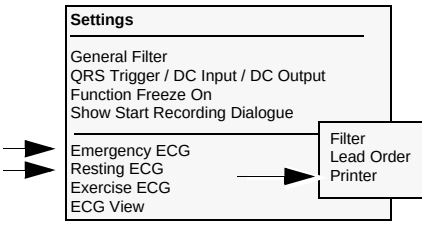
Required Equipment

- Calibrated test ECG Patient Simulator (e.g Müller & Sebastiani MS410 ECG Simulator)

IMPORTANT!

- The measurement devices listed above are subject to the instructions according to ISO Standards in regards to Test Equipment Control.

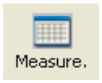
Procedure



1. Connect the simulator to the unit and select the calibrated ECG reference waveform EN 60601-2-51 > CAL 20160
2. Login at Administrator level and in the Resting ECG printout menu (standard lead configuration) select:
   – **1 page Landscape 2 x 6 Rhythms 25 mm/s 5s** (see page 60)

3. Enter the resting ECG acquisition screen and press the **Auto Start** key to make an auto mode recording printout.
4. Check the waveform and polarity against the reference waveform given on the following page. Note that the printout is representative of the waveform shape only and is not accurately scaled

If the printout waveform shape does not match the template, check the auto mode settings.



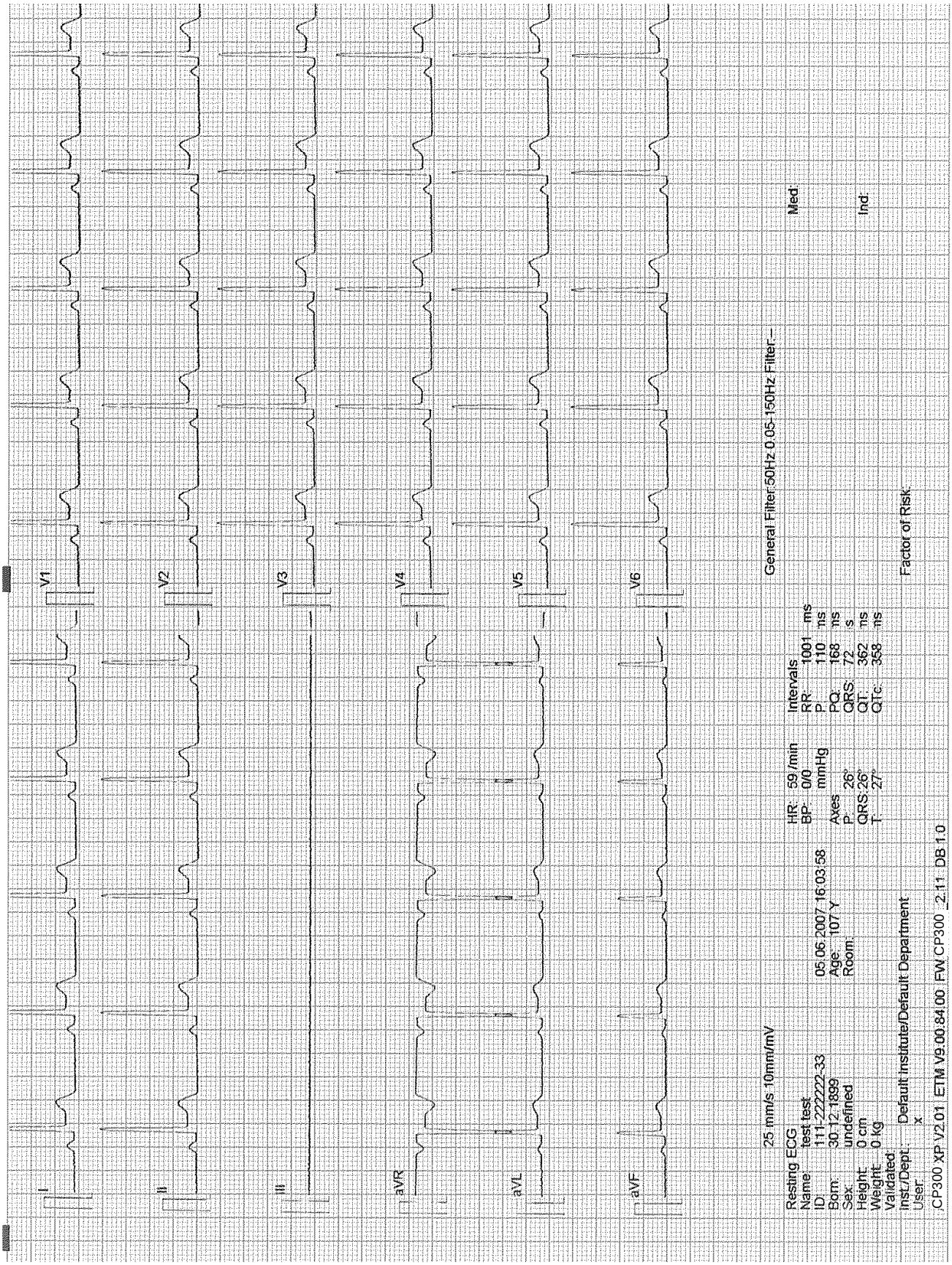
5. Check the intervals on the printout according to the following table.
6. Check the voltages (lead V1) on the measurement table (displayed when the Meas icon is clicked after the recording has been made) according to the following table.

Reference Table (CAL 20160)

Curve	Measurement	Value	Tolerance	Minimum	Maximum
Interval	RR	1000 (ms)	± 10	990	1010
	P	116 (ms)	± 10	106	126
	PR	178 (ms)	± 10	168	188
	QRS	56 (ms)	± 6	50	62
	QT	356 (ms)	± 12	344	386
V1	P	0.15 (mV)	± 0.02	0.13	0.17
	R	2.00 (mV)	± 0.2	1.80	2.20
	Rd	56 (ms)	± 10	46	66
	J	0.2 (mV)	± 0.02	0.18	0.22
	ST	0.2 (mV)	± 0.02	0.18	0.22
	T	0.4 (mV)	± 0.03	0.37	0.43

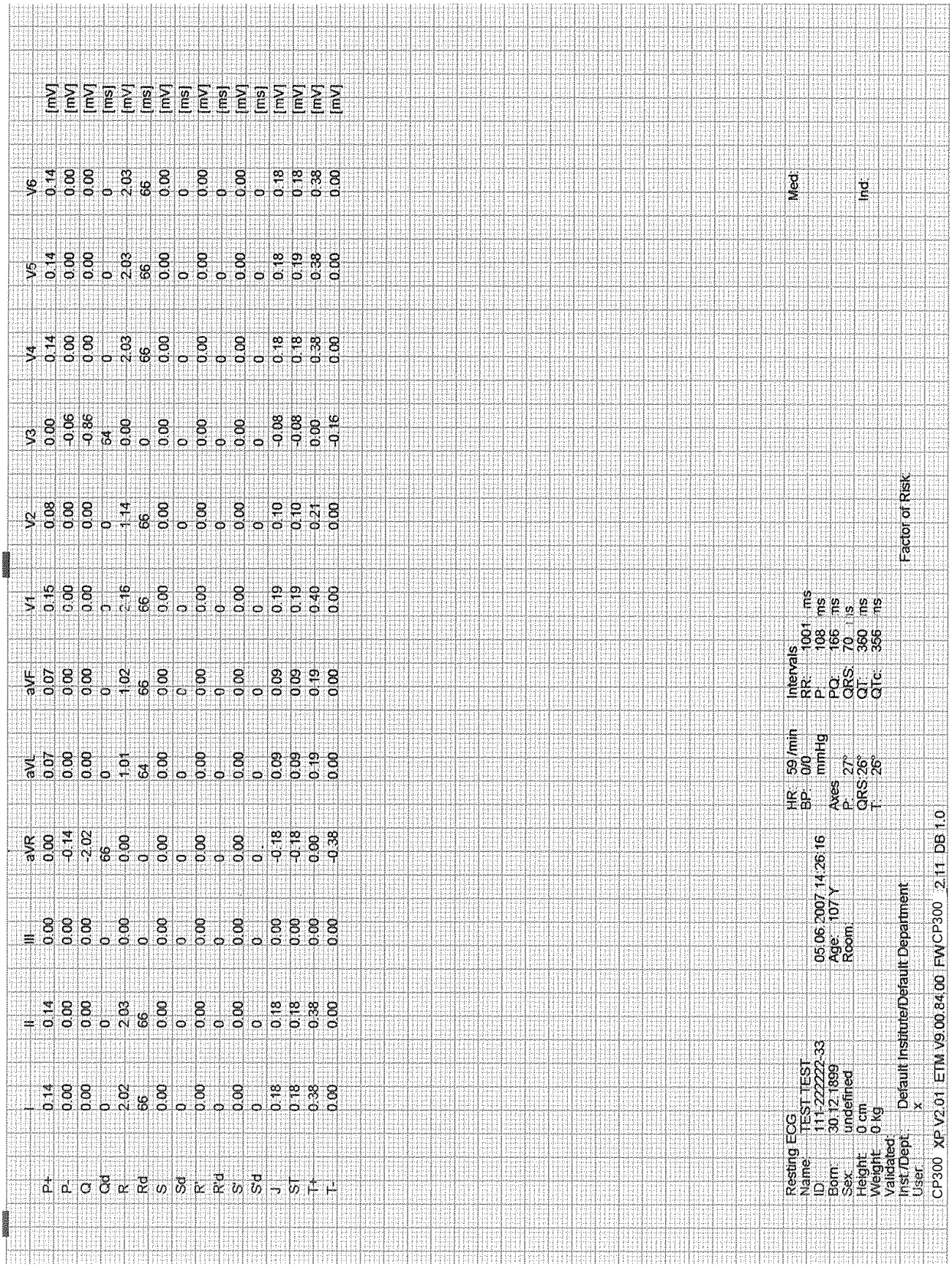
Art. no.: 714095 rev.: b

Reference Printout (Waveform and Intervals)



Art. no.: 714095 rev.: b

Reference Printout (Measurements)



	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6	
P+	0.14	0.14	0.00	0.00	0.07	0.07	0.15	0.08	0.00	0.14	0.14	0.14	[mV]
P-	0.00	0.00	0.00	-0.14	0.00	0.00	0.00	0.00	-0.06	0.00	0.00	0.00	[mV]
Q	0.00	0.00	0.00	-2.02	0.00	0.00	0.00	0.00	-0.86	0.00	0.00	0.00	[mV]
Qd	0	0	0	66	0	0	0	0	64	0	0	0	[ms]
R	2.02	2.03	0.00	0.00	1.01	1.02	2.16	1.14	0.00	2.03	2.03	2.03	[mV]
Rd	66	66	0	0	64	66	66	66	0	66	66	66	[ms]
S	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	[mV]
Sd	0	0	0	0	0	0	0	0	0	0	0	0	[ms]
R'	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	[mV]
R'd	0	0	0	0	0	0	0	0	0	0	0	0	[ms]
S'	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	[mV]
S'd	0	0	0	0	0	0	0	0	0	0	0	0	[ms]
J	0.18	0.18	0.00	-0.18	0.09	0.09	0.19	0.10	-0.08	0.18	0.18	0.18	[mV]
ST	0.18	0.18	0.00	-0.18	0.09	0.09	0.19	0.10	-0.08	0.18	0.19	0.18	[mV]
T+	0.38	0.38	0.00	0.00	0.19	0.19	0.40	0.21	0.00	0.38	0.38	0.38	[mV]
T-	0.00	0.00	0.00	-0.38	0.00	0.00	0.00	0.00	-0.16	0.00	0.00	0.00	[mV]

Resting ECG
Name: TEST TEST
ID: 111-222222-33
Born: 30.12.1899
Sex: undefined
Height: 0 cm
Weight: 0 kg
Validated:
Inst./Dept.: Default Institute/Default Department
User: x

HR: 59 /min
BP: 0/0 mmHg
Axes
P: 27°
QRS: 26°
T: 26°

Intervals
RR: 1001 ms
P: 108 ms
PQ: 166 ms
QRS: 70 ms
QT: 360 ms
QTc: 356 ms

Med:
Ind:
Factor of Risk:

05.06.2007 14:26:16
Age: 107 Y
Room:

CP300 XP V2.01 ETM V9.00.84.00 FW/CP300 2.11 DB 1.0

Art. no.: 714095 rev.: b

6.4 I / O Port Checks

The input / output check uses a RS-232 test plug and the comms test program (provided with the unit). The test program sends a test signal and then checks that it is received correctly. All the RS-232 ports can be tested.

6.4.1 Equipment Required

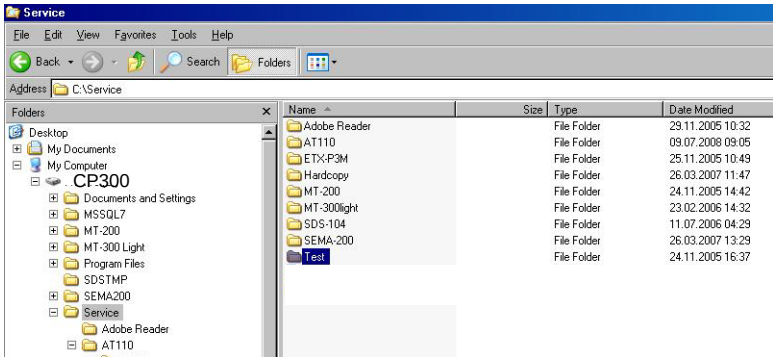
The testing of the ports requires the following test equipment.

- I /O test program (provided with the unit).
- RS-232 test plug.

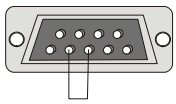
I/O Test Program

The test program is found on the hard disk of the unit:

C: Drive (CP300) > Service > Test > Commport.exe



RS Test Plug



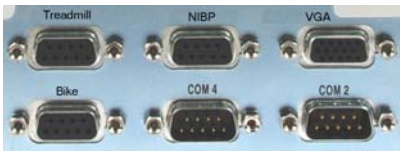
RS-232 Test plug
(viewed from the rear)

Using an RS plug, solder together pins 2 and 3.

Art. no.: 714095 rev.: b

6.4.2 Checking the RS-232 ports

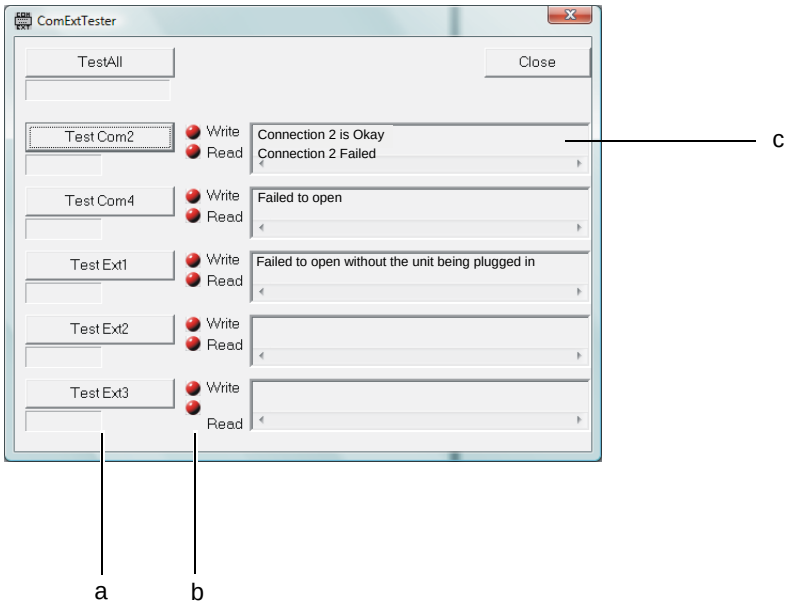
The following ports can be checked (on back panel):



- Bike (Ext 1)
- Treadmill (EXT 2)
- NIBP (EXT 3)
- Spare (Com 2)

Proceed as follows:

1. Exit the CP-300 application.
2. Position the RS-232 test plug (pin 2 (TX) and 3 (RX) shorted together) in the port to be tested.
3. Click the test icon (**a)**.
4. The red squares **(b)** change to green indicating transmit / receive Ok for selected port.
5. A message is also displayed **(c)** indicating success or failure of the test.



Com 4 will show always “Failed to open”, because it is not used.

If “Failed to open” is displayed, the port is occupied by an application running on the CP300. Exit this application and try again.

Art. no.: 714095 rev.: b

6.5 Safety tests

Required equipment

- Safety Tester IEC/EN 60601-1
- Bender Safety Tester (recommended)
- HA2000D High voltage measuring unit (recommended)

IMPORTANT!

The measurement devices listed above are subject to the instructions according to ISO Standards in regards to Test Equipment Control.

The Electrical safety tests is carried out in accordance with either:

– IEC 60601-1, Clause 18 and 19, or
– EN 62353:2005, or
– Local directives

This test may only be carried out with a tester that fulfils the above mentioned norms and has been calibrated in accordance with ISO norms.

Carry out the high voltage leakage test in accordance with the EN 60601-1, Clause 20, or local directives

To carry out all tests, follow the instructions of the manufacturers.

Documentation

Note the results or have them printed by the tester. Always include one copy of the results with the repair report. The original remains with the device and is given to the customer for his files.

6.5.1 Maximum Values Safety Test

Ground Resistance: ≤ 0.2Ω

Voltage	Type BF		Type CF	
	normal condition	first error	normal condition	first error
Earth current general [mA]	0.5	1.0	0.5	0.5
Shell current [mA]	0.1	0.5	0.1	0.5
Patient current [mA]	0.1	0.5	0.01	0.05
Patient current [mA] (Mains voltage at signal entrance and exit)	--	--	--	--
Patient current [mA] (mains voltage at used part)	--	5.0	--	0.05
Patient independent current [mA] Direct Alternating Current [mA]	0.01 0.1	0.05 0.5	0.01 0.01	0.05 0.05

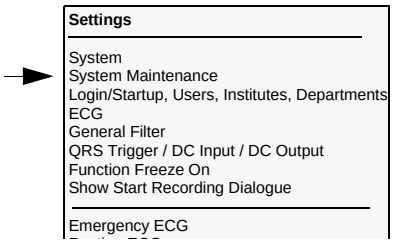
Art. no.: 714095 rev.: b

7 Software, Firmware and Test Screen

Software, firmware and test screens are entered via a service screen. The service screen is accessed at login level **manufacturers technician** only. The following user name and password can be used to login as manufacturers technician:

- User name: **sysop**
- Password: **pt160**

When logged in an extra menu item **System Maintenance** appears in the **Settings menu**.



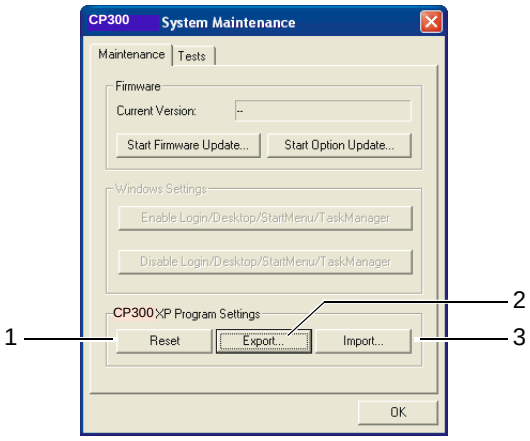
The CP300 does not have a CDROM drive so uploads / downloads the CP300 is over a network, USB memory stick, etc.

Art. no.: 714095 rev.: b

7.1 Unit Settings

7.1.1 Importing / Exporting / Reset to Default

It is possible to export and import the unit settings (color, default speed etc., but not language and some other settings). These can then be used to define the settings of any unit, for example, to set the same unit settings for all units in a department / hospital, etc.



- Select Reset **(1)** to reset all settings to the default.
- Select export **(2)** to export current settings for future use or for installation on another unit. You are prompted to define the file name and location.
- Select Import **(3)** to import previously defined settings. You are prompted to define the file name and location.

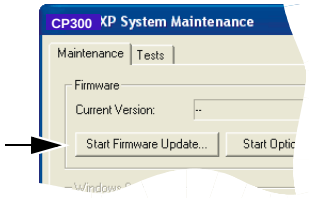
Art. no.: 714095 rev.: b

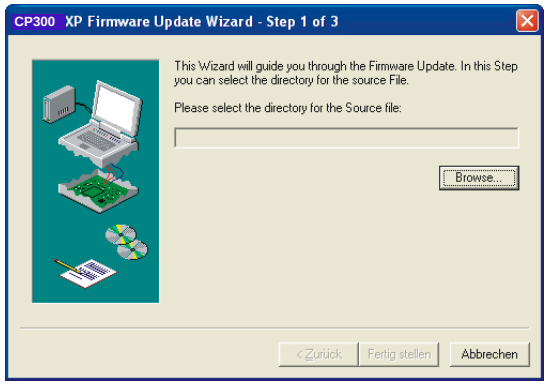
7.2 Updating Firmware

The procedure is a follows:

1. Unzip and copy the file on the desktop / memory stick / network folder.

2. Click the Start **Firmware Update** icon. The following is displayed:





3. Click the browse button to locate the firmware file (.abs file) and install in the normal way.
4. Enter the CRC code that is available on the release note and follow instructions.

7.3 Updating the Software

The procedure is a follows:

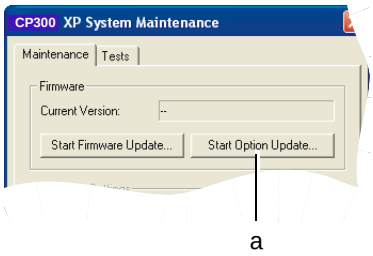
1. Unzip and copy the file on the desktop / memory stick / network folder.
2. Unzip the file on the desktop / memory stick / network folder, and click on the install.exe file.
3. Follow the instructions to install the software in the normal way.

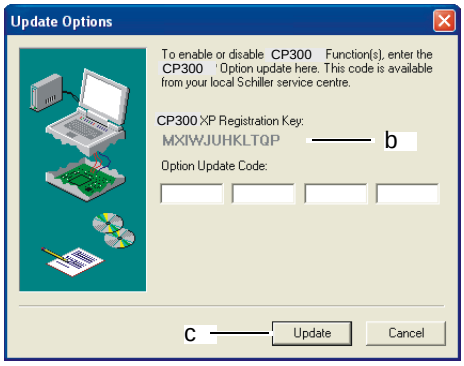
Art. no.: 714095 rev.: b

7.4 Updating the Unit Options

The Exercise and Interpretation options are already prepared in the software and are activated by entering an upgrade code.

1. Click the **Start Option Update (a)** icon. The following screen is displayed:





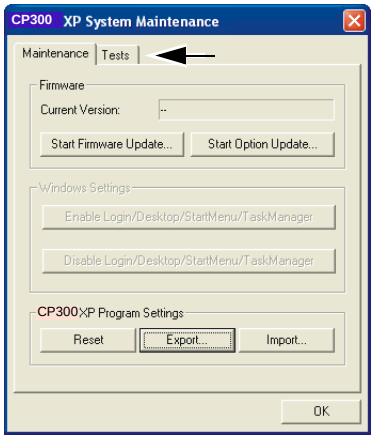
- Every unit has a registration number **(b)**. To obtain the upgrade code contact Technical Support with the registration number of your unit. When the registration number of the unit is stated, theTechnical Support can provide an upgrade code for your unit.

2. Enter the code and confirm with **Update (c)**.

Art. no.: 714095 rev.: b

7.5 Tests Screen

When the test screen is entered a code can be entered to perform certain functions. The test screen is a development tool and is not intended for service personnel and the codes given here are for information only.



The codes are as follows:

Code	Function
JOBLIST16341	• enables Joblist functionality
JOBLIST06341	• disables Joblist functionality
EXPORT16341	• enables export functions for testing
EXPORT06341	• disables export functions for testing
Note that the export function is now obsolete because export is now included in the software.	
UCPROT16341	• enables the logging of the µC <=> PC protocol on the COM interface
UCPROT06341	• disables the logging of the µC <=> PC protocol on the COM interface.

Art. no.: 714095 rev.: b

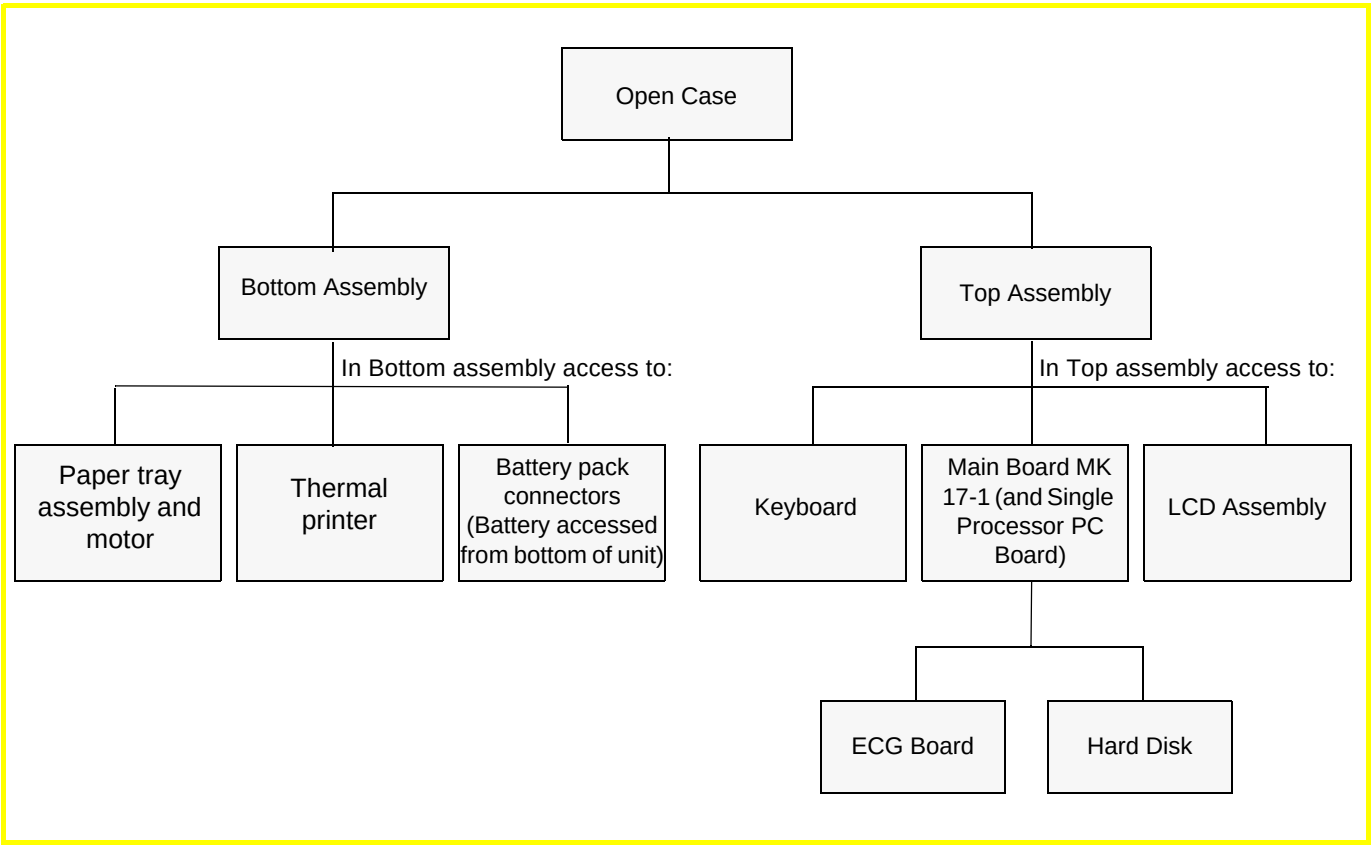
8 Replacing Major Components

8.1 Safety Notes

- Danger of electrical shock. Remove mains cable. When working on a open device connect the device via an isolation transformer.
- Follow the procedures for the prevention of accidents and environmental protection according your national guidelines.

Observe precautions for handling electrostatic sensitive devices when opening the device.

8.2 Overview



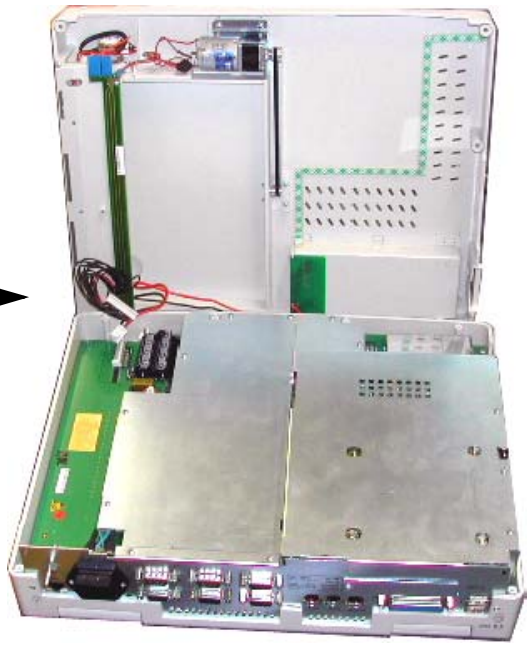
Art. no.: 714095 rev.: b

8.3 Opening the Unit

The top and bottom assemblies are secured with seven recessed screws. Access to the screws is gained from the underside of the unit. To separate, proceed as follows:

1. Turn the unit up-side-down and rest on a soft antistatic cloth.
2. Unscrew and remove the countersunk retaining screws and washers situated in the extreme corners and edges of the unit.
3. Unscrew the four screws at the back of the unit attaching the back panel to the casing.
4. Gently lift the Top Assembly sufficiently to gain access to the interconnecting cables. Disconnect the cable assembly between the main board MK 17-1 and the keyboard and the ribbon and dual-wire cable assemblies between the power supply and the LCD screen board.
5. Gently lift the Bottom Assembly away from the Top Assembly and place on a soft cloth.

Support the bottom casing in an upright position to prevent straining the cable assemblies and connectors to disconnect.



Art. no.: 714095 rev.: b

8.4 Main Board MK 17-1 & PC1-1 Board

1. Remove the EMC shield by unscrewing the securing screws.

2. The ETX base board processor os positioned on the PC1-1 single processor board that is located on spacers on the main board (MK17-1). Remove the securing screws and gently hinge the board as shown. Disconnect the interconnecting cable assemblies between the boards.

Hard disc

ECG Board MK16-2

Main Board MK17-1

Single Board Computer PC1-1 (ETX base Board

Art. no.: 714095 rev.: b

8.5 ECG Board MK 16-2

1. Unscrew the EMC shield and remove
2. Remove the connector to the Main Board (P30)
3. Unscrew the four board retaining screws. Remove the two screws securing the patient connector to the casing.
4. Remove the Board.

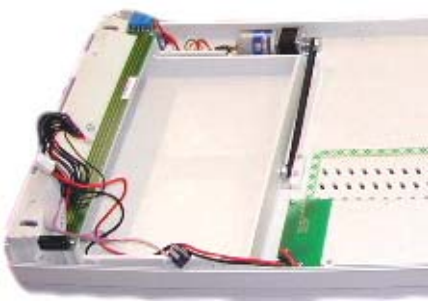
8.6 Thermal Printer

8.6.1 Removing

1. Unscrew the four retaining screws securing the printer in position.
2. Gently remove the printer taking care to retain the two tensioning springs.

8.6.2 Replacing

To replace the thermal printer proceed as follows:



1. Position the printer in the paper tray/print assembly so that the printer mounting plate lips slot into the dedicated cutouts in the assembly;
2. Insert the two tensioning springs so that the springs are positioned over the outer two molded spring supports and in the indent (hole) in the printer mounting plate
3. Position the printer retaining bar and secure the printer and printer retaining bar with the four retaining screws. Ensure that the cable assemblies from the printer to the PCB are not caught and are not strained.

8.7 Battery

To remove the Battery Pack proceed as follows:

1. Remove the top assembly as detailed previously.
2. Disconnect the two bayonet connectors for the Main board (P2).
3. Gently return the top assembly in position, and firmly holding both parts, turn the unit up-side-down.
4. Unscrew the battery compartment cover plate retaining screws and remove the battery.

Art. no.: 714095 rev.: b

8.8 Reassembling the Unit

8.8.1 Internal Sight Control

If the device has been opened, the device must be given a full sight control before it is screwed back together.

Check following items:

- All printed boards are securely screwed.
- Plugs are properly in the socket and secured.
- All protective cable (green/yellow) are properly laid out and securely connected to an earth point (potential equalization).
- All Cable connections between the individual boards are not crushed or lying on or close to, a sharp object (e.g. protective shields). If cables are positioned by a sharp object, it is important that they are protected by a special shield.
- Isolation foils and shields are inserted and correctly positioned.
  - Check that no loose parts are inside the device by tipping the device, or turning it upside down.

8.8.2 Functional Test

Once the sight control has been completed, the device can be closed and the functional and Safety Test must be carried out according to the checklist at the end of this book (see page 81) or released service repair form (s).

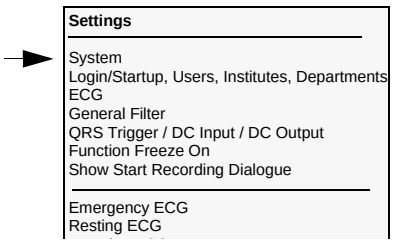
Art. no.: 714095 rev.: b

9 Unit Settings

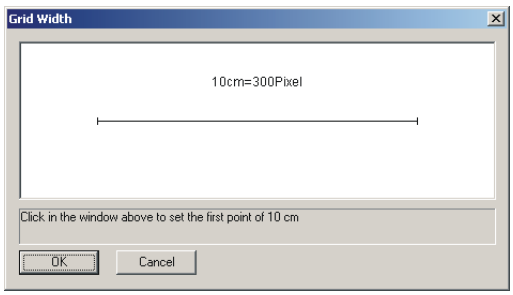
9.1 Settings at Administrator login level

Detailed in this section are all settings available at Administrator login level.

9.1.1 System



Parameter	Options	Description
Appearance	**colors**	In this screen, color preferences can be defined for grid (background and foreground), leads, and lead designation text etc. when a recording is displayed.
	Trend curve colors	Define colors for trend 1, 2, 3, and 4
	Screen Calibration Width	The screen calibration enables the scale on the screen to be precisely defined.



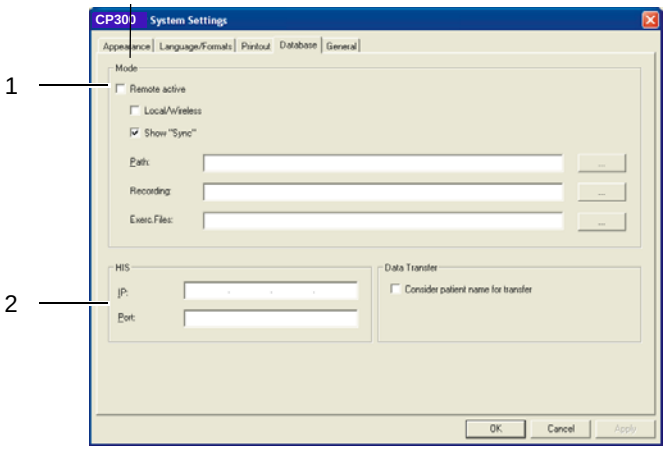
It should be periodically checked against a ruler to ensure correct scaling. To do this:

1. Position the cursor in the left section of the screen and tap the glide point controller (or left click if using a mouse). A dotted vertical line is displayed.
2. Move the cursor and a second vertical line is displayed. With a ruler held against the monitor, position the second line 10 cm from the first.
3. Tap the glide point controller anywhere between the two vertical lines to set.
4. Click OK to confirm or Cancel to return without saving.

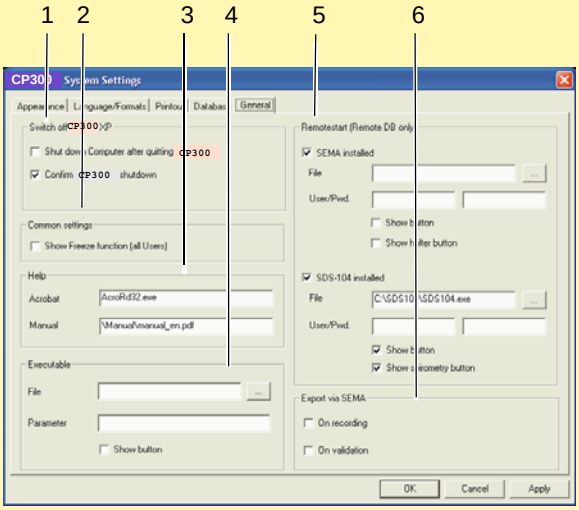
Art. no.: 714095 rev.: b

Parameter	Options	Description
Language / Formats	**Language**	Select language of choice. This changes the program language immediately without rebooting. All operating system dialogues however, (e.g. printer setup), will remain in the language of the operating system.
	Units	This defines the units used for patient data and printout. Select between kg/cm and lbs/ins.
	Treadmill Units	Select between mph or Km/h. Note that this must be the same as that defined for the connected treadmill. **Errors can occur if not set the same.**
	Date	Enter: dd.MM.yyyy or MM/dd/yyyy
	Time	No selection available and defined as 24 hour format as HH.mm.ss
	Patient ID	The format of the patient identification is defined here. A number of format options exist to fit into your system. The number of characters, the case (upper/ lower), the type of character (letters only, numbers only) along with other attributes can all be defined. The number and the type of characters entered in this field defines the format of the patient id. The maximum number of characters is 20. Characters that can be entered are as follows: • # (hash) - number • **A** (upper case A) - any alpha characters (upper case or lower case), any number • **&** (ampersand) - any ASCII character • **?** (question mark) - alpha character lower case and upper case • **U** (upper case u) - alpha character upper case • **l** (lower case L) - alpha character lower case Any other characters entered will appear as entered in the position in the patient id in the position entered here. Example: if you required that patient IDs began with the letters ABC followed by a dash then a 6 digit number followed by a dash and then three lower case alpha characters, the following would be entered: ABC - ###### - lll
Printout	**Margins and Font Size**	Define the print margins and font size. Experiment to find the best print combination for preference and for the printer connected.
	Patient Data Position	Select to print the patient data at the top or bottom of the printout
	Hide patient data on printout	Select this box if the you do not wish the patient data to be printed, for example if carrying out clinical trials, etc.

Art. no.: 714095 rev.: b

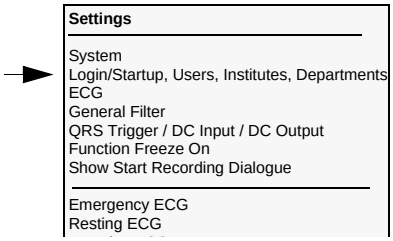
Parameter	Options	Description
Database	**Mode**	 Select the **Remote active** box **(1)** to store recordings remotely (i.e. not on the CP300 database, for example on SEMA-200). select the **Local / Wireless** box if the SEMA-200 database is installed on the CP300 hard drive. If the SEMA program is installed on a network, do not select this box. Select the **Show Sync** Box to display the **sync tab in the patient screen** when a network connection is reconnected. Clicking this tab in the patient screen updates the SEMA data base with any recordings made by the CP300 when the network was not connected. If recordings are to be stored locally the CP300 database (SQL server) select neither box. **Path -** Define here the drive and location where the SEMA-200 program is located. Typically this will be **\\name of server\SEMA\SDSDB** **Recording -** This is the folder where the recordings are stored. Typically this will be **\\name of server\SEMA\SDSRECS**. **Exec Files -** This is the folder where the full disclosure exercise files are stored. Typically, this will be **\\name of server\SEMA\FULLDISC**
	HIS	The Hospital Information System (HIS) path **(1),** (e.g. SEMA200) must be defined. **IP Address -** Identifier address of the device in the TCP/IP network. If set 0.0.0.0 the IP address will be set by the DHCP server. The IP address of the server (this can be left blank when the drive is mapped). **Port -** The IP address of the server (this can be left blank when the drive is mapped).
	Data Transfer	**Consider patient name for transfer -** The Consider patient name for transfer is used to control the administration of name conflicts when transferring to the Database. Leave this box **unselect** if you wish to log name/number conflicts for future editing. **Select** this box to display the name conflict during transfer. When a conflict is detected (during transfer), a message box appears and shows the conflict. The patient name must then be edited by using the **Edit** icon in the patient screen.

Art. no.: 714095 rev.: b

Parameter	Options	Description
General	**(1) Switch Off Mode**	Check the shut down the computer after quitting the CP300 box to shut down the unit directly when the program is exited. If this box is not checked, the unit will enter the Windows environment when the CP300 program is exited. To display a prompt screen before exiting the program, check the Confirm CP300 shutdown box.  To display a prompt screen before exiting the program, check the **Confirm CP300 shutdown** box.
	(2) Common Settings (Freeze Function)	Select the **Show freeze function (all users)** box for the user to be able to display the freeze icon in the toolbar - (a menu item in the settings menu is given when this box is selected). If this box is not selected, the freeze menu item is not given in the settings menu and the freeze icon is not able to be displayed (see page 58).
	(3) Help	In the Help section the location of the user guide and the latest newsletters are defined. These are displayed when the help menu is displayed.
	(4) Executable	A separate program can be opened directly from the CP300 (for example a text editing program like word, or a read program like acrobat). Define here the location of the exe. file to be opened. The program defined can be locally installed on the CP300 or can be located on a network. To display the **Exec icon** in the toolbar, the **Show button** box must be Selected.
	(5) SEMA-200 Database	If SEMA is installed either locally or on a network, the SEMA program can be opened directly from the CP300 and a SEMA icon appear on the toolbar. To display the **SEMA icon** in the toolbar, the **SEMA Installed** box must be Selected. Define the location of the SEMA-200 exe program For example, if the SEMA-200 program is stored locally, the first entry could be: C:\SEMA200\Sema200.exe Under the program location enter the **username** and the **password** of the program if required, to open the program with the defined user.
	(6)SEMA Export	To export an auto mode recording (Resting ECG only) to SEMA200 select the required box (export on validation / export after recording made). Note that these options will only be available when a SEMA database is defined (see above).

Art. no.: 714095 rev.: b

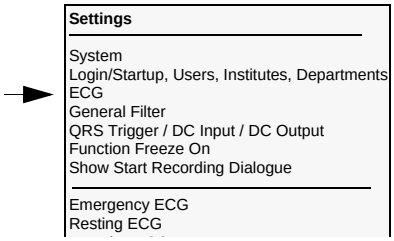
9.1.2 Login/Startup, Users, Institutes, Departments



Parameter	Options	Description
Login / Startup	**Login**	If you wish to skip the login screen and go directly into the program when the unit is first switched on, check the 'skip the login...' box, and specify the user. When the unit is next switched on the CP300 will automatically login with the defined user.
Institutes / Departments	**Institute entry** **Department entry**	In this screen the administrator can delete, edit and define new institutions and departments. These are used in various program locations and can be given on the printout of a recording. Enter the relevant data and save when finished.
Users	**Name** **Password** **Authorisation level** **Full name** **Institute** **Department**	Assign rights to individual users as required. An overview of the user categories is given in the introduction (see page 12). The User ID and the password defined for a user must be remembered. These are required when first opening the program and when a new login is requested. To create a new user, click the new icon, and enter the required data in the left section of the screen. The arrows - to the right of the departments and institutes fields - display the user entered data. The maximum number of characters that can be entered in the ID field of all sections is 8. The maximum number of characters that can be entered in the address fields is 40.

Art. no.: 714095 rev.: b

9.1.3 ECG

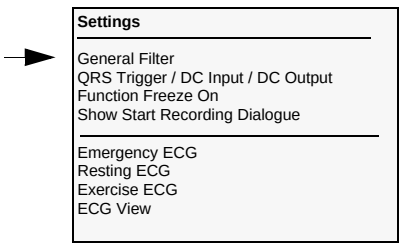


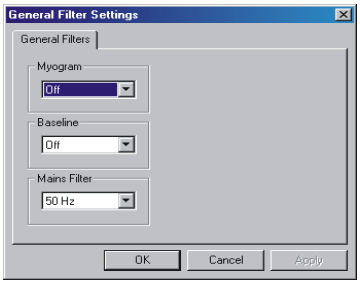
Parameter	Options	Description
Heart rate	**Average over 4, 8, 16 beats**	The heart rate is averaged over 4, 8 or 16 beats. Check the required option.
QRS Beep	**Frequency, Duration, Volume**	The frequency, the duration, and the volume of the QRS beep are set in this screen.

Art. no.: 714095 rev.: b

9.2 Settings at Physician/Administrator level

9.2.1 General Filter





Myogram

On / Off - The Myogram filter reduces muscle induced noise. The use of the Myogram filter can reduce the signal amplitudes by 20%. Average cycles and measurements are not affected by this filter. The setting here defines if the filter is applied by default or not applied.

Baseline

On / Off - The baseline filter (SBS Baseline stabilizer) greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of the this filter is to keep the ECG-signals on the baseline of the printout and screen. The setting here defines if the filter is applied by default or not applied.

Mains

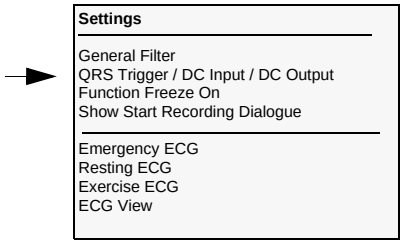
50 Hz / 60Hz - The mains filter is an interference filter that suppresses AC interference without distorting the ECG. Select between OFF (not recommended), 50 Hz, or 60 Hz, according to your local mains supply frequency. 50 Hz for international ; domestic should be 60 Hz unless other Operator/user instructions provide for changing the HZ on the device.

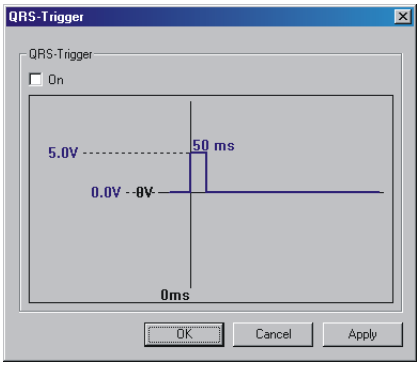
The filters are switched **On** or **Off** during a recording with the **Filter** key icon at the top of the screen. When the filters are switched on, the filter icon is highlighted.

The default setting (on or off) when the acquisition screens are entered is defined in the ECG settings (see page 59).

Art. no.: 714095 rev.: b

9.2.2 QRS /Trigger / DC Input / DC Output





This graphically displays the output of the QRS trigger pulse on the DC output. When enabled, this output can be used for example, to trigger an external Blood pressure unit. The following can be set:

- delay time (10 ms to 250 ms in steps of 10 ms)
- pulse width (10 ms to 250 ms in steps of 10 ms)
- amplitude (-10 V to +10 V),

Proceed as follows:

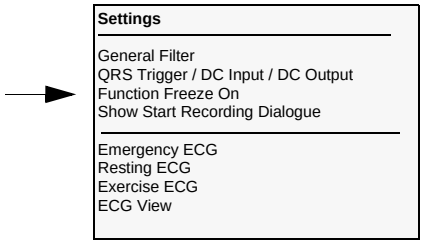
1. Move the cursor so that it is positioned on the waveform
2. Double click with the glide point controller, and move to cursor to the desired setting.

The recommended setting for use with the BP200plus blood pressure unit is as follows:

- **QRS Trigger: On**
- **Amplitude: +5 V**
- **Duration: 50 ms**
- **Delay: 0ms**

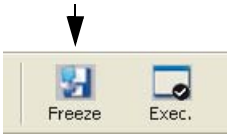
Art. no.: 714095 rev.: b

9.2.3 Function Freeze



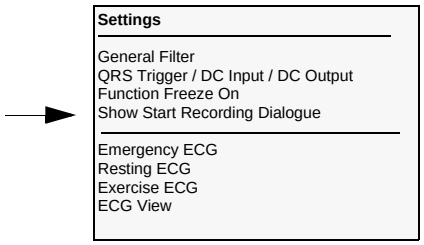
The freeze function is an easy way of saving screen settings so that when the screen is next visited, the same display settings (e.g. lead order, print settings, etc.,) are set. When Freeze is enabled (select before the option), an extra freeze icon appears in the tool bar.

When this icon is clicked the current screen settings are remembered for the next visit. The freeze function is available in both view and data acquisition screens as well as the patient screen.



The menu option **Function Freeze on**, (and therefore the freeze icon) can only appear if enabled by the administrator (settings > system > general > show freeze function (all users) - see page 50)

9.2.4 Show Start Recording Dialogue

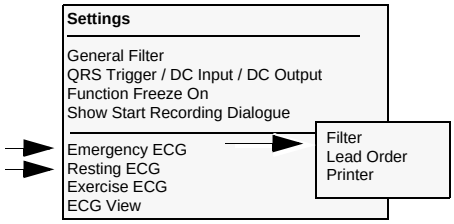


When this is Selected a dialogue box is displayed before entering the resting or exercise acquisition screens enabling the user to confirm or edit the current patient or select a different patient. When this box is not Selected, the current patient is selected by default.

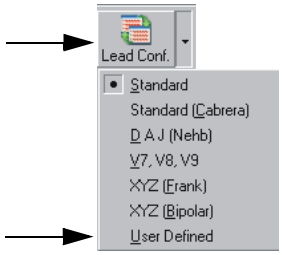
Art. no.: 714095 rev.: b

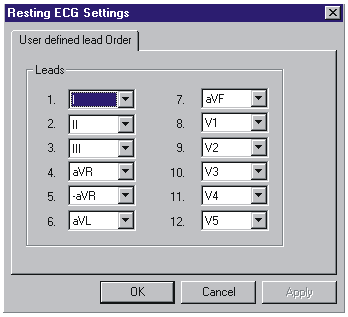
9.2.5 ECG Settings Filter and Lead Order

Note that all of these settings are also available in the settings menu of the recording screens.



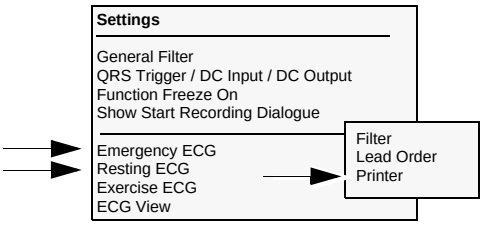
Parameter	Options	Description
Filter	**Myogram** **Baseline**	The default setting for the Myogram and Baseline filters are defined here and applied to viewed recordings when the filter icon is clicked. Note: The **General Filter** setting is universal and if set, individual emergency, resting, exercise and view filter settings cannot be made and the filter options will be dimmed. To define filter settings individually the general filter setting must be set to off.
Printer	**See Next Page**	
Lead Order		Select the leads (and lead order) when **user defined** is selected in the acquisition screens The user defined leads are displayed when **user defined** is selected in the **Lead Conf** icon (recording screen).





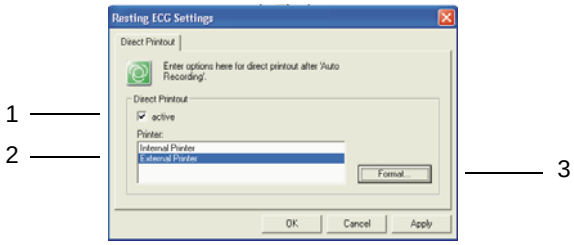
Art. no.: 714095 rev.: b

9.2.6 ECG Settings Printer and Printout settings

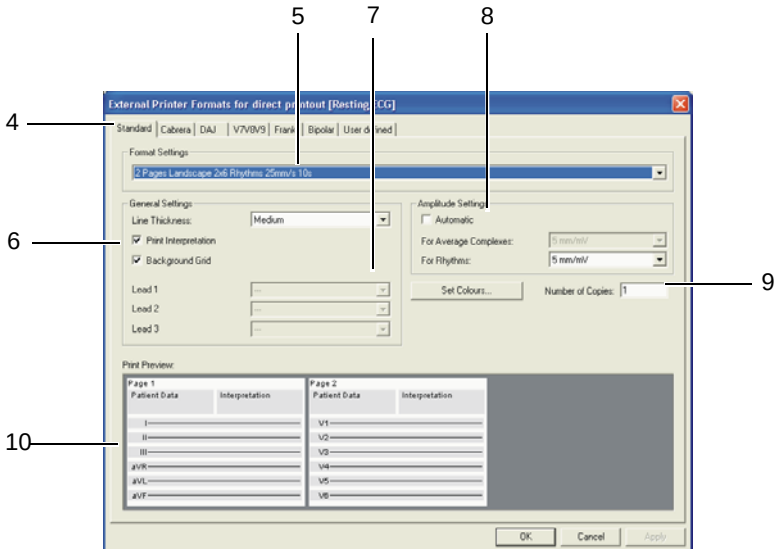


A printout can be obtained on the internal, or an external printer, directly after an auto recording has been made.

The format of the printout for both the internal and external printer is defined by the user (see below). In both cases the printout obtained after an auto mode recording is independent of the screen display.



- Check the active box **(1)** to obtain a printout after an auto mode recording. If this box is not Selected a printout will not be printed automatically.
- Highlight the printer for direct printing (external or the thermal internal printer **(2)**).
- Use the format icon to edit the **direct printout** formats **(3)** as follows.



- Select the lead configuration on the printout by clicking on the tabs at the top of the screen **(4)**.
- Select the printout format **(5).**
- Check the print interpretation and / or grid box to have the interpretation / grid on the printout **(6)**.
- Select the Rhythm Leads for printout - the amplitude and speed are defined in the ECG format **(7)**.

Note that rhythm leads can only be selected for print formats that define + 1 lead, or + 3 lead, in the ECG format (5). When a single lead is selected for the ECG format (5), the lead defined for rhythm 1 is printed.

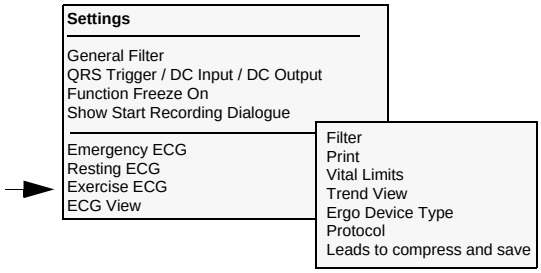
- Define amplitude for average and rhythm printout. When auto is set, the amplitude is optimised for the printout **(8).**
- Define the number of copies **(9).**

As the settings are made a representation of the pages are given in the bottom section **(10)**.

Art. no.: 714095 rev.: b

9.2.7 Exercise ECG Settings

Note that all of these settings are also available in the settings menu of the recording screens.

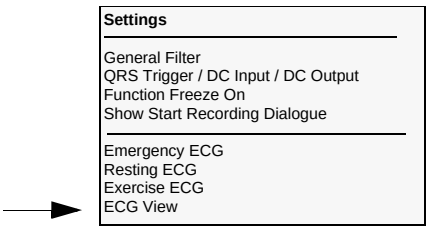


Parameter	Options	Description
Filter	**Myogram** **Baseline**	The default setting for the Myogram and Baseline filters are defined here and applied to viewed recordings when the filter icon is clicked. Note: When **General Filter** settings are defined they are universal and individual emergency, resting, exercise and view filter settings cannot be made - the filter options will be dimmed. To define filter settings individually the general filter setting must be set to off.
Printer	**Step print external / Internal printer**	The Step print options are displayed when printer is selected. If a printout is required on completion of every exercise step the **active** option must be Selected, and external or internal printer selected. The format of the step printout can be defined when the **format** tab is clicked. The options are similar to those for the resting ECG and described on the previous page.
	10 second print external / Internal printer	The format of the 10 second printout is factory defined and obtained when the **10 s icon** is clicked in the exercise acquisition screen. The printout can be on an external or the internal thermal printer.
Vital Limits	**Heart Rate** **Blood Pressure** **ST**	• The Heart rate can be set to: – 90% of 220 - age – 85% of 205 - 1/2 age – 200 - age – 220 - age – Male: 205 - 1/2 age; Female: 200 - age – Manual - you are prompted to enter a limit. – No limit • The BP limit can be set between 0 and 350 mmHg. • The ST measuring point can be set between 0 and 99 mm after the j-point Note that these can also be changed at any time when taking an exercise test by clicking on the displayed limit.

Art. no.: 714095 rev.: b

Parameter	Options	Description
Trend View	**Table 1** **Table 2** **Table 3**	Define here the default data in the **three trend graphs** displayed above the ECG waveforms in the exercise recording screen. The data that can be set for each table (graph) is as follows: • HR / Load • ST Ampl / Slope • ST all. absolute • ST all. relative • ST amplitude all. + ref • ST slope all. + ref • Protocol Preview Select data to be included in the trend tables and click the **Apply** icon. The trend diagrams can also be selected by **right clicking in the trend graph during exercise recording**.
Ergo Device Type	**Treadmill** **Blood Pressure** **General**	Three tabs enable the user to define the **treadmill type** and the **blood pressure type** connected to the system. In the bicycle screen the device and maximum load is defined. For the treadmill screen, minimum and maximum speed and elevation can be defined along with the treadmill speed units (km/hr or mph). In the general tab, the default ergo device on entering the exercise acquisition screen is specified. This can be eithe • Treadmill • Last device specified, or • Mandatory selection i.e. prompted every time the exercise screen is entered.
Protocol		See following
Leads to compress and save		Here the two rhythm leads that are saved with the recording are defined. (Because a full disclosure exercise recording would take a lot of memory, only two leads are saved for rhythm reference)..

9.2.8 View

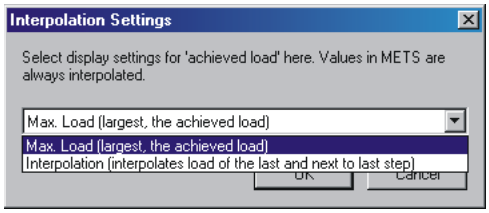


Printer

Select the default printer (internal / external) and data format for **resting ECG recordings, exercise ECG recordings and rhythm recordings.** Printer settings, color settings and data format etc., are detailed earlier in this section.

Interpolation

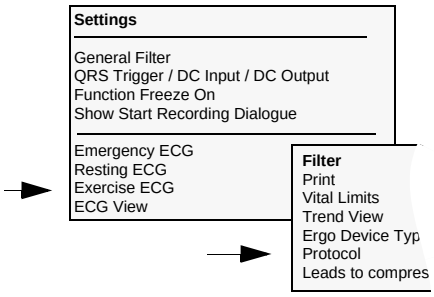
Select the setting of the load to maximum, or interpolate the load to that of the last and second to last load stages. An explanation of interpolation is given in the CP300 user guide.

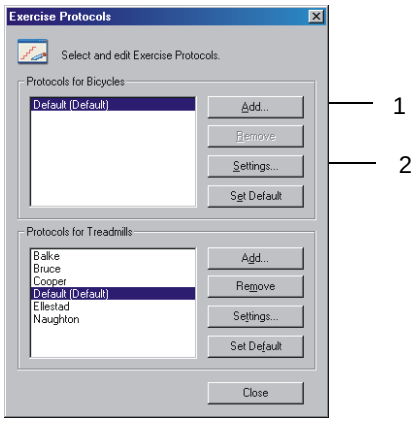


Art. no.: 714095 rev.: b

9.2.9 Defining a Protocol

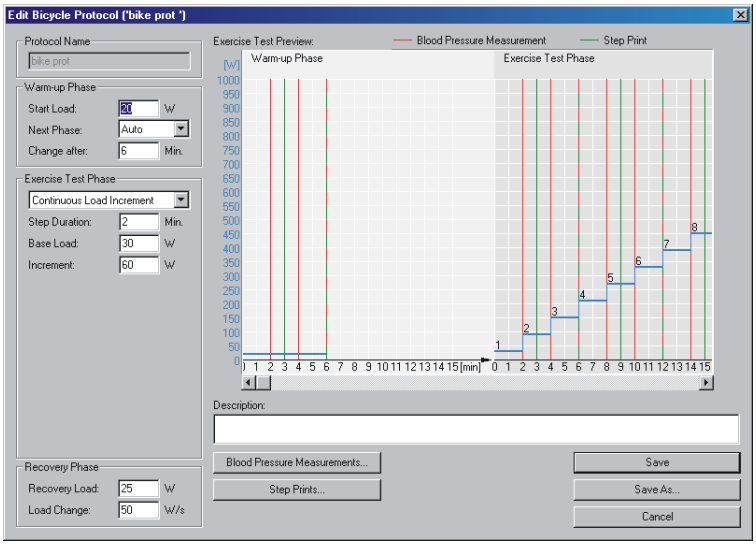
Select the protocol option from the Exercise ECG menu. All of the defined protocols are listed. To define a new protocol click the **Add** icon **(1).** To view a previously defined protocol, highlight it in the list and click the **Settings** icon **(2**).





Treadmill Protocol

A graphical representation of the protocol is displayed and is updated as settings are entered. The red and green vertical lines in the exercise area indicate respectively when a blood pressure measurement will be initiated and when a stage printout will be initiated. The blue horizontal lines indicate the load and stage.



The settings / selections are as follows:

Protocol Name — Selects the protocol that you wish to edit, delete or use as the basis for a new protocol.

Warm-up Phase — **Start Load** - Defines the load applied during the warm-up phase.

Next phase - Progression from the warm-up phase can be initiated manually (via the dedicated keypad), or automatically after a defined time. When Auto is defined, the time interval is defined in the `change after` field.

Change After - The duration of the stage.

Art. no.: 714095 rev.: b

Exercise Phase

Ramp - A ramp protocol means that the load increase is applied gradually over the duration of the test at a rate of x Watts per minute. When this option is selected, the start load and the load increase per minute must be entered.

Step List - individual durations and loads can be defined for each step of the test. When this option is selected, a table is displayed to enter the duration and load data.

Continuous Load Increment - With this protocol fixed step durations and load increases are defined.

When set, the fields under the type name change for the type of protocol selected to include the base load, load increment, step increment etc. as required.

Recovery Phase

Recovery Load - Defines the load applied during the recovery phase.

Load Change - Defines the rate of change from the last exercise load applied, to the recovery load.

Blood Pressure Measurements

Time Interval - A measurement is taken /printout obtained, at the interval defined in the `time interval` slot.

Step End - BP measurement/printout approximately 50 seconds before the next step is initiated

Number per Step - A defined number of blood pressure measurements/printouts can be taken for every step.

Step Prints

Automatic Stage Print - The settings for the stage printout interval are the same as for the BP measurement above.

Blood pressure and **step prints** can also be set by 'right clicking' to display the menu for entry.

Art. no.: 714095 rev.: b

10 Maintenance

10.1 Cleaning

10.1.1 Cleaning the Casing

WARNING

▲ Switch the unit off before cleaning and disconnect the mains. Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilize with hot water, steam, or air.

The casing of the CP300 can be cleaned with a soft damp cloth on the surface only. Where necessary a domestic non-caustic cleaner can be used for grease and finger marks.

10.1.2 Cleaning the Patient Cable

The patient cable must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plug and not the cable. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.

The cable can be cleaned with luke warm soapy water holding the cable in the middle and gently wiping from the center.

To disinfect the cable, wipe the cable (from the middle) with a chemical disinfectant containing:

- ethanol (70% - 80%)
- propanl (70% - 80%)
- aldehydes (2% - 4%)

Sterilization, if required, must only be carried out with gas and not with steam.

10.1.3 Cleaning the Thermal Print Head

If the printer is used a lot, a residue of ink from the grid on the paper can build up on the print head. This can cause the print quality to deteriorate. We recommend therefore that every month the print head is cleaned with alcohol as follows:

Extend the paper tray and remove paper. The thermal print head is found under the paper tray.

With a tissue dampened in alcohol, gently rub the print head to remove the ink residue. If the print head is badly soiled, the color of the paper grid ink (i.e. red or green) will show on the tissue.

Art. no.: 714095 rev.: b

10.2 Trouble Shooting

10.2.1 Trouble Shooting Table

Fault	Possible Causes and indicators	Remedies and Fault Location
Unit does not switch on, blank screen	• No mains supply, Green mains indicator off.	➜ Check mains supply, check fuses. ➜ If mains indictor is lit it indicates that power is reaching the unit and the internal power supply should be Ok. Press and hold the On/Off key for 5 seconds. Wait a few seconds and switch on again.
	• Mains supply ok, but the screen is still not lit.	➜ If the screen is still not lit it indicates a software fault, monitor problem or internal power supply. Call your local Technical Support.
QRS traces overlap	• Incorrect settings for Patient. • Bad electrode contact.	➜ Change sensitivity setting. ➜ Ensure that the automatic sensitivity reduction is not switched off. ➜ Reset signals to baseline - press the 1 mV key. ➜ Check electrode contact - Replace electrodes. ➜ If traces still overlap: Call your local Technical Support. ➜ Note: Some patients have very high amplitudes and even on the lowest sensitivity settings, the QRS traces can overlap.
'Noisy' traces	• High resistance electrode contact / cable high resistance / Also, when form customer: • Patient not relaxed. • Incorrect settings.	➜ Check electrode contact (see page 33). Resistance readings should be ± 20mV. ➜ Change patient cable ➜ Change ECG Amplifier ➜ Ensure that the patient is relaxed and warm. ➜ Check all filter settings > Settings > Filter. ➜ Activate Myogram filter. ➜ Ensure mains filter is correct for mains supply.
No printout obtained after an auto mode recording	• No paper. • Paper incorrectly loaded. • Incorrect settings.	➜ Ensure that paper is loaded. ➜ Reload Paper. ➜ Ensure that the paper has been installed correctly with the paper mark at the top. ➜ Check Settings - ensure that a printer is selected and at least one item is selected for print after an auto ECG is recorded > Settings Resting ECG (Exercise ECG) > Printer ➜ If the printer still doesn't work: Call your local Technical Support.
Printout fades, is not clear, or the printout is 'patchy'.	• Old paper inserted. • Dirty print head. • Print-head out of adjustment.	➜ Ensure that fresh CP300 paper is installed. ➜ Note that the thermal paper used for the CP300 is heat and light sensitive. If it is not stored in its original seal, stored in high temperatures or is simply old, print quality can deteriorate. ➜ Over a period of time, the printing ink from the grid on the paper can form a film on the thermal print head. Clean the thermal print head. ➜ Adjust the printhead tension according to the CP300 service handbook. ➜ If the problem persists call your local Technical Support.
No printout of interpretation statement average cycles or measurements	• Incorrect setting.	➜ Check that the interpretation and measurement options are enabled for the printout > Settings Resting ECG > Printer.

Art. no.: 714095 rev.: b

Fault	Possible Causes and indicators	Remedies and Fault Location
Patient recordings not shown on patient screen **No connection to Network**	• No connection with SEMA database	➜ Connection to network lost, check network. ➜ In system settings **Settings > system > database** (administrator login), check the network path ➜ In system settings **Settings > system > database** (administrator login), check the Mode Active box is Selected.
No key response, LCD locked	• Software hangs up	➜ Switch off, and switch on again after a few seconds. ➜ Master reset the software as described below. ➜ Disconnect the mains and leave for 30 minutes to force switch off. Reconnect mains and switch on. ➜ If the unit is still not working call your local Technical Support.

10.3 Master Reset

Occasionally, the unit may lock-up or freeze. When this happens the unit can be reset by using a pointed instrument to access and press the **Master reset** on the rear panel..

Art. no.: 714095 rev.: b

10.4 Changing the Mains Fuse

DANGER

- ▲ Before the fuse and mains voltage are changed, the device must be disconnected from the mains and the mains plug removed for the wall socket.
- ▲ The fuse may only be replaced by the fuse type the table below.

10.4.1 Fuse Types

Voltage range	Number	Fuse type
100 - 240 VAC	2	250 V / 630 mA (T = slow blow)

10.4.2 Changing a Fuse

1. Disconnect the device from the mains and remove the mains plug.
2. Loosen the fuse inset by using pushing up the release catch and remove the fuse inset.
3. Replace existing fuses with the same type (see table above). Re-insert the fuse inset and ensure it clicks in place.

Art. no.: 714095 rev.: b

11 Technical Data

11.1 System

Dimensions	100 x 285 x 350 mm, (0.328 x 0.935 x 1.148 feet) 6.8 kg (14.99 lbs)
Monitor	• Backlit for graphic and LCD alphanumeric representation • 15" TFT- display, high-resolution 1024 x 768 pixels
Power supply	
Mains Voltage	• 110 - 230 Vac (nominal), 50/60 Hz
Power consumption	• 75 VA (Max)
Battery	• Emergency built-in rechargeable battery
Battery	• 24 V Lithium rechargeable (built in charger); giving bridging power for a minimum of 15 minutes • Battery life under normal conditions more than 4 years
Printer	• Integrated high-resolution thermal printhead, 8 dots/mm / 200 dots/in (amplitude axis), 40 dots/mm / 1000 dots/in (time axis), @ 25 mm/s
Paper speeds	• 10 / 25 / 50 mm/s (Manual)
Chart paper	• thermoreactive, Z-folded, 8 1/2 in x 11 in (letter size), ready-to-file
Frequency	• Frequency response of digital recorder: 0 Hz - 150 Hz (IEC/AHA)
Sensitivity	• 5 / 10 / 20 mm/mV
Recording tracks	• 6 channels, positioned at optimal width on 200 mm / 8 1/2 in, automatic baseline adjustment
Interfaces	• USB 1 to 4. Universal Serial Bus connector (V1. 1) for USB devices, e.g. mouse, wireless LAN, printer, etc. • EXT 1 RS-232 for the connection of a Bicycle • EXT 2 RS-232 for the connection of a treadmill • EXT 3 RS-232 for the connection of an external blood pressure device • COM 2 - modem or other units. • COM 4 - reserved • PS-2 for the connection of an external control device (e.g. mouse, trackball), and /or external keyboard • LAN RJ45
Environmental conditions	
Operating temperature	• 50 - 104 °F
Storage temperature	• 14 - 122 °F
Relative humidity	• 25 - 95% (no condensation)
Pressure during operation	• 700 - 1060 hPa

Art. no.: 714095 rev.: b

11.2 ECG

Patient input	Fully floating and isolated, defibrillation-protected (only with original patient cable)
Leads	• 12 simultaneous leads • Standard • Cabrera
Monitor display	
Leads	• 3 - 12 channel display of the selected leads – selectable speed of 5, 10, 20 mm/s – selectable amplitude 10 or 20 mm/mV
Status	• Filter status (on/off) • Power source • Lead selection • Electrode contact status • Heart Frequency, HF • Date and Time
Filters	• Myogram filter (muscle tremor filter): 25-150 adaptive filter (not active on averaged waveform). Stored ECGs can be printed with or without filter. ECGs are always stored unfiltered. • Line frequency filter: distortion-free suppression of superimposed 50 or 60 Hz sinusoidal interferences by adaptive digital filtering.
Automatic lead programs	3/12-channel presentations of 12 simultaneously recorded leads
Exercise ECG with final report	• Automatic control of bicycle ergometer and treadmill (user programmable) • Final report showing trend plots of heart rate, load and blood pressure, physical working capacity (PWC 150, PWC 170, PWC max.) • Interpretation
Data record	• Patient data (name, age, height, weight, BP), user ID • Listing of all ECG recording conditions (date, time, filter)
With optional interpretation program	• ECG measurements results (intervals, amplitudes, electrical axes) • Average complexes with optional measurement reference markings • Guidance on interpreting adult and paediatric ECGs
ECG amplifier	Simultaneous recording of all 9 active electrode signals (= 12 leads)
Sampling frequency	• 1000 Hz
Resolution	• 5 µV / 12 bit
Pacemaker detection	• ≥ ±2 mV /pulse widths ≥ 0.1 ms
Frequency range	• 0.05 - 150 Hz (IEC/AHA)
Measurement range	• dynamic ±10 mV, DC ±300 mV
CMRR	• > 100 dB
Input Impedance	• 100 MΩ
Defibrillation protection	• 5000 VDC
Patient leakage current	• < 5 µA

Art. no.: 714095 rev.: b

11.3 Safety Standards

Safety standard	• IEC/EN 60601-1 • IEC/EN 60601-2-25 • UL 2601-1 (2nd Edition) • CSA22.2 No. 0-M91 • CSA22.2 No. 601.1 M90 • CSA22.2 No. 601.1 S1-94 • CSA22.2 No. 601.1 • CSA22.2 No. 2-25-94 • CSA22.2 No. 2-25A-94
EMC	IEC/EN 60601-1-2
Protection class	I according to IEC/EN 60601-1 (with internal power supply)
Conformity/Classification	CE/IIa according Directive 93/42/EEC
Safety class	CF according to IEC 601601-1, IEC 60601-2-25, CSA, UL; IIb according to MDD 93/42/EEC
Protection	This device is not designed for outdoor use (IP 20)

Art. no.: 714095 rev.: b

11.4 EMC Information

The unit meets the Collateral Standards of Electromagnetic compatibility – Requirements and tests IEC/EN 60601-1-2 the limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment.

Medical electrical equipment is subject to the electromagnetic compatibility (EMC) regulations.

This medical device is intended for use in the electromagnetic environment specified in the following tables 201, 202, 204 and 206. The user of this device must ensure that the device is installed and operated with reference to these tables.

11.4.1 Electromagnetic Emissions - Table 201

Emission	Test Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 6100-3-3	Complies	

11.4.2 Immunity - Table 202

Immunity Test	IEC 606101 Test level	Compliance Level	Electromagnetic environment guidance
ESD EN 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2 kV Power supply lines ± kV I/O lines	±2 kV Power supply lines ±1 kV I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The unit shutoff during the >95% for 5 second disturbance. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterrupted power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Art. no.: 714095 rev.: b

11.4.3 Emissions Equipment and Systems - Table 204

Emissions Equipment and Systems that are NOT Life-Supporting

Immunity Test	IEC 606101 Test Level	Compliance Level	Electromagnetic environment guidance
			Portable and mobile communications equipment should be used no closer to any part of this device, including cable, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance:** $d = \frac{3.5}{V_1} \times \sqrt{P}$ for 150 Khz to 80 MHz $d = \frac{3.5}{E_1} \times \sqrt{P}$ for 80 MHz to 800 MHz $d = \frac{7}{E_1} \times \sqrt{P}$ for 800MHz to 2.5 GHz where P is the maximum power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site[a] survey, should be less than the compliance[b] levels (V_1 and E_1). Interference may occur in the vicinity of equipment marked with following Symbol  "non ionizing radiation"
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	$[V_1]$ = 3 Vrms	
Radiated RF EN 61000-4-63	3 V/m 80 MHz to 2.5 GHz	$[E_1]$ = 3 V/m	

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 ant TV broadcast cannot be predicted theoretically with accuracy. To access 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

Art. no.: 714095 rev.: b

11.4.4 Recommended Separation Distances - Table 206

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the Device

The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and this device as recommended below, according to the maximum output power of the communication equipment

Maximum Power Output **[Watts]**	**Separation distance according frequency of the transmitter** **[m]**	
	150 kHz to 800 MHz $d = \frac{3.5}{V_1} \times \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \frac{7}{V_1} \times \sqrt{P}$
0.01	0.12	0.7
0.1	0.37	2.21
1	1.17	7.0
10	3.7	22.1
100	11.7	70

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 To calculate the recommended separation distance of transmitters in the frequency range at 80 MHz to 2,5 GHz an additional factor of 10/3 was used, to limit the possibility for the patient area that unintentional brought in mobile or portable communication equipment cab cause any disturbance.

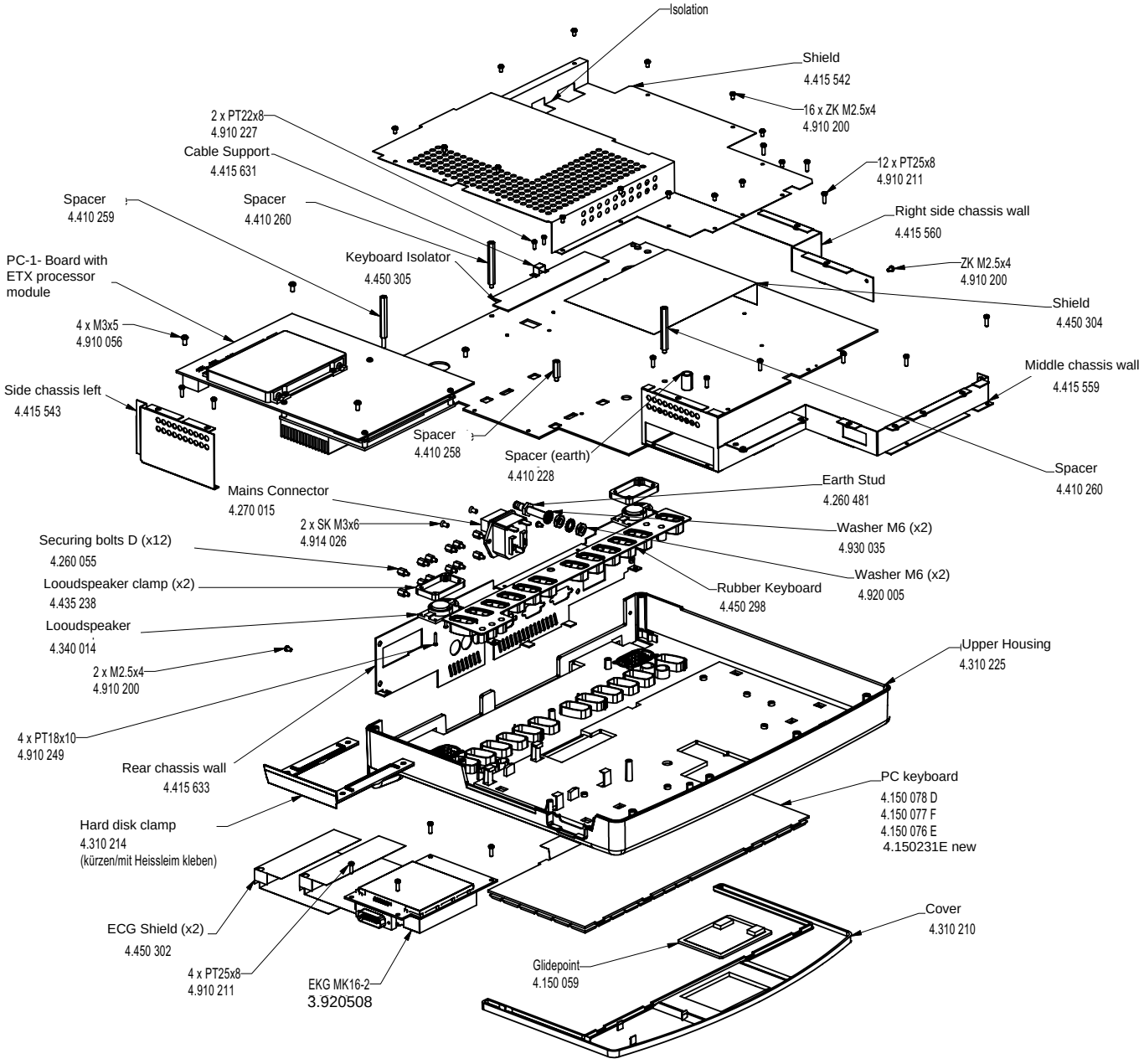
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Art. no.: 714095 rev.: b

12 Construction Drawings

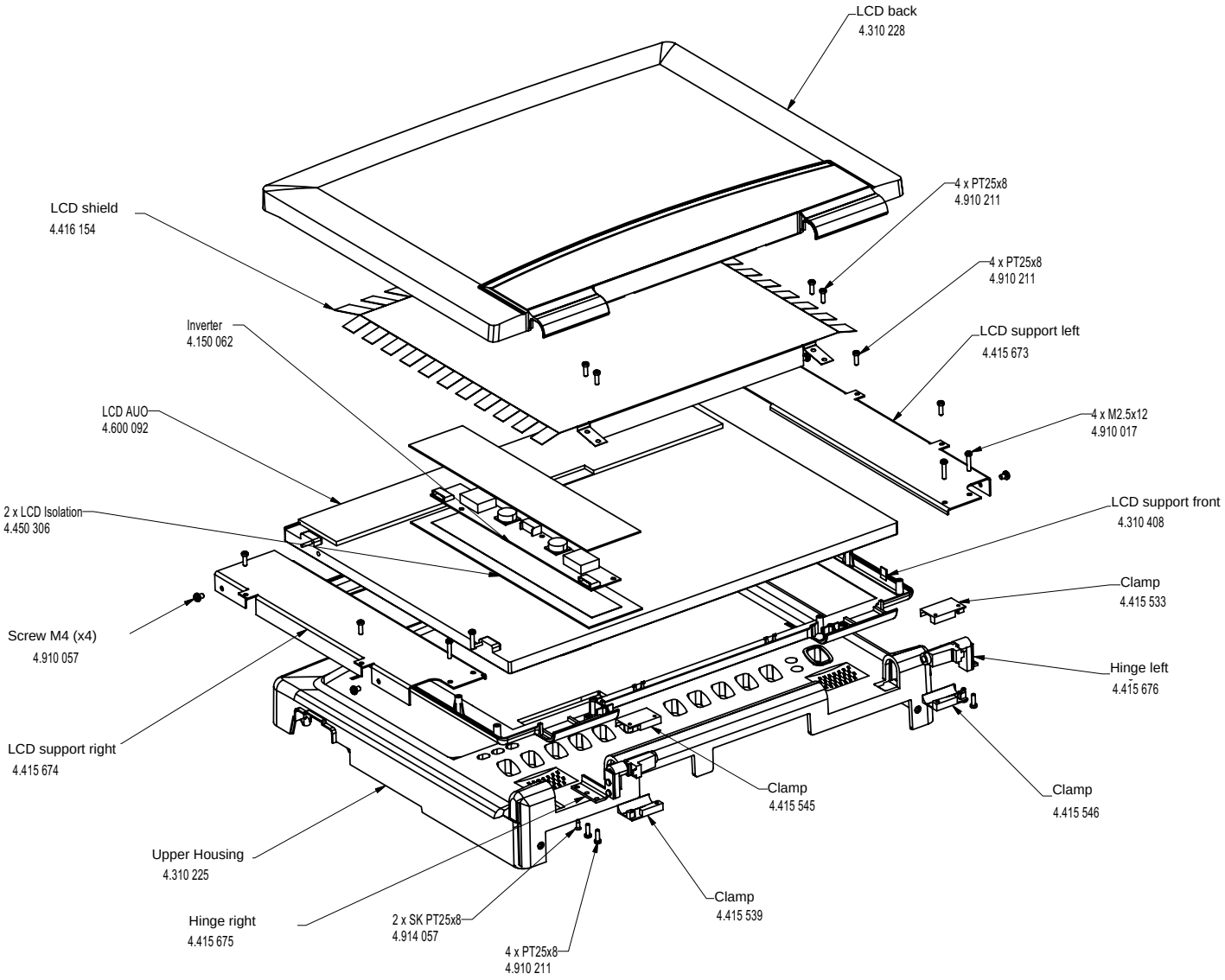
Conversion from drawing number to Welch Allyn PN refer to DIR30034004.

12.1 Upper Assembly



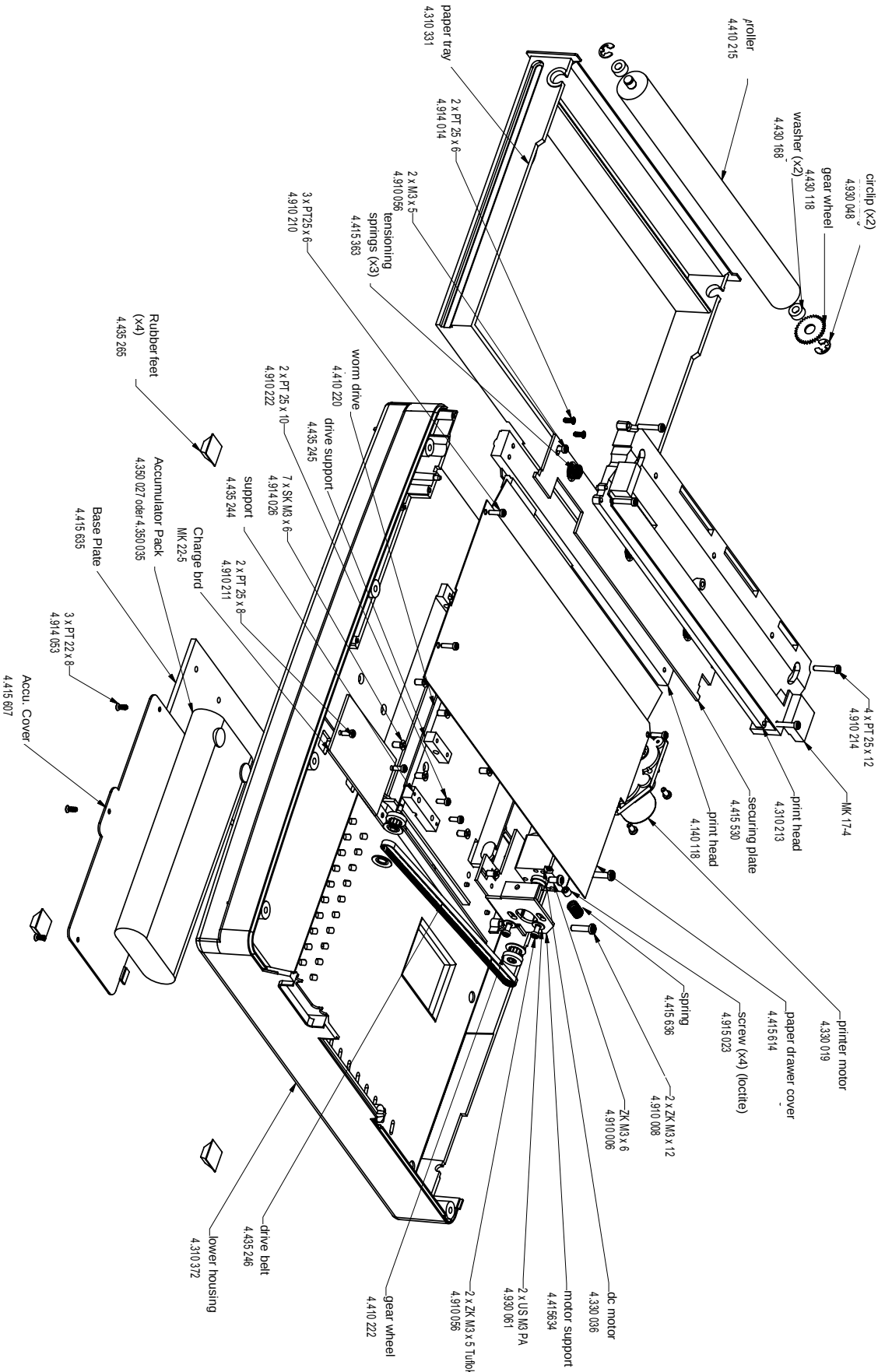
Art. no.: 714095 rev.: b

12.2 LCD Assembly



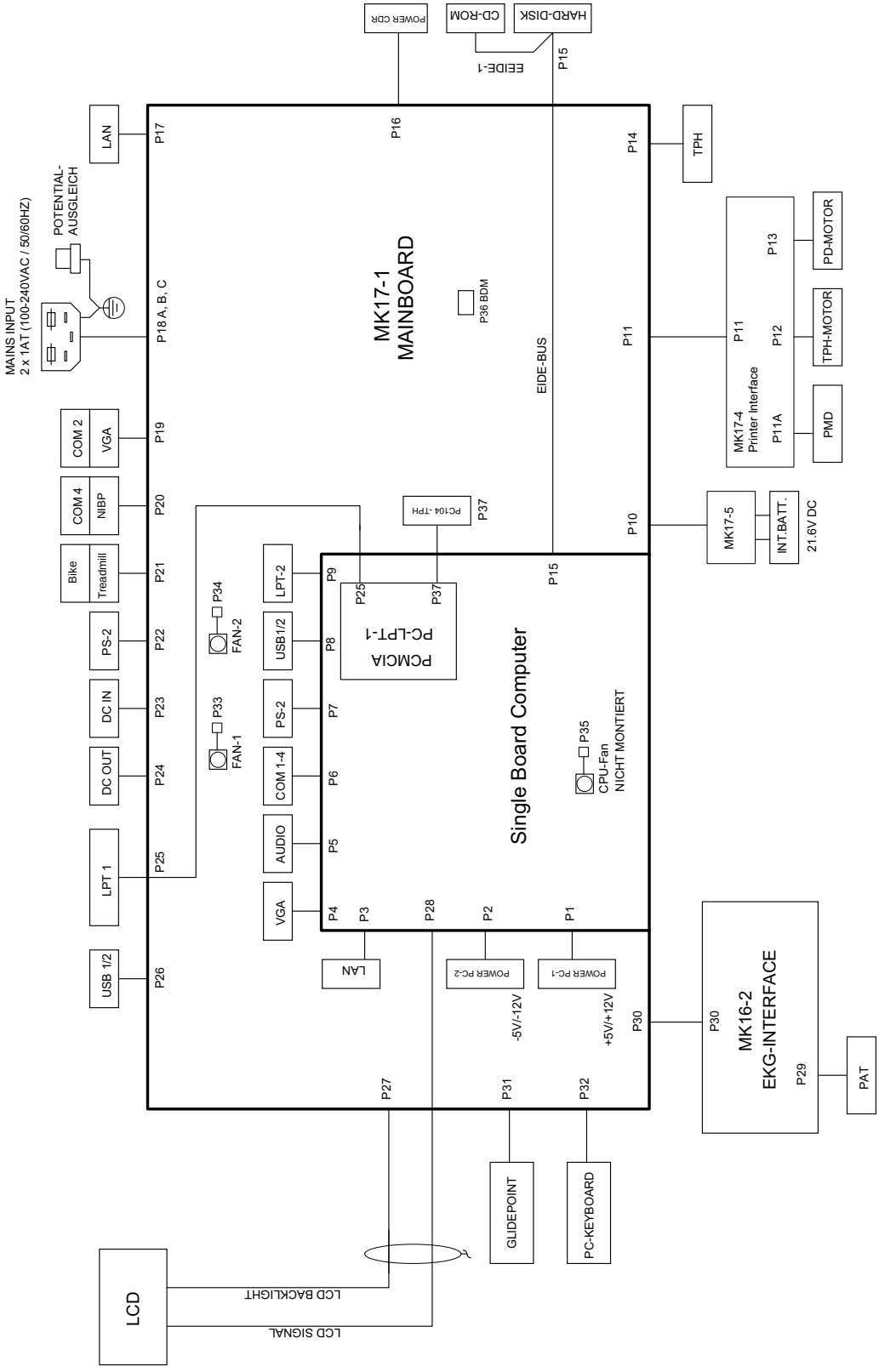
Art. no.: 714

12.3 Lower Casing



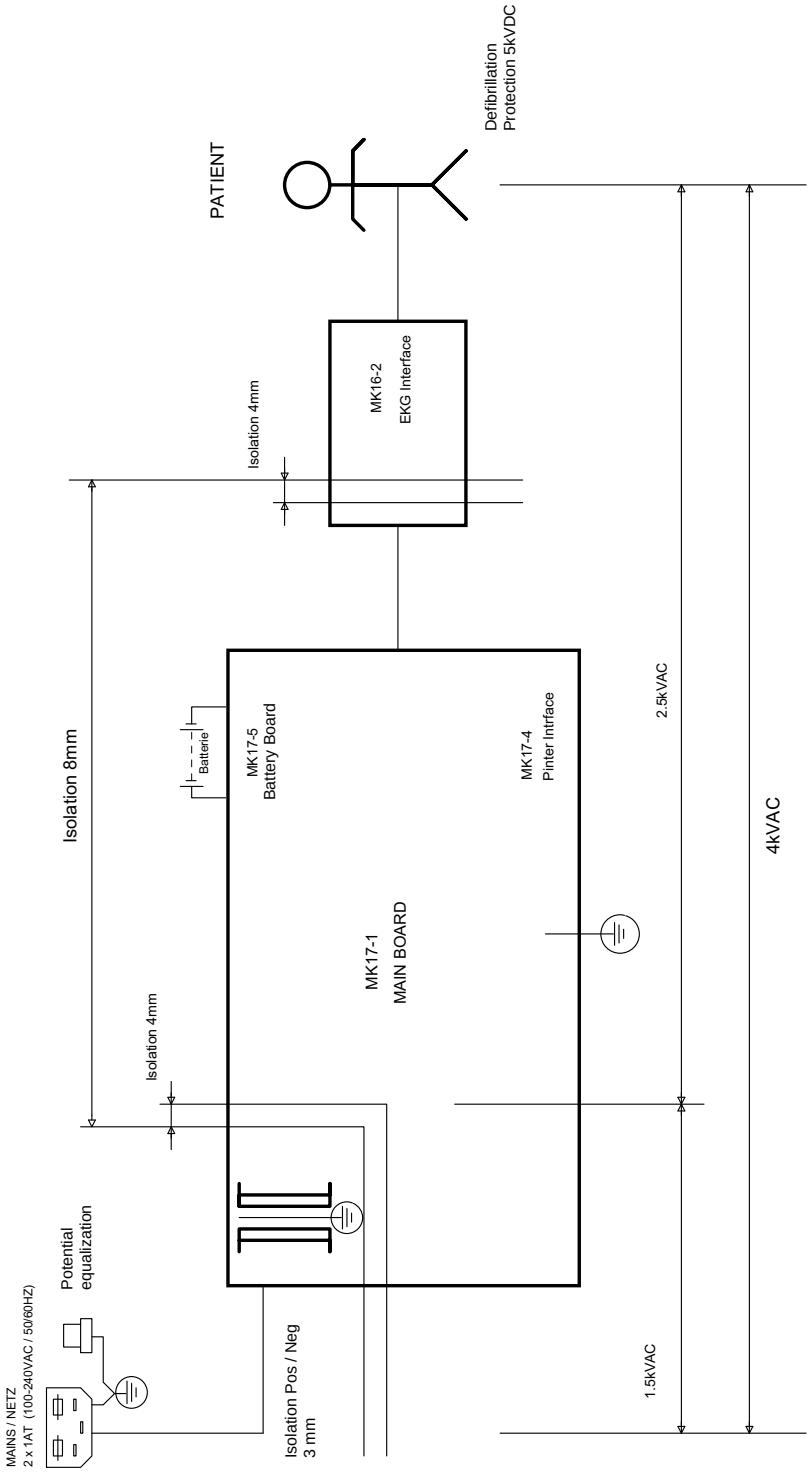
Art. no.: 71409 5 rev.: b

12.4 Interconnections

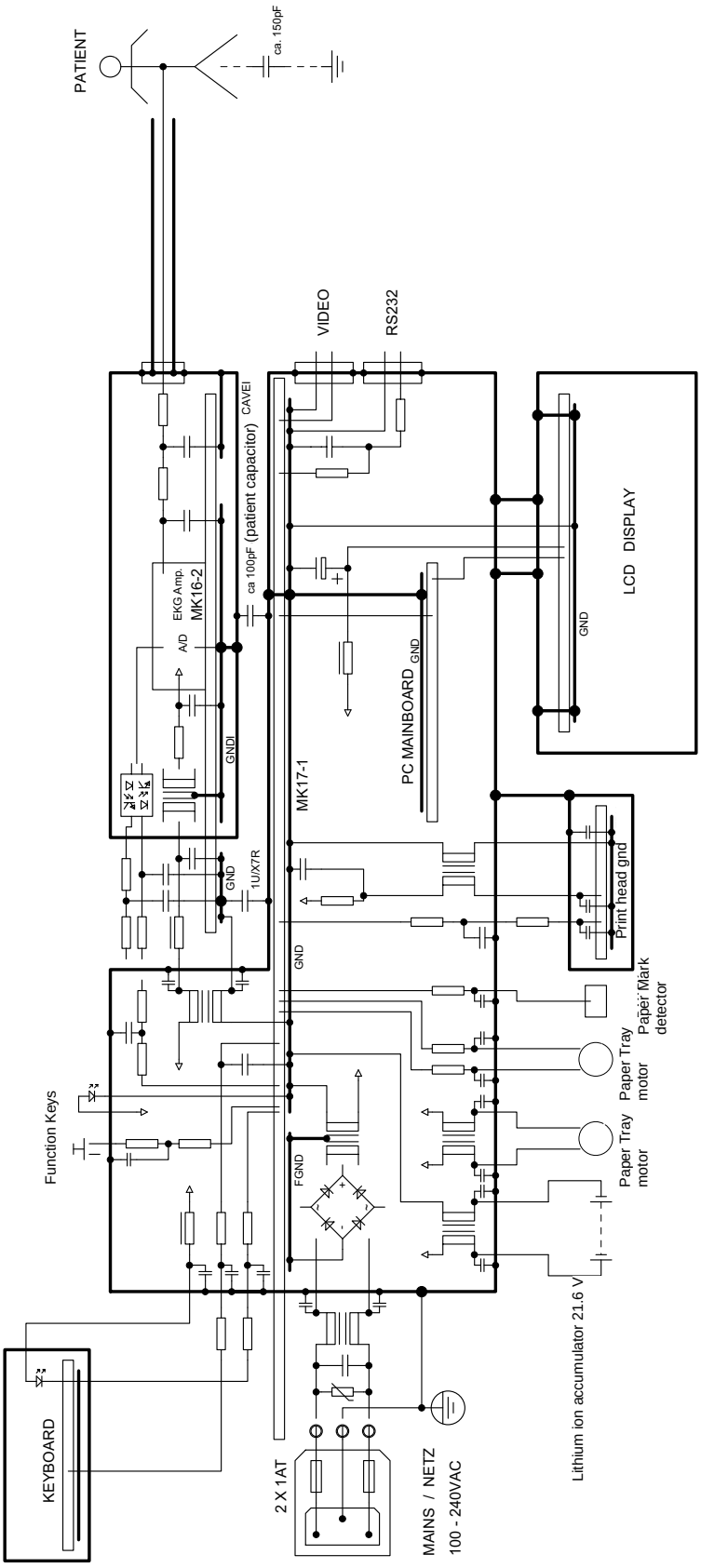


Art. no.: 714095 rev.: b

12.5 Isolation Diagram



12.6 EMC Concept



Art. no.: 714095 rev.: b

13 Checklist

The following procedural checklist must be carried out by authorized Welch Allyn trained personnel. The recommended interval is that the unit is checked every 12 months.

▲ It is a requirement of EN 60601 that the unit undergoes a safety test at defined intervals (see page 37), and a complete functional check at least every 24 months (detailed in the following checklist).

13.1 CP300 checklist table

Name of tester:		**Signature:**	
Device serial number:		**Software Version:**	
Customer:		**Date:**	

Reference	OK	False	Remarks
6.3.1 External Sight Control (page 29)			
1. Mechanical condition of the device:			
– no cracks or chips in the casing			
– mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc.			
– All plugs and sockets are straight and in good condition.			
2. No soiling which could hamper the safety of the device.			
3. Voltage selector is set correctly.			
4. Correct fuse rating (see page 68).			
5. Safety labels:			
– back panel, type designation and fuse rating label readable.			
– side panel (patient connector), CF label and ‘attention‘ symbol readable.			
6.3.2 Mains and Battery Indicators (LED) test (page 30)			
1. Mains indicator lamp lit when the unit is connected to the mains supply.			
2. Mains indicator lamp off and the battery lamp is lit when mains disconnected.			
3. Battery lamp blinks (limited capacity) after 10 - 25 minutes			
6.3.3 Battery Capacity Check (page 30)			
1. Unit operates for a minimum of 10 minutes on battery power.			
6.3.4 Keyboard Test (page 30)			
1. No mechanical damage or excessive wear.			
2. All keys function.			

Art. no.: 714095 rev.: b

Reference		OK	False	Remarks
6.3.5 LCD Screen Test (page 31)				
1. No spots or black fields on the screen.				
2. LCD shade (contrast and brilliance) is even all over.				
6.3.6 Printer Checks (page 32)				
1. No fading				
2. Alignment OK				
3. No faulty pixels				
4. Blackness, regularity and good readability on the complete print width				
Paper Feed (page 32)				
1. Paper stops at the perforation (paper mark)				
Printing Speed (page 32)				
1. On the 25 mm/s printout the space between 2 R peaks is 25 mm ± 0.5 mm.				
Parallelism test (page 32)				
1. Calibration waveforms line up vertically and the maximum deviation is not more than ± 0.5 mm.				
6.3.7 ECG Amplifier and Patient Cable Test (Electrode/ Lead Resistance) (page 33)				
1. Disconnect ECG patient simulator. Check the following:				
– device beeps 4 times				
– all lead designations highlighted				
– the mV reading for all leads is -350 to -550 mV				
2. Connect ECG simulator:				
– all leads stop blinking				
– the mV reading for all leads is -20 to+20 mV				
6.3.8 ECG Printout Reference (page 34)				
1. The measurements table on the printout gives the following values:				
Intervals	RR 1000 ± 10			
	P 116 ± 10			
	PR 176 ± 10			
	QRS 56 ± 6			
	QT 356 ± 12			
V1	P 0.15 ± 0.02			
	R 2.0 ± 0.01			
	Rd 56 ± 6			
	J 0.2.0 ± 0.02			
	ST 0.2 ± 0.02			
	T 0.4 ±0.03			
2. Waveform shape and polarity same as reference printout				

Art. no.: 714095 rev.: b

Reference	OK	False	Remarks
6.4 I / O Port Checks (page 37)			
1. Com 2 port I/O ok - both green lights lit			
2. Com 4 port I/O ok - both green lights lit			
3. Ext 1, 2 and 3 ok - both green lights lit for all ports			
6.5 Safety tests (page 39)			
1. The safety test is carried out in accordance with the EN 60601-1, Clause 18 and 19. This test may only be carried out with a tester that fulfils the above mentioned norms and has been calibrated in accordance with ISO norms.			Add protocol with results to this checklist.
2. High Voltage Leak test in accordance with EN 60601-1, Clause 20.			Add protocol with results to this checklist.

Art. no.: 714095 rev.: b

Other remarks

Art. no.: 714095 rev.: b