INSTRUCTIONS FOR USE

LP110S

Trigger Monitor

774306EN-6 2025-03

HUNTLEIGH
A MEMBER OF THE ARJO FAMILY

Contents

1. Quality, Reliability & Safety

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operating techniques. Ensure each user fully understands the safety and operation of the unit, as mis-use may cause damage to the unit or injury to the user or the patient.

This equipment has been manufactured using quality components and designed to operate safely and reliably.

All modifications and repairs to the equipment must carried out by qualified service engineers, agents or hospital technicians authorised by Huntleigh Healthcare Ltd.

CE MARKING:

This equipment carries a CE mark but this is only fully valid if it is used in conjunction with cables and accessories approved by Huntleigh Healthcare Ltd.

1.1 Warnings and Cautions

 General Warning

 Attention, consult accompanying documents / Instructions for Use

Note: The following are descriptions of general hazards and unsafe practices that could result in death, severe injury or product damage. Specific warnings and cautions not appearing in this section are found throughout the manual.

- **Do not use this equipment in the presence of flammable gases. A possible explosion hazard exists if used in the presence of flammable anaesthetics. Explosion or fire can result.**
- **Do not immerse any part of the equipment in any liquids. Fluid spills may damage the instrument's electrical components.**
- **Do not use solvent cleaner on any part of the system.**
- **Do not use high temperature sterilising or E-beam / gamma sterilisation processes.**
- **Do not sterilise this product. Sterilisation environments can cause severe damage.**
- **Do not autoclave or gas sterilise accessories unless manufacturer instructions clearly approve it.**
- **The unit is equipped with a touchscreen designed to be operated by fingertouch. Do not use sharp instruments to operate.**
- **Do not mount the equipment directly above the patient. Place the equipment in a location where it cannot harm the patient should it fall from its shelf or other mount.**
- **Do not operate the equipment using damaged cables and wires, or loose snap fittings, which may cause interference or loss of signal.**
- **Perform frequent electrical and visual inspections on cables and wires.**
- **The accuracy of the readings obtained from this equipment may be affected by the presence of a pacemaker or by cardiac arrhythmia.**

- **Do not substitute accessories. Use only recommended accessories listed in this manual. Substitution may cause the instrument to work improperly. The correct accessories are shielded to prevent conductive parts of the electrodes contacting other conductive parts or earth. No action should be taken which permits this to happen.**
- **All interconnecting equipment must meet their relevant safety standards i.e. EN60601-1. When several pieces of equipment of various origins are interconnected, the summation of leakage currents mayconstitute a hazard.**
- **If it is thought that interference is occurring from or with other equipment, such as that used for Diathermy, then either shut-off, or move, the offending devices, increase the separation or reduce lead lengths.**
- **Electromagnetic Compatibility (EMC). This product complies with the requirements of applicable EMC Standards. The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.**
- **This product contains sensitive electronics; strong radio frequency fields could interfere with the operation of the system. In the event where this occurs, we suggest that the source of interference is identified and the equipment is used 'out of range'.**
- **Do not use the simulator connector points as a storage facility for the patient cable.**
- **If any doubt exists concerning the use of this equipment, an alternative method should be used.**
- **LP110S can be isolated from the AC mains supply by removing the IEC mains inlet connector. Ensure that this is fully accessible at all times.**
- **LP110S is a Class 1 product that relies for safety on its protective earth. Ensure it is connected to a suitably earthed AC mains supply.**
- **During defibrillation, the operator should not come into content with the patient, the monitor or the supporting table; otherwise serious injury or death could result.**
- **After defibrillation, the electrocardiogram (ECG) wave will recover within 5s.**
- **It is recommended that the Alarm function is checked daily by disconnecting a lead and confirming that "LEAD OFF" message is displayed.**
- **Certain items such as ECG cables provide particular levels of protection. Do not use compatible cables otherwise leakage current and defibrillator protection may be compromised.**
- **If the mains supply is interrupted for more than 30 seconds, the monitor will switch off and will need to be re-started by the operator.**

1.2 Service Life

This has been defined as the minimum time period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective.
Huntleigh Healthcare Ltd's commitment is that the expected service life for this Device has been defined as 7 years.

2. Introduction

The LP110S is a compact ECG Trigger monitor, which provides the user with a single or dual channel presentation of the patients ECG complex.

The monitor is of fully moulded construction in a tough flame retardant ABS material.

The liquid crystal display (LCD), with touch screen, provides a clear presentation of patient information.

All controls, with the exception of the front panel ON/OFF switch, are software-controlled.

The LP110S series weighs 2.0Kg and is powered from an AC mains supply.

An optional mounting plate can be fitted to the underside of the LP110S to enable the monitor to be mounted on a wall bracket, stand or gantry.

2.1 Intended Purpose for LP110S

Structure and Function of the device

The LifePulse LP110S is intended to be used to facilitate cardiac computed tomography (CT) scans.

The device generates a trigger pulse at the peak of each R wave, enabling the CT scanner to determine the optimal timing for X-ray activation.

Intended population

To monitor on both adult and paediatric patients while performing a CT scan.

Intended user

For use by healthcare trained professionals in radiology

Intended use environment

For use in imaging departments (radiology).

2.2 Contraindications

Is not designed to be used in isolation and shall only be used in conjunction with a CT scanner.

2.3 Clinical Benefits

Cardiac gating or ECG gating in CT is a technique that triggers a scan during a specific part of the heart's cycle. This helps to minimise imaging artefacts caused by cardiac motion.

2.4 Preliminary Checks

Contents (supplied with each system)

Item	
1 x LP110S Lifepulse Trigger Monitor	
1 x ECG Trunk Cable with 900mm chest leads	
1 x Trigger Interface cable (10M)	
1 x Pack of 30 Adult Ag/AgCL electrodes	
1 x Instructions for Use	1 x NUPREP Skin preparation gel (114g)

Delivery Inspection
Huntleigh Healthcare Ltd takes every precaution to ensure that their goods reach you in perfect condition. However, accidental damage can occur in transit and storage. For this reason we recommend that a thorough visual inspection is made immediately the unit is received. Should any damage be evident or any parts missing, ensure that Huntleigh Healthcare Ltd is informed at once.

Storage
Should the unit not be required for immediate use, it should be re-sealed in its original packing, after carrying out the initial delivery inspection, and stored under covered conditions at a temperature between -10 and 50 °C, and relative humidity of 0-99% (non-condensing).

2.4.1 Installation

LP110S monitors are supplied with a plug-in mains lead, fitted with a 3 pin mains plug. The cores use the European colour code :

BROWN	LIVE
BLUE	NEUTRAL
GREEN/YELLOW	EARTH

If it becomes necessary to fit a new mains plug take care that the wires have correct lengths, so that in the event of extreme strain, the earth wire will be the last to break. Make sure that the cable clamp secures the outer sheathing so that there is no direct strain on any individual wires at the terminals.
Where the plug is fused, a 5A fuse should be fitted.

2.4.2 Line Power Operation

No alterations are required to change between 100 and 240 Volt operation.
Connect the equipotential earth terminal to a potential equalisation conductor where provided. Connect the power cable to the line power socket.

Note.
To isolate the LP110S from the mains or line supply, disconnect the power cable from the mains inlet at the rear of the unit.

2.4.3 System Connection

An Equipotential earth point is provided on the rear of the monitor for connection to a recommended earth point at the installation. The earth wire should be run separately from any mains or current carrying cables and should be kept as short as possible.

Connection is achieved using a DIN 42801 type female terminal terminated onto 4mm^2 56/28AWG yellow and green earth wire, connected to the Equipotential Earth Point at the installation.

At no point should a patient be connected directly to Earth.

All external earth connection should be visually inspected to ensure that all cables and connections are of good condition. Earth bonding checks should be carried out with a suitable portable appliance tester. The Impedance between the protective earth and Equipotential earth at the installation shall not exceed 0.1Ω.

2.4.4 Fuses

Fuses are fitted in both the live and neutral lines. Correctly rated fuses must be fitted as below:-

T2AH 250VAC

2.5 Front Panel Controls and Indicators

1	~	Green “~ “ ON Indicates mains power connected.
2		Amber above the “On” / Off” button indicates the unit is switched on.

2.6 Rear Panel Features

1	Mains Input Socket
2	I/O Sockets (from the top) : • RS232,Trigger O/P, ECG O/P • Equipotential Earth Connector
3	Serial Number Label
4	Rating Label

2.6.1 External Pin Out Connections

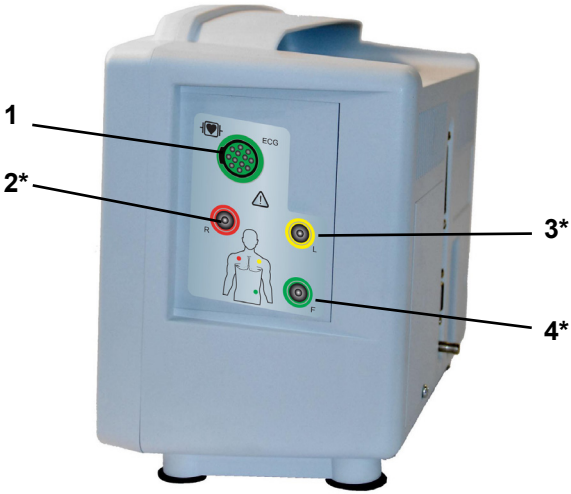
Note
External connections are to be made to IEC60601-1 compliant equipment only.

25 Way 'D' Type Socket

Pin No.	Description
1, 7	GND
9	sync pulse output
12	ECG output 1V/mV

2.7 Patient Inputs

All patient inputs are fully isolated from electrical earth. ECG rate is achieved via conventional electrodes and a 3 way patient cable.
The side panel of the LP110S has the patient input connector (1).

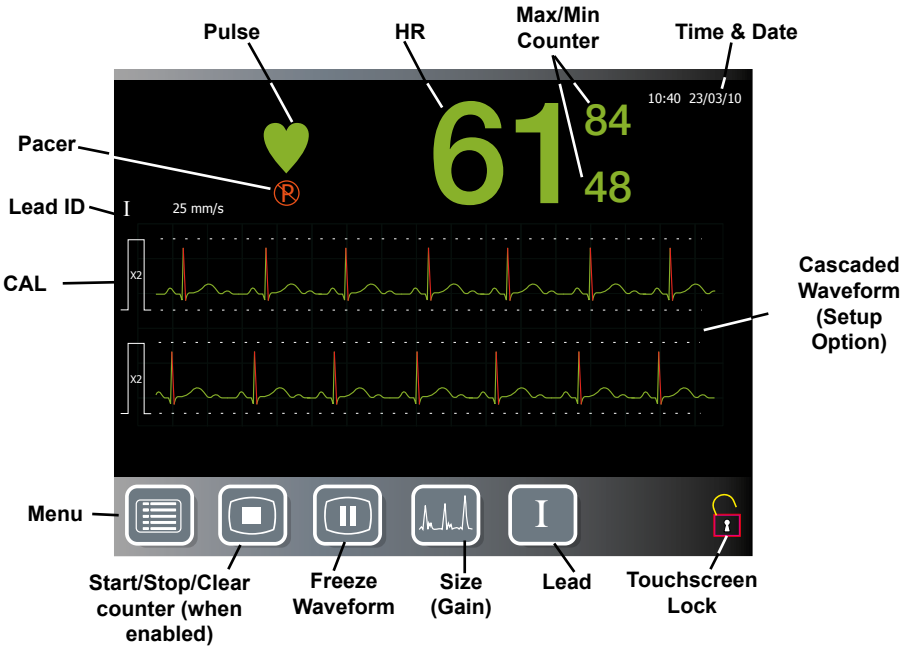


*** Important**
Do not use the simulator connector points as a storage facility for the patient cable.

1	ECG Input The LP110S is supplied with an integrated ECG Simulator (2,3,4). This should only be used to verify system integrity (patient cable and system connections). The simulator is software controlled. The terminals located on the right hand side of the monitor are colour coded according to AHA and IEC protocol.
2	Simulator Output (R)
3	Simulator Output (L)
4	Simulator Output (F)

2.8 Display

The display comprises a waveform for ECG, either single or dual trace.



The readouts are displayed as follows:

Lifesign	Trace Description
ECG	The trace is displayed either as a single or cascaded trace. The HR is presented as a large numeric display in the central area of the screen. Also displayed is the selected lead and gain setting.

2.9 Alarms

Alarm	Description
LEAD OFF	LEAD OFF message displayed if any ECG chest lead is disconnected from patient.
ASYSTOLE	If within 10 seconds of last R Wave no further R Wave is detected, 'ASYSTOLE' will be displayed.

3. Specifications

3.1 Equipment Classification

Type of protection against electric shock.	Class 1 and Internally powered equipment
Degree of protection against electric shock	Type CF - equipment with an applied part (ECG input), intended for direct electrical connection to the heart. The equipment is defibrillation discharge protected.
Mode of operation.	Continuous
Degree of protection against harmful ingress of water.	IPX0
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE
Electrosurgery Surgical Equipment	This unit does not provide protection against HF burning from other surgical equipment.
Complies with Medical Electrical Equipment 25EA	IEC 60601-1-6:2010, AMD1:2013, AMD2:2020, CAN/CSA-C22.2 No. 60601-1-6:11 IEC60601-2-27:2011 is partially applied in order to ensure safe Trigger monitor functionality. WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY, IN ACCORDANCE WITH UL60601-1, CAN/CSA C22.2 No 60601-1

3.2 Environmental

Operating		Storage
10°C to 40°C	**Temperature range**	-10°C to 50°C
15% to 90% (non condensing)	**Relative Humidity**	0% to 99% (non condensing)
860hPa to 1060hPa	**Pressure**	860hPa to 1060hPa

3.3 General

Supply voltage	100 to 240V 50/60Hz.
Fuse Type	T2AH 250VAC
Power input	55 VA
Screen	8.4 inch diagonal high brightness TFT SVGA flat panel display
Trace speed	25mm / 50mm per second.
Size	240mm wide, 223mm high (including feet), 160mm deep (including equipotential earth connector)
Weight	2.0Kg (LP110S)

3.4 ECG Monitoring Functions

Heart Rate range	15 – 260 BPM ±1% ±1 digit
Selectable leads	I, II, or III
Selectable display gain	0.5, 1, 2 or 4.
Lead fault detection	Displays LEAD OFF warning for any of the leads.
QRS indication	Flashing heart symbol. Audible tone with volume control off
Synch ID	Trigger mark on ECG Complex
Esis/defibrillator protection	Yes
Bandwidth	3Hz - 25Hz (Filter ON) 0.5 – 45Hz (Filter OFF)
Filter	50Hz and 60Hz notch (automatic)
Input impedance	> 20MΩ at 10Hz
CMMR	>90db
Lead off sensing current	100nA
Active Leg Drive Current	< 2µA
Pacemaker indication	'P' symbol appears in place of 'Heart' symbol and the trace displays a vertical marker.
Pacer Pulse Rejection	**Width:** 0.1 to 2ms at ±2 to ±700mV **Overshoot:** <120ms
Alarms	'Lead Off' and 'Asystole' alarms

3.5 Accessories

Item	Part No.
ECG Electrodes - box 1200	ACC-OBS-132
3 Way IEC Patient Cable (complete with 900mm chest leads)	ACC-VSM-213
Chest Leads - 600mm (IEC)	ACC-VSM-214
Chest Leads - 900mm (IEC)	ACC-VSM-215
3 Way Trunk	ACC-VSM-216
Fixing Kit (a)	ACC-VSM-152
Mobile cart with intergrated storage basket (b)	ACC-VSM-153
Table Pedestal (c)	ACC-VSM-212
Trigger Interface Cable (5M)	ACC-VSM-217
Trigger Interface Cable (10M)	ACC-VSM-218
Trigger Interface Cable (15M)	ACC-VSM-219
Trigger Interface Cable (20M)	ACC-VSM-237
Trigger Interface Cable (25M)	ACC-VSM-238
Trigger Interface Cable (30M)	ACC-VSM-239
NUPREP Skin preparation gel (3 x 114g)	ACC-VSM-242
Gantry Spacer	ACC-VSM-231

(a) + (b) - Items must be purchased together
(a) + (c) - Items must be purchased together

3.6 Equipment Markings

The following is an explanation of the equipment markings and classification as defined in BS5724: Part 1: 1989 (IEC 601-1:1988), ISO 8790 and BS ISO/IEC 8878:1992.

Symbol	Description
	Type CF and the input is protected against defibrillation damage.
	This product may be disposed of only through a government approved collection scheme or treatment facility. Do not dispose of in the domestic refuse. If in doubt contact your local Huntleigh Healthcare Ltd representative.
CE 2797	This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745).
	Attention - consult accompanying documents / Instructions for Use
	Warning
Manufactured By:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden

	Equipotentiality		On/Off
	Alternating current		Trigger O/P, ECG O/P
	Monitor	DI	Device Identifier
MD	Medical Device	REF	Reference Number
SN	Serial Number		

4. Operation

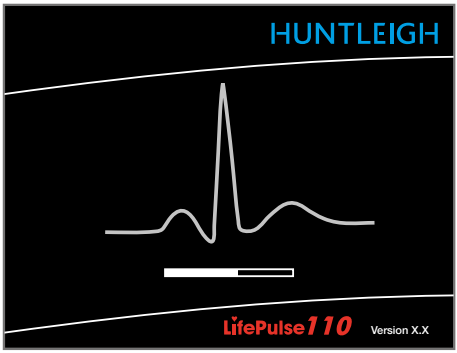
4.1 General

4.1.1 Switching On

To switch the LP110S ON, press the main ON / OFF button on the unit front panel. The amber LED will illuminate followed by a short tone.

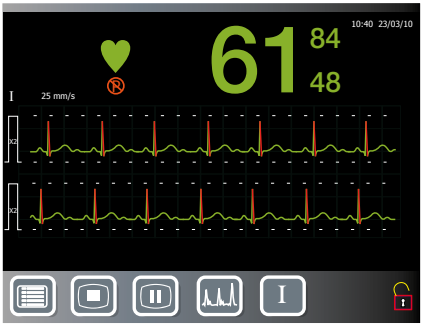
4.1.2 Displays

At switch ON, the LP110S will carry out a system self test and display the following welcome screen:



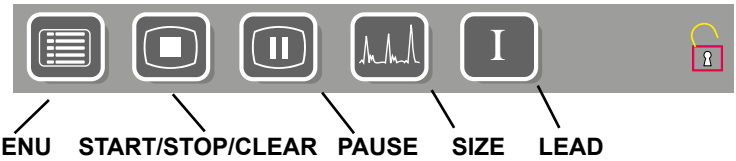
After a few seconds, the monitor will display the main application screen.

Single Trace



Dual Trace (Cascade)

The LP110S is controlled from a series of touch sensitive programmable soft keys which are located along the bottom of the screen. Pressing these will enable the user to access a function or sub menu level.



4.1.3 Menu

Pressing the MENU button will enable the user to access the following settings:
(Note : BOLD text = default setting)

ECG Display (**single** or dual)
- Synch pulse ID (**ON**, OFF)
- Size (1/2, **1**, 2, 4)
- Speed (**25** / 50 mm/s)
- Counter (ON / **OFF**)
- Processing (**4**, 6, 8 beats)
- PACER (ON/**OFF**)
- Tone (**ON**, OFF)
- EXIT

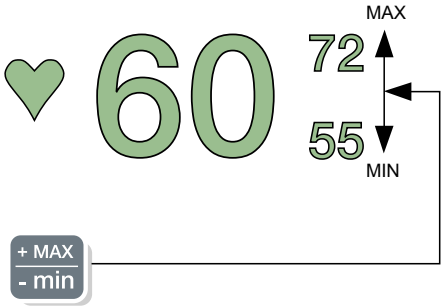
System Language (**English**, Spanish, French, Italian, German, Flemish / Dutch, Russian),
- Time (HH:MM)
- Date format (**DD:MM:YY** / MM:DD:YY)
- Brightness 1, **2**, 3
- EXIT

Simulator ON / **OFF**
- Rate 30,35,40,45,50,55,**60**,65,70,75,80,85,90,95,100,105, 110,115,120,125,130,135,140,145,150,155,160,165,170, 175,180

Service (requires access code)

- Application
- Firmware version
- Max run time
- USB Upgrade
- Calibrate TS
- Filter ON
- ALD ON
- Reset to factory default settings (Y/N)
- Exit

4.1.4 Start / Stop / Clear Counter

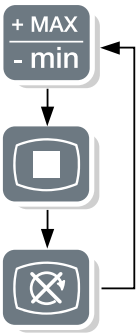


The start / stop / clear counter softkey is only available if the COUNTER setting is switched ON in the ECG set up option. This softkey is dynamic and performs three functions.

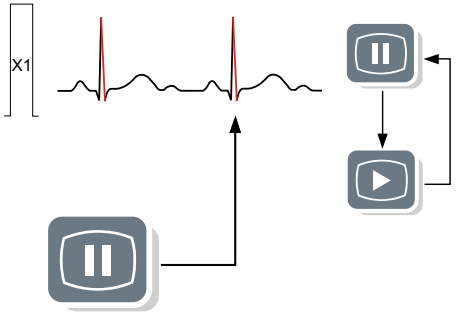
With the feature switched ON, pressing the soft key once starts the heart rate counter. The small digits alongside the main HR display will automatically store the max and min heart rate values (range).

Pressing the soft key will stop the counter.

Pressing the softkey again will clear the counter display.



4.1.5 Pause



Pressing the PAUSE soft key will freeze the waveform on the screen, other background applications will continue.

Press the PAUSE soft key again to un-freeze the waveform

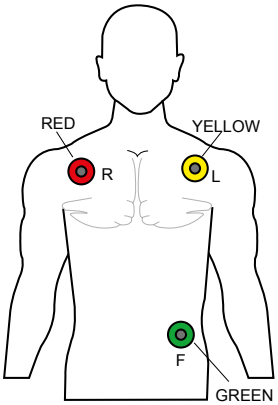
4.1.6 Size

Pressing the SIZE soft key will enable the user to change the size of the waveform (½, 1, 2, 4) on the screen.

4.1.7 Lead

Pressing the LEAD soft key will enable the user to change the selected lead (I, II, III) on the screen.

4.2 ECG Monitoring



To monitor the patient's ECG, apply the electrodes as shown in the diagram.

Optimum sites may vary with the patient's individual physiological characteristics and condition.
The best monitoring results will be obtained by placing the electrodes on the chest.

(IEC Colour scheme shown)

4.2.1 Patient Preparation

Good quality electrodes and patient contact are essential for reliable measurements.

Pre gelled electrodes, silver / silver chloride electrodes are recommended.
Do not mix electrode types.

Prepare the area where the electrode is to be placed, the skin should be abraded slightly with a gauze pad or alternatively, an electrode preparation solution may be used in place of abrasion.

Clean the area with an alcohol pad to remove all abrading residue.
Dry the skin

Connect the patient cable to the ECG input on the monitor.

Snap the electrodes onto the chest leads before placing onto the patient.
Ensure any conductive parts (electrodes and associated conductors) do not contact other conductive parts including earth.

4.2.2 ECG Setup

Use the following softkey procedure to adjust the ECG display.
Press MENU to display the ECG set up options, press ECG to display the following options:
Press DISPLAY to select SINGLE or DUAL channel display
Select SYNCH PULSE ID to enable or disable the Synch ID on the waveform
Press PROCESSING to set the HR processing period
Press TONE to enable or disable the ECG pulse tone
Press SPEED to switch between 25mm/s and 50mm/s
Having made a selection, press EXIT to return to the main application screen.

4.2.3 Starting the HR counter

Press the MIN/MAX counter softkey to start the HR counter.

4.2.4 PAUSING the ECG waveform

Press the PAUSE soft key to freeze the ECG waveform on the screen.
Press the PAUSE soft key to un-freeze the waveform.

4.2.5 Adjusting the ECG waveform amplitude

Press the SIZE soft key once to increase the size of the waveform on the screen.

4.2.6 Adjusting the Lead selection

Press the LEAD soft key to adjust the lead selection. The lead identification is displayed alongside the waveform (I, II, III).

4.2.7 Locking and unlocking the touch screen

Press the LOCK symbol  in the bottom right hand corner of the display to LOCK the touch screen. The symbol will change to indicate status.

Press the LOCK symbol  to un-lock the touch screen.

4.2.8 Pacer ID

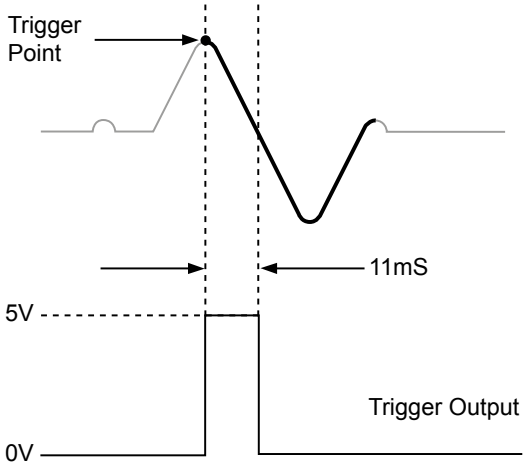
The system incorporates an automatic PACER detection system. When a pacemaker has been detected, a ‘P’ will flash adjacent to the HR display and a vertical marker will be placed on the ECG waveform.

WARNING :Keep pacemaker patients under close observation as rate meters may continue to count during a cardiac arrest.

4.3 Synchronised Output

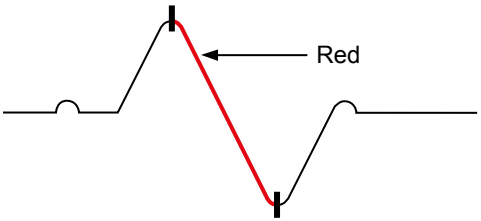
The LP110S provides a trigger pulse which is used to control other equipment. The synchronised output produces a trigger pulse which is synchronised with the peak of each ‘R’ wave.
The synchronised output is provided via the 25 way ‘D’ type connector on the rear panel. (Use Trigger Cable provided with monitor to interface with the Aquillon CT Scanner.)

Timing of Trigger Pulse



4.3.1 Synch Pulse ID

The user has the capability to display the synch marker on the ECG complex as described in Section 4.1.3. (The preferred lead should be lead II).
The trigger mark will be shown as:



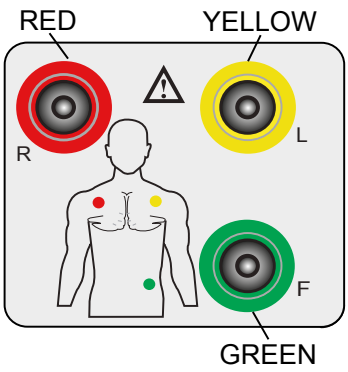
4.4 ECG Simulator

Note.

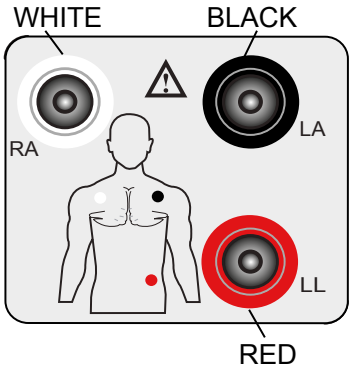
- **The ECG simulator should only be used for testing purposes. When the simulator is switched ON, a status message 'SIMULATION' is displayed on the screen.**
- **Do not use the simulator connector points as a storage facility for the patient cable.**

Connect the patient cable to the unit and the chest leads to the simulator terminals on the right side of the unit.

Simulator Terminals



IEC



AHA

Press the MENU soft key and then SIMULATOR. Set simulator ON.

Select the appropriate rate. The system will display the corresponding simulated rate on the screen.

This feature will enable authorised personnel to verify system performance.

5. Trouble Shooting

This section gives some of the more common problems encountered during use together with their possible causes. If the operator cannot locate the problem after consulting the table in this section, the monitor should be switched off, disconnected from mains power source and a qualified technician should be consulted.
Before attempting trouble-shooting, verify that the power cable is properly connected to both the monitor and the mains power source.

SYMPTOM	POSSIBLE CAUSE/REMEDY
Green power indicator not illuminated	1. Power cable not connected to live power source 2. Defective power cable 3. Mains input fuses blown
Amber unit “ON” indicator not illuminated	1. Unit not switched on
No signal on trace	1. Defective patient cable
Excessively noisy trace	1. Electrode site not properly prepared 2. Poor electrode contact 3. Defective patient cable
No heart rate display or flashing heart symbol	1. Patient electrodes incorrectly sited.
No QRS bleep	1. Switched off, check the ECG SETUP screen.
Continuous alarm indications. No ECG signal on display (LEAD OFF displayed	1. Defective patient cable 2. Electrode or lead off
Poor ECG Trigger	1. Select lead with largest amplitude 2. Check placement of electrodes.

6. Maintenance

6.1 Care of your Equipment

Although the LP110S is robust and has been designed to withstand normal clinical use, the unit contains delicate components, such as the display and accessories, which should be handled and treated with care.

It is recommended that the unit and accessories are inspected and tested on a regular basis.

To preserve system integrity, we recommend patient cables be replaced every 2 years, (or sooner if the institution delivers a high number of cardiac examinations).

We recommend that the system is included into an annual calibration programme where the accuracy of the system is checked against the manufacturers' specifications.

If any part of the system appears to be damaged, the system should be returned to your service centre for repair.

Ensure the unit is completely dry before use.

The display can be wiped with a soft dry tissue.

6.2 Cleaning and Disinfecting

The monitor unit:

- **The system, excluding the display, can be wiped with a soft disposable cloth dampened with a mild detergent and warm water solution. Avoid the electrical contacts and connectors. Do not allow any fluid to seep into the system.**
- **Check mains power connections weekly and examine outer sheath of power lead for signs of damage. If signs of damage are found label as unsafe for use and consult/refer to a qualified electrician for repair.**
- **Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system, as permanent damage will result.**

Patient ECG leads:

- **After use the patient leads should be cleaned with warm water or a neutral cleaner and wiped dry.**
- **To disinfect, use chemical disinfectants containing ethanol (70% - 80%).**
- **Do not autoclave the unit or patient cable.**
- **Electrical connectors must not be immersed in any fluid.**
- **DO NOT use any of the following cleaning solutions as they may cause permanent damage to the cable assembly:- Butyl alcohol, Denatured ethanol, Freon™, Mild chlorine bleach solution, Isopropyl alcohol, Trichloroethane, Trichloroethylene, Acetone, Vesphene II, Enviroquat®, Staphene®, Misty®, Glutaraldehyde.**

6.3 Further Maintenance

Huntleigh Healthcare Ltd recommends that preventative maintenance checks are carried out at least annually.

Maintenance must only be carried out by suitably qualified personnel

7. Warranty & Service

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

Service Returns

If for any reason the LP110S has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

For further details, refer to NHS document HSG(93)26 (UK only).

Huntleigh Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate.

Service Department.
Huntleigh Healthcare, Diagnostic Products Division,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20485885
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Email: sales@huntleigh-diagnostics.co.uk
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www.huntleigh-diagnostics.com

This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.

UK Symbol:

UK CA 0086	UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) Figures indicate UK Approval Body supervision.

UK Responsible Person & UK Importer:

Arjo (UK) Ltd., ArjoHuntleigh House, Houghton Regis. LU5 5XF

Is the appointed UK Responsible Person as defined in UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.

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CE 2797

The LP110S complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745)

Manufactured by Huntleigh Healthcare Ltd for CANON Medical Systems.

Manufactured in the UK by Huntleigh Healthcare Ltd. As part of the ongoing development programme the company reserves the right to modify specifications and materials of the Lifepulse range without notice.

Manufactured by Huntleigh Healthcare Ltd for CANON Medical Systems.

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufactured in the UK by Huntleigh Healthcare Ltd on behalf of;

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden

CE 2797

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A Member of the Arjo Family
As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

HUNTLEIGH

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