LIFEPULSE 400

OPERATING MANUAL

PART NO. 400-900

For use with LP 400 & LP 410

€ 0120

Model No: Serial No:

Issue:

12

Date:

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Cautions

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.

Possible Fire or Explosion

A possible explosion hazard exists if used in the presence of flammable anaesthetics. Explosion or fire can result.

Possible Safety Hazard 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.

Possible Electrical Hazard 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.

Possible Shock or Fire Hazard

Do not immerse any portion of the instrument in water. Fluid spills may damage the instrument's electrical components.

Possible Equipment Damage

Do not sterilise this product. Sterilisation environments can cause severe damage. Do not autoclave or gas sterilise accessories unless manufacturer instructions clearly approve it.

Possible Safety Risk

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.

Warning

All interconnecting equipment must meet their relevant safety standards i.e. EN60959 in the case of computers, network terminals and display monitors. When several pieces of equipment of various origins are interconnected, the summation of leakage currents may constitute a hazard.

Warning

The accuracy of the readings obtained from this equipment may be affected by the presence of a pacemaker or by cardiac arrhythmia

Warning

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.

PORTABLE MULTI-PARAMETER MONITOR

LIFEPULSE 400 & 410

OPERATING MANUAL

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1 INTRODUCTION

The LP400 is a compact multi-parameter monitor capable of measuring and displaying ECG, SpO₂, and two temperatures in it's basic configuration. Respiration may also, optionally, be part of this basic configuration. Anther optional basic configuration extra is a printer, this is designated LP 410. Subsequently, NIBP, IBP (two channels) and CO₂ (side stream) can be provided. These latter functions can be added using plug in modules which are interchangeable with other LP 400/410 units. The LP 400/410 is fully controlled through software which can be updated at any time from a PC with appropriate software. The liquid crystal display (LCD), with it's touch screen, provides an easy to control and read presentation of patient information and life signs. The monitor is of fully moulded construction in a tough flame retardant ABS material. All controls, with the exception of the front panel ON/OFF switch and the rear mains I/O switch, are via an on screen touch panel display making the monitor extremely simple and intuitive to operate. Protection is provided to prevent patient burning when this equipment is used with high frequency surgical equipment.

The LP400/410 is highly portable, weighing a mere 4.7 kg with battery, and may be operated directly from the AC mains supply, via the integral rechargeable battery pack or from an external 12 Volt supply in a vehicle. This makes this monitor ideal for use in situations where portability is required.

1.1 The Display

The LP400/410 display comprises an ECG trace at the top of the screen, which can be cascaded to the second position. Respiration (if present) comes next, followed by SpO₂ and other modules or options which may be fitted. The order of the remaining reports is determined by which options or modules, if any, are present. This is because readouts presented as a waveform take precedence over readouts presented as figures. Each readout, as shown in Fig. 1, is clearly identified by caption and colour.

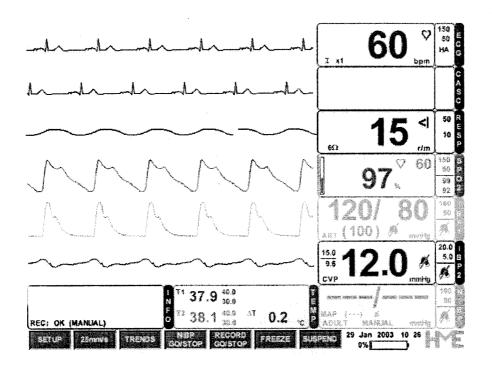


Fig 1

1.2 Touch screen

Note that a slight finger pressure or gently tapping any of the touch screen buttons will normally turn them "on" or "off". The same action on areas of the screen, such as the readouts will also have the effect of bringing up the appropriate SETUP screen.

It is possible to turn off the touch screen facility, if desired, by pressing the HME logo at the bottom right hand corner of the screen. If the touch screen needs to be used again, the HME logo must be pressed once more. Any alarm occurrence will automatically re-activate the touch screen if it is disabled at the time.

RESP	High and low limit alarm. This may be either enabled or disabled and is not adjustable. APNEA alarm is set automatically. The minimum separation between the High and Low values is 5	250	10	245	5
CO ₂	High and Low limits for CO ₂ are programmable in steps of 0.1%. The minimum separation between the High and Low values is 2%. Respiration rate limits are as for Respiration above	13	2	11	0

Table 2

All set alarm limits are checked automatically and continuously. The alarms in Table 2 can be selected and modified independently by touching the appropriate right hand section of the screen. All enabled alarms may be auto set and there is a screen message to inform the user that all the alarms are mute.

Patient Information

This is always displayed on all screens and may be changed only by entering the patient setup screen All information, including alarm settings, are automatically retained when the LP400 is switched off. Each time the monitor is switched off for more than 2 minutes then, at switch on a box is displayed asking if this is a NEW PATIENT. Pressing the ✓ deletes all existing stored patient information and re-sets the alarm limits to the preset defaults. Pressing the ➤ will retain, not only the patient information, but also current alarm settings

	_
Othor	Features:
v ancı	realules.

Lead select Leads I, II or III of the ECG 3 way patient cable may be selected

ORS indication A heart symbol is displayed on screen as part of the ECG display and, if

enabled, an audible tone is emitted.

Filtering A switchable line frequency notch filter is provided for the ECG function.

Gain selection The gain of ECG trace is selectable.

Trace freeze May be selected to examine the traces.

Digital displays Heart Rate, Temperatures, Respiration rate, SpO₂, Blood Pressure (invasive

and non-invasive) are all displayed in digital form, as well as the alarm limits

Inputs

All patient inputs are fully isolated from electrical earth. ECG and respiration rate pick-up is obtained via conventional electrodes and a standard 3 way patient cable. Temperature readings are obtained via thermocouple temperature sensors. Non-invasive Blood Pressure readings are gained using a plethysmographic cuff technique with cuff inflation provided by an internal pump. Blood pressure readings are gained using standard catheterisation techniques. SpO₂ readings are taken from an oximeter sensor and CO₂ from cannula (with or without an Oxygen feed) or from intubated patients using a sample line.

Rear Panel Controls

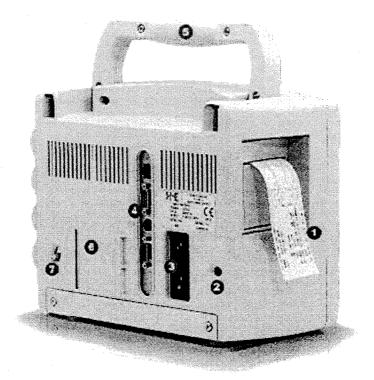


Fig. 3

The printer (1) is an optional extra which is fitted at the time of manufacture.

The socket (2) on the right hand side is for connection to a vehicle battery system supply of 12 volts negative earth.

Item (3) is the mains inlet and mains on/off switch.

The LP 400/410 input/output sockets are located at (4) and comprise, from top to bottom, an Ethernet socket, a Serial Port, a Keyboard socket, provision for an external monitor and an equipotential earth socket.

- (5) is the fold down carrying handle.
- (6) is for mounting the unit on a stand.

The button (7) at the bottom left is used to release the module catch system enabling a module to be removed.

PRELIMINARY CHECKS

Delivery Inspection

HME Limited 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 prior to installation. Should any damage be evident or any parts missing, ensure that HME 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).

2.1 Installation

LifePulse monitors are supplied with a 3 core plug-in mains lead, fitted with a corresponding 3 pin mains plug. The cores are identified in 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 5 amp fuse should be fitted.

Line Power Operation

No alterations are required to change between 115 and 230 Volt operation. Connect the equipotential earth terminal to a potential equalisation conductor where provided or mandatory. Connect the power cable to the line power socket.

2.3 **Battery Operation and Low Battery Alarm**

The battery, when fully charged will provide approximately 3 hours continuous use. An on screen battery indicator shows the state of charge at all times. Battery charging takes place whenever the LP400 is connected to the mains. When the battery is discharging two flashing arrows >> point away from the battery indicator. When the battery is charging the flashing arrows << point towards indicator. If the battery charge drops below 15% the indicator will change to a red colour and an alarm will sound.

2.4 **Fuses**

Fuses are fitted in both the power live and neutral lines. The correctly rated fuses must be fitted.

T. 1A

250V

Type

IEC 127 20mm x 5mm

3 **SPECIFICATIONS**

Equipment classification 3.1

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, intended for direct electrical connection to the heart. The equipment is defibrillation discharge protected. The SpO₂ and invasive blood pressure defibrillation discharge protection is provided by the applied parts themselves and intrinsically by the probe and blood pressure cuff.

The fly leads used for ECG are fitted with resistors to minimise problems associated with stray currents generated by defibrillation, diathermy etc. These leads are not suited for use with respiration measurement.

Mode of operation.

Continuous

Degree of protection against harmful ingress of water.

IPX1

Degree of safety of application in the presence of a

Equipment not suitable for use in the presence of a FLAMMABLE

flammable anaesthetic

ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

3.2 General

Supply voltage

115 or 220-240V 50/60Hz.

Power input

60 VA

Screen

10.4 inch diagonal high brightness TFT flat panel display 50, 25, 12.5 and 6.25mm per second for ECG waveform.

Trace speed

On all traces.

Trace freeze **Battery**

12V NiMH type with smart charger. and fuel gauge type indication of

battery status. Approximately 3 hours of continuous monitoring from a fully

charged battery.

Size

310mm wide, 240mm high (including feet), 140mm deep

Weight

Outputs

RJ45 network socket for connection to LP800 series Central Station, Serial port (9 pin 'D'), 6 pin mini DIN for eternal keyboard and a VGA socket for

a slave monitor.

3.3 Environmental

Operating

Temperature range Relative Humidity 10°C to 40°C

30% to 90% (non condensing)

Pressure

860mb to 1060mb

Storage

Temperature range

-10°C to 50°C

Relative Humidity

0% to 99% (non condensing)

Pressure

860mb to 1060mb

Respiration (If fitted)

Method Impedance measurement via the ECG chest electrodes.

Accuracy $\pm 2\% \pm 1$ digit

Sensitivity $1 \text{ cm/}\Omega$; $3 \text{cm/}\Omega$ selectable.

Range 4 - 125 Resp/min.

Trend 1, 8 or 24 hour trend of respiration rate

Alarms Apnea, high and low rate.

Temperature

Method Thermistor (YSI 400 series compatible)

Range $20^{\circ} - 45.5^{\circ}$ C Accuracy $\pm 0.1^{\circ}$ C ± 1 digit Display T1 or T1+T2+ Δ T

Trends 1, 8 or 24 hour trend of T1 and T2

Alarms High and Low temperature on T1, and T2.

CO₂ (If fitted)

Method Sidestream with IR absorption
Accuracy ± 3mm Hg at 0 to 40 mm Hg

Concentration range 0 - 99 mm Hg.

Range 1-99 breaths per minute Trend 1, 8 or 24 hour trend of CO_2

Recorder (If fitted)

Type Thermal array 8 dots/mm, 50mm width x 30m roll

Speed 50, 25, 12.5, 6.25mm/s

Waveform Up to 3 as selected in the menu function.

Alarms Recorder will record on alarm if required

3.5 Standard Accessories

Item	Part No.
1 x AC power lead	XC0019
1 x 3-way ECG patient cable with fly leads	XC0069
1 x Re-usable finger pulse sensor	001-374
1 x Pulse sensor extension cable	XC0064
1 x Operators manual	400-900

3.6 Optional Extras

Note:- The fly leads used for ECG are fitted with resistors to minimise problems associated with stray currents generated by defibrillation, diathermy etc. These leads are not suited for use with respiration measurement.

ECG:

Item	Part No.
1 x 3-way ECG patient cable without fitted fly leads	XC0065
Fly lead with pinch clip – Red	XC0066
Fly lead with pinch clip - Green	XC0067
Fly lead with pinch clip – Yellow	XC0068

Respiration:

Item	Part No.
ECG module with Respiration and standard accessories	400-006
3-way Respiration cable with fly leads	XC0070
Fly lead with pinch clip – Red	XC0036
Fly lead with pinch clip – Green	XC0037
Fly lead with pinch clip - Yellow	XC0038

3.8 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	Explanation
	Type CF and the input is protected against defibrillation damage.
\odot	"On" Only for part of the equipment
Ċ	"Off" Only for part of the equipment
	Protective earth (ground).
Å	Equipotentiality
~	Alternating current
\triangle	Attention - consult accompanying documents
1	Communication link
10101	Serial port
<u></u>	Keyboard
	Monitor
E + 12V DC	12 Volt DC negative earth
4 1	Battery

Diagram 1

4 OPERATING INSTRUCTIONS

4.1 General

4.1.1 Turning ON

Connect the monitor to the mains AC power supply and move the ON / OFF power switch on the rear panel of the unit to the ON position. The green AC power LED on the front panel will illuminate. Alternatively, use the internal battery. Depress the button on the front panel to switch the unit on; the adjacent amber LED will be illuminated and a short tone will be heard.

4.1.2 The Initial Display

At switch-on the LP400 displays briefly a statement about update information which should be disregarded. A "NEW PATIENT?" question is displayed and it is necessary to press either the ✓ or the ★ to proceed. Pressing the ✓ will clear any patient information and non default alarm settings (whenever the unit is turned off for more than 2 minutes the "New Patient" question will be asked and the alarms set to "ON"). The display then produces a start-up screen of which diagram 4 is an example. The readouts available will, of course, be dependent on the options/modules available.

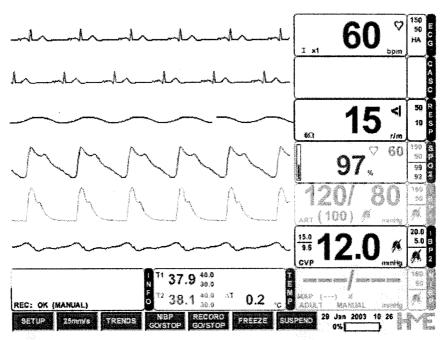


Fig. 4.

At the extreme right of the screen the name of each available function is displayed. The next column shows the alarm limits which may have been set or an alarm suspend symbol.

If the individual alarm has been switched off for 2, 5 or 15 minutes then a bar graph of the time remaining will be shown next to the word SUSPEND in red at the bottom left of the screen. At the end of this period the alarm will turn back on. In addition to the time periods, the option to mute the alarms permanently is included and is identified as ∞ .

The next column displays appropriate settings and digital averages of the dynamic waveforms in the large column which appears on the left.

The bottom of the display is a command bar which, from left to right, allows entry to the setup screen, trace speed, trends, NIBP stop/go, recorder stop/go, freeze trace, suspend alarms, date/time and battery condition indication. Note that if German is selected as the operating language then freeze trace is replaced by the symbol * and suspend alarms by

4.1.3.1.1 Set time and date

From the start-up screen press SETUP then SYSTEM then TIME/DATE. Using the + or - symbols set the time and date. Press the "tick" at the bottom of the TIME/DATE section to exit from this function.

4.1.3.1.2 Suspend

Pressing this option will offer, in turn, the suspension options of the alarms as "2 minutes", "5 minutes", 15 minutes or permanently off " ∞ ", the default is 2 minutes. Select that which is appropriate then either press the tick mark to exit the screen or set another function. The suspend option affects all alarms and, when activated, removes any individual alarm suspends which may already be active. A bar graph indication will appear to show the passage of suspension time, if a time has been selected.

If the permanently off mode is selected the user will be asked to confirm this choice before it becomes operative.

4.1.3.1.3 Brilliance

This can be adjusted for optimal viewing using the + or - symbols and the bar indicator.

4.1.3.1.4 Volume

This adjusts the QRS bleep volume and the Touch Screen activation sound using the + or - symbols and the bar indicator.

4.1.3.1.5 Alarm Vol.

Alters the alarm volume using the + or - symbols and the bar indicator.

4.1.4 Demo Mode

This is a teaching and demonstration mode where artificial waveforms are displayed. This button is password controlled to prevent accidental use. Once the Demo mode has been activated the waveform parameters can be set to desired levels. All the time the demo mode is in use a flashing sign near the bottom left of the screen will provide a warning.

4.1.4.1.1 Exiting the System screen

Press the "Tick" symbol, or wait for about 20 seconds after the last use.

4.1.4.2 Patient

Pressing PATIENT from the SETUP screen produces the PATIENT INFORMATION page. Touching CHANGE PATIENT NAME produces the NAME/REF screen from which, after touching the patients name, and then deleting any existing name with the DEL symbol, a name can be inserted by touching appropriate letters or SPC for spaces. Alternatively the NEW PATIENT button on the SETUP screen can be pressed to delete all patient information and to re-set the alarm limits to the default value. This action will also clear the stored TREND information.

A reference such as bed number, doctors name, etc. can be inserted by touching REF and deleting/entering data as above.

Other patient details such as height and weight can also be entered on the PATIENT INFORMATION page by using the + and - buttons.

4.1.4.3 Recorder

If a recorder is fitted, pressing this gives access to a screen from which the readouts to be printed can be selected. Additionally, the printer can be set to run manually or automatically in the event of an ECG alarm.

4.1.4.4 Defaults

This button brings up the following screen shown as Fig. 7.

4.1.6.2 Clearing Trends

The SET UP TRENDS screen also contains a button marked CLEAR TRENDS, pressing this clears all stored trend information from memory. Alternatively, selecting NEW PATIENT on the PATIENT screen then pressing CONFIRM or switching the unit off will also clear all trend information.

Graphical or Tabular display of Trends

When trends are first switched on graphical trends is the default display. If one or more readout have been selected for display it will take 2 or 3 minutes before the first graphical trends start to display in the default 1 HOUR mode. It will take much longer in the 8 or 24 hour modes

Switch from graph to a tabular display using the SELECT TABLE button. This shows a table of readings, with the time at the left side. Up and down arrows enable the table to be scrolled as required. Note that if the table is scrolled back to an earlier time then it will remain static until scrolled back to the present time

If Temperature has been selected as a trend, a button at the top of the temperature column can be pressed to switch between T1 and T2. If any other dual readout trends are present and selected these will also be provided with similar buttons.

Touch screen disabled

It is possible by pressing the HME logo in the bottom right hand corner of the screen to disable the touch screen. This brings up large lettering on the display TOUCH SCREEN DISABLED. In order to operate the touch screen again it is necessary to re-press the HME logo.

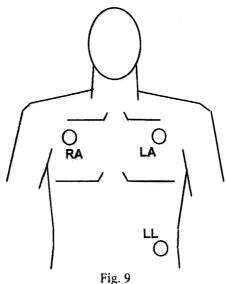
If an alarm condition arises while the touch screen is disabled then the disablement is overridden and the screen becomes operative again.

ECG Monitoring 4.2

Electrode application for ECG monitoring 4.2.1

Before ECG monitoring can begin the electrodes must be placed on the patient and connected correctly to the monitor. The ECG lead supplied is fitted with pinch clip fly leads which have built in resistors to protect the patient from stray currents which may be generated by adjacent equipment.

There are several acceptable sites for positioning ECG electrodes. Optimum sites may vary with the patients' individual physiological characteristics and condition. In most cases, ECG signal deficiencies may be improved by repositioning one or more of the electrodes. The best monitoring results will be obtained by placing the electrodes on the chest because there are fewer skeletal muscles to cause artefact. Fig. 9 shows typical electrode positions for 3 lead ECG monitoring.



Filter

Switches a 50/60 Hz filter ON or OFF.

QRS Beep

Turns the QRS bleep ON or OFF. See the description above headed "System" for a description of how the QRS volume is adjusted.

1mV

Pressing this produces a 1 millivolt calibration pulse which should measure 1 cm high on the screen.

Casc. (Cascade)

This enables or disables the cascading of the ECG trace as a second waveform.

Alarms

These can be set for both high or low limits using the + or - symbols near the bottom of the ECG setup screen. Pressing the adjacent "Bell" symbol turns the alarm status off or on.

Auto Limit

Pressing this sets the alarm limits to a fixed amount above and below the reading currently being displayed. For ECG this is 30 beats per minute above and below the patients stable heart rate. This function will not operate if the appropriate alarm is muted.

4.3 Non-invasive Blood Pressure (NIBP) Monitoring

NIBP measurement uses the oscillometric method via a cuff, inflated and deflated through the LP400. In the AUTOMATIC mode

4.3.1 Connecting the cuff device to the LP400

Connect the bayonet fitting end of the cuff extension hose to the NIBP spigot on the module by pushing gently on to the connector and turning clockwise until locked.

NB do not force operation to avoid breaking the locking lugs.

The required cuff should be connected to the patients limb to fit snugly without feeling either loose or tight. Next, connect the extension tubing via the push in male to female connector device (Luer fitting). Ensure that there are no kinks or compression restrictions in the tubing. Check the limb concerned to ensure that there is no likelihood of prolonged impairment of the patient's circulation. Set the appropriate cuff type, to adult or neonate using the NIBP setup screen.

General Information

The LP400 is capable accurately sensing blood pressure on any portion of the arm or leg which has sufficient blood flow. This includes the general regions of the upper arm, lower arm, thigh, calf, ankle, and arch of foot.

Throughout a measurement cycle the cuff pressure is displayed within the NIBP display area. This display area also shows the high and low alarm limits which can be set for Systolic, Diastolic and MAP. When the unit is first switched on only the systolic limits are active. If it is desired to set alarms for Diastolic and MAP then it is necessary to enter the NIBP setup screen and press the ALARMS button. On the left hand side of this screen the DIA and MAP buttons turn these alarms off and on.

Back in the main screen pressing any of the alarm limit figures will turn that particular limit off and display instead the mute symbol . Touching the symbol will turn the mute function off and re-establish the alarm limits.

Cautions

Change cuff placement site every 4 to 6 hours. Avoid cuff placement which could interfere with infusions. As will be seen from Fig 12 above, the cuff type and operating mode are displayed together with the average BP (MAP) and the time of the last measurement. Error messages are also displayed in this area together with the alarm status or limits.

4.3.6 Calibration check

Pressing this gives the additional option of MANOMETER in place of AUTO, MANUAL or TURBO. When MANOMETER is selected this enables static pressure to be displayed and compared to a simultaneous reading on a connected Sphygmomanometer or suitable simulator.

4.3.7 Operational error messages

During operation the software is able to detect various malfunctions and display an appropriate message on the screen. The following table gives some examples of error message and their remedy:-

PRESSURE ERROR' Press VIBP to restart. Cuff tubing loose at connectors. Tubing constricted. Disconnect and reconnect at tubing connections pushing home firmly. Ensure that the tubing is not pinched i.e. kinked or trapped. Press NIBP to restart. Constant fluctuations of pressure preventing the oscillometric determination of systolic or diastolic blood pressure. This can arise if the patient is restless and can flex the arm at the elbow thereby trapping the cuff or if the patient tenses the muscles of the forearm. Check the cuff for correct adjustment and calm the patient. Press NIBP to restart. PRESSURE ERROR' Evoked by a combination of the above. Work through above correction procedures. Press NIBP to restart. ABORTED' Caused by problems with fitting of the cuff which mean that an accurate determination is not possible. EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. REPOSITION CUFF' Indicates that the applied air pressure has reached its safe maximum.		The second secon
Reposition and tighten cuff. Press NIBP to restart. 'AIR LEAK' Cuff tubing loose at connectors. Tubing constricted. Disconnect and reconnect at tubing connections pushing home firmly. Ensure that the tubing is not pinched i.e. kinked or trapped. Press NIBP to restart. 'SIGNAL SATURATED' Constant fluctuations of pressure preventing the oscillometric determination of systolic or diastolic blood pressure. This can arise if the patient is restless and can flex the arm at the elbow thereby trapping the cuff or if the patient tenses the muscles of the forearm. Check the cuff for correct adjustment and calm the patient. Press NIBP to restart. 'PRESSURE ERROR' Evoked by a combination of the above. Work through above correction procedures. Press NIBP to restart. Caused by problems with fitting of the cuff which mean that an accurate determination is not possible. 'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident	ERROR MESSAGE	CAUSE AND REMEDY
'AIR LEAK' Cuff tubing loose at connectors. Tubing constricted. Disconnect and reconnect at tubing connections pushing home firmly. Ensure that the tubing is not pinched i.e. kinked or trapped. Press NIBP to restart. Constant fluctuations of pressure preventing the oscillometric determination of systolic or diastolic blood pressure. This can arise if the patient is restless and can flex the arm at the elbow thereby trapping the cuff or if the patient tenses the muscles of the forearm. Check the cuff for correct adjustment and calm the patient. Press NIBP to restart. 'PRESSURE ERROR' Evoked by a combination of the above. Work through above correction procedures. Press NIBP to restart. 'ABORTED' Caused by problems with fitting of the cuff which mean that an accurate determination is not possible. 'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident	'LOOSE CUFF'	
Disconnect and reconnect at tubing connections pushing home firmly. Ensure that the tubing is not pinched i.e. kinked or trapped. Press NIBP to restart. 'SIGNAL SATURATED' Constant fluctuations of pressure preventing the oscillometric determination of systolic or diastolic blood pressure. This can arise if the patient is restless and can flex the arm at the elbow thereby trapping the cuff or if the patient tenses the muscles of the forearm. Check the cuff for correct adjustment and calm the patient. Press NIBP to restart. 'PRESSURE ERROR' Evoked by a combination of the above. Work through above correction procedures. Press NIBP to restart. Caused by problems with fitting of the cuff which mean that an accurate determination is not possible. 'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident		Reposition and tighten cuff. Press NIBP to restart.
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'SIGNAL SATURATED' Constant fluctuations of pressure preventing the oscillometric determination of systolic or diastolic blood pressure. This can arise if the patient is restless and can flex the arm at the elbow thereby trapping the cuff or if the patient tenses the muscles of the forearm. Check the cuff for correct adjustment and calm the patient. Press NIBP to restart. 'PRESSURE ERROR' Evoked by a combination of the above. Work through above correction procedures. Press NIBP to restart. 'ABORTED' Caused by problems with fitting of the cuff which mean that an accurate determination is not possible. 'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident		
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determination is not possible. 'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident		
'EXCESSIVE MOTION' Caused by patient movement judged to be sufficient to cause an un-reliable reading. 'REPOSITION CUFF' This is self evident	'ABORTED'	
reading. 'REPOSITION CUFF' This is self evident		determination is not possible.
'REPOSITION CUFF' This is self evident	'EXCESSIVE MOTION'	Caused by patient movement judged to be sufficient to cause an un-reliable
100000000000000000000000000000000000000		reading.
'RANGE EXCEEDED' Indicates that the applied air pressure has reached its safe maximum.	'REPOSITION CUFF'	This is self evident
'RANGE EXCEEDED' Indicates that the applied air pressure has reached its safe maximum.		
	'RANGE EXCEEDED'	Indicates that the applied air pressure has reached its safe maximum.

4.3.8 Alarms

Pressing this button produces the screen shown at Fig. 13 enabling the NIBP alarms to be turned on or off and their limits set. The AUTO LIMIT button can be used to set the limits 20 above and 20 below the last recorded NIBP reading.

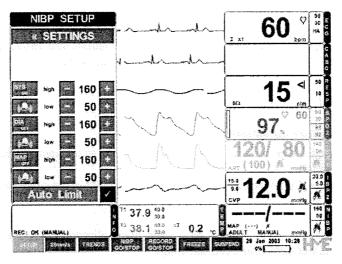


Fig. 13

If used in a MRI or C.T. environment there is potential for interference. There is also the potential for patient blistering or burns attributable to R.F. generation by the MRI unit. This may occur even when the pulse oximeter is not turned on.

4.5.2 SpO₂ Monitoring

To initiate this function, press the SpO₂ area of the screen and select PARAMETER "ON" this activates the trace (after a brief period during which a consistent signal is being characterised.

It should be noted that the trace is not necessarily proportional to the pulse volume and is presented for illustrative purposes only.

The vertical bar graph indicates the signal strength and therefore, to some extent, the reliability of the reading. If the signal strength is low then check that the probe and finger is free from any material which may reduce the light strength. Also ensure that the blood flow to the measuring site is not impeded resulting in a reduced pulse.

If the symbol appears in the SpO₂ box it indicates that the probe is no longer connected.

The symbol appears when the probe does not sense a finger.

When the unit is initialising its first reading the symbol is displayed with the word "SEARCHING".

If no satisfactory reading can be obtained A appears with the words "LONG SEARCH". If this occurs investigate to ensure that the circulation is not being impeded and that no foreign object, such as sticking plaster, is blocking the inside of the probe. If no obvious reason can be seen try connecting a different probe.

If the pulse is lost, becomes too weak or the signal is in other ways inadequate then the symbol will appear.

As with other functions touching on the SpO_2 box or waveform will bring up the Setup screen shown in Fig. 14 where the PULSE BLEEP can be turned on or off and the alarm limits set. The AUTO LIMIT button can be used to set the limits 30 above and 30 below the current pulse reading and 5 above (up to a maximum of 100%) and 5 below the current SpO_2 value.

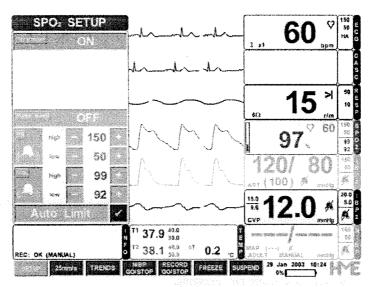


Fig. 14

4.5.3 Interference

The pulse oximeter may interfere with magnetic resonance imaging (MRI) and C.T. procedures. Typical causes of interference to the function of the pulse oximeter are restricted blood flow due to a blood pressure cuff or extremes of systemic vascular resistance, high ambient light, movement, electromagnetic interference, electrosurgery equipment, C.T. equipment, artefacts, dysfunctional haemoglobin and certain dyes (methylene blue, indocyanine green, indigo carmine and fluorescein).

4.7 Temperature Monitoring

Insert the required temperature probe(s) into the jack plug sockets labelled T1 and T2 on the ECG/TEMERATURE/SpO₂ module. Depending on the type of probe used, the appropriate number of digital displays (a maximum of two) will appear in the lower part of the screen display. If dual temperatures are being monitored then ΔT is also digitally displayed. When a probe has been inserted the alarm limits for T1 and T2 may be altered by pressing the 'Temperature' area of the screen. This will cause the TEMP SETUP screen to appear where the appropriate alarm limits may be altered.

The AUTO LIMIT button sets the alarm limits 1°C above and below the present measured temperature.

4.8 CO2 Monitoring (If fitted)

4.8.1 Start-up

Call up the CO₂ SETUP screen by touching the CO₂ area of the display. Monitoring can be started by turning the parameter ON.

If CO₂ monitoring is switched on and a water trap, or water trap substitute, is fitted, then at start-up the sampling pump will be heard.

If no water trap is fitted a message to this effect will be displayed and the pump will not run.

From the SETUP screen select CALIBRATION and check that both dates shown indicate that the unit is in calibration. If an OVERDUE message is displayed refer to the section on "Calibration"

4.8.2 Compensation

If the unit is within its calibration date press the COMPENSATION button. To obtain an accurate reading the appropriate compensation buttons should be selected. The available compensations are as follows

O₂

If this is selected to show a "tick" then a mathematical correction is applied to the reading to compensate for patients who are being supplied

with Oxygen

NO₂ This is used to compensate if the patient is being given Nitrous Oxide

Desflurane This is used to compensate if the patient is being given Desflurane

Water Vapour Used if extra compensation for water vapour is required.

BTPS Compensates for the different temperature, ambient pressure and water

vapour content of the deep lung compared to the measurement site.

Baseline Compensates for the effect of low level gas mixing.

NOTE:- For a patient breathing air with no additional gasses only the BTPS and Baseline compensations should be corrected.

Separate alarms can be set for Respiration Rate (RR) and end-tidal CO_2 (et CO_2). Automatic limits are also provided for convenience but these must be checked for suitability for an individual patient. These limits are 10 above and 10 below the respiration rate and 2% above and below the CO_2 %.

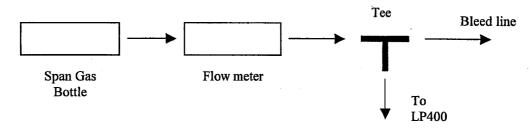
4.8.3 Measurement

Ensure that an appropriate cannula or sample line as shown by the illustrations below in Fig. 16 are connected to the LP400, also ensure that the required measurement mode is selected in the setup screen. The options are millimetres of Mercury (mmHg), % CO₂ and kilo Pascals (kPa).

Note:- The manufacturers of the sampling system and measurement module used by the LP400 is Welch Allyn® who from time to time introduce improvements to their sampling systems. One such improvement is the introduction of their 'Sure CO2' sampling lines based on lengths of 'Nafion™' instead of water traps. Where the illustrations and text in this section refer to 'Watertrap' this may be taken to mean a water trap or substitute adaptor.

CALIBRATION OK message should be displayed. The OVERDUE message should be replaced by the date of the next calibration. Note that the CO₂ content of the span gas does <u>NOT</u> appear on the display during calibration.

The Two-Point calibration described above requires a suitable span gas containing an exactly known content of CO₂ between 8 and 12% in air. This needs to be regulated down to about 5 p.s.i with a flow rate of 1 L/min. This span gas should be fed through a sample "T" (Part No. ZD0025) to which is connected the sample line (ZD0024).



4.8.6 Error Messages

Most error messages are self explanatory and, in addition to the ones mentioned above are:-

No Watertrap

A Watertrap needs to be fitted

Watertrap or Cannula Occlusion

Use a new Watertrap and/or Cannula

Exhaust Occlusion

Make sure the exhaust is not obstructed

Low Run time

Unit has not been sampling for a minimum of 5 minutes prior to a

calibration attempt.

4.9 Alarms

4.9.1 Altering & Viewing Alarms

The alarms for every function are set initially at factory default values that will suit most applications. By entering the appropriate setup screen, any alarm can be adjusted up or down within its maximum and minimum permissible values. Alternatively, when a stable waveform or reading has been established, the AUTO LIMIT area of the setup screen can be pressed to automatically set typical limits around the measurement being obtained.

The factory set default values can be re-set to suit local requirements by entering the default setup screen as described in section 4.1.4.4.

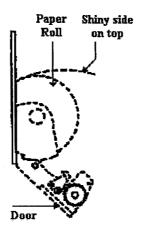
For all alarms there is a few seconds delay, between the condition exceeding the limits and the alarm being triggered, to eliminate false events.

4.9.2 Alarm Activation

The alarm will sound when the alarm limits on any function that has been set and have been exceeded, unless these have been muted or the alarm suspension is active.

If an alarm has been disabled from the setup screen the alarm off symbol will be displayed continuously on the right of the screen next to the function name.

If the SUSPEND button, at the bottom of the screen, is pressed, all alarms will be disabled and the word SUSPEND will be displayed in red in the patient information area. A bar graph display will indicate the proportion left out of the chosen suspend time. If the option to suspend alarms indefinitely has been chosen the symbol ∞ will be displayed by the word SUSPEND which will flash.



Place a new paper roll (Part No. ZA0002) between the two round tabs of the paper holder so that when you pull the paper towards the door, the sensitive (shiny) side of the paper is facing the print-head at the top of the recorder.

Pull the paper towards you until approximately 4 inches (10 cm) of paper has been unrolled.

Align the paper with the pinch roller attached to the recorder door.

Holding the paper against the roller, close the recorder door.

To ensure that the paper is aligned in the slot and has not been pinched in the door, pull the loose edge until a few inches of paper is showing. If the paper will not move, open the door and repeat the steps above.

The recorder is now ready to print.

4.10.2 Recording Procedure

The recorder has two modes of operation:

Record - activated by pressing the RECORD GO/STOP area at the bottom of the screen. In this mode the recorder runs in real time continuously. The trace on the recorder corresponding to the waveforms selected on the RECORD SETUP screen.

Automatic - If this mode has been selected using the "Setup Screen" menu then the recorder will start automatically when an ECG related alarm occurs other than 'lead off'.

4.10.3 Recorder setup

If the recorder section of the setup screen is pressed the following options are available.

Pressing WAVE 1 will bring up ECG as the first trace on the printout. Pressing the same area again will make wave 1 the next function down on the main screen. Cycle through the available functions until the one that is required to print out first on the paper is selected.

Repeat the above operation with WAVE 2 and the other WAVE options until all desired waveforms are selected up to a maximum of four.

MODE gives two options, either MANUAL or AUTOMATIC. In the MANUAL mode the printer starts and stops only in response to the on-screen area RECORD GO/STOP. The AUTOMATIC mode enables the printer to start and run for sufficient time to give a full record of an ECG alarm event both before and after it took place.

4.10.4 Recorder reset

A "RESET" button is provided on the recorder setup screen. This button is for use if ever the recorder logic becomes locked up. This can happen on rare occasions after some errors. If the recorder becomes inoperative for no apparent reason press the reset button and then try printing again.

4.12 Maintenance

4.12.1 Cleaning and Maintenance by the User

The monitor unit:

The unit and power lead should be kept clean and checked for signs of damage. It is recommended that it is wiped clean with a cloth or tissue dampened with water and detergent.

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.

Functional checks - If the unit is not in constant use the battery charge level should be checked monthly and recharged if necessary. Recharging a flat battery will take 3 hours and is achieved by connecting the unit to the mains power and switching the rear power switch to I (on). Observe that the green ' \sim ' indicator and amber "CHG" are illuminated.

NOTE The monitor does not have to be running for battery charging.

Patient ECG leads. - After use the patient leads should be cleaned with warm water and wiped dry. Do not autoclave the unit or patient cable. Electrical connectors must not be immersed in any fluid

Invasive BP equipment.- The recommended MEDEX domes are disposable and should NOT be reused. The MEDEX transducer is reusable and may be cleaned and/or sterilised.

For cleaning, use a mild detergent solution to clean blood and other foreign material from the external surfaces of the transducer and cable.

For liquid sterilisation, place the cleaned transducer and cable (except the connector) in a solution of activated dialdehyde, glutaraldehyde or equivalent. Immerse for a minimum of 10 hours to destroy resistant pathogenic spores including Clostridium sporogenes and Clostridium tetani.

To disinfect only, immerse for a minimum of 10 minutes to destroy viruses and vegetative pathogens. Using a sterile technique remove the transducer and cable from the sterilising solution and rinse with sterile water avoiding fluid contact with the connector. Wrap the transducer in sterile gauze and wrap in a sterile dressing. Place in sterile wrapping and label 'liquid sterilised'.

SpO₂ equipment cleaning. Unplug the device before cleaning or disinfecting. Do not autoclave or ethylene oxide sterilise, or immerse in any liquid. Clean with soapy water and dry.

Temperature probe cleaning and sterilisation. - After use the probe should be cleaned with warm water and wiped clean and dry. Sterilisation may be achieved by:

- 1. Low temperature steam 73°C ± 2°C
- 2. Ethylene oxide
- 3. Cold sterilisation fluids under medical supervision

Under no circumstances should probes be boiled, autoclaved or cleaned with chlorhexidine based fluids.

4.12.2 Further Maintenance

HME recommend that preventative maintenance checks are carried out on the unit under a HME Service Contract at 6-monthly intervals. Alternatively, the maintenance may be carried out by suitably qualified personnel.

5 EQUIPMENT CHANGES

Date Change

YTNAЯЯAW

operative nor shall the Company be under any liability to the customer materials and workmanship for one year from the date of delivery, PROVIDED that this guarantee shall not be HME Limited ('the Company') guarantees such equipment against defects (normal wear and tear exempted) in

- 1. unless the customer notifies the Company in writing of the defect not more than [two days] after the defect
- 2. unless the defective equipment is returned (as a unit) to the Company works, freight prepaid within fourteen tirst becomes apparent to the customer;
- 3. in the event of any improper use or mishandling of the equipment, removal of date Serial Numbered Medical days after the defect first becomes apparent;
- 4. stamps or markings from the equipment or it's component parts or the repair or replacement of any parts or
- 5. if the equipment is used at any time after the discovery of the defect; the repair or replacement of any parts thereof by unauthorised persons;
- if the equipment is sold by the customer
- Terms Act, 1977; 7. if the equipment is sold pursuant to an international supply contract as defined by S.26 of the Unfair Contract
- in respect of any consequential or special loss or damage sustained by the customer howsoever caused.

equipment at the customer's location. of the Company will not extend the starting date for this guarantee more than one month from the receipt of the equipment or damages not exceeding the invoice price of the equipment. Delay in installation beyond the control The Company's liability under this guarantee shall be limited at its option to the repair or replacement of the

on the part of the Company implied by statute common law or otherwise all of which are expressly excluded. Act, 1893. Save as aforesaid, this Guarantee is in substitution for and shall replace all conditions and warranties agency of the Company; or for breach of any undertaking as to the title implied by S. 12 of the Sale Of Goods itself or its servants or agents (but not independent contractors) while acting in the course of their employment or The Company does not exclude or restrict its reliability for death or personal injury resulting from negligence of

Spare Parts

numbered medical equipment. workmanship for 30 days from delivery and otherwise on the same terms as the guarantee in respect of serial The Company guarantees spare parts against defects (normal wear and teat excepted) in materials and

Electrical Safety

:li ylno The Company considers itself responsible for the effects of safety, reliability and performance of this equipment requirements of BS5724 Part One, 'Specification for Safety of Medical Electrical Equipment'. The Company considers that the equipment has been designed, constructed and tested so as to comply with the

installation, preventative maintenance, re-adjustments modifications or repairs are carried out by

persons authorised by the Company.

Authorised persons are:

equipment is used. The standard for the United Kingdom is 'Regulations for the Electrical Equipment of The electrical installation in the relevant room complies with the current regulations of the country in which the the Company, its employees, the Company's approved agents or distributors and their employees.

Buildings' published by the Institution of Electrical Engineers.

The equipment is used in accordance with the operating instructions.

Service Agreements

the Company or its approved agents or distributors for further information on service contracts. Periodic inspection and preventative maintenance are essential to ensure continued effective operation. Contact

Operating and Service Manuals

copyright. prior notification, and resulting manual inaccuracies may occur. This manual and any changes are protected by development may result in equipment changes. The Company reserves the right to make such changes without Although every care has been taken to ensure that the information in this manual is accurate, continuous

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Program code developed using DJGPP compiler tools: ref http://www.delorie.com Acknowledgement

4.13 Recommended Spare Parts

4.13.1 Electronic and Electro-Mechanical Spares

Certain items have a long shelf life but a limited life in use. Items in this category are mains power leads, patient input cables, which are subject to physical damage in use, and fuses.

4.13.2 Ordering Spare Parts

Due to developments improving the product, over the years certain spare parts may not be readily interchangeable between early and late production units. Always quote the serial number of the unit and date of purchase, if known. This information is in addition to the circuit reference and the reference number and issue of the PCB required.

Items returned for replacement under guarantee should be labelled with the unit type, serial number, date of purchase, if known, and written details of the symptoms or fault found.

Orders for spare parts may be sent by post, telex, fax or telephoned to HME or approved agents or distributors.

4.13.3 Spare Parts Recommended as Essential

Number of un	its to be maintained		1	5	10
		Part No.			
ECG Patient ca	ble 3 way	XC0069	1	2	3
Flying leads	Red	XC0066	1	2	3
-	Green	XC0067	1	2	3
	Yellow	XC0068	1	2	3
Mains lead (IE	C/Schuko)	XC0015		ĺ	2
Mains lead (3	pin UK)	XC0019	1	2	3
Mains fuses	ŤÍÅ	FA0060	4	6	10

4.13.4 Spare Parts Recommended as Desirable

Number of units to be maintained			5	10
	Part No.			
Battery pack	400-316	-	1	2
Recorder (if fitted)	JR0007	_	1	1
Motherboard assembly	400-345	-	. 1	1
Processor assembly	400-348	-	1	1
Memory module	SC3313		1	1
Low voltage power supply board	400-301-DS	-	1	2
Mains power supply board	400-300		1	2
LCD screen	DL0001	_	1	1
Touch screen	DT0001	-	. 1	1
Inverter Board	400-343		1	1
ECG/Temperature Module	400-322	-	1	1
ECG/Temperature/Respiration Module.	400-347	_	1	1
NIBP module (if fitted)	400-321	_	- 1	1
Dual Pressure Module (if fitted)	400-325	-	1	1
CO ₂ Module (if fitted)	400-333		1	1

NOTE: If a replacement battery is fitted the old one must be disposed of in accordance with any national or local regulations which may be in force.

4.11 Operator First Line 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	 Power cable not connected to live power source Rear panel AC power switch in OFF position Defective power cable Mains input fuses blown
Amber unit "ON" indicator not illuminated	1. Unit not switched on
Unit shuts down suddenly after the LOW BATTERY alarm has been sounding for a while	1. Battery exhausted. Plug into mains or a 12 Volt supply and re-start the LP400.
No signal on trace	Defective patient cable
Excessively noisy trace	 Electrode site not properly prepared Poor electrode contact Defective patient cable
No heart rate display or flashing heart symbol	Patient electrodes incorrectly sited.
No QRS bleep	Switched of f on the ECG SETUP screen or volume set too low in SETUP screen
Continuous alarm indications. No ECG signal on display (LEAD OFF displayed)	Defective patient cable Electrode or lead off
Faulty plethysmograph cuff connection and related NIBP errors indicated on screen display	1. See table in section 4.3.7.
No temperature digits	Check connection of probe to module Replace temperature sensor
Temperature digits reading 20 degrees	Replace temperature sensor

4.9.3 Alarm Sounds and Indications

Requirements for alarm sounds vary from user to user and so the facility to change both the sound and priority of vital alarms. The SETUP screen as shown in Fig. 5 earlier gives access to an ALARM SETUP screen as shown below by FIG. 15.

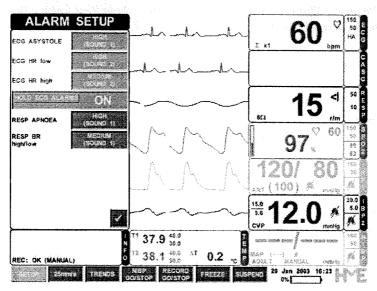


Fig. 15

The ECG ASYSTOLE, ECG HR LOW and ECG HR HIGH can be cycled through 'HIGH SOUND $1 \rightarrow$ HIGH SOUND $2 \rightarrow$ MEDIUM SOUND $2 \rightarrow$ MEDIU

The additional button on this screen enables 'latching' of the ECG alarms to be turned on and off. This facility enables transient alarms to be retained for subsequent checking because even when the alarm condition disappears the alarm limit which was triggered will continue to flash red. A held alarm can be cleared by pressing the flashing signal once to mute the alarm then again to turn the alarm function back on.

4.9.4 Factory Alarm Priority Settings

As despatched the factory default setting for the alarms are

ECG Asystole	High	Sound 1
ECG HR Low	High	Sound 2
ECG HR High	Medium	Sound 2
RESP. APNOEA	Medium	Sound 1
RESP. BR High/Low	Medium	Sound 1

4.9.5 Technical Alarms

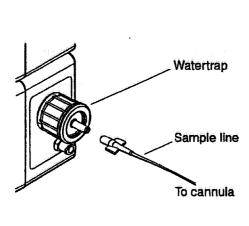
'Technical' low level alarms are generated by such conditions as a lead off or unplugged, no finger in the SpO₂ probe, low battery, etc. These low level alarms are two pairs of lower frequency bleeps repeated at 20 second intervals. A flashing graphic or a message is displayed in red.

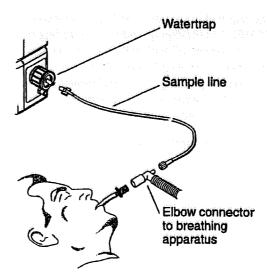
4.10 The Printer/Recorder

4.10.1 Paper Loading.

Open the door at the side of the unit by pressing the ribbed button at the lower right of the recorder. The door should swing down. If the recorder's door does not open completely, pull it towards you until it is completely open.

Reach in and remove the spent paper core by pulling it towards you gently.





Typical Connection to Non-Intubated Patient

Typical Connection to Intubated Patient

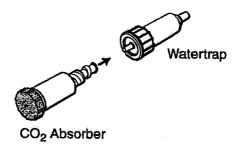
4.8.4 Inflammable gasses

If the gas being sampled is thought to be inflammable then a tube should be fixed to the exhaust outlet situated next to the Watertrap. This exhaust should be led away to a safe distance from the LP400 and any other non-flameproof electrical equipment.

4.8.5 Calibration

If, when CALIBRATION is selected an OVERDUE warning is displayed, calibration is required.

ZERO calibration requires only that a CO₂ Absorber (Part No. ZD0020) is connected directly to the Water Trap inlet as shown.



Watertrap and CO2 Absorber

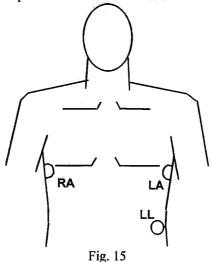
Make sure the unit has been operating for at least 5 minutes before performing a calibration. When the unit has been running long enough with the Absorber in place press the ZERO CALIBRATION button. The CO₂ Readout area should display the word CALIBRATING and then after a few seconds this should change to CALIBRATION OK. If the unit has been operated for an insufficient time then the words LOW RUN TIME will be displayed. Following a successful calibration the OVERDUE warning will be replaced by the date on which the next zero calibration is required.

TWO-POINT calibration requires the Absorber to be connected as described above. The TWO-POINT USER CALIBRATION button should be pressed, after a few seconds a message will be displayed underneath the CO₂ readout saying CONNECT SPAN GAS. Check first at the top of the calibration screen that the correct CO₂ concentration is set as the Span Gas. When this has been done again press the TWO-POINT USER CALIBRATION button again. The word CALIBRATING should appear and after a few seconds a

4.6 Respiration Monitoring

4.6.1 Electrode application for RESP Monitoring

Respiration monitoring is achieved using a Respiration cable or the ECG patient cable fitted with fly leads which do not contain protective resistors (see section 3.6). However, the required positioning of the electrodes is different from ECG. The positions in the following diagrams should be used for adult and neonate monitoring respectively. Note that the electrode positioning may be optimised for either transthoracic or transabdominal respiratory monitoring. These electrode positions will, in most cases, offer the maximum strength for combined respiration and ECG signals when both parameters are to be monitored.



Proper electrode application is particularly critical when monitoring respiration. Use the following steps to apply the ECG electrodes, otherwise erroneous results may occur.

- 1. If necessary, shave the area where the electrode is to be placed
- 2. The skin should be abraded slightly with a gauze pad or, alternatively, commercially available electrode preparation solutions may be used in place of abrasion.
- 3. Clean the area with an alcohol pad to remove all abrading residues and baby oils (not necessary with prep solutions)
- 4. Dry the skin.
- 5. Snap the ECG lead wire to the electrodes prior to placement on the patient's chest.
- 6. Ensure that conductive parts of the electrodes and associated connectors do not contact other conductive parts including earth.
- 7. If reusable or non-gelled electrodes are used, apply gel to the electrodes. If pre-gelled disposable electrodes are used, peel the backing from the electrode adhesive and apply the electrodes.

NOTE Do not apply excessive pressure to the centre of the electrode as it may force gel beneath the adhesive and cause the electrode to loosen.

8. The monitor end of the connector must be inserted into the green ECG socket on the module panel.

There is only one possible way of connecting this lead. DO NOT TRY TO FORCE THE

CONNECTOR as this will damage the pins inside.

If any part of the equipment becomes accidentally wetted during use, disconnect from the patient, isolate from the mains supply and dry the wet parts before reconnecting.

4.6.2 Respiration Monitoring

To select the respiration function press the respiration area of the screen. This will produce an area entitled RESP SETUP. From this area turn respiration monitoring ON, if necessary, under the heading PARAMETER. With the exception of the alarm setting symbols the only other control is labelled SENS and switches the sensitivity between 2 Ohms and 6 Ohms. A respiration waveform will now be displayed. The breathing rate (BR) is displayed digitally in the patient's status column on the right and the value is continuously updated. The AUTO LIMIT button sets the alarm limits 10 above and below the present breathing rate.

4.4 Invasive Blood Pressure Monitoring

4.4.1 Blood Pressure application

Invasive Blood Pressure measurements must only be carried out by, or under the supervision of, qualified personnel.

To obtain perfect pressure measurements with the selected transducer/s, appropriate monitoring cable and kit while ensuring the safety of the patient, the following procedures must strictly be observed and carried out in the sequence indicated:

- The monitor end of the connector/s must be inserted into the socket/s on the module. There is only one
 possible way of connecting the transducer cable. DO NOT TRY TO FORCE THE CONNECTOR as
 this will damage the pins inside. Like all electrical connections, the connector should not be exposed to
 moisture or immersed into liquid.
- 2. Remove the monitoring kit from its undamaged sterile packaging and connect the dome along with the monitoring kit to the transducer. Note that the monitoring kit is not designed for re-use. If you are not familiar with the assembly and operation of this device, consult the manufacturer's instructions
- To avoid air bubbles hold the dome horizontally and allow the fluid to flow in slowly. Check the entire system for bubbles including hidden areas and dislodge them by tapping. Pressurise the system to 300 mm Hg. Flush the system for 2-3 sec and check again for bubbles
- 4. Place the transducer in its holder and adjust the height to that of the patient's organ to be monitored.
- 5. Avoid conductive connections with other monitoring devices e.g. via metal cocks.
- 6. Allow the system to warm up for 5 minutes before calibration.

Precautions:-

Do not use a syringe smaller than 5 ml.

Do not use excessive force on the syringe while attaching fluid-filled components.

Do not kink cables.

Do not autoclave or ethylene oxide sterilise transducers, interface cables or clamps.

If any part of the equipment becomes accidentally wetted during use, disconnect from the patient, isolate from the mains supply and dry the wet parts before reconnecting.

4.4.2 Zeroing the BP Transducer

After the assembly has been allowed to warm up for 5 minutes, ensure that the pressure transducer is open to atmospheric pressure, touch the appropriate IBP area of the screen and press the ZERO symbol that appears. A 2 second delay occurs while the adjustment takes place. If an error message appears, check that the pressure transducer is not pressurised and that the electrical connectors are correctly fitted.

Other options available

From the IBP1 or IBP2 SETUP screens the method of displaying the results can be set using LAYOUT.

Separate alarms are provided for Systolic, Diastolic and MAP. When the unit is first switched on only the Systolic limits are active. If it is desired to set alarms for Diastolic and MAP then it is necessary to enter the IBP setup screen. On the left hand side of this screen the DIA and MAP buttons turn these alarms off and on. The AUTO LIMIT button can be used to set the limits 20 above and 20 below the last recorded IBP reading.

4.5 SpO₂ Monitoring

4.5.1 Attaching and removing sensor

The SpO_2 sensor is connected, either directly or via an extension lead, to the appropriate socket (Black) on the ECG/Temperature/ SpO_2 module.

The SpO₂ sensor is disconnected from the monitor by grasping the barrel of the connector and pulling gently.

Precautions:

If any part of the equipment becomes accidentally wetted during use, disconnect from the patient, isolate from the mains supply and dry the wet parts before reconnecting.

4.3.2 The screen

The NIBP settings screen (see Fig. 10) is accessed by touching the NIBP area of the screen or from the SETUP screen. In the NIBP SETUP screen the cuff type, operating mode and cycling can be set as well as the alarm functions.

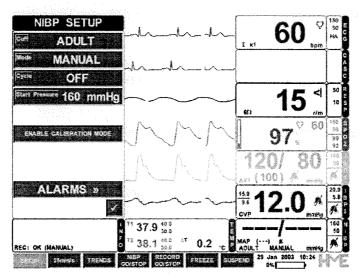


Fig. 11

Cuff

This can be changed between ADULT and NEONATE. If an incorrect choice is made to suit the cuff in use, then, the first time the unit tries to take a measurement, it will detect the anomaly and stop.

Mode

Can be changed between MANUAL, AUTOMATIC and TURBO

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MODE SETTING	FREQUENCY OF RECORDING
'AUTOMATIC'	Every 2, 3, 4, 5, 10, 15, 30, 60 or 90 minutes.
'TURBO'	Consecutive recordings over 5 minutes.
'MANUAL'	A single, immediate determination.

4.3.3 Cycle

This is only effective if the MODE is set to AUTOMATIC when it can set the recording frequency.

4.3.4 Start Pressure

This button can be used to set the initial inflation pressure; for an adult cuff the options are 140, 160 and 180 mmHg. For a Neonate cuff only 100 and 120 are available as start pressures. If the MODE is set to MANUAL each measurement initially starts at this chosen pressure and only subsequently pumps higher if the measurement requires this. In either the AUTOMATIC or TURBO modes the start pressure is used for the first measurement but the second and subsequent start pressures are based on the lowest satisfactory pressure reached in the previous check.

4.3.5 Readout

To initiate monitoring press the NIBP GO/STOP button area at the bottom of the screen. The readout takes place on the right of the screen and is in the format shown below.

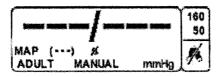


Fig 12

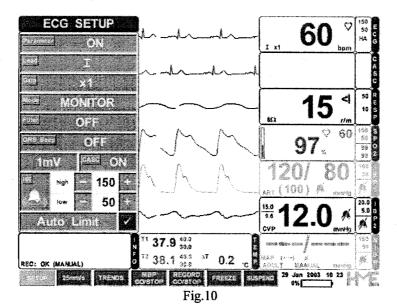
Under certain conditions it may be preferred to place the electrodes on the limbs. This electrode configuration would normally be used on a short-term basis to monitor an anaesthetised patient during surgery. This method is not recommended for continuous long-term monitoring because of excessive muscle artefact caused by movement of the limbs.

Use the following steps to apply the ECG electrodes, otherwise erroneous results may occur:

- 1. If necessary, shave the area where the electrode is to be placed.
- 2. The skin should be abraded slightly with a gauze pad or, alternatively, commercially available electrode preparation solutions may be used in place of abrasion.
- Clean the area with an alcohol pad to remove all abrading residues and oils (not necessary with prep solutions).
- 4. Dry the skin.
- 5. Snap the ECG lead wire to the electrodes prior to placement on the patient's chest.
- 6. Ensure that all conductive parts of electrodes and associated connectors do not contact other conductive parts including earth.
- 7. If reusable or non-gelled electrodes are used, apply gel to the electrodes. If pre gelled disposable electrodes are used, peel the backing from the electrode adhesive and apply the electrodes.
- 8. The monitor end of the connector must be inserted into the green and yellow ECG socket on the monitor front panel.

4.2.2 ECG Monitoring

An ECG setup screen can be produced by pressing either ECG from the setup screen or by pressing anywhere within the ECG display area. See Fig 10 below.



The following controls then become available:

Parameter

This switches the ECG monitoring function off or on. When monitoring is off this is repeated in large letters on the right of the main screen.

Lead

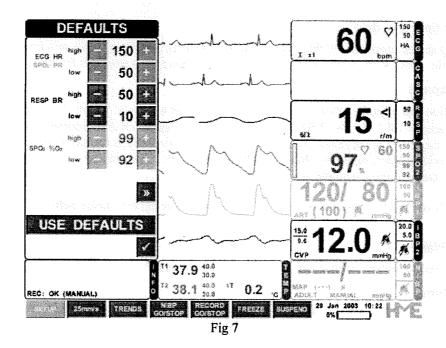
This enables the lead type to be selected by touching until the appropriate choice appears. Choices are I, II, III or STD. The STD selection is not required for monitoring purposes and can not be selected during monitoring operations.

Gain

Allows gain selection between x ½, x1, x2, and x4

Mode

Switches between "MONITOR" and "DIAGNOSTIC"



In this screen a set of user defaults for alarm limits may be set which come into play whenever NEW PATIENT is selected from the opening screen or in the PATIENT SETUP SCREEN. Set the limits using the + or - keys at either side of each limit to choose values which are of most general use for the monitor location. Press USE DEFAULTS if you wish them to become operative immediately.

4.1.5 Speed

Pressing this button, which is next to the SETUP button, switches between trace speeds of 50, 25, 12.5 and 6.25 mm/second for both the screen and the recorder. At switch-on, the trace speed defaults to 25 mm/second

4.1.6 Trends Monitoring

Trends on any function available on the unit can be monitored over pre-programmed periods of 1 hour, 8 hours or 24 hours. Trends are displayed as a table or graphically with scale of the y-axis (beats per minute, etc) adjusted automatically to accommodate the range of variation by the LP400 software.

4.1.6.1 Setting the LP400 to record trends:

From the default screen press TRENDS button at the bottom of the screen. This turns on the trends screen which displays (see Fig. 8) a box instead of the usual function displays. Also displayed are three buttons. The top one switches the trend scale between 1, 8 or 24 hours. The middle button switches the trend display between graphical and tabular displays. The third button labelled SET UP TRENDS enables selection of which trends are to be displayed simply by pressing the appropriate button.

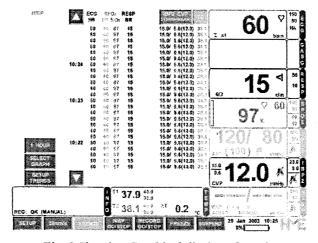


Fig. 8 Showing Graphical display of trends.

Above the command bar to the left is a space for the patient's name and any warning messages. Patient information is also saved at switch off and displayed again at power up unless 'NEW PATIENT' is chosen. ECG will always be displayed as the first trace and this will be cascaded if space on the display is available and this option is selected. The order of the next traces will be dependent on the options available.

4.1.3 Setup

Touching the screen at this point produces the Setup screen which is a table appearing on the left of the screen as shown by fig. 5. If the setup screen is unused for more than 20 seconds the display reverts to the main screen.

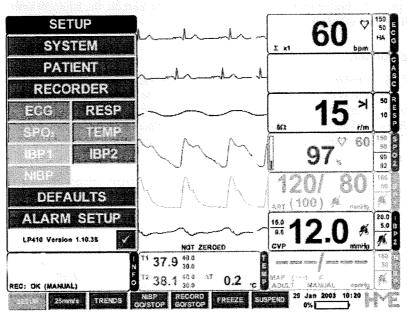


Fig. 5

4.1.3.1 System

Pressing System at the top of the setup screen as shown in Fig. 6 enables the basic system parameters such as language, time/date, alarm suspend options, display brilliance, QRS bleep volume and alarm volume to be set.

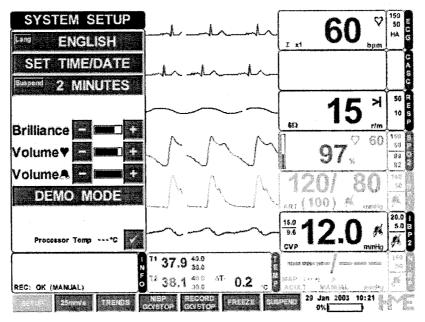


Fig. 6

SpO₂ sensors:

Item	Part No.
Re-usable ear sensor	001 375
Disposable finger (adult)	001 361
Disposable (neonate)	001 363
Disposable (infant)	001 364
• ' '	

NIBP

Item	Part No.
NIBP module with standard accessories	400-002
Blood pressure cuff	ZD0016
NIBP tubing with connector	001-351
Neonate(max. circumference 122 mm)	ZD0012
Child (max. circumference 266 mm)	ZD0013
Adult, wide-range (max. circumference 420 mm)	ZD0014
Adult, outsize (max. circumference 482 mm)	ZD0015

Invasive blood pressure:-

Item	Part No.
IBP module (Twin channel) with standard accessories	400-003
Reusable transducer (One off)	TP0001
Single line monitoring kit (Red)	ZB0001
Single line monitoring kit (Blue)	ZB0002
Dual Line Monitoring Kit	ZB0003
Blood pressure cable	400-340
Bracket for two transducers	HB0104
Stand clamp for bracket above	HB0103

Temperature sensors:-

Item	Part No.
Paediatric – core	001-380
Paediatric – skin	001-381
Adult – core	001-382
Adult – skin	001-383
Adult – dual	001-385

CO2 (Side stream):-

Item	Part No.
CO ₂ module with standard accessories	400-008
CO ₂ Absorber for zero calibration testing	ZD0020

Remove the 'V' from in front of the following numbers if ordering direct from Welch Allyn

Nasal cannula for CO ₂ sampling and O ₂ delivery (Soft) (Adult)	V008-0787-00
Nasal cannula for CO ₂ sampling only (Adult)	V008-0789-00
7ft Sample line – for use with intubated patients	V008-0781-00

More information on Welch Allyn sampling lines can be found in Section 4.8

3.7 System Connectors

This model may be connected to an LP800 series Central Station via the LAN socket situated on the rear panel. Contact HME for details prior to attempting this connection.

A set of normally open contacts across pins 2 & 6 on the keyboard socket can be utilised for a "Nurse Call" or other facility in the event of an alarm.

Monitoring Functions

ECG

Heart Rate range

15 - 250 BPM

Selectable leads

I, II, or III

Selectable gain

0.5, 1, 2 or 4 times.

Lead fault detection

Displays LEAD OFF warning

QRS indication Pacemaker indication Flashing heart symbol, and audible tone with volume control / off 'P' symbol appears by the QRS "Heart", trace displays a positive 2cm

pulse.

Esis/defibrillator

Yes

protection

Bandwidth

0.5 - 30 Hz (monitor mode),).05 - 100Hz (diagnostic mode)

Filter

50 Hz/60Hz

Input impedance

 $> 20M\Omega$ at 10Hz

Trend

1, 8 or 24 hour trend of ECG heart rate

Alarms

High and Low rate, Asystole. With visual and audible warning with

optional latching.

Non-invasive Blood Pressure (If fitted)

Range

30 to 280mmHg. Cuff over pressure 300mmHg

Accuracy

±5 mm Hg with a standard deviation no greater than ±8 mmHg

Display

Systolic/diastolic and mean numerical display; graphical manometer display

during cuff inflation/deflation also graphical bar display, with mean, on

trend screen.

Automatic repeat

interval

In 'Turbo' mode continuous repeated measurements for a 5 minute period or 'Automatic' mode taken from manual start to manual stop commands with

repeat intervals programmable from 2-90 minutes in steps of 2, 3, 4, 5, 10,

15, 30, 60 or 90 minutes.

Trends

Graphical and tabular display of last 24 readings of systolic, diastolic and

MAP readings.

Alarms

Systolic, Diastolic, MAP. High, and low pressure. with visual and audible

warning

Invasive Blood Pressure (if fitted)

Range

-10 to 245 mm Hg

Accuracy

±2 mm Hg or 2% of reading

Display

Dynamic waveform and digital display of diastolic, systolic MAP

Trend

graphical representations of 1, 8 or 24 hour trends of systolic, diastolic and

MAP

Alarms

Systolic, Diastolic, MAP. High, and low pressure, with visual and audible

warning

SpO₂

Range

0 - 100%

Accuracy

±2% (70 -100%)

±3% (50 - 69%)

Averaging Pulse rate range 8 beat average

30 - 250 bpm, accurate to $\pm 2\%$ over full range

Patient input leakage

 $< 10 \mu A$

Trends

1, 8 or 24 hour trend of SpO₂%, and Pulse rate.

Alarms

SpO₂ saturation, High (55 - 100%), and Low (50 - 95%).

Pulse Rate, High (250 - 35 BPM), and Low rate (245 - 30 BPM)

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1.3 Front and Rear Panel Controls

Front Panel Controls

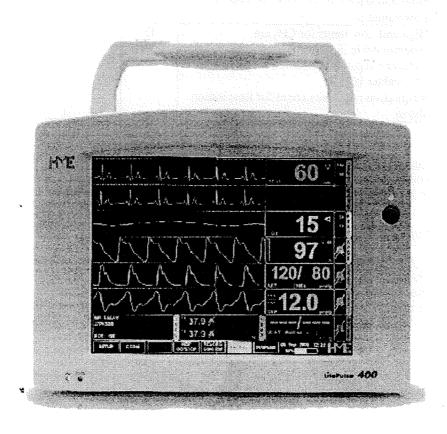


Fig. 2

The "on/off" button at the top right does not switch the power directly but initiates a sequence which permits the systems software to manage start up or shut down so that no data loss occurs. In order to fully isolate the unit from the mains the power cord must be removed after the unit has been turned off as above.

Front panel indicators

~

Green "~ " ON Indicates mains power connected.

CHG

Yellow "CHG" ON Indicates that the internal battery is charging.

Yellow above the "On" / Off" button indicates the unit has been switched on.

The standard and optional readouts are displayed as follows:

LIFESIGN	TRACE DESCRIPTION
ECG	Always presented and displayed as a continuous trace in the upper section of the screen. The beats per minute averaged over 8 are presented as a numeric display on the right of the screen. Also displayed is lead selected, sensitivity and alarm status.
SpO ₂	SpO ₂ is displayed as a continuous trace on the next lower portion of the screen, (if Respiration is not fitted). Summary digital values of SpO ₂ % and pulse oximeter determined heart rate are continuously updated in the patient summary down the right side of the screen. Additionally, a vertical bar graph to the left of the digital display represents signal strength.
Blood Pressure	NIBP measurement uses the oscillometric method via a cuff which is inflated and deflated through the LP 400/410. The resultant information is presented as both numeric and as graphical bar displays. IBP is available as an option which provides two channels and can display as dynamic waveforms or digitally.
Temperature	T1, T2 and Δ T are displayed digitally when dual temperature sensors are connected. Otherwise, T1 is continuously updated in the patient summary down the right side of the screen.
Respiration	When fitted, respiration rate is determined by a thoracic impedance method via the ECG electrodes. This 12 second cardiorespirogram appears as a trace and a 3 minute trend of respiration rate is shown on the right.
CO ₂	The side stream method is used to provide this optional information.

Table 1

Alarm Facilities

ALARM	DESCRIPTION		HIGH LIMIT		LOW LIMIT	
		MAX	MIN	MAX	MIN	
ECG	High and low limits are programmable in	250	35	245	30	
	steps of one unit. A minimum separation of					
	5 BPM is maintained between the High and					
	Low values. ASYSTOLE & LEAD OFF					
	alarms are set automatically.					
SpO ₂	High and Low limits for Oxygen are	100	55	95	50	
	programmable in steps of one unit. The					
	minimum separation between the High and					
	Low values is 5%.					
	Pulse rate limits are as for ECG above and					
	are linked to the ECG limits.					
TEMP	T1 has high & low limits programmable in	45.0	21	44.5	20.5	
	steps of 0.1°C. The minimum separation				i i	
	between the High and Low values is 0.5.					
NIBP	High & Low limits are programmable in	250	10	245	5	
	steps of one unit for Systolic, Diastolic and					
	Mean Average Pressure (MAP). The					
	minimum separation between the High and					
22	Low values is 5 mmHg in every case					
BP	High and Low limits are programmable in	250	9	245	4	
1	steps of one unit for Systolic, Diastolic and					
	Mean Average Pressure (MAP). The					
	minimum separation between the High and					
	Low values is 5 mmHg.	<u> </u>		<u> </u>		

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LP 400 & 410

QUALITY, RELIABILITY AND SAFETY

This equipment has been manufactured using quality components and designed to operate safely and reliably. HME Limited can accept responsibility only if the following conditions are observed.

- 1. The equipment is used in accordance with the instructions for use provided by HME Limited.
- 2. The equipment is used in a building whose electrical installations conform to the standards specified by the country in which the building is situated.
- 3. If the integrity of the protective earth conductor arrangement is in doubt, the equipment should be operated from its internal electrical power source.
- 4. All modifications and repairs to the equipment are carried out by service engineers, agents or hospital technicians authorised by HME Limited.

CE MARKING

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

Manufactured in England by HME Limited, Arlingham House St Albans Road, South Mimms Hertfordshire, EN6 3PH

Telephone: +44 (0) 1707 601300 Fax: +44 (0) 1707 646250

Email:- Service@HME.Ltd.UK

United Kingdom.