P8000 Power

ECG and Spirometry Unit

Article Number 9740440033
ESAOTE SPA 2003

User Guide

P8000 Power

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P8000Power User Guide
Article Number 9740440033

Revision e
December 2003

Associated Documents

- Physicians Guide to the Interpretation and Measurement Program - Article Number 9740440008
- P8000Power Spirometry Supplement
- P8000Power Service Handbook
- This user guide is also available in other languages

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http://www.ESAOTE.com

CE 0123

Intended Use

The P8000Power is a 12-channel, ECG device used for the recording, analysis and evaluation of ECG Recordings. Recordings made with the P8000Power can be used as a diagnostic aid for heart function and heart conditions. The P8000Power is designed for indoor use and can be used for all patients of both sexes, all races, and all ages.

Physician`s Responsibility

The P8000Power ECG Unit is provided for the exclusive use of qualified physicians or personnel under their direct supervision. The numerical and graphical results and any interpretation derived from a recording must be examined with respect to the patient`s overall clinical condition. Patient preparation and the general recorded data quality, which could effect the report data accuracy, must also be taken into account.

It is the responsibility of the physician to make the diagnosis or to obtain expert opinion on the results, and to institute correct treatment if indicated.

FEDERAL LAW IN THE USA RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Declaration of Conformity

Electrocardiograph: **ESAOTE P8000 Power**

We, the undersigned, hereby declare that the medical device (classe II a) specified above conforms with the Essential Requirements listed in Annex I, of EC Directive 93/42/EEC

This declaration is supported by:

TÜV Product Service GmbH, Management Service, D – 80339 Munich

Certificate of approval No:

12 100 13897	DIN EN ISO 9001:2000
Q1Z 01 03 41505 002	DIN EN ISO 9001:1994 / DIN EN 46001:1996
G1 01 03 41505 001	Annex II, Section 3 of the Directive 93/42/EEC Medical Devices

Valid date 02/2004.

Baar (Switzerland), 26.03.02

Markus Bütler
Quality Assurance Manager

P8000Power User Guide

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Terms of Warranty

The ESAOTE P8000Power 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 ESAOTE P8000Power and approved attached equipment is used in accordance with the manufacturers instructions.

THERE ARE NO EXPRESS OR IMPLIED WARRANTIES WHICH EXTEND BEYOND THE WARRANTIES HEREINABOVE SET FORTH. ESAOTE MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF.

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commission) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Disposal Instructions and Battery Care

- DO NOT DISPOSE OF THE BATTERY BY FIRE OR INCINERATOR - DANGER OF EXPLOSION
- DO NOT OPEN THE BATTERY CASING - DANGER OF ACID BURN

Only dispose of the battery in official recycling centres or municipally approved areas.

Units no longer required can be disposed of in municipally approved recycling centres.

Safety Notices

Operational Precautions

- Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided by a product representative.
- The guidelines for patient electrode placement are provided as an overview only. They are not a substitute for medical expertise.
- IEC/EN 60601-1-1 states that the patient must remain at least 1.5 metres clear of the unit. When this is not possible an isolation transformer must be installed.
- It must be ensured that neither the patient nor the electrodes (including the neutral electrode) come into contact with other persons or conducting objects (even if these are earthed).
- Only connect the original ESAOTE patient cable to the patient socket.
-  This unit is CF classified and defibrillation protected when the original patient cable is used. However, as a safety precaution when possible, remove electrodes before defibrillation.
- Do not touch the unit casing during defibrillation.
- If the patient cable should become defective after defibrillation, an electrode becomes displaced, or an electrode resistance is too high, lead-off is displayed in the upper right part of the screen and an acoustic alarm given.
- Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
- This product is not designed for sterile use.
- This product is not designed for internal use. Type CF applied parts are not suitable for direct cardiac application.
- This product is not designed for outdoor use.
- Do not use this unit in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.
- Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
- There is no danger when using the ECG unit for a patient with a pacemaker fitted.
- Surface temperature of applied parts must not exceed 41°.

Safety Notices

Precautions for Operation with other Devices

- Use only accessories and other parts recommended or supplied by ESAOTE. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- Accessory equipment connected to the analogue and 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.
- Externally connected units must use the same common earth.
- Externally connected units must use an original ESAOTE interface cable.
- If several units are coupled, there is a danger of summation of leakage currents. When two or more units are coupled together, an isolation transformer must be used in the mains supply.
- The unit complies with EMC regulations for medical products which affords protection against emissions and electrical interference. However, special care must be exercised when the unit is used with high frequency equipment.
- There is no danger when using the ECG unit simultaneously with other electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes. In case of doubt, the patient should be disconnected from the recorder.
- To avoid possible interference from the Ergometer when carrying out an exercise test, it is recommended that both the P8000 and the Ergometer are connected to the same common ground.
- If the P8000 is part of a medical system, the original ESAOTE patient cable must only be used with, and connected to, the patient connector on the P8000.

Safety Notices

Maintenance Precautions

- Do not use high temperature sterilisation processes (such as autoclaving). Do not use e-beam or gamma radiation sterilisation.
- Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- To prevent electric shock do not disassemble the unit. No serviceable parts inside. Refer servicing to qualified personnel only.
- Before cleaning and to isolate the mains power supply, switch the unit off and disconnect from the mains by removing the plug.
- Do not, under any circumstances, immerse the unit or cable assemblies in liquid.
- The unit is protected by double pole / neutral fusing for continued protection against the risk of fire. Replace only with the same fuse type and rating.

Safety Notices

Extra Precautions for Spirometry

Sensor SP-250

- The disposable mouthpiece of the SP-250 spiro sensor is designed for one-time use to eliminate the danger of cross contamination - do not use the mouthpiece for more than one patient. Do not attempt to clean the mouthpiece.

Sensor SP-260

- The mouthpiece of the SP-260 spiro sensor is reusable. Thoroughly disinfect the mouthpiece assembly before using for another patient. Replace the filter after every patient - do not use the filter for more than one patient.

General

- For correct predicted values and diagnosis, it is important that all patient data is entered correctly. In particular gender, date of birth, ethnic, height and weight must be entered.
- The unit must be calibrated at the beginning of every day, or after a significant change in temperature.
- False measurements can result when the sensor is not held vertically - always ensure that the sensor is held upright at all times.

Symbols and Conventions Used in this User Guide

Warnings and Cautions

General warning applicable to following text and/or chapter. Text set off in this manner indicates that failure to follow directions could result in bodily harm or loss of life.

WARNING:

Specific warning applicable to associated instruction. Text set off in this manner indicates that failure to follow directions could result in bodily harm or loss of life.

CAUTION:

Specific caution applicable to associated instruction. Text set off in this manner indicates that failure to follow directions could result in damage to equipment or loss of information

Symbols and Conventions Used in this User Guide

General Symbols

NOTE:

Text set off in this manner presents clarifying information, specific instructions, commentary, sidelights, or interesting points of information.

CF Symbol. Unit is classified safe for internal and external use. The paddles at the side indicate that the unit is defibrillation protected when the original ESAOTE patient cable is used.

Potential Equalisation Point.

The unit /component can be recycled.

Type and approving body.

Section 1

Getting Started

This section contains an introduction to the P8000Power and an overview of all external connections. It also gives an overview of the operating philosophy of the P8000Power and an introduction to the basic functions of the unit.

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Initial Preparation

The P8000Power requires no special tools for preparation. To commission the P8000Power proceed as follows:

1. Open the box and remove the unit. Store the packaging for reuse if necessary.
2. Place the unit on a suitable work surface.

Location

- Do not keep or operate the unit in a wet or dusty environment
- Avoid exposure to direct sunlight or heat from other sources
- Do not allow the unit to come in contact with acid vapours or liquids
- Do not place the unit in the vicinity of X-ray or diathermy units, large transformers or electric motors.

3. Connect the mains supply to the mains connector on the rear panel of the unit with the supplied mains cable. The Mains LED below the ON key, will light. Leave the P8000Power connected to the mains for 24 hours to fully charge the battery.

ON Key and mains indicator

4. Switch the unit on - the LCD will light and the patient data screen or ECG acquisition screen (see Section 4 - Setup), is displayed.

5. Connect the patient cable to the patient connector on the right side panel.

Initial Preparation

6. Press the paper tray release key to open the paper tray.

7. Insert the thermal print paper and again press the paper tray key to return the paper tray - full details are given in Section 5.

8. If an external monitor is to be connected, connect it to the VGA connector on the rear panel with the cable supplied. If an external printer is supplied, connect it to the printer connector..

CAUTION

To prevent the possibility of leakage current when the external printer is connected, always ensure that the mains lead, or the potential equalisation (next to the mains connector), is attached to the P8000Power.

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P8000Power

Introduction

The ESAOTE P8000Power is a 12-channel ECG unit designed to record, display, and analyse resting ECGs (exercise ECGs can also be recorded). The unit has been extensively researched to give an ergonomic, clear interface that`s easy to use without compromising functionality. The P8000Power has the following features:

Standard Features

- Alphanumeric keypad and dedicated soft key interface for easy, user friendly operation.
- Storage and transmission facilities for recordings.
- Integral full size thermal quality printer with various user defined print format options.
- VGA socket for connection of an external monitor (ECG traces only).

Optional Features

- Excercise ECG with interface for control of digital ergometers and treadmills.
- External deskjet printer.
- ECG Interpretation including measurements and average cycles with automatic and manual printout of the recording.
- Sensor for spirometry recording (software is standard and pre installed on the P8000).

  Two sensors are available; the SP-260 sensor with a disposable filter, and the SP-250 sensor with a disposable mouthpiece assembly. When using the SP-260 sensor, the filter must be changed and the mouthpiece sterilised after every patient. With the SP-250 sensor, the mouthpiece assembly is replaced complete removing the need to sterilise after every patient.

Introduction

Operating Philosophy Overview

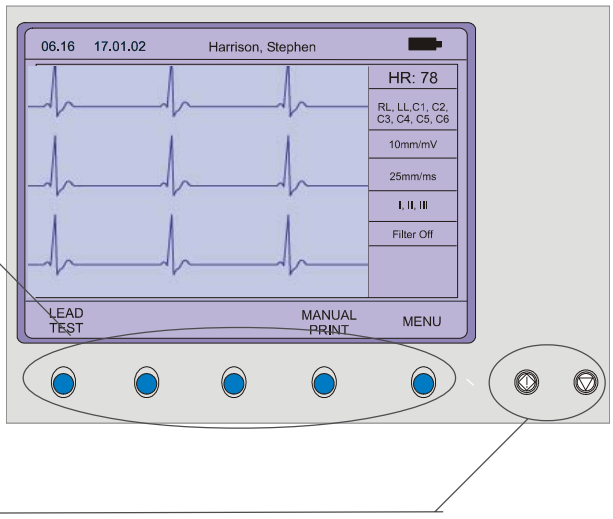
There are broadly four types of data display as follows

Data Acquisition and ECG Recording Screen	In this screen the real-time ECG is displayed. From this screen a continuous printout can be initiated and/or an auto recording can be made. In auto mode 10 seconds of ECG data is analysed and averaged and the results given on a printout. The format and data of an auto mode printout is independent of the screen display, and is defined in the setup screens. (See section 4). An auto mode recording can also be stored in the memory for later print or transmission.
Memory Screen	In this screen stored recordings can be accessed.
Patient Data Screen	Patient data entry via the keypad.
Data Entry and Setup	In these screens all system settings, resting and exercise ECG settings, and spiro settings are made.

Initiating Functions or Tasks

Most functions and tasks are initiated by the 5 softkeys situated immediately below the LCD. The function of the softkeys varies according to the screen displayed and is displayed on the LCD immediately above the key itself.

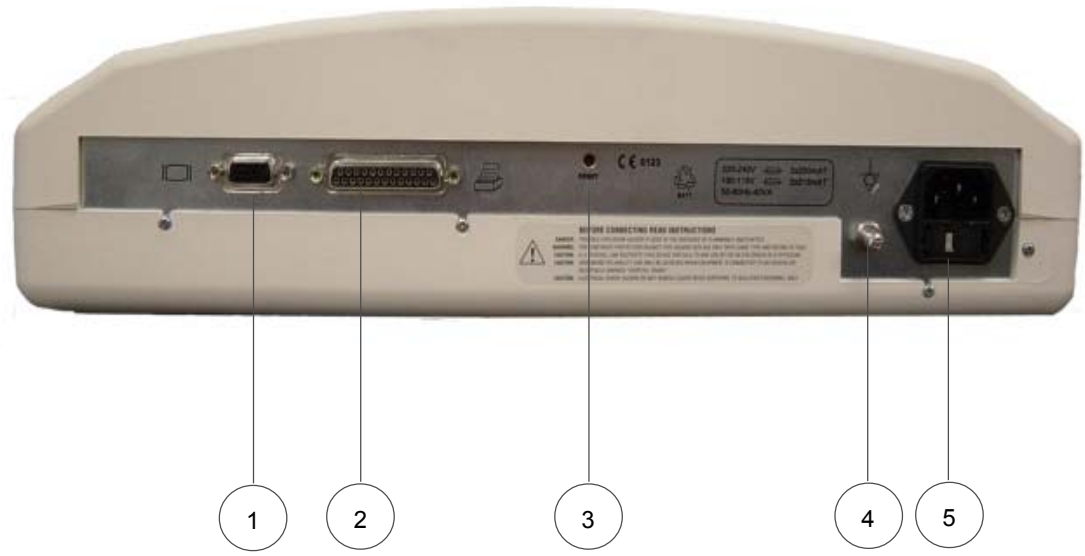
During data acquisition, further dedicated function keys are provided to make an auto mode recording (START) and to stop a manual printout (STOP). The top line of the alphanumeric keypad, additionally enables direct settings of lead group, trace speed and sensitivity, filter on/off and other functions, for both the real-time display and (manual) printout.



Main Components of the P8000Power

1. Keypad and dedicated function keys
2. Patient cable connector
3. RS-232 for any of the following:
   - ° connection of an ergo device
   - ° connection of a spiro sensor
   - ° connection of a modem or a PC for export of stored recordings
4. Softkey control
5. LCD Display.

Back Panel



1. VGA connector for the connection of an external monitor (option)
2. LPT connector for the connection of an external printer
3. Master Reset
4. Potential equalisation stud
5. Mains connector (with fuse below)

CAUTION:

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

Power Supply

The mains connection is on the rear of the unit.

The power supply voltage is factory set for 220-240V (nom. 230V) working. The setting is indicated by the indented metal strip on the fuse panel. If the voltage needs to be changed for 100-115V (nom. 110V) working, consult the quick reference sheet.

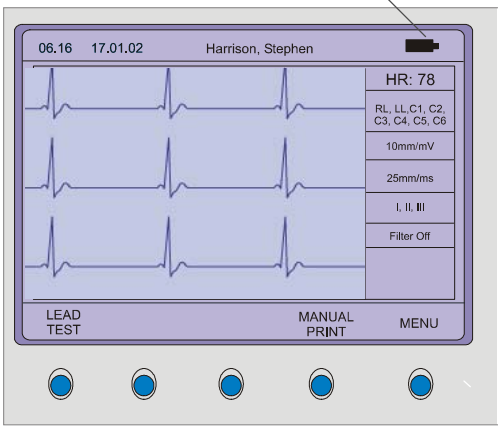
Switching On and Off

The P8000Power is switched on with the ON key (right key) and off with the OFF key. These keys are situated on the top right of the keypad.

The mains indicator lamp on the keypad is always lit when the unit is connected to the mains supply.

The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicated on the top line of the LCD. When mains is connected a mains symbol is displayed. When the unit is running on battery power a battery symbol is displayed

Power Indicator symbol



The internal battery provides power for up to 3 hours. The Battery indicator blinks when the battery capacity is limited.

To recharge the battery, connect the apparatus to the mains supply by means of the supplied power cable. A totally discharged battery requires approximately:

- 15 hours to be fully recharged
- 7 hours to be 90% recharged
- 3 hours to be 60% charged

The unit can remain connected to the mains supply without damage to either the battery or the unit.

NOTE:

When working from battery power, the unit is automatically switched off after 5 minutes (30 seconds if battery capacity is limited) if no key is pressed.

Power Supply

Changing a Mains Fuse

WARNING

Before changing a fuse, isolate the mains supply by removing the plug from the wall socket.

CAUTION

Always replace fuses with the correct rating i.e. 2x200mAT for 230V, or 2x315mAT for 110V.

To change a fuse press the retaining lug in the middle of the fuse panel (situated below the mains connector on the back panel). Remove the fuse panel and replace the fuse(s). Click the fuse panel back in position. See quick reference sheet supplied for full details.

Potential Equalisation

The potential equalisation stud at the rear of the unit can be used to equalise the ground potential of the P8000Power to that of all mains powered equipment in the vicinity. Use the hospital or building common ground.

CAUTION:

To avoid possible interference from the Ergometer when carrying out an exercise test, it is recommended that both the P8000Power and the Ergometer are connected to the same common ground.

To prevent the possibility of leakage current when an external printer is connected, always ensure that the mains lead, or the potential equalisation (next to the mains connector), is attached to the P8000Power

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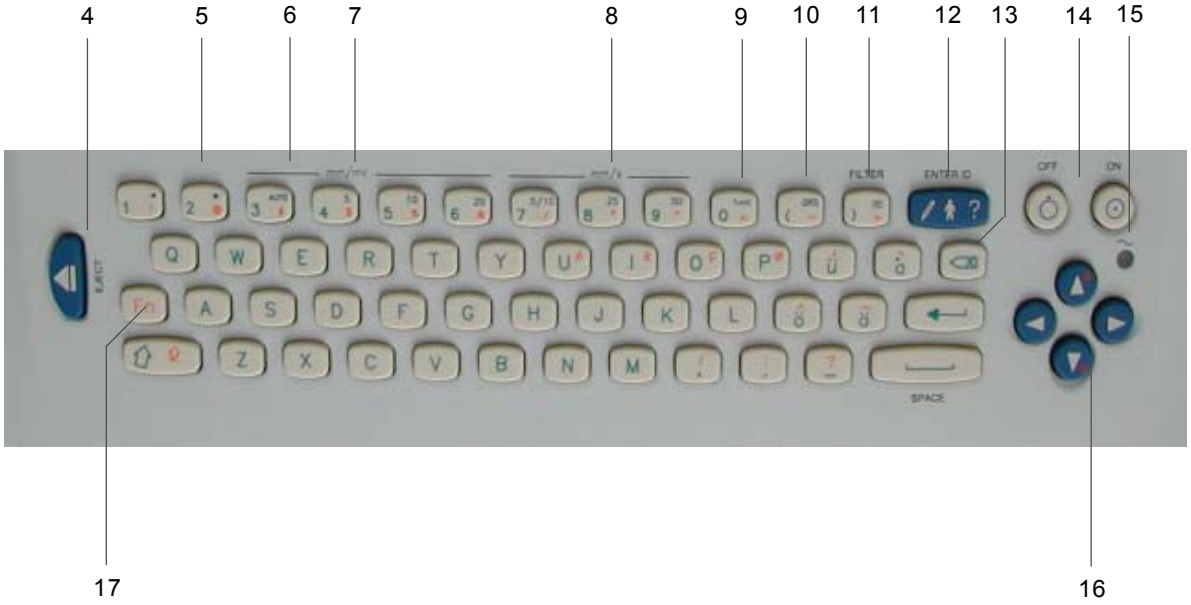
P8000 Power

Keypad



Keypad

1. Softkeys - the function of these keys changes depending on the screen displayed. The function of these keys is shown on the screen above the keys. If nothing is written above a softkey, it has no function for the current screen.
2. Auto Mode recording (in Auto mode 1).

   Press the SHIFT followed by the AUTO key (2) for auto mode 2.
3. STOP printout / confirm (new) setting
4. Open / Close paper tray (to replace thermal printing paper)
5. The top figures on the number keys `1` and `2 ` (designated < and >), change the lead group displayed on the screen, forward and backward resp.
6. Auto sensitivity key - automatically sets the ECG printout sensitivity (in AUTO mode only) to the best setting for the signal strength (5mm/mV or 10mm/mV)
7. The top figures on the number keys designated 5, 10, and 20 set the sensitivity of the ECG both on the screen and on the (manual) printout. The sensitivity is 5, 10 or 20 mm / mV.
8. The top figures on the number keys designated 5/10, 25, and 50 set the speed of the ECG both on the screen and on the (manual) printout. The speed on the screen can only be set to 25 or 50 mm/s. The speed of the manual printout can be 5, 10, 25 or 50 mm/s. The 5 and 10 mm/s settings are both on the same key which toggles the two speeds.
9. Inserts a 1mV reference marker on the screen and printout. Recentres the trace.
10. Toggles the QRS beeper ON/ OFF
11. Myogram filter ON / OFF. The cutoff frequency can be user defined in `Setup`.
12. Patient data key. Press this key to enter a new patient or modify the data for the current one.

NOTE:

The patient data screen, or the ECG screen is the first screen displayed on inital switch on. This is set for user prefernece in the system settings (Section 4)

13. Delete last typed character.
14. ON / OFF Keys
15. Mains Indicator - lit when mains connected.
16. Press the function key (17) and the UP/DOWN arrows to adjust screen contrast.

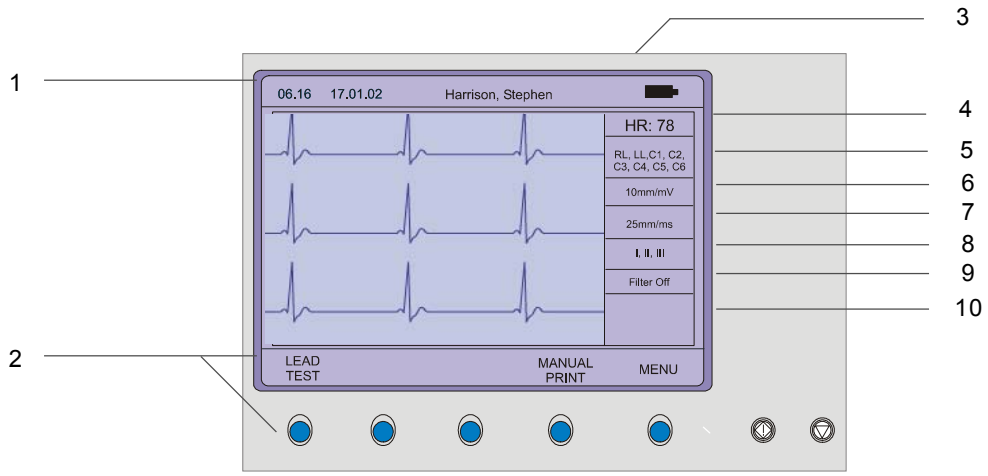
    When entering patient data use the LEFT/RIGHT arrow keys to move the cursor in the data field. Use the UP/DOWN arrow keys to go up/down to the next data entry
17. Function Key. When pressed before another key, initiates the second function of that key

    For example, second letters on the keypad - è, é, ç, ø @ etc., are entered by holding the function key before pressing the letter key.

LCD Screen

The display will vary according to the current task being carried out. In all screens however, the top and bottom lines always display the same information: the top line displays system information, and the bottom line always gives the softkey options.

The following is an example of a typical resting ECG screen.



Items 1, 2 and 3 are in the same position for all screens.

1. Top line - time, date, patient name, and current power source - mains (⏦), or battery ( ). When battery capacity is limited the battery symbol flashes.
2. Softkey designation. Pressing the key below the text carries out the function indicated. The options available will change according to the screen displayed.
3. Data acquisition area or data entry area.

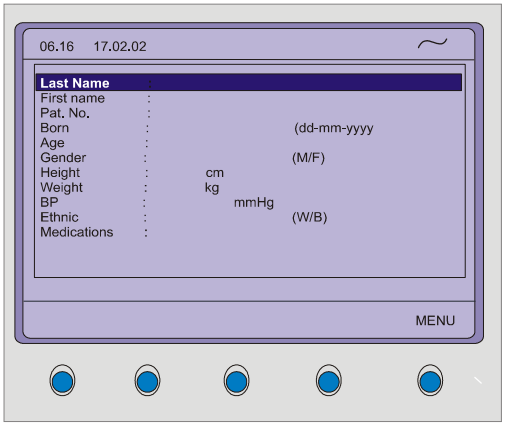
LCD Screen

Items 4 to 10 are specific for ECG acquisition only:

4. Current Heart Rate (averaged over 4 beats and refreshed every 2 seconds). The HR is also given on a manual printout. *Note that with an auto mode printout the HR is averaged over the full 10 seconds of the recording.*
5. Electrode connections - when an electrode indication flashes it indicates that the electrode resistance is too high. The electrode(s) must be reapplied.
6. Sensitivity - 5, 10 or 20 mm/mV. Change the sensitivity with the keys 3 (auto), 4, 5 and 6. An `A` in this box indicates that automatic sensitivity is selected (auto mode printout only).
7. Speed - 25 or 50 mm/s. Change the speed with the keys 8 and 9.
8. Lead indication (leads currently displayed on the screen). Change the lead group with the < and > keys on the keypad.
9. Myogram Filter indication - 'Filter ON' or 'Filter OFF'. The filter is applied with the filter key.
   Note: the frequency of the filter cutoff is defined in Section 4 Setup.
10. Area for system messages or instructions.

Entering Patient Data

In this screen a new patient can be entered, or a the details of a selected patient can be modified. Press the patient data key.



Last Name Enter patients name (maximum 20 characters)

First Name Enter patients first name (maximum 20 characters)

Pat. No. The patient number is an easily identifiable short form of identifying a patient - a maximum of 20 characters can be entered.

Born Enter patient`s date of birth dd-mm-yy

Only the patients year of birth need be entered (2 or 4 digits), - patient age is calculated to the nearest year. To calculate the age precisely, the day, month and year (2 or 4 digits) must be entered.

Gender Enter the patient`s sex - M or F

Weight Enter patient`s weight 0.5..250kg

Height Enter patient`s height 20..250cm

BP Enter the patient`s systolic (or diastolic) blood pressure.

Ethnic The setting made here is mainly used by the Spiro option when calculating norm values. Enter B (Black) or (W) White.

Medication Up to 23 characters can entered for medication notes

When all entries are made, press the softkey `menu` to confirm the entered data.

Section 2

Resting ECG

This section contains all the information required to make a resting ECG Recording.

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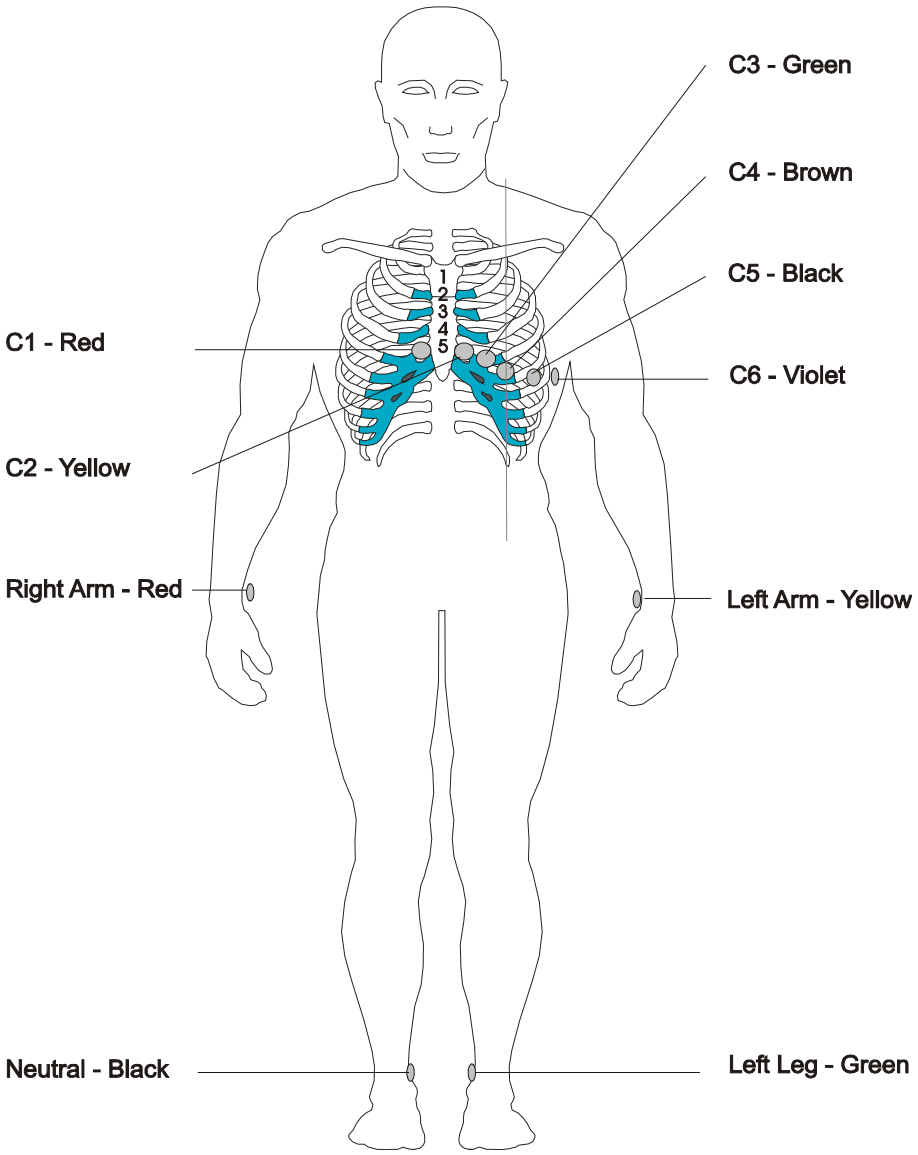
Electrode Placement

Resting ECG



Note: The colours shown here are according to Code 1 (European) requirements. The equivalent code 2 colours are given on Page 2.6

Electrode Placement

A minimal resistance between skin and electrode is required to obtain the best ECG signal and ensure the highest quality ECG recording. Therefore please note the following points:

- Ensure that the patient is warm and relaxed.
- Shave electrode area before cleaning.
- Thoroughly clean the area with alcohol.
- When applying the electrodes, ensure that a layer of gel is between the electrode and the skin.
- Place the C4 electrode first - in the 5th intercostal space (ICS) so that it lines up approximately with the middle of the clavicle.

  Then place:

  - C1 in the 4th ICS parasternal right
  - C2 in the 4th ICS parasternal left
  - C3 between, and equidistant to, C4 and C2
  - C6 on the patient`s side and aligned with C4
  - C5 between, and equidistant to, C4 and C6

The electrode resistance can be checked in the recording screen - see page 2.7.

Note: When making an ECG with a child it is sometimes physically difficult to place all electrodes. When this is the case electrode V4 can be placed on the right side of the chest.

WARNING

During the ECG recording, ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrodes) come in contact with other persons or conductive objects, even when these are earthed..

Further Lead Combinations

Nehb Leads

The Nehb leads are bipolar chest leads. They are of special interest for the diagnosis of changes in the posterior ventricle wall. Three leads are arranged in the form of a triangle, also called the "small cardiac triangle". Nehb dorsal (D) is measured between the electrode positions Nax and Nst; Nehb anterior (A) between Nap and Nst, and Nehb inferior (J) between Nap and Nax.

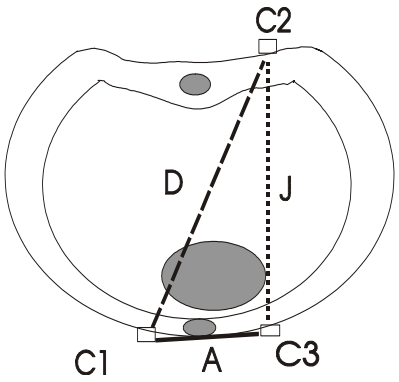
Place the electrodes as follows:

Red	C1	applied to position (Nst)	-	2nd rib at the right sternal border
Yellow	C2	applied to position (Nax)	-	directly opposite (on the back, posteriorly) from 3 (Nap)
Green	C3	applied to position (Nap)	-	5th intercostal space medioclavicular line (cardiac apex)

All other electrodes can be placed in their normal position The user defined lead order must be set in the Setup menu:

SETUP > ECG SETTINGS > NEXT > NEXT > NEXT > NEXT > NEHB (D, A, J) > on

See Section 4 for full details.



Further Lead Combinations

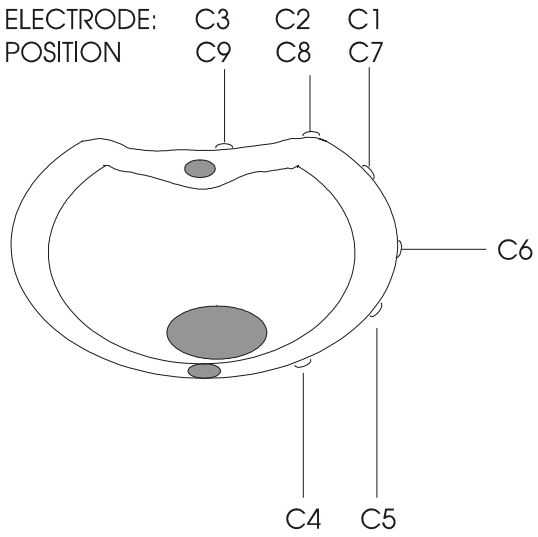
Electrode Positions for Additional Leads

The clips from the chest electrodes C1 through C3 have to be removed and connected to the electrodes C7 through C9 placed on the patients back in the appropriate positions.

All other electrodes can be placed in their normal position The user defined lead order must be set in the Setup menu:

SETUP > ECG SETTINGS > NEXT > NEXT > NEXT > NEXT > posterior and precordials options. Set on or off to display and print the lead group using the lead group keys during data acquisition:

See Section 4 for full details.



NOTE:

The additional leads C7 through C9 can only be recorded in manual mode.

Electrodes and Neutral Electrodes Identification and Colour Code

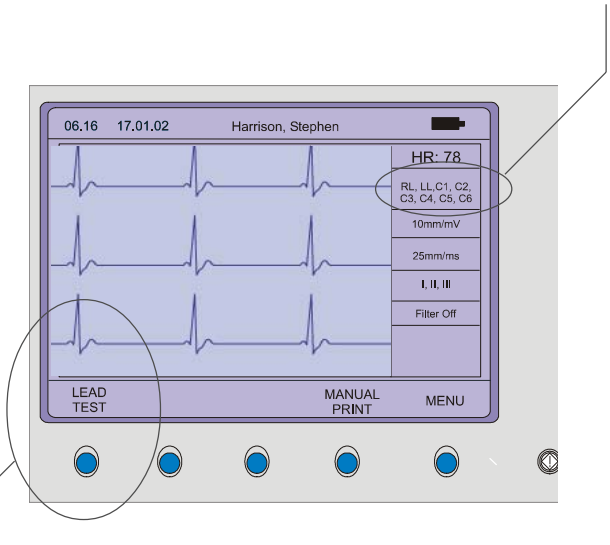
The electrode placements shown in this handbook are labelled with the colours according to Code 1 requirements. The equivalent Code 2 colours are given below.

	CODE 1 (Usually European)		CODE 2 (Usually American)	
System	**Electrode Identifier**	**Colour Code**	**Electrode Identifier**	**Colour Code**
Limb	R	Red	RA	White
	L	Yellow	LA	Black
	F	Green	LL	Red
Chest according to Wilson	C	White	V	Brown
	C1	White/Red	V1	Brown/Red
	C2	White/Yellow	V2	Brown/Yellow
	C3	White/Green	V3	Brown/Green
	C4	White/Brown	V4	Brown/Blue
	C5	White/Black	V5	Brown/Orange
	C6	White/Violet	V6	Brown/Violet
Position according to Frank	I	Light blue/red	I	Orange/red
	E	Light blue/yellow	E	Orange/yellow
	C	Light blue/green	C	Orange/green
	A	Light blue/brown	A	Orange/brown
	M	Light blue/black	M	Orange/black
	H	Light blue/violet	H	Orange/violet
	F	Green	F	Green
Neutral	N	Black	RL	Green

Skin/Electrode Resistance

High Electrode Resistance Indication

If an electrode resistance is too high for a good recording, or an electrode becomes dislodged during a recording, the electrode indication flashes on the screen and an audible beep is heard. The electrode(s) must be reapplied.



Electrode (and Patient cable) Check (Lead Test)

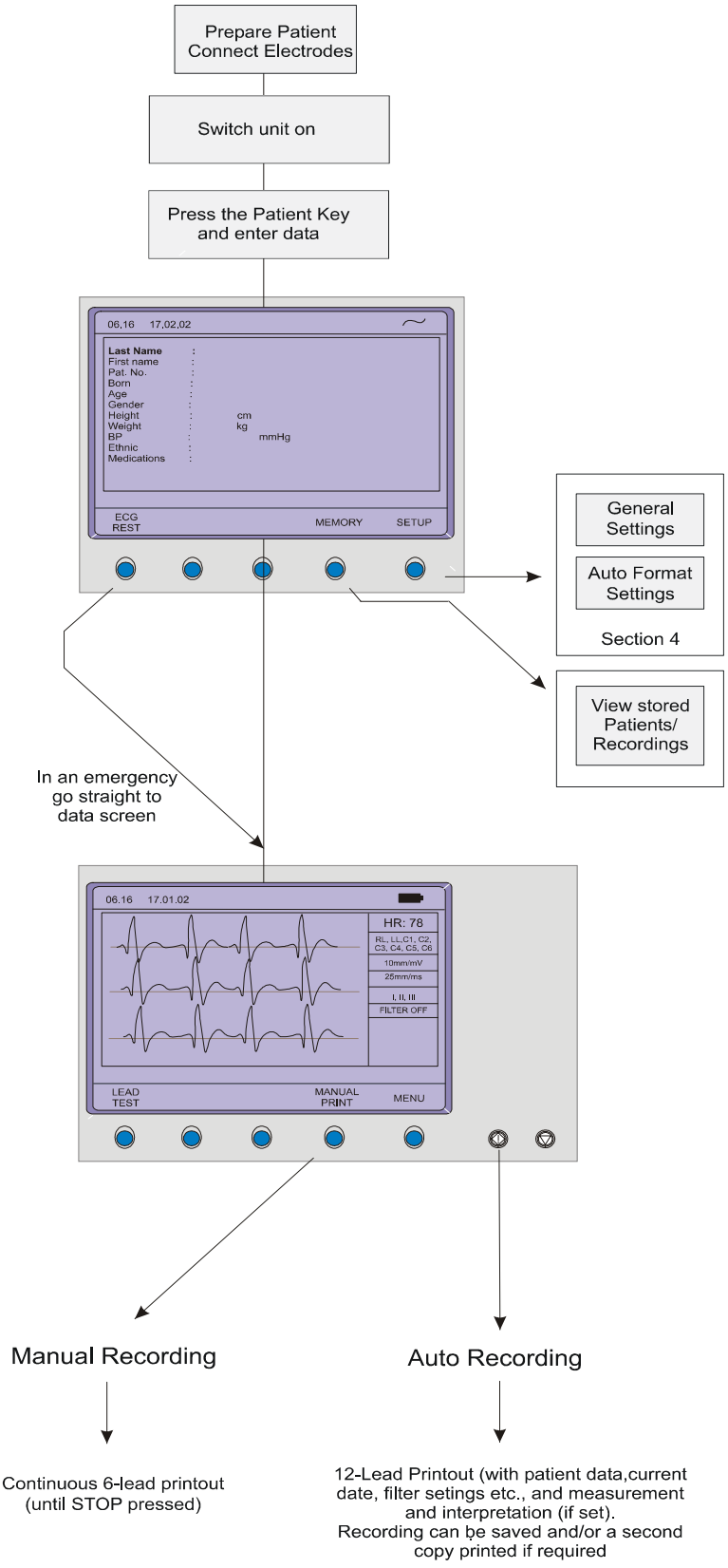
To check the electrode resistance and the integrity of the cable, press the LEAD TEST key from the data acquisition screen: The following is displayed:

LEAD TEST (mV)		
R-89	C1 -98	C4 -72
L-102	C2 -78	C4 -121
	C3 -109	C6 -96

This gives electrode dc offset and is the voltage drop in the patient cable. It can indicate any faults in the patient cable or patient electrode. The value given is the dc voltage between the left leg electrode and all other electrodes. The measurements obtained will indicate any cable short circuits or open circuits. 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 (good connection, low resistance) - ± 100mV. An offset of up to +300mV 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: -350 to -500mV

Modes of Operation and Procedural Overview



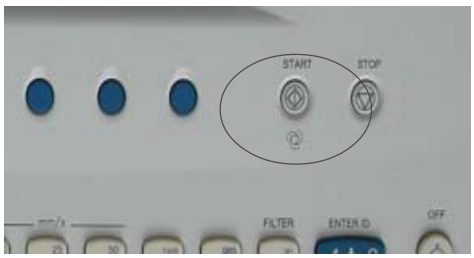
Automatic Mode

Two, user defined automatic mode formats are available. The following can be programmed freely for each of the 2 formats before recording:

- Lead Format
- Chart Speed
- With the optional interpretation program it is also possible to select the rhythm lead(s), measurement table, average cycles with optional markings and interpretation statements for the printout.

For further information and to define the auto formats see Section 4 `Setup`.

- To start an automatic ECG recording in Auto Mode Format 1, press the START key.
- To start the automatic ECG recording in Auto Mode Format 2, press the SHIFT key followed by the START key.

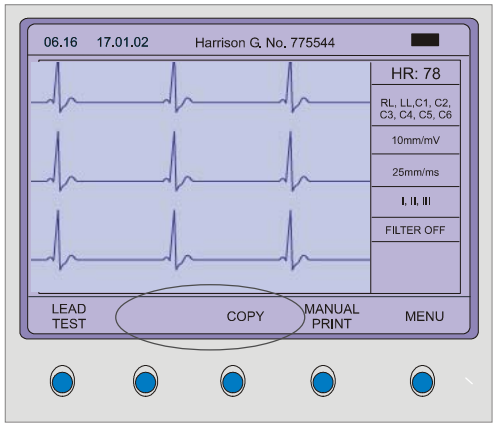


Automatic Mode

After approximately 10 seconds the recording is analysed * and the printout** gives the following:

- ECG recording of all leads in either Standard or Cabrera format according to selection
- Sensitivity
- Heart Rate
- Speed
- Filter Settings
- Time and Date
- Interpretation statements
- Average Cycles
- Intervals
- Axis
- Sokolow Index (ECG index for hypertrophy)
- Detailed Measurement Table

The softkey options change at the end of the recording to enable you to save the recording*** or to obtain an extra copy. When a recording has been saved, it remains stored by the P8000 until deleted, even when the unit is switched off. Accessing recordings in the memory is detailed on page 2. 14 et. seq.



Notes:

* During ECG Acquisition the message `RESTING ECG BEING TAKEN` is displayed. If the P8000 cannot discern a trace, the message `QRS NOT DETECTED` is displayed. If the interpretation program detects an abnormality, the message `UNUSUAL ECG` is displayed.

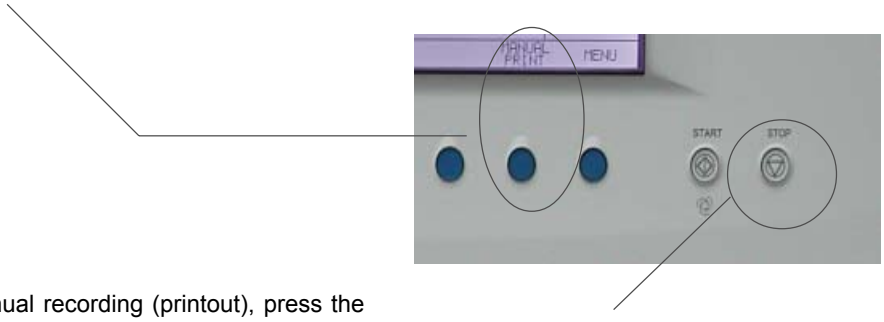
** When an external printer is connected and switched on, the printout is automatically directed to the external printer. When the external printer is unconnected or switched off, the P8000 automatically switches to the internal thermal printer.

*** ECGs can also be saved automatically - see ECG settings, Section 4

Manual Mode

Manual mode provides a direct printout of the real-time ECG with full control of parameter selection.

- To start the manual recording of a real-time ECG, press the MANUAL printout soft key



- To stop the manual recording (printout), press the STOP key, or the stop softkey

The printout provides you with the following:

° Six (selected) leads with lead identification.

° On the lower edge, the chart speed, user identification and the mains filter setting (50 or 60 Hz) and the Myogram filter cutoff frequency (if filter applied) 25Hz or 35Hz.

° At the top, the heart rate as current average of 4 beats, trace sensitivity, and the time and date

The lead group, the sensitivity, and the speed of the printout are changed using the display/printout keys (see next page).

WARNING

After heavy artefacts or lead off, the indication of the heart rate may not be reliable.

Note:

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

Screen (and Manual Printout) Settings

The following can be freely chosen during data acquisition, for both the display and for a manual printout, using the top line of keys of the keypad:

Lead Group by means of the LEAD FORWARD and LEAD BACKWARD key. The following lead groups are selectable:

Standard		
■ I, II, III	/	aVR, aVL, aVF
■ V1, V2, V3	/	V4, V5, V6

Cabrera		
■ aVL, I, -aVR	/	II, aVF, III
■ V1, V2, V3	/	V4, V5, V6

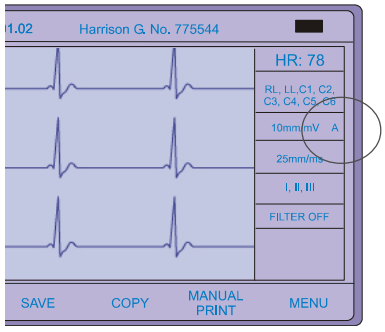
Additionally, the following lead groups can be viewed when manually set (on) in ECG settings - SETUP > ECG SETTINGS > LEADS (see Section 4 for details).

Rhythm		
■	II, avF, III /	V2, V4, V5
Left Posterior		
■	V4, V5, V6 /	V7, V8, V9
Right Precordial up to V5r		
■	V1, V2, V3 /	V3r, V4r, V5r
Right Precordial up to V6r		
■	V1, V2, V3r /	V4r, V5r, V6r
Nehb		
■	D, A, J	

Sensitivity Select 5, 10 or 20 mm/mV

NOTE:

Auto Sensitivity To reduce the possibility of overlapping traces, an auto sensitivity reduction is applied in Auto Mode (default). This means that the unit detects very large waveform amplitudes and sets the sensitivity for the extremity and/or precordial leads to 5 mm/mV. An `A` by the side of the sensitivity indicates that Auto sensitivity is set. To disable this function, the AUTO SENSITIVITY key (key 3) must be pressed.

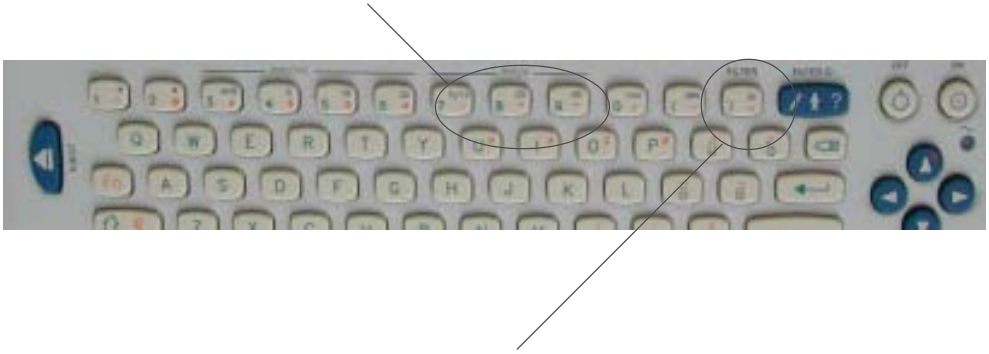


Screen (and Manual Printout) Settings

Chart Speed Select speed 5, 10, 25 or 50mm/s

Key 7 is a toggle key - press once and 5 is selected, press a second time and 10mm/s is selected.

When the 25 or 50mm/s key is pressed, the same speed is set on both the screen and the (manual) printout. When 5 or 10 mm/s is selected, this affects the manual printout speed only.



Myogram Filter Switch the filter ON or OFF with the FILTER key:

`FILTER ON` is displayed on the LCD when the filter is switched on and the cutoff frequency is shown at the bottom of the printout. That is 0.05 - 25 Hz, or 0.05 - 35 Hz. The cutoff frequency is defined in Section 4 Setup.

Recentering To re-centre the ECG traces, press the 1mV key

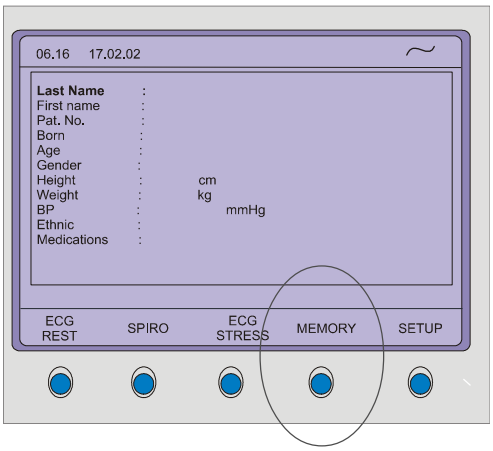
QRS Beep To activate / Deactivate the QRS beep, press the QRS key

Memory

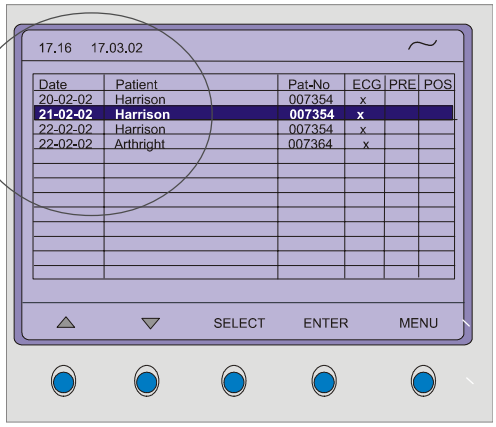
The memory option allows approximately 45 recordings (depending on size and parameters specified when the recording was taken) to be stored, edited, printed, and transmitted over the RS-232 interface. When no more recordings can be stored, the message `MEMORY FULL` is displayed. Old recordings must be deleted before further recordings can be stored.

Recordings can be automatically saved after a recording has been made (auto save), or you are prompted to save a recording individually after a recording has been made. This setting is defined in ECG settings (see Section 4).

Enter the memory from the initial screen.



All recordings are stored in date order.



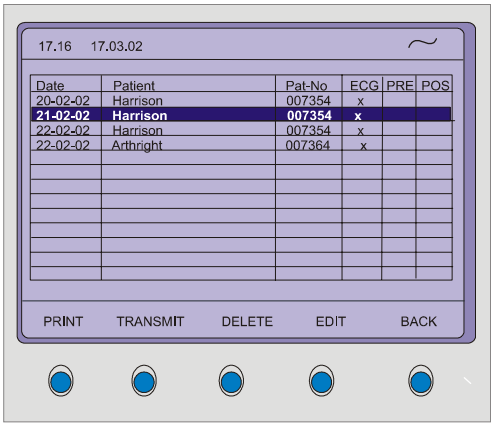
Memory

Highlight required recording by pressing the up/down softkeys and press the select softkey.

NOTE:
Highlight all recordings by pressing the function key (Fn), followed by key `A`.

When the required recording(s) is(are) highlighted, press the ENTER softkey.

Softkey options then enables you to obtain a printout, to delete the selected recording(s), or to send over the RS-232 interface to the ARCHIMED data management software.



When Delete is selected, you are prompted to confirm that you wish to delete the selected file(s). The message `ERASING` appears in the message box, during the erasing process.

Note: The print settings are defined in Setup and are described in Section 4

Transmitting the Recordings

The contents of the memory can be transmitted to the ARCHIMED data management program (or similar), using the RS-232 connected directly to the computer, or over the telephone system. Sending directly is termed LINE transmission; sending over the telephone system requires a modem and this form of sending is termed MODEM.

When Transmit is selected, the message `TRANSMITTING` appears in the message box, during the transmission.

Safety Notices when Transmitting

WARNING

When non-medical devices are connected to the RS-232 interface ensure that both units are securely connected to the same earth potential.

When operating the unit on battery and simultaneously using non-medical devices, the RS-232 interface must be fully isolated.

An external device must only be connected using the original interface cable assembly.

Line Transmission

To transmit recordings over line, proceed as follows:

- Set Communication mode to LINE - see Section 4
- Connect the cable assembly (optional accessory, art. No. 8830649000) between the RS-232 connector on the P8000Power plus and the COM interface of the Computer.
- Ensure that the communication program (designated SEMACOMM) is active on the computer (see ARCHIMED handbook).
- Press the `TRANSMIT` softkey

Transmitting the Recordings

Modem Transmission

To transmit recordings over the telephone network, proceed as follows

- Set Communication mode to MODEM - see Section 4
- Enter Phone number and modem initialisation codes - see Section 4
- Connect the modem cable assembly (supplied with modem) between the RS-232 connector on the P8000Power and the modem.
- Ensure that the communication program (SEMACOMM) is active on the remote computer (see ARCHIMED handbook).
- Press the `TRANSMIT` softkey

The message `TRANSMITTING` appears while the unit is sending

If a transmission error occurs the message `Tx ERROR` is displayed.

- Check all settings in the ARCHIMED program (baud rate; parity - none; stop bit - 2; time between blocks, records - 100ms). The settings must be as follows:
  - parity - none;
  - stop bit - 2;
  - time between blocks, records - 100ms.
- Check that the transmission speed is the same in both the P8000Power and the ARCHIMED program.

Note: The transmission settings are defined in Setup and are described in Section 4