

P A S S P O R T
O P E R A T I N G I N S T R U C T I O N S



Table of Contents

| | |
|--|------------|
| FOREWORD | v |
| WARNINGS, PRECAUTIONS and NOTES | v |
| UNPACKING | vi |
| | |
| 1. GENERAL DESCRIPTION | 1-1 |
| | |
| 2. CONTROLS AND INDICATORS | 2-1 |
| Symbols Chart | 2-1 |
| 2.1 Front Panel | 2-2 |
| 2.2 Left Side Panel | 2-8 |
| 2.3 Left Side Panel with Nellcor [®] SpO ₂ | 2-10 |
| 2.4 Right Side Panel | 2-12 |
| | |
| 3. OPERATION | 3-1 |
| Abbreviated Operating Instructions | 3-1 |
| Detailed Operating Instructions | 3-2 |
| 3.1 Setting-Up/Turning Power On | 3-2 |
| 3.2 Factory - Default Control Settings | 3-2 |
| 3.3 Display | 3-4 |
| 3.3.1 Menu Display Area | 3-5 |
| 3.3.2 ECG Display Area | 3-7 |
| 3.3.3 Multi-function Display Area | 3-8 |
| 3.3.4 Parameters Display Area | 3-10 |
| 3.3.5 Message Display Area | 3-10 |
| 3.4 Use Of Menus | 3-11 |
| 3.5 Initiation of NIBP Measurements | 3-12 |
| 3.5.1 Manual Initiation of NIBP Measurements | 3-12 |
| 3.5.2 Automatic Initiation of NIBP Measurements | 3-15 |
| 3.5.3 NIBP Pressure Limit Fail Safe | 3-16 |
| 3.5.4 Cuff Inflation Time | 3-16 |
| 3.5.5 Start and Deflate Functions | 3-16 |
| 3.6 ECG Acquisition | 3-17 |
| 3.6.1 Adult Electrode Placement | 3-18 |
| 3.6.2 Neonatal Electrode Placement | 3-18 |
| 3.7 Invasive Pressure Acquisition (optional) | 3-19 |
| 3.8 Sequence for Establishing SpO ₂ with Datascope Pulse Oximetry | 3-19 |

| | | |
|-----------|--|------------|
| 3.8.1 | Sensors | 3-20 |
| 3.9 | Respiration Monitoring | 3-25 |
| 3.10 | CO ₂ Monitoring | 3-25 |
| 3.10.1 | Sequence for Establishing CO ₂ | 3-25 |
| 3.10.2 | Adapter Calibration | 3-26 |
| 3.10.3 | Adapter Selection | 3-26 |
| 3.10.4 | Use of Adult Airway Adapter | 3-27 |
| 3.10.5 | Use of Neonatal Airway Adapter | 3-28 |
| 3.10.6 | CO ₂ Sensor Calibration Verification | 3-29 |
| 3.10.7 | CO ₂ Sensor Calibration | 3-30 |
| 3.11 | Status Messages | 3-31 |
| 3.11.1 | NIBP Measurement Messages | 3-31 |
| 3.11.2 | SpO ₂ Messages | 3-32 |
| 3.11.3 | Recorder Messages | 3-34 |
| 3.11.4 | CO ₂ Messages | 3-34 |
| 3.11.5 | Monitor Operation Messages | 3-36 |
| 3.12 | Monitor Problem Solving | 3-37 |
| 3.13 | Alarms | 3-40 |
| 3.13.1 | Setting Parameter Alarm Limits | 3-40 |
| 3.13.2 | Alarm Limits | 3-40 |
| 3.13.3 | Alarm Violations | 3-41 |
| 3.13.4 | Battery Indicators | 3-42 |
| 3.14 | User Configuration Mode (Time/Date/Trend/Other) | 3-42 |
| 3.15 | Recorder (optional) | 3-44 |
| 3.15.1 | Operation of Printer | 3-44 |
| 3.15.2 | Printer Formats | 3-45 |
| 3.16 | Sequence for Establishing SpO ₂ with Nellcor Pulse Oximetry | 3-47 |
| 3.16.1 | Nellcor Sensors | 3-48 |
| 3.16.2 | Special Features | 3-49 |
| 3.17 | Connection to External Devices | 3-51 |
| 4. | USER MAINTENANCE | 4-1 |
| 4.1 | Introduction | 4-1 |
| 4.2 | Care and Cleaning of Monitor | 4-1 |
| 4.3 | Care and Cleaning of Sensors | 4-1 |
| 4.4 | Sterilization of Sensors | 4-2 |

| | | |
|-----------|--|------------|
| 4.5 | Battery Replacement and Maintenance | 4-2 |
| 4.6 | Sterilization of Disposable Cuffs | 4-2 |
| 4.7 | Recorder Paper Replacement | 4-3 |
| 4.8 | Cleaning CO ₂ Sensors and Adapters | 4-3 |
| 5. | ACCESSORIES | 5-1 |
| 5.1 | Standard Datascope Accessories | 5-1 |
| 5.2 | Optional Accessories | 5-6 |
| 5.2.1 | NIBP Accessories | 5-6 |
| 5.2.2 | SpO ₂ Accessories | 5-7 |
| 5.2.3 | CO ₂ Accessories | 5-8 |
| 5.2.4 | Temperature Probes | 5-8 |
| 5.2.5 | Pressure Transducers | 5-8 |
| 5.2.6 | Power Packs | 5-8 |
| 5.2.7 | ECG Accessories | 5-8 |
| 5.2.8 | Mounting Accessories | 5-9 |
| 5.2.9 | Miscellaneous Accessories | 5-9 |
| 6. | APPENDIX | 6-1 |
| 6.1 | Performance Specifications | 6-1 |
| 6.2 | Indirect Blood Pressure Measurements and Associated Errors | 6-4 |
| 6.3 | Precautions with Using Automatically Cycled Blood Pressure Cuffs | 6-4 |
| 6.4 | Cuff Bleed Rate Selection | 6-5 |
| 6.5 | User Verification of PASSPORT Measurements | 6-5 |
| 6.6 | Newborn NIBP Technique | 6-5 |
| 6.7 | How To Get Help | 6-6 |
| 6.8 | References | 6-7 |
| 6.9 | Warranty | 6-9 |
| 6.10 | Datascope's Responsibility | 6-9 |
| 6.11 | Extended Warranty | 6-10 |

FOREWORD

This manual is intended to provide information for the proper operation of the Datascope PASSPORT Monitor.

General knowledge of monitoring and an understanding of the features and functions of the Datascope PASSPORT Monitor are prerequisites for its proper use.

DO NOT OPERATE THIS MONITOR BEFORE READING THESE INSTRUCTIONS.

Information for servicing this instrument is contained in the Datascope PASSPORT Monitor Service Manual, Part No. 0070-00-0237. For additional information or assistance, please contact an authorized Datascope representative in your area.

Federal Law restricts this device to sale by or on the order of a physician or other practitioner licensed by state law to use or order the use of this device.

WARNINGS, PRECAUTIONS and NOTES

Please read and adhere to the following list of warnings, precautions and notes, some of which are repeated in the appropriate areas throughout this manual.

A **warning** is provided if there is reasonable evidence of an association of a serious personal hazard with the use of this device.

A **precaution** is provided when any special care is to be exercised by the practitioner and/or patient to avoid causing damage to this device or other property.

A **note** is provided when extra general information is applicable.

WARNINGS:

Possible Explosion Hazard - This instrument is not explosion proof in the presence of flammable anesthetics.

Internal Electrical Shock Hazard - This unit does not contain any user-serviceable parts. Do not remove instrument covers. Refer servicing to qualified personnel.

When attached to other products, insure that the total chassis leakage currents of all units (total) do not exceed 100ua.

For continued protection against a fire hazard, replace all fuses with the specified type and rating. See the PASSPORT Service Manual, P/N 0070-00-0237.

Do not use in presence of flammable gases.

Do not clean monitor while it is on and/or plugged in.

This unit uses a common isolation path for the ECG leads and the invasive pressure channels. Do not connect any non-isolated accessories to either of the inputs when connected to a patient, as this may compromise the safety of the unit.

PRECAUTIONS:

Only use the Abbreviated Operating Checklist if you are already familiar with this product. If not please use the Detailed Operating Instructions.

Observe all PRECAUTION and WARNING labels on the monitor.

Always place the monitor on a rigid, flat surface or on approved mounts.

Never place fluids on top of this monitor.

When the integrity of the protective earth conductor arrangement is in doubt, the equipment should be operated from its' internal battery.

This unit must only be operated with Datascope approved software.

Cuffs must be used with Datascope hoses because of safety luer fitting.

Use only Datascope accessories with this product.

When cleaning sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with the cleaning solution.

NOTES:

This unit is not designed to be used with a peripheral pulse sensor. SpO₂ is a standard function in this monitor, and may be used to obtain a plethysmograph waveform and heart rate.

UNPACKING

Remove the instrument from the shipping carton and examine it for signs of shipping damage. Save all packing materials, invoice, and bill of lading. These may be required to process a claim with the carrier. Check all materials against the packing list. Contact the Datascope Service Department (800) 288-2121 for prompt assistance in resolving shipping problems.

Copyright © Datascope Corp., 1991. Printed in USA. All rights reserved. Contents of this publication may not be reproduced in any form without permission of Datascope Corp.

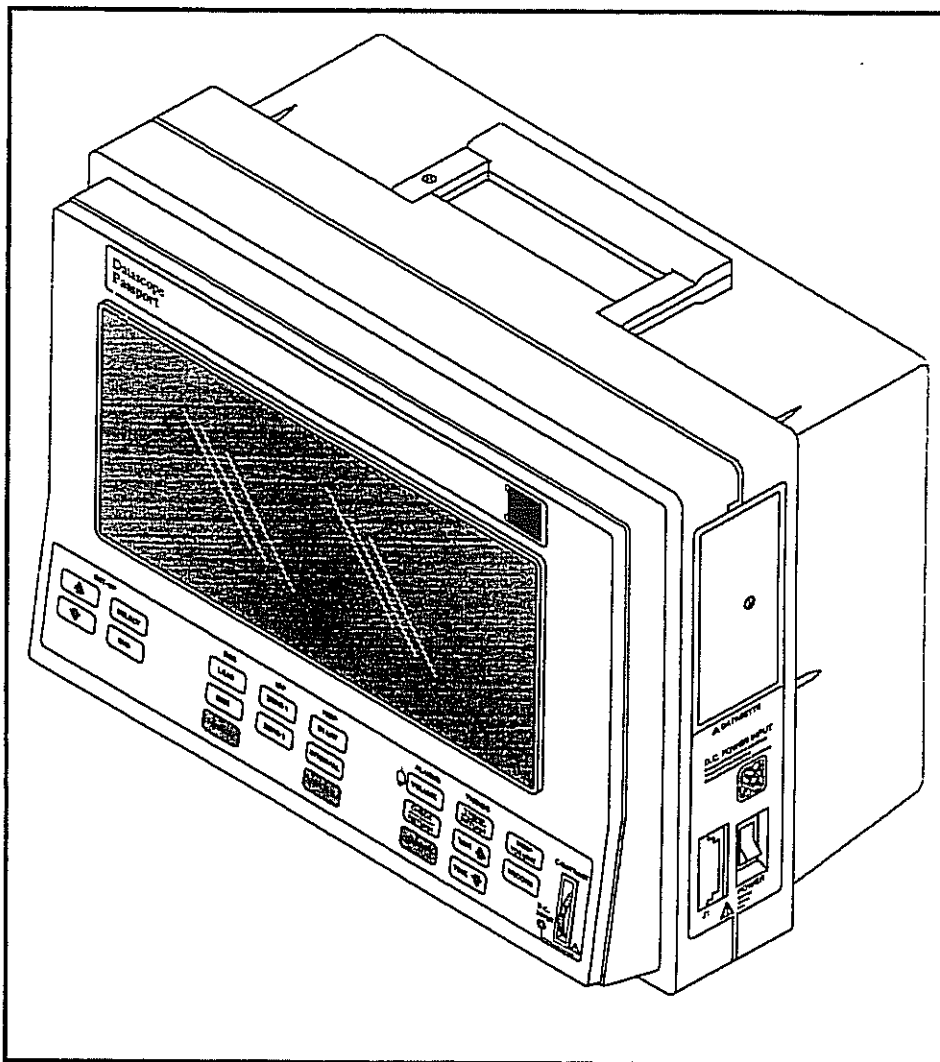
1.0 GENERAL DESCRIPTION

The Datascope PASSPORT Monitor is an ECG, Invasive (optional) and Non-invasive Blood Pressure, Pulse Oximeter, Respiration Rate, Temperature and CO₂ (optional) monitoring device. It is designed for use in hospital units at bedside, during special procedures and during transport. It can be mounted on a monitor stand, a wall mount bracket, a bed rail or operated as a tabletop instrument.

The Datascope PASSPORT provides a 22 cm x 10 cm display for viewing non-fade waveforms and digital information. The front panel keys are membrane touch switches. Digital displays are provided for Heart Rate, Invasive BP1 and BP2 (optional), Non-invasive Blood Pressure (NIBP), Pulse

Oximetry (SpO₂), Respiration Rate, Temperature and CO₂ (optional). The built-in digital recorder (optional) provides hard copies of delayed ECG, Invasive Blood Pressures 1 & 2, NIBP, SpO₂ Pleth, CO₂, Respiration, Temperature, and Tabular Trend Information.

It is powered from an external AC to low voltage DC power supply or internal batteries. Different line voltages and connector types are accommodated by separate AC to DC power packs. A set of two batteries is offered as standard equipment. Battery option consists of two user replaceable lead acid cells of the type used in commercial VCR equipment. The monitor can operate with either battery removed so that fresh batteries can be installed during monitor operation.



**FIGURE 1 - PASSPORT MONITOR
LCD Version**

Key features of the PASSPORT Monitor are:

- I, II, & III lead ECG channel (0.5 - 30Hz)
- 2 invasive blood pressure channels (optional)
- NIBP
- SpO2
- Respiration
- CO₂ (optional)
- 1 YSI 400/700 temperature channel
- Dual channel thermal array recorder (field installable option)
- Low power back-lit LCD or EL (electro luminescent) display (640 x 200)
- Battery operation, with fully charged batteries, greater than 2 hrs. (2 batteries fitted)
- Tabular trend (120 entries)
- ECG cascade
- 3 trace erase bar refresh
- External isolated power module
- Mounting Kit (optional accessory)
- Handle

NOTE: Monitors with serial number 3000 and above, incorporate electrosurgical interference suppression (ESIS). For optimum monitoring, use of the patient ESIS choke cable is recommended if an electrosurgical device is to be used on the patient. Respiration function is not available with Patient ESIS Choke/Cable (P/N 0012-00-0722-05 & -06) attached.

English Language LCD Versions

| | | |
|--|-----------------|------------------|
| Portable Monitor | 0998-00-0095-03 | 0998-00-0095H03* |
| Portable Monitor with IBP | 0998-00-0095-01 | 0998-00-0095H01* |
| Portable Monitor with Recorder | 0998-00-0095-04 | 0998-00-0095H04* |
| Portable Monitor with IBP and Recorder | 0998-00-0095-02 | 0998-00-0095H02* |

English Language EL Versions

| | | |
|--|-----------------|------------------|
| Portable Monitor | 0998-00-0095-43 | 0998-00-0095H43* |
| Portable Monitor with IBP | 0998-00-0095-41 | 0998-00-0095H41* |
| Portable Monitor with Recorder | 0998-00-0095-44 | 0998-00-0095H44* |
| Portable Monitor with IBP and Recorder | 0998-00-0095-42 | 0998-00-0095H42* |
| Portable Monitor with Recorder and CO ₂ | 0998-00-0095-64 | 0998-00-0095H64* |
| Portable Monitor with IBP, Recorder, and CO ₂ | 0998-00-0095-62 | 0998-00-0095H62* |
| Portable Monitor with IBP and CO ₂ | 0998-00-0095-61 | 0998-00-0095H61* |
| Portable Monitor with CO ₂ | 0998-00-0095-63 | 0998-00-0095H63* |

*These versions have the Hewlett Packard ECG and Pressure Connectors.

Mains voltage options are selected using the power packs listed under Optional Accessories, Section 5.2.

NOTE: The system does not include a Datascope bus connector and as such does not interface with any of the existing Datascope products using this analog and serial communication channel.

2.0 CONTROLS AND INDICATORS

This section of the Operating Instructions identifies and describes each control and display of the Datascope PASSPORT Monitor.

Refer to the paragraph and page numbers listed below for the location of specific controls and displays.

Step-by-step instructions for operation of the monitor are provided in Section 3 "Detailed Operating Instructions".

| <u>Paragraph Number</u> | <u>Description</u> | <u>Control/Display Number</u> | <u>Page Number</u> |
|-------------------------|--|-------------------------------|--------------------|
| 2.1 | Front Panel | 1 - 21 | 2-2 |
| 2.2 | Left Side Panel | 22 - 29 | 2-8 |
| 2.3 | Left Side Panel with Nellcor [®] SpO ₂ | 22-29 | 2-10 |
| 2.4 | Right Side Panel | 30 - 33 | 2-12 |










| <u>SYMBOL</u> | <u>DESCRIPTION</u> | <u>SYMBOL</u> | <u>DESCRIPTION</u> |
|---|---|---|---------------------------|
|  | ATTENTION, CONSULT ACCOMPANYING DOCUMENTS / REFER TO MANUAL |  | EARTH (Ground) |
|  | "ON" (Only for a part of Equipment) |  | DANGEROUS VOLTAGE |
|  | "OFF" (Only for a part of Equipment) |  | ALTERNATING CURRENT (AC) |
|  | TYPE B EQUIPMENT |  | PROTECTIVE EARTH (Ground) |
|  | DEFIBRILLATOR PROOF OF EQUIPMENT | | |

FIGURE 2 - Symbols Chart

2.1 FRONT PANEL

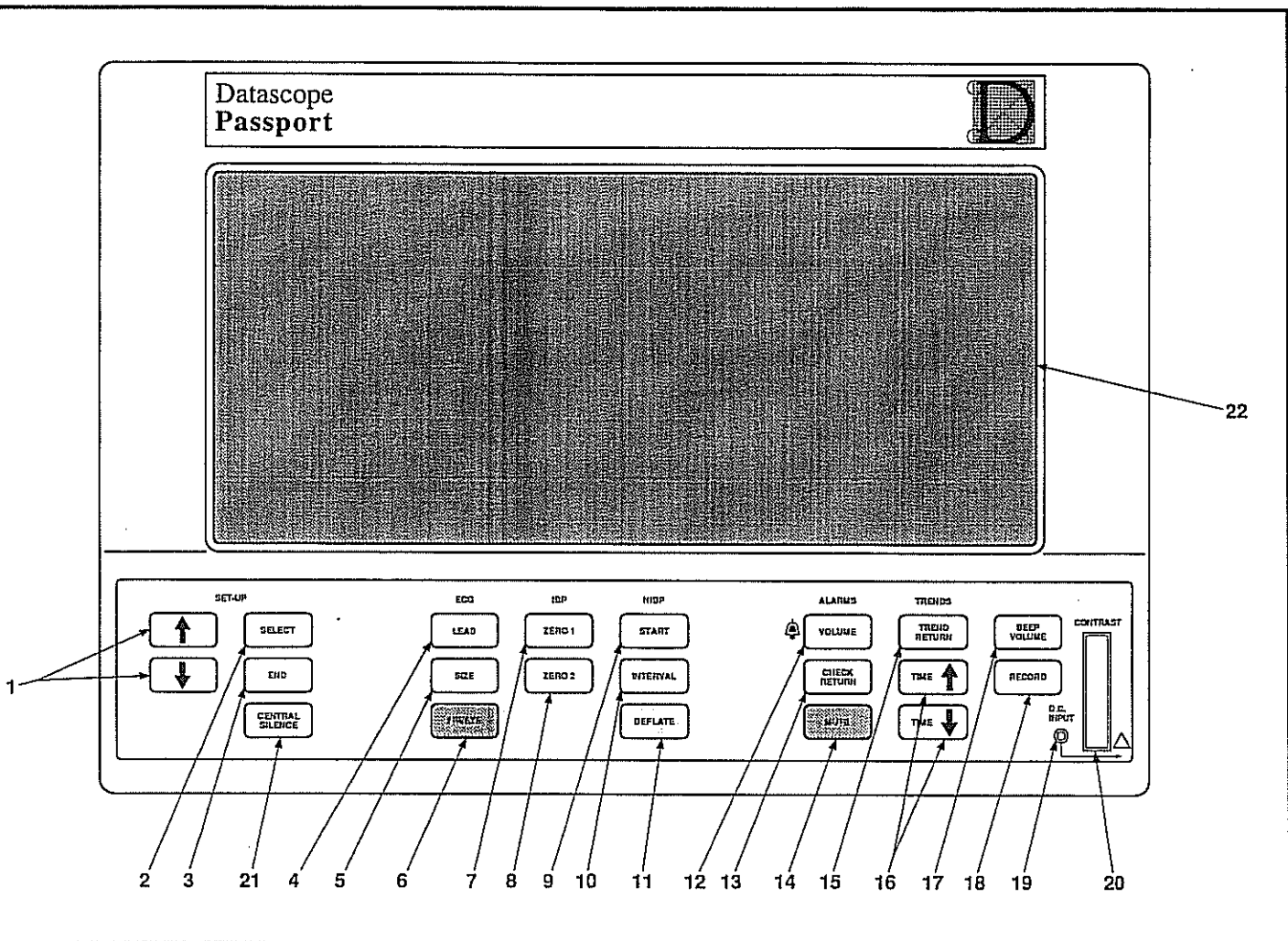


FIGURE 3 - Front Panel Controls

- | | | |
|-------------------------------|----------------------------|---|
| 1. ↑ & ↓ (Set-up) | 8. ZERO 2 (IBP) (Optional) | 15. TREND/RETURN (Trends) |
| 2. SELECT (Set-up) | 9. START (NIBP) | 16. TIME ↑ & ↓ (Trends) |
| 3. END (Set-up) | 10. INTERVAL (NIBP) | 17. BEEP VOLUME |
| 4. LEAD (ECG) | 11. DEFLATE (NIBP) | 18. RECORD (Optional) |
| 5. SIZE (ECG) | 12. VOLUME (Alarms) | 19. DC INPUT |
| 6. FREEZE (ECG) | 13. CHECK/RETURN (Alarms) | 20. CONTRAST (View Angle) (LCD Units Only) |
| 7. ZERO 1 (IBP) (Optional) | 14. MUTE (Alarms) | 21. CENTRAL SILENCE (Optional) |
| | | 22. DISPLAY |

INTRODUCTION

The keys on the front panel of the PASSPORT MONITOR are classified as single action, repeat action, or delayed action keys.

A **single action** key provides a single action each time it is pressed, regardless of how long it is held.

A **repeat action** key provides the first action when depressed, then waits half a second before repeating the action until the key is released.

A **delayed action** key provides an action, but only after the key has been held depressed for a (key specific) period of time.

NOTE: Only one key function will be recognized at any time. The PASSPORT will ignore multiple key selections.

All key actions are acknowledged by a key click, except for BEEP VOL and ALARM VOL. If a key is not available a double key click will sound.

1. & (UP & DOWN) (Set-Up)

Two repeat action keys used to move the highlighted screen cursor or change the setting/value of a menu item. As the cursor is moved, the highlighted menu window is displayed.

2. SELECT (Set-Up)

A repeat action key used to select the function or value indicated by the highlighted cursor.

3. END (Set-Up)

A single action key which causes the display to return to the main screen display (as specified in the DISPLAY section). This key is always available.

4. LEAD (ECG)

A single action key which selects the ECG lead to be displayed. Each depression of the key selects and displays the next ECG lead from the list. The list wraps around after the last entry is selected. Choices are: I, II, III.

5. SIZE (ECG)

A single action key which selects the ECG size to be displayed. Each depression of the key selects and displays the next ECG size from the list. The list wraps around after the last entry is selected. Choices are: .25, .5, 1, 2, 3, 4 cm/mV.

6. FREEZE (Screen)

A single action key which enables or releases the screen freeze function. The freeze key stops or starts the ECG waveform (waveform 1), except when waveform 2 is used for cascaded ECG. When this is the case, pressing the freeze key the first time causes the currently displayed ECG waveform data to be transferred to waveform 2 and frozen. Waveforms 1 and 3 continue to move. Pressing FREEZE again causes waveform 2 to return to cascaded ECG.

7. ZERO 1 (IBP) (Optional)

A delayed action key which zeros the current pressure in the BP1 channel. If the transducer zero process is unsuccessful, "UNABLE TO ZERO" is displayed in the window containing BP value. This key is only available when a pressure transducer is present.

8. ZERO 2 (IBP) (Optional)

A delayed action key which zeros the current pressure in the BP2 channel. If the transducer zero process is unsuccessful, "UNABLE TO ZERO" is displayed in a temporary window within the parameter window. This key is only available when a pressure transducer is present.

9. START (NIBP)

A single action key which initiates an NIBP measurement. This function is not available if a measurement is in progress.

10. INTERVAL (NIBP)

A repeat action key which selects the interval setting for NIBP measurements. Values wrap around at the lowest/highest choices. Choices are: Off, Continuous, 1, 2.5, 5, 10, 15, 20, 30, 60, and 120 minutes. Five seconds after the selection is made and the key is released, the new interval takes effect.

11. DEFLATE (NIBP)

A single action key which stops any NIBP measurement in progress, including any timed measurement sequence, and deflates the cuff. When a timed measurement is stopped a "NIBP: DEFLATE" message followed by a "NIBP: IDLE" message displays in the NIBP message window until the timer mode is restarted by either pressing START or changing the interval.

12. VOLUME (Alarms & Alarm LED)

A repeat action key which adjusts the alarm volume in 5 steps. There is no off position for this tone. The tone wraps to the minimum volume once the maximum is reached. The red alarm bell LED illuminates when an alarm condition exists. See Section 3.13 for detailed information on alarm situations.

13. CHECK/RETURN (Alarms)

A single action key which provides access to the alarm menu to view and select alarm values. Press SELECT to change the alarm values. Pressing CHECK/RETURN a second time or the END key, returns the display to the main screen and exits the alarm menu.

14. MUTE (Alarms)

A single action and delayed action key which silences all currently alarming parameters. A single key press will silence the alarm tone for 2 minutes. Any new alarms that occur while the alarm tone is muted will disable the mute and sound the alarm tone. An alarm mute symbol is displayed next to each muted parameter. The word **MUTE** is displayed above the menu selections.

If the key is pressed and held for 3 seconds, all set alarms will be suspended for 2 minutes. This mode is indicated by a reverse graphics loudspeaker with an X through it. The words **ALL MUTE** are displayed above the menu selections.

If the MUTE key is pressed and held for 4 seconds, all audio alarms are indefinitely suspended. (**NOTE:** To enable this function the "Audio Alarms Standby" option in the User Configuration must be on, see section 3.14.) This mode is indicated by a flashing reverse graphics loudspeaker with an "X" through it in all parameter windows. The words **Aud Alm Sby** are displayed above the menu selections and flash in reverse graphics.

The All Mute and Audio Alarms Standby functions can be exited by pressing the mute key once.

15. TRENDS/RETURN (Trends)

A single action and delayed action key which displays and clears trended data. The most recent page of data is displayed when changing from the waveform display. Pressing this key a second time, returns the monitor to the main screen. Pressing and holding the key for 3 seconds clears all trended data.

16. TIME UP & TIME DOWN (Trends)

Two repeat action keys which are used to scroll through the trend data.

17. BEEP VOLUME

A repeat action key which adjusts the beep volume in 5 steps plus OFF. When the maximum volume is reached, then the volume will wrap around to OFF, then to the minimum volume

18. RECORD (Optional)

A combination single action and delayed action key which initiates or stops a recording. Pressing the key once initiates a printout. Holding the key pressed for three seconds, when waveforms are displayed (see section 3.15), initiates a continuous printing of waveforms. Pressing the key while the printing is in progress, stops the recorder.

The recorder prints either waveforms or trend data, depending on what is displayed (i.e. trend data is printed when trend list is displayed.). The Recorder Set-up will determine which waveform or waveforms are printed. The Recorder Set-up will also determine the Record Destination - Local (recording from the PASSPORT), Remote (recording from the VISA, no recording from the PASSPORT), or Local and Remote (recording from both the PASSPORT and VISA). **NOTE:** When a remote (VISA) recording is printed, the information that is printed is determined by the set-up in the VISA.

19. DC INPUT

A green LED used to indicate that the POWER Switch (33) is in the ON position.

20. CONTRAST (View Angle - on LCD Units Only)

A recessed single turn potentiometer used to adjust the view angle (contrast) of the LCD.

21. CENTRAL SILENCE (Optional)

A single-action key which mutes the alarms of the corresponding channel on the VISA Central Station. The amount of time the alarms are silenced for is determined by the VISA.

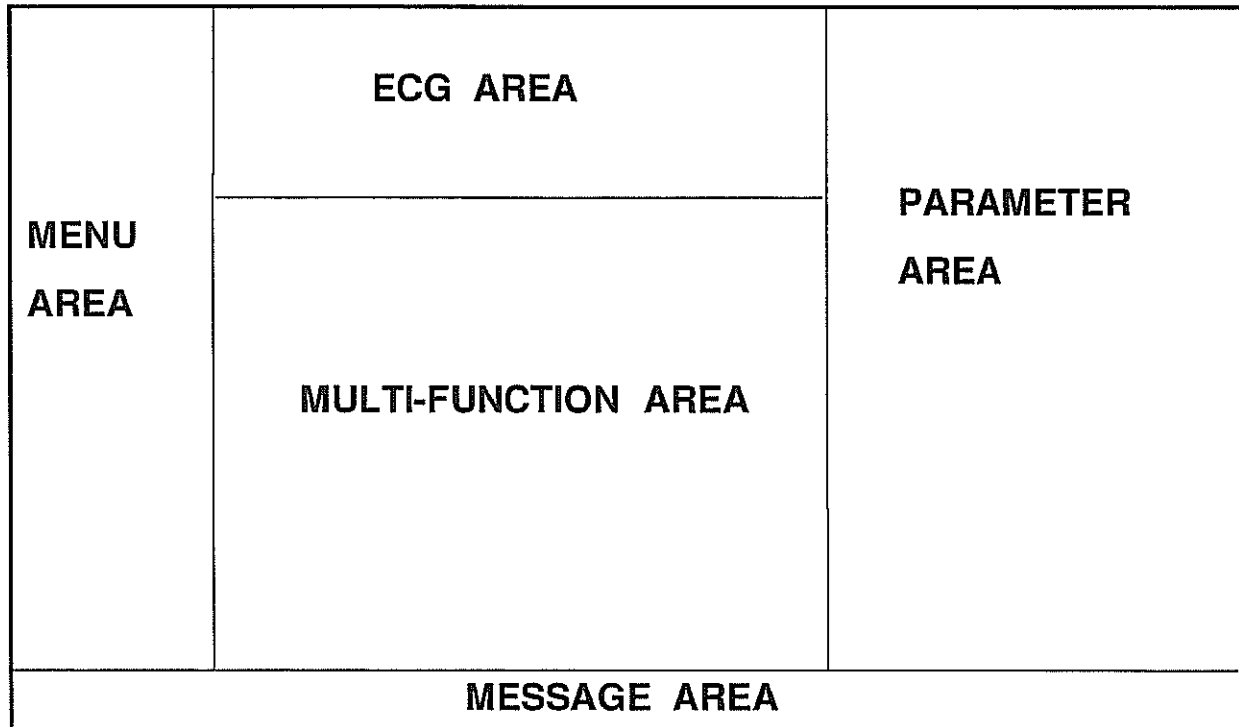


FIGURE 4 - Display

22. DISPLAY

The Display is used to present information which is divided into 5 graphic display areas. They are:

- A. MENU Display Area
- B. ECG Display Area
- C. PARAMETER Display Area
- D. MULTI-FUNCTION Display Area
- E. MESSAGE Display Area

See Section 3.3 for details.

2.2 LEFT SIDE PANEL CONNECTORS / COMPONENTS

23. RECORDER (Optional)

A two trace thermal strip chart recorder with integral paper spool.

24. BATTERY PACK

Two internal, user replaceable, rechargeable, sealed lead acid batteries that provide power to operate the monitor when not connected to the power pack. The battery packs may be removed and replaced independently while the unit is operating.

25. CUFF

A connector used to attach the NIBP cuff assembly to the monitor.

26. SpO₂

An 8-pin DIN type female connector used to attach the SpO₂ sensor assembly to the monitor.

27. T (Temperature)

A standard three wire phone jack used to mate with either the YSI series 400 or 700 temperature probes.

28. ECG / EKG

A six-pin AAMI (ECG-D10/75) standard connector (AMP P/N 864900-1; Datascope P/N 0131-00-0079) used for patient cable connections.

A 12-pin male connector (Datascope P/N 0012-00-0846) used for Hewlett Packard 12-pin patient cable connections.

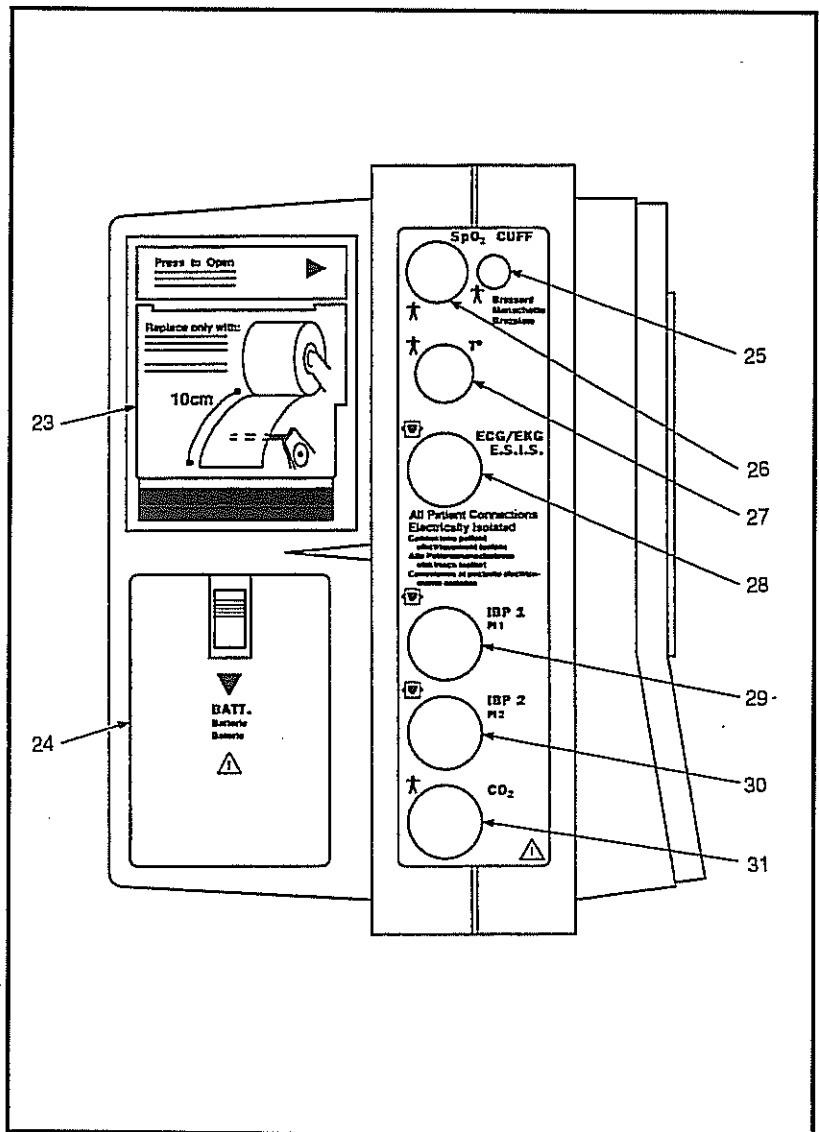


FIGURE 5 - Left Side Panel

29. IBP1 (Optional, Datascope or Hewlett Packard)

A six-pin male connector (Datascope P/N 0131-00-0094) used for Datascope specified pressure transducers listed in Chapter 5, Accessories.

A 12-pin male connector (Datascope P/N 0131-00-0231) used for Hewlett Packard specified pressure transducer cables.

30. IBP2 (Optional, Datascope or Hewlett Packard)

A six-pin male connector (Datascope P/N 0131-00-0094) used for Datascope specified pressure transducers listed in Chapter 5, Accessories.

A 12-pin male connector (Datascope P/N 0131-00-0232) used for Hewlett Packard specified pressure transducer cables.

31. CO₂ (Optional)

A 20 pin connector used to attach the CO₂ sensor to the monitor.

2.3 LEFT SIDE PANEL CONNECTORS / COMPONENTS with NELLCOR[®] SpO₂

23. RECORDER (Optional)

A two trace thermal strip chart recorder with integral paper spool.

24. BATTERY PACK

Two internal, user replaceable, rechargeable, sealed lead acid batteries that provide power to operate the monitor when not connected to the power pack. The battery packs may be removed and replaced independently while the unit is operating.

25. CUFF

A connector used to attach the NIBP cuff assembly to the monitor.

26. SpO₂

An 8-pin DIN type female connector used to attach the SpO₂ sensor assembly to the monitor. Use only NELLCOR[®] sensors with this style connector.

27. T (Temperature)

A standard three wire phone jack used to mate with either the YSI series 400 or 700 temperature probes.

28. ECG / EKG

A six-pin AAMI (ECG-D10/75) standard connector (AMP P/N 864900-1; Datascope P/N 0131-00-0079) used for patient cable connections.

A 12-pin male connector (Datascope P/N 0012-00-0846) used for Hewlett Packard 12-pin patient cable connections.

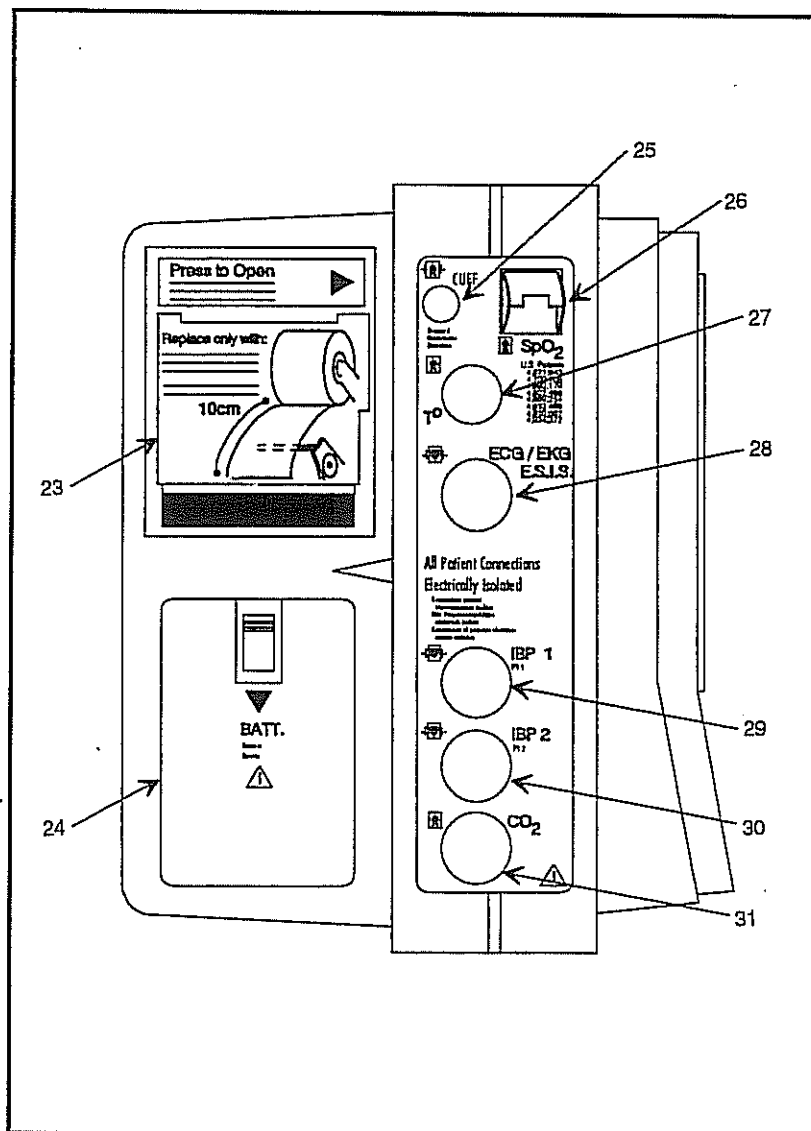


FIGURE 6 - Left Side Panel
with NELLCOR[®] SpO₂

29. IBP1 (Optional, Datascope or Hewlett Packard)

A six-pin male connector (Datascope P/N 0131-00-0094) used for Datascope specified pressure transducers listed in Chapter 5, Accessories.

A 12-pin male connector (Datascope P/N 0131-00-0231) used for Hewlett Packard specified pressure transducer cables.

30. IBP2 (Optional, Datascope or Hewlett Packard)

A six-pin male connector (Datascope P/N 0131-00-0094) used for Datascope specified pressure transducers listed in Chapter 5, Accessories.

A 12-pin male connector (Datascope P/N 0131-00-0232) used for Hewlett Packard specified pressure transducer cables.

31. CO₂ (Optional)

A 20 pin connector used to attach the CO₂ sensor to the monitor.

2.4 RIGHT SIDE PANEL CONNECTORS / COMPONENTS

32. DATASETTE

A user replaceable software cartridge used for installing updated software revisions.

33. DC POWER INPUT (CONNECTOR)

A four terminal connector to supply low voltage DC power to the unit and charge the batteries. The power pack provides power to the unit independent of battery installation.

34. J1

A communication interface connector used to connect the PASSPORT to a VISA Central Station Monitor or other peripheral devices.

35. POWER

A recessed rocker switch which interrupts power to the main unit but does not prevent charging of the batteries.

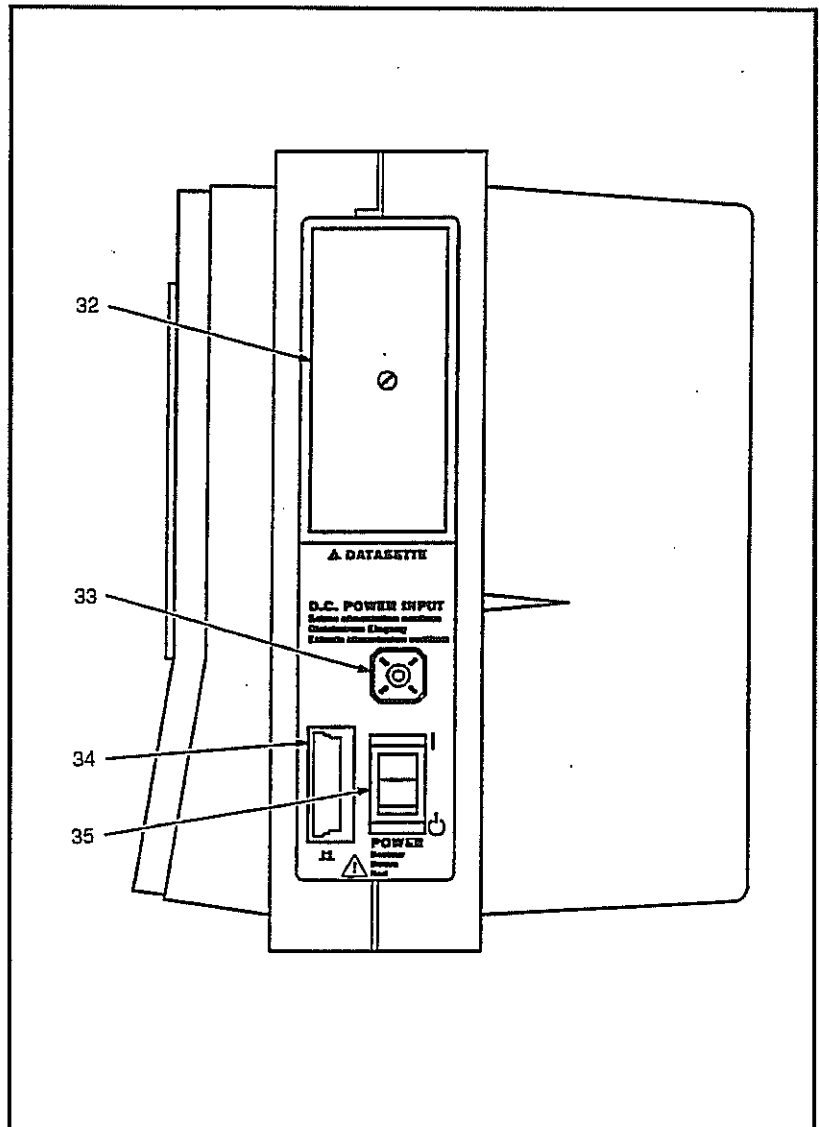


FIGURE 7 - Right Side Panel

3.0 OPERATION

Abbreviated Operating Checklist

PRECAUTION: Only use the Abbreviated Operating Checklist if you are already familiar with this product. If not, please continue with the remainder of this chapter, Detailed Operating Instructions.

A. Setting-Up

1. Set POWER Switch to OFF.
2. Connect, if desired, peripheral equipment.
3. Attach power pack and/or install charged batteries as needed.
4. Set POWER Switch to ON.
5. Using the menus and keyboard, set (when appropriate) the following:
 - Patient Size & Trend Clear
 - Set Up Information (speed, waveform 2 & 3, etc.)
 - Recorder Information (when available)
 - Alarm Limits
 - NIBP Information
 - IBP Information
 - HR Information
 - SpO₂ Information
 - ECG Information
 - Resp. Information
 - Alarm Volume
 - Beep Volume
 - View Angle (contrast) (LCD units)

B. Initiating NIBP Measurement

1. Select cuff.
2. Attach cuff hose to NIBP connector and place cuff on patient.
3. Select timer interval, if desired.
4. Select cuff pressure, if necessary.
5. Press START to begin NIBP measurement.
6. Press DEFLATE to suspend measurement.

C. Establishing SpO₂

1. Select appropriate sensor.
2. Attach sensor to SpO₂ connector and apply to the patient.
3. Set either waveform 2 or 3 in the set-up menu to display the SpO₂ waveform, if desired.

D. Establishing CO₂

1. Plug sensor into the side of the monitor.
2. Apply sensor to the breathing circuit.
3. Set Waveform 2 or 3 to CO₂.
4. Set the Resp. Source to CO₂.

E. Recording Information

1. Select wave to be recorded through Record Menu or if desired to record tabular trend, press TREND/RETURN.
2. Press Record to start recording function.
3. Press Record again to stop the recording function.

Detailed Operating Instructions

This section of the Operating Instructions provides guidelines and step-by-step instructions for proper operation of the monitor. Numbers in parentheses () relate to the displays and controls described in Section 2.0 "Controls and Indicators".

3.1 SETTING-UP / TURNING POWER ON

1. Set the POWER Switch (35) to OFF.
2. Check the power pack for correct voltage model. If incorrect power pack, contact a Datascope Service Representative.

WARNING: When attached to other products, insure that the total chassis leakage currents of all units (total) do not exceed 100ua.

3. Attach the power pack to the DC POWER INPUT connector (33). If battery operation is required, ensure that two fully charged batteries are installed. **NOTE:** If power pack is connected ensure that the screw is tightened so that the cord does not detach.
4. Set the POWER Switch (35) to ON.

Internal self tests will run and the display will come on. A "DIAGNOSTIC IN PROGRESS" message will display and once the self tests have been completed a "SELF TEST COMPLETE" message will display. After this the main screen is displayed.

If any failures occur, see Section 3.11, "Status Messages" for further instructions.

3.2 FACTORY - DEFAULT CONTROL SETTINGS

The following are the factory initial control settings. This is the state that the unit will power up in unless a "current configuration" has been saved from the set up menu.

| <u>FUNCTION</u> | <u>DEFAULT SETTINGS</u> |
|-----------------|-------------------------|
| • Patient Size | Adult |
| • Set Up: Speed | 25mm/sec. |
| Resp Source | Off |
| Resp Speed | 12.5mm/sec. |
| Waveform 2 | ECG Cascade |
| Waveform 3 | Pleth |

FUNCTIONDEFAULT SETTINGS

- Record (Optional):
 - Waveform ECG
 - Record On Alarm Off
 - Record Destination Local
- Alarms:

| | <u>Low</u> | <u>High</u> |
|-------------------|---|-------------|
| BP1/NIBP Sys | Off | Off |
| BP1/NIBP Dia | Off | Off |
| BP2 (mean) | Off | Off |
| SpO ₂ | 85 | Off |
| Heart Rate | Off | Off |
| Resp Rate | Off | Off |
| ETCO ₂ | Off | Off |
| Apnea Delay | 30 sec Adult, 20 sec Ped., 10 sec Neonate | |
- NIBP: Start Pressure 180mmHg Adult, 140mmHg Ped., 120mmHg Neonate
- BP1: Scale Range 150mmHg
- BP2: Scale Range 37.5mmHg
- HR: Source Auto
- SpO₂:
 - Pleth Scale* 2
- CO₂: Scale Range 40 Torr
- Trend:
 - List Off
 - Trigger Alarms & NIBP
 - Interval Timer 5 min
- Respiration: Off
 - Waveform Speed 12.5mm/sec
 - Scale 1 cm/ohm
- ECG:
 - Lead II
 - Scale 1 cm/mV
- NIBP Interval Off
- Volume:
 - Beep 3
 - Alarm 3
- Temperature °F

*If your unit is equipped with NELLCOR[®] SpO₂, there is no pleth scale adjustment. This is replaced with operating mode options 1, 2, and 3. See NELLCOR[®] SpO₂ special features in section 3.16.2.

3.3 DISPLAY

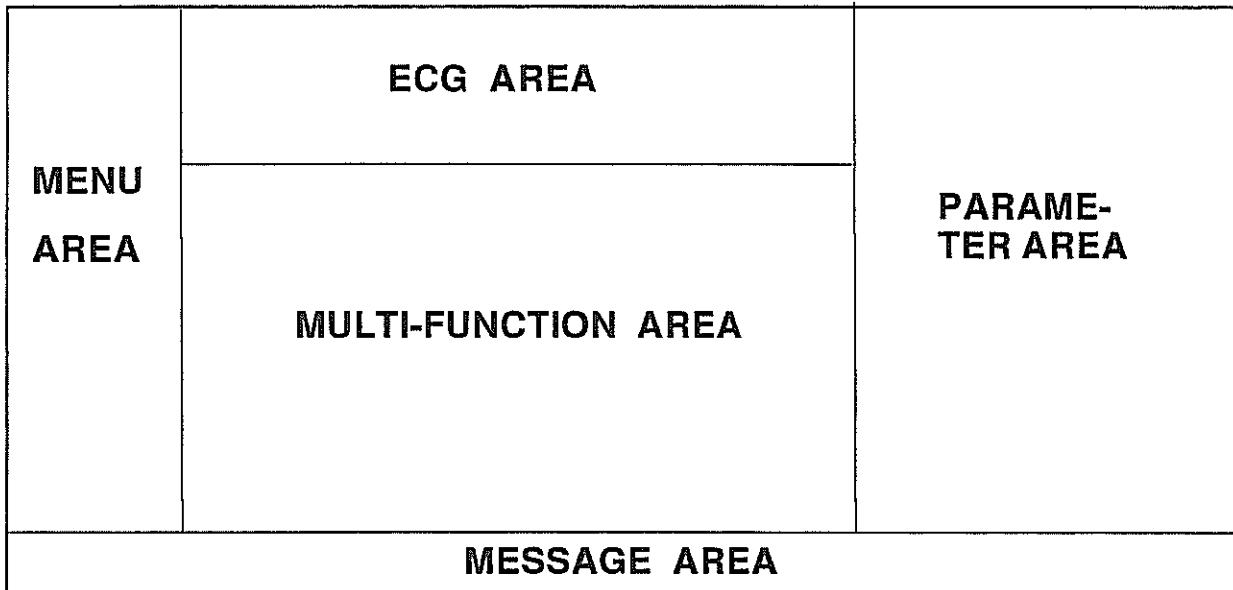


FIGURE 7 - Window Layout

The Display is divided into five graphic areas as shown above.

MENU Display Area - displays the main menu selections available with the cursor and select keys, the battery symbol and the mute categories.

ECG Display Area - displays the ECG trace, ECG information and pacer enhancement status.

PARAMETER Display Area - displays the current values of patient parameters.

MULTI-FUNCTION Display Area - displays additional waveforms and temporary boxes for menu functions.

MESSAGE Display Area - displays messages relating to NIBP, SpO₂, CO₂, and recorder operation.

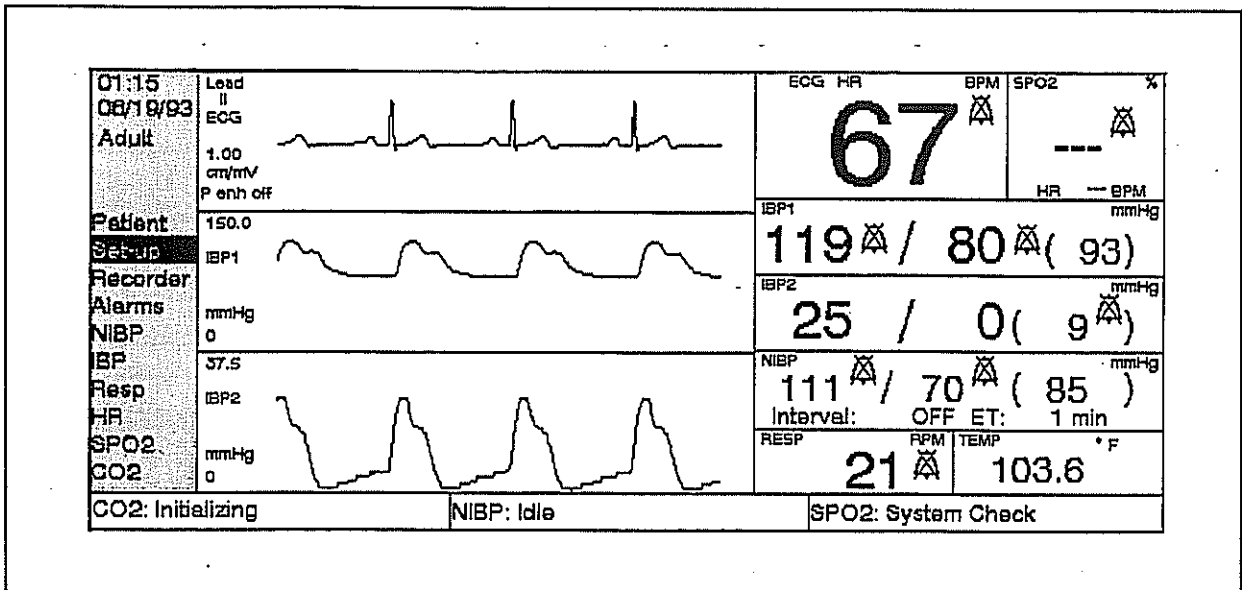




FIGURE 8 - Menu Area

3.3.1 Menu Display Area

The menu area displays the main menu selections available. These are accessed by using the UP  & DOWN  (1) and SELECT (2) set-up keys. See Section 3.4 for details on using these keys. One of the menu items is always highlighted by the cursor. This window also contains the TIME, DATE, PATIENT SIZE and MUTE CATEGORY (when active) information.

For each patient size available there are different choices within the menu selections. The following table indicates the choices for each menu set-up and also where there are different selections for each patient size.

NOTE: The "IBP" menu item only appears on models which include the invasive pressure option and the "Recorder" menu item only appears on models which include the recorder option.

| MENU LIST | MENU ITEM | CHOICES | |
|--------------|------------------------|---|---|
| Patient | Size | Adult, Pediatric, Neonate | |
| | Clear Patient Memory | No, Yes | |
| | Pacer Enhancement | Off, On | |
| Setup | Speed | 12.5, 25, 50mm/Sec. | |
| | Resp Speed | 3.125, 6.25, 12.5, 25.0 | |
| | Waveform 2 | BP1, Casc. ECG, Pleth., Resp., CO2 | |
| | Waveform 3 | BP1, BP2, Pleth., Resp., CO2 | |
| | Resp Source | Off, CO2, ECG | |
| Recorder | Power Up Settings | No Change, Save Current, Restore Factory | |
| | Wave Selection | ECG, Pleth, Resp., ECG & IBP1, ECG & IBP2, IBP1 & IBP2, CO2, ECG & RESP | |
| | Record on Alarm | Yes, No | |
| Alarms | Record Destination | Local, Remote, Local and Remote | |
| | HR | Low (OFF, 30 - 100) - High (OFF, 100 - 250) bpm | |
| (Adult, Ped) | SpO2 | Low (50* - 100) - High (80 - 100) % | |
| | IBP1 Sys | Adult Low (OFF, 5 - 130) - High (OFF, 70 - 240)mmHg Ped/Neo Low (OFF, 5-130) - High (OFF, 40 - 180)mmHg | |
| | IBP1 Dia | Adult Low (OFF, 5 - 90) - High (OFF, 40 - 130)mmHg Ped/Neo Low (OFF, 5 - 50) - High (OFF, 50 - 100)mmHg | |
| | NIBP Sys | Adult Low (OFF, 50 - 150) - High (OFF, 70 - 240)mmHg Ped/Neo Low (OFF, 15 - 130) - High (OFF, 40-180*)mmHg | |
| | NIBP Dia | Adult Low (OFF, 30 - 120) - High (OFF, 40 - 130)mmHg Ped/Neo Low (OFF, 10 - 50) - High (OFF, 50 - 100)mmHg | |
| | IBP2 (Mean) | Adult Low (OFF, 2 - 100) - High (OFF, 5 - 150) mmHg Ped/Neo Low (OFF, 2 - 50) - High (OFF, 5 - 100)mmHg | |
| | Respiration | Low (Off, 5 - 50) - High (Off, 30 - 200) RPM | |
| | Apnea Delay | Adult Off, 10 -40 secs. Ped. Off, 10 - 30 secs. Neonate 10 - 20 secs. | |
| | ETCO2 | Adult, Ped, Neonate Low (Off, 0-60) - High (Off, 20-100) | |
| | NIBP | Start Pressure | Adult 100 - 260 mmHg Ped. 60 - 180 mmHg Neonate 40 - 120 mmHg |
| | | BP1 Scale Range | 37.5, 75, 150, 300 mmHg |
| | | BP2 Scale Range | 37.5, 75, 150, 300 mmHg |
| | Resp | Scale | 1, 2, 3, 4, 5 |
| | HR | Source | AUTO, ECG, BP1, SpO2 |
| | SpO2 | Pleth Size** | 1, 2, 3, 4 |
| CO2 | Scale | 0-40, 0-60, 0-100 Torr | |
| | Start Zero Calibration | Yes, No | |
| | Start Adapter Cal | Yes, No | |
| | N2O Compensation | On, Off | |
| | O2 Compensation | 0, 21, 40, 60, 80, 100 | |

TABLE 1 MENU CHOICES

The menu items that are highlighted in grey only are applicable in models equipped with the invasive pressure option.

The menu items that are highlighted in boxes only are applicable in models equipped with the CO₂ option.

*These alarm parameters may be set outside the accurate measurement range. Refer to the specifications, Chapter 6, for accuracy ranges.

**If your unit is equipped with NELLCOR[®] SpO₂, there is no pleth scale adjustment. This is replaced with operating mode options 1, 2, and 3. See NELLCOR[®] SpO₂ special features in section 3.16.2.

3.3.2 ECG Display Area

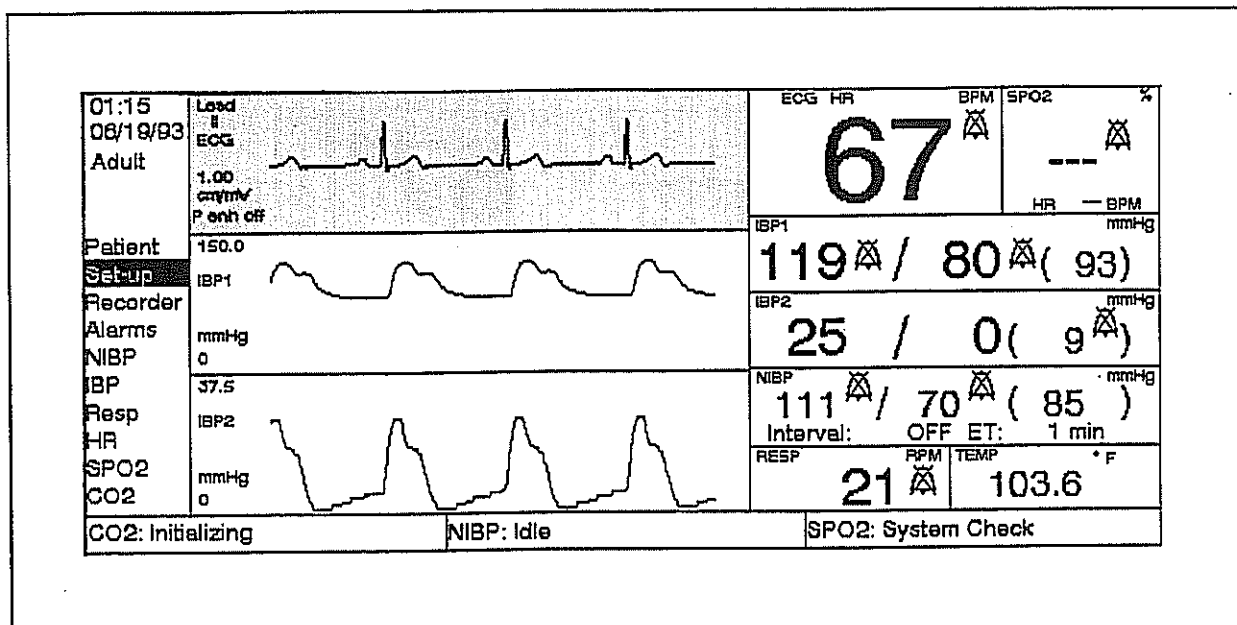


FIGURE 9 - ECG Display Area

The ECG Display Area contains the ECG waveform, the ECG size, scale, lead information, Pacer Enhancement ON/OFF message, and when appropriate a message indicating there is no ECG waveform available.

- **ECG SIZE** - The ECG size display shows the current size option and a units label. The size options are 0.25, 0.5, 1, 2, 3, & 4 cm/mV.
- **ECG LEAD** - The ECG lead display shows the current ECG lead selection. The lead display options are I, II, & III.
- **ECG WAVEFORM** - The display shows the ECG waveform at a user selectable speed. This provides 4 seconds of data on the display (at 25mm/sec). The scale of the waveform is determined by the ECG size selected.
- **LEAD FAULT MESSAGE** - The lead fault message box displays "ECG Lead Fault" and is positioned over the area where the ECG waveform normally resides.
- **PACER ENHANCEMENT** - Factory default is "P enh OFF" (pacer enhancement off). The OFF setting allows any pacer to appear as it normally would on the ECG waveform. When pacer enhancement is turned on via patient menu selection, detected pacers are enhanced and appear as full scale, narrow square waves.

3.3.3 MULTI-FUNCTION Display Area

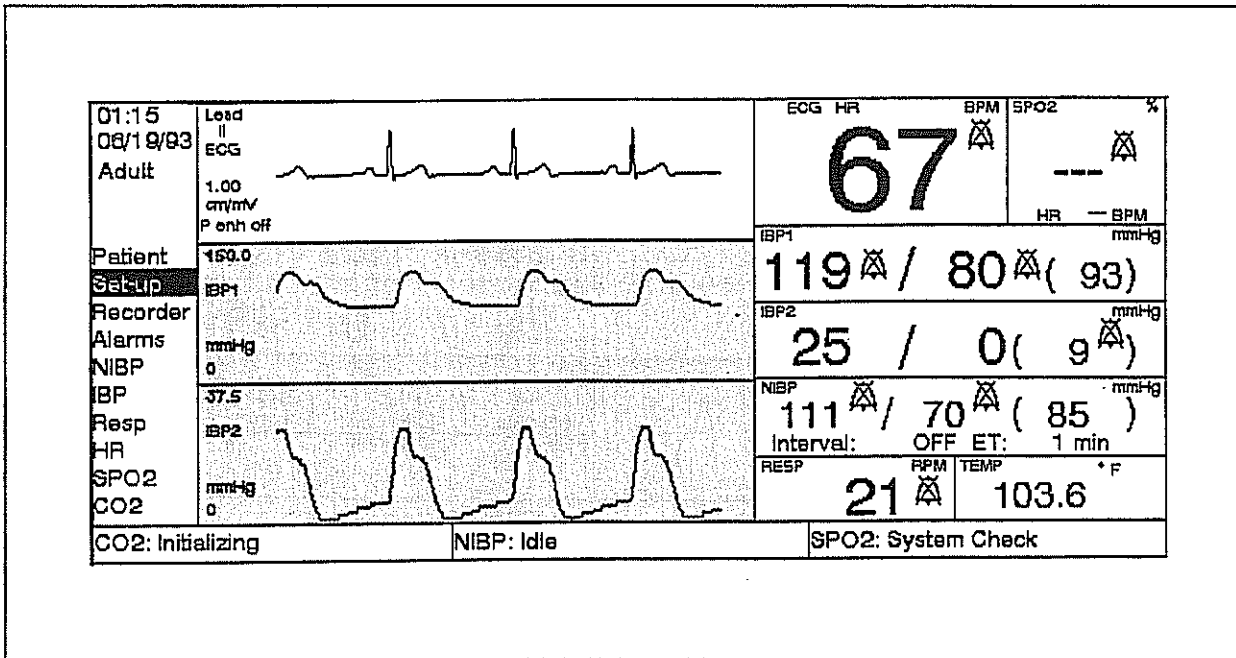


FIGURE 10 - Multi-Function Display Area

Displayed within the Multi-function Area of the screen are the:

- A. Waveforms
- B. Trend Lists

A. Waveforms

The waveform display is the normal display in the multi-function area. The waveforms occupy the entire multi-function area.

This area is divided horizontally in two. These two areas are used for waveforms 2 and 3.

The options for each waveform are listed in Table 1, page 3-6.

The scale information for invasive pressures consists of a 0 at the bottom of each window to represent zero pressure level and the scale range value at the top of the window.

The waveform provides four seconds of data when the selected speed is 25mm/sec.

B. Trend Lists

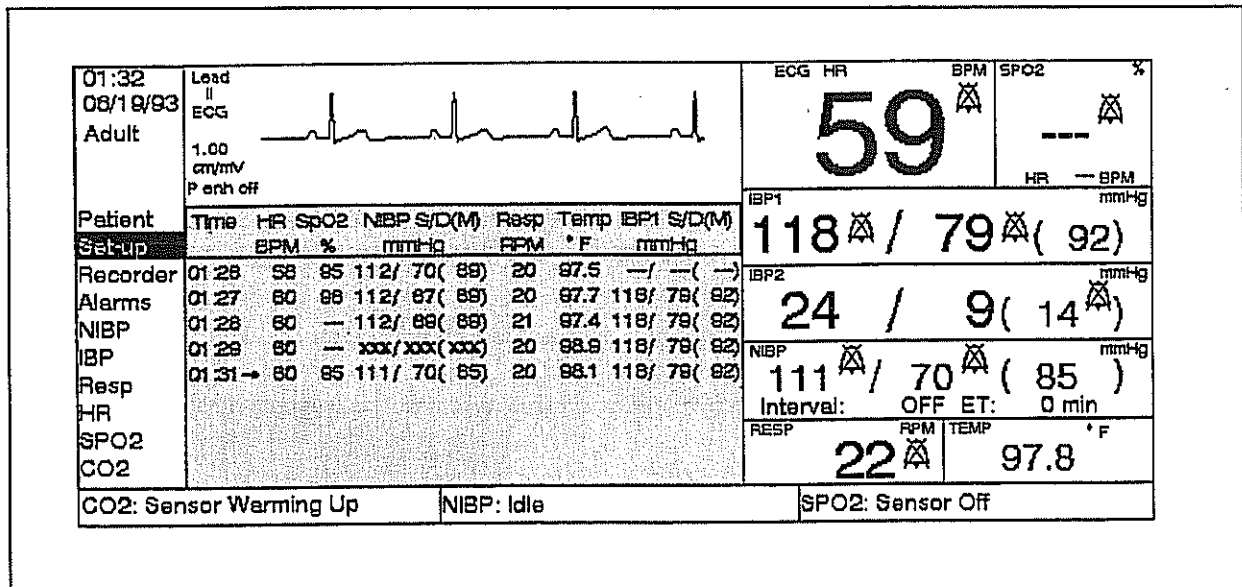


FIGURE 11 - Trend Lists Display

Pressing the TREND/RETURN key (15) displays the trend lists, as shown above. The trend lists take up the entire area of the Multi-function area. The trend data memory is large enough to contain more than one screen of data. Additional pages of data are accessed using the TIME UP \uparrow and TIME DOWN \downarrow trend keys (16). Pressing and holding the TREND/RETURN key (15) for 3 seconds will clear all trended data.

The trend lists display consists of a heading displaying the time, the displayed parameters with their units, and the data in columns under the appropriate heading.

If no data is available for a particular column dashes (---) are displayed. If an NIBP measurement was attempted and a valid reading was unable to be obtained (xxx) will be displayed in the NIBP column.

If respiration is turned off, "OFF" is displayed in the respiration column.

Eleven lines of data can be displayed on each page. New data lines are added below the existing data until the page is full. When the most current page is full and new data is available, the top line of data in the window is removed (but kept in memory), the other lines of data are scrolled up and the new data is added as the last line of data in the window. To scroll through the data that is in memory press the TIME UP \uparrow or DOWN \downarrow keys (16).

NOTE: The IBP1 column displays only in models that are equipped with the invasive pressure option.

3.3.4 Parameters Display Area

The parameters display area contains the current values of the patient parameters. The contents and the layout of the parameters area depends on how many invasive blood pressure transducers are connected to the monitor. The example below is with one transducer connected and the CO₂ option is installed.

Within the NIBP parameter area the interval chosen is displayed and the elapsed time (ET) since the last NIBP measurement was taken is displayed. If another NIBP measurement is not taken within 15 minutes the ET and the NIBP readings will change to dashes.

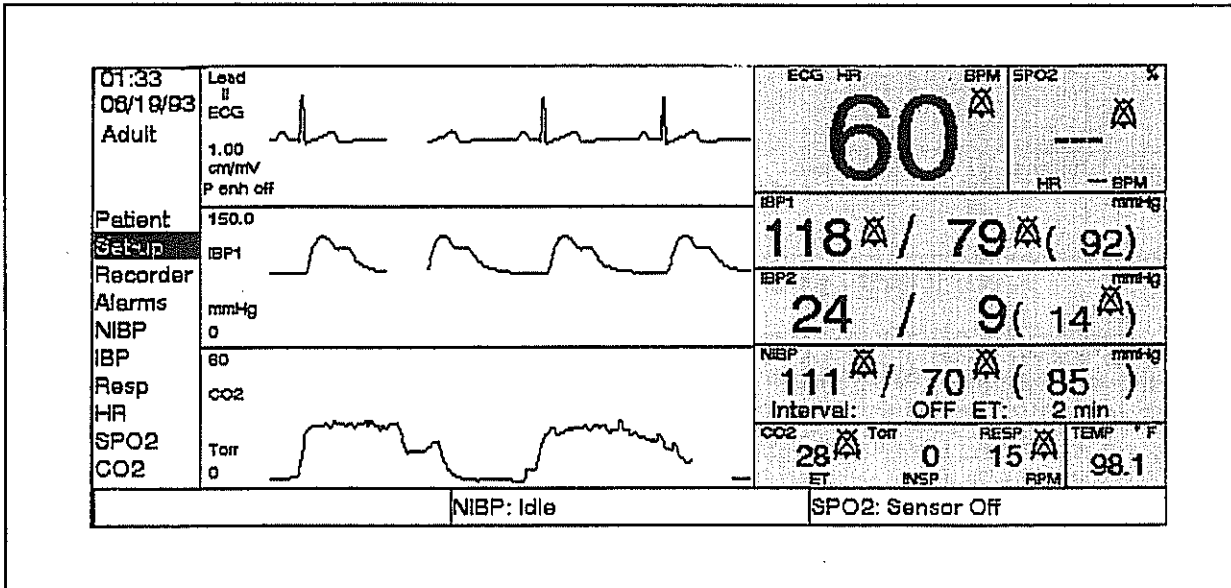


FIGURE 12 - Parameter Display Area

3.3.5 Message Display Area

This area of the display contains messages relating to NIBP, SpO₂, and recorder operation. See Section 3.11, "Status Messages" for a complete list of these messages.

3.4 USE OF MENUS

The main menus are accessed by using the UP ▲ & DOWN ▼ (1), SELECT (2), and END (3) keys.

The following is an example of how to set the menu options.

- Using the UP ▲ & DOWN ▼ (1) cursor keys, move the cursor to select the desired main menu item.

NOTE: As the cursor is moved up and down the list of menu items, view windows for each menu item are displayed.

- When the desired menu item is highlighted, (in this case SET-UP has been chosen) press SELECT (2) to enter into the change window.

When SELECT is pressed, the first item in the sub-menu will be highlighted.

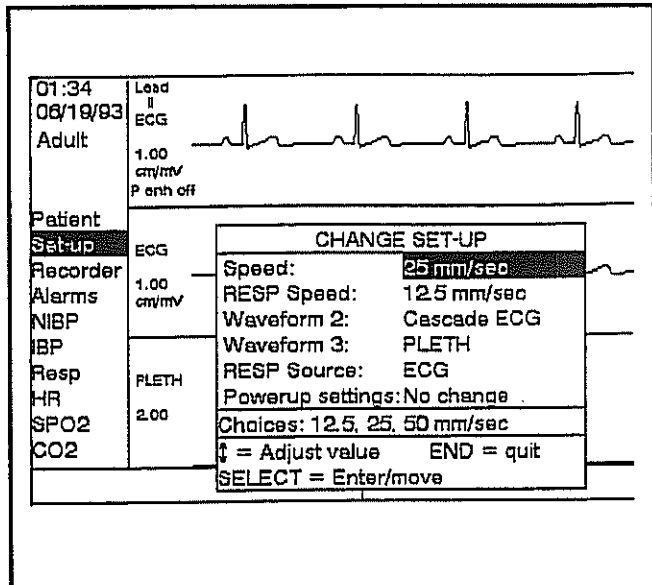


FIGURE 13

- To change the highlighted item use the UP ▲ & DOWN ▼ (1) keys. The choices available are listed in the CHOICES bar. Once the desired choice is displayed, press SELECT (2) to enter it and move the cursor down to the next item in the sub-menu.

If no change is required to the highlighted item, press SELECT to move the cursor down to the next item on the list. Keep pressing SELECT until the required item to change is highlighted.

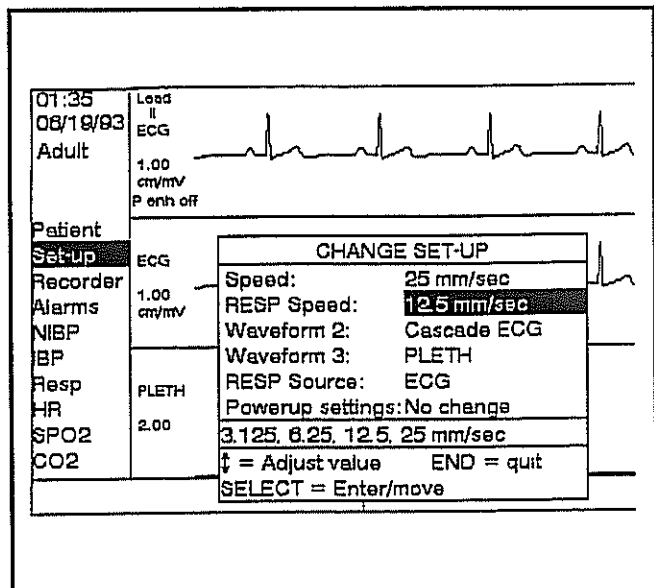


FIGURE 14

4. Press the END (3) key to return to the normal monitoring mode when all of the sub-menu items have been set as desired.

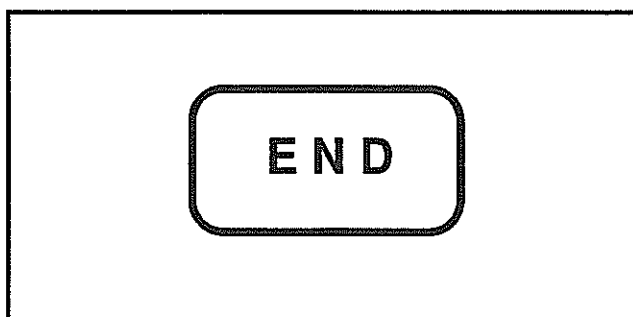


FIGURE 15

3.5 INITIATION OF NIBP MEASUREMENTS

3.5.1 Manual Initiation of NIBP Measurements

1. Select a pressure cuff that is appropriate for the size of the patient using the chart below as a guideline.

| Limb Circumference (cm) | Description / Cuff Name | Datasclope Part Number | |
|----------------------------|-------------------------|------------------------|-----------------|
| | | Reusable | Disposable |
| 45 - 65 | Thigh * | 0998-00-0003-05 | |
| 30 - 45 | Large Adult | 0998-00-0003-02 | 0683-07-0001-01 |
| 24 - 36 | Adult | 0998-00-0003-01 | 0683-07-0001-02 |
| 18 - 27 | Child | 0998-00-0003-03 | 0683-07-0001-03 |
| 16 - 25 | Small Child | 0998-00-0003-04 | 0683-07-0001-04 |
| 11 - 19 | Infant | 0998-00-0003-06 | |
| 6 - 11 | Newborn | 0998-00-0003-07 | |
| 12 - 17 | Neonatal, Size 3 | | 0683-03-0003-02 |
| 9 - 13 | Neonatal, Size 2 | | 0683-03-0002-02 |
| 7 - 10 | Neonatal, Size 1 | | 0683-03-0001-02 |
| 5 - 8 | Neonatal, Size 0 | | 0683-03-0004-02 |
| Color Coded Cuffs** | | | |
| 45 - 66 | Thigh - Brown | 0998-00-0003-26 | |
| 30 - 47 | Large Adult - Grey | 0998-00-0003-25 | |
| 24 - 36 | Adult - Tan | 0998-00-0003-24 | |
| 18 - 27 | Child - Red | 0998-00-0003-23 | |
| 10 - 19 | Infant - Green | 0998-00-0003-22 | |
| 6 - 11 | New Born - Blue | 0998-00-0003-21 | |

TABLE 2 - Cuff Selections

*When using the thigh cuff this product will not comply with AAMI accuracy standards.

**The limb circumferences of the Color Coded Cuffs adhere to the AHA guidelines for size.

A cuff that is too narrow for the limb will result in erroneously high readings. The correct size of the pressure cuff for a given patient has, among other considerations, a direct bearing on the accuracy of the obtained NIBP measurements. Base your selection of the cuff size on the limb circumference of the patient. The following table indicates the available Datascope cuffs for use with the Datascope PASSPORT Monitor. The design dimensions of the cuffs and their intended uses are based on recommendations of the American Heart Association.

NOTE: See Optional Accessories, Section 5.2 for a detailed list of cuffs.

NOTE: Disposable cuffs may be sterilized. Refer to Chapter 4 for sterilization instructions.

NOTE: Cuffs become more supple as they age and sometimes develop permanent folds that can leave temporary marks on the limb. Any cuffs that exhibit this effect should be replaced.

The pressure on the limb may not fall to zero between measurements if the cuff is wrapped too tightly. Therefore, assure that the cuff is properly applied.

The skin is sometimes fragile (i.e., on pediatrics, geriatrics, etc.). In these cases, a longer timer interval should be considered to decrease the number of cuff inflations over a period of time. In extreme cases, a thin layer of soft roll or webril cotton padding may be applied to the limb in order to cushion the skin when the cuff is inflated. This measure may affect NIBP performance and should be used with caution.

2. Attach cuff hose to NIBP Connector (24).
3. Apply the cuff to the patient. To reduce errors, the cuff should be fitted snugly, with little or no air present within the cuff. Be sure the cuff lies directly against the patient's skin. No clothing should come between the patient and the cuff.
4. Select Patient Size through the PATIENT MENU as described in Section 3.4, Use of Menus. Choices are ADULT, PEDIATRIC or NEONATE.
5. If necessary, enter the NIBP parameter menu to change the initial cuff inflation pressure.

Initial cuff inflation pressures depend on the PATIENT SIZE setting. The choices of cuff inflation are:

| <u>PATIENT SIZE Setting</u> | <u>Initial Cuff Inflation Values</u> |
|-----------------------------|--------------------------------------|
| Adult | 100 - 260mmHg |
| Pediatric | 60 - 180mmHg |
| Neonate | 40 - 120mmHg |

6. Press START (9) to begin an NIBP measurement.

NOTE: Inflate the cuff only after proper application to the patient's limb. Cuff damage can result if the cuff is left unwrapped and then inflated.

The cuff begins to inflate to the selected cuff pressure. After reaching the selected value the cuff begins to slowly deflate and the Datascope PASSPORT Monitor collects oscillometric pulsations.

If the initial cuff inflation is found to be inadequate, the unit retries with a higher inflation pressure (+50mmHg in the adult mode; +30mmHg in the pediatric and neonate modes).

Have the patient remain still to avoid the introduction of unnecessary motion artifact. After the cuff pressure drops below the diastolic pressure, the results of the measurement are displayed.

If NIBP is the only parameter measured with the PASSPORT, a heart rate can be derived from NIBP. The HR source menu selection must be in the Auto mode (i.e., not selected for ECG, IBP or SpO₂) and no heart rate alarms limits are set. (See Alarms, section 3.13, for details).

If NIBP is a selected trend trigger (see section 3.14 for details on user configuration), then NIBP and heart rate values are stored in trend lists. The NIBP and NIBP heart rate will be automatically removed from the display after 15 minutes have elapsed.

If another heart rate source is selected (ECG, IBP or SpO₂) before the 15 minute display time has elapsed, the NIBP heart rate will be replaced by the heart rate from the selected source.

To display heart rate from NIBP:

- a. Chose AUTO for HR source.
- b. Discontinue monitoring of ECG, SpO₂ and IBP.
- c. Set high and low heart rate alarms to off.
- d. Make a valid NIBP measurement.

During or after an NIBP measurement, one of several advisory messages may be displayed. Refer to Section 3.11, Status Messages, for their explanations.

7. If desired, press DEFLATE (11) to interrupt a measurement. The cuff will deflate.

3.5.2 Automatic Initiation of NIBP Measurements

Follow Steps 1 - 5 in the Manual Procedure, Section 3.5.1.

6. Press INTERVAL (10) until the desired time displays. The choices are: OFF, continuous, 1, 2.5, 5, 10, 15, 20, 30, 60, and 120 minutes.

7. A measurement will be taken when the selected interval has elapsed. If an immediate measurement is desired, press START (9).

NOTE: If the monitor is in the interval mode when it is turned on, no measurement will be taken until the "START" key is depressed. Subsequent measurements are referenced to the time the unit was turned on. See example in section 3.5.5.

NOTE: When the NIBP continuous interval is chosen, the PASSPORT will continually take back to back blood pressure readings. As a safety precaution, a five minute limit is placed on continuous measurements. After 5 minutes, the NIBP interval will automatically switch to measurements taken every 5 minutes.

Automatic Adjustment in the Timer Mode

In the timer mode, the unit adjusts the inflation pressure according to the previous reading of the systolic pressure. After the first measurement in the timer mode, the inflation pressure is the previous systolic +50mmHg in the Adult Mode and +30mmHg in the pediatric and neonate mode.

Suspension of Automatic NIBP Feature

To suspend an automatically timed measurement sequence or to end a measurement cycle already in progress (deflate cuff):

1. Press DEFLATE (11).

To take an immediate measurement and resume a suspended timed measurement sequence:

2. Press START (9).

NOTE: Press DEFLATE (11) at any time to postpone a scheduled measurement or to terminate a measurement cycle already in progress.

PRECAUTION: Observe Extreme Caution On All Patients (Neonates, Pediatrics, and Adults) When NIBP is set to the Continuous Mode.

Reports have been made of nerve injury occurring during use of automatically cycled blood pressure cuffs. See the Appendix, "Precautions when Using Automatically Cycled Blood Pressure Cuffs".

3.5.3 NIBP Pressure Limit Fail Safe

If the cuff pressure is over-pressurized, the cuff will automatically vent to atmosphere, the alarm tone is sounded, and the NIBP message window reads CUFF OVERPRESSURE.

The unit must be turned off and back on again to reset the overpressure switch before any new measurements are taken.

3.5.4 Cuff Inflation Time

If the cuff pressure does not attain 20mmHg within 40 seconds of the start of inflation or if the target pressure is not reached within another 60 seconds, then the cuff is vented and the "RETRY" or "UNABLE TO MEASURE" message will display in the NIBP message window.

3.5.5 START and DEFLATE Functions

The START and DEFLATE functions have the following effects on the timed measurement sequence.

- INTERVAL is set and you Press START (9):
An unscheduled measurement is made. Taking this unscheduled measurement does not affect the timing of the interval cycle, therefore, the scheduled measurements will be taken as if there were no interruptions . Only one measurement is taken for each measurement cycle - even if the unscheduled measurement coincides with the scheduled measurement.
- INTERVAL is set and you press DEFLATE (11):
The timed measurement is suspended and the cuff deflates.
- INTERVAL is set and you change the interval:
The measurement cycle is reset with the new interval. A measurement will be taken after the new interval has elapsed.

For **example**, with the interval set to five minutes:

| <u>Time</u> | <u>Mode/Timer Interaction</u> | <u>Result</u> |
|-------------|--|---|
| 9:45 | Unit turned on with interval set to 5 minutes. | No measurement taken |
| 9:52 | Start key pressed | Measurement taken |
| 9:55 | Timer requests a measurement | Measurement taken |
| 10:00 | Not in Deflate mode and timer requests a measurement | Measurement taken |
| 10:04 | Deflate mode is entered | Deflate message is displayed on display |
| 10:05 | Timer requests a measurement | Measurement is skipped |
| 10:07 | Interval is changed to 10 min. | Interval timing is reset |
| 10:17 | Timer requests a measurement | Measurement taken |

3.6 ECG ACQUISITION

The patient ECG signal is acquired with a patient cable and skin electrodes. The type of skin electrode and technique of applying the electrodes are major factors in determining the quality of the signal obtained. Use high quality, silver-silver chloride electrodes. These are designed to acquire the ECG with excellent baseline stability, recovery from defibrillation, and minimum artifact from patient movement.

1. For optimal skin contact, thoroughly prep patient skin for electrode placement by doing the following.

- Shave hair from electrode sites.
- Cleanse skin thoroughly with alcohol to remove skin oils.
- Dry with a rough towel or gauze to remove dry skin.
- Attach electrodes to lead wire first before placing onto patient.

NOTE: Using more than one type of electrode on the same patient should be avoided because of variations in electrical resistance.

2. Use the ESIS choke cable if an electrosurgical device is to be used on the patient.

3. Plug patient cable into the ECG (28) connector.

An ECG waveform should now be present on the screen and the heart rate readout should now be functional.

4. Select desired lead setting by pressing the front panel ECG LEAD key (4). Lead II is automatically selected at power-up.

5. Select desired ECG size by pressing the front panel ECG SIZE key (5). An ECG of 1 cm/mV is automatically selected at power-up.

6. If cascaded ECG is desired in waveform 2, use the Set-up menu, Section 3.4, to choose this option.

7. Choose HR source for rate meter from HR menu. Choices are: ECG, BP1, SpO₂, or AUTO. AUTO selects the source from a hierarchy (ECG, IBP1, SpO₂) of what is currently monitored. If no HR source is found, then an alarm tone is sounded.

8. Press BEEP VOLUME (17) to set the volume of the systole beep.

3.6.1 Adult Electrode Placement

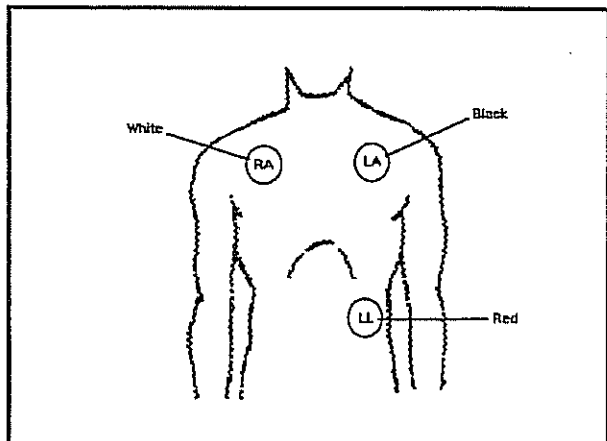


FIGURE 16 (A)- 3 Lead Electrode Placement (standard configuration)

For Lead II ECG Monitoring

- Place black electrode on left shoulder under clavicle.
- Place white electrode on right shoulder under clavicle.
- Place red electrode on lower left abdomen under the sixth rib.
- Place lead select on lead II.

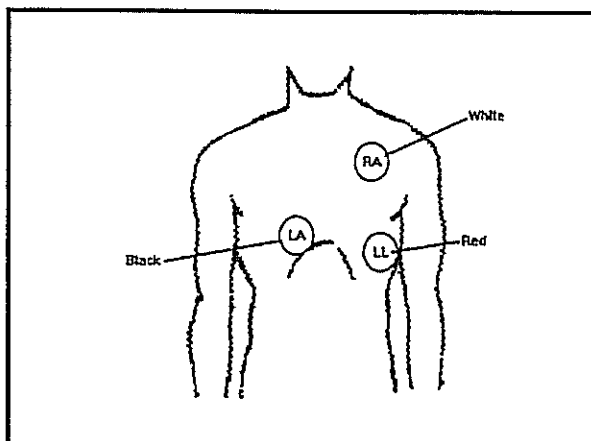


FIGURE 16 (B) - 3 Lead Electrode Placement (for MCL)

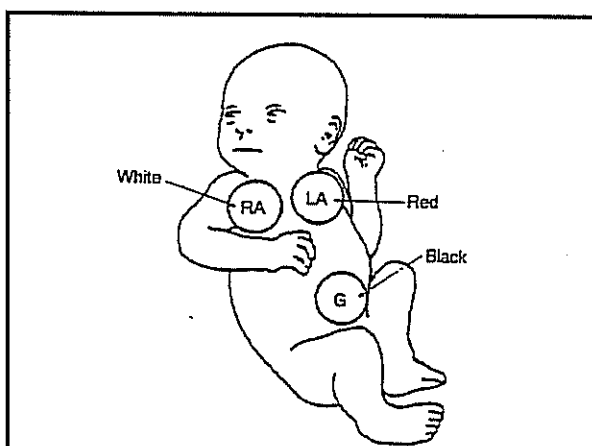
For MCL

- Place white electrode on left shoulder under clavicle.
- Place black electrode on right sternal border, 4th intercostal space.
- Place red electrode on midaxillary line, 5th intercostal space.
- Select lead I for monitoring.
- For MCL, select lead II for monitoring.

3.6.2 Neonatal Electrode Placement

Lead placement on the neonate with a three lead set is directed towards obtaining the best respiration waveform. The thoracic impedance is measured between the RA and LA electrodes therefore, the electrodes must be placed across the chest from each other to optimize measurement of chest movement.

FIGURE 16 (C)- Neonatal Electrode Placement



3.7 INVASIVE PRESSURE ACQUISITION (Optional)

1. Plug the pressure transducer into the PRESSURE TRANSDUCER connector (29) or (30) on the side panel.
2. To establish a monitoring site introduce an arterial pressure catheter into the patient's artery in accordance with standard hospital procedures. "Best practice," as determined by the medical community, should be observed.
3. Connect catheter line with flushing device to the pressure transducer.
4. Zero pressure transducer as follows:

Initially, a "TRANSDUCER NOT ZEROED" message is displayed in the parameter window, indicating the need to zero the transducer.

- a. Open transducer vent to atmosphere.
- b. Press ZERO (7) or (8) and hold for a minimum of one second.

After one second has elapsed, an audible click will sound, and the automatic zero process is complete. The pressure display should indicate zeros.

NOTE: If the transducer offset should exceed 120mmHg, it will not be possible to automatically zero the transducer. Pressure values will be --- and an "UNABLE TO ZERO" message replaces the "TRANSDUCER NOT ZEROED" message.

3. Close the pressure transducer vent from atmosphere and check that the pressure waveform is displayed on the screen.
4. Select the desired pressure scale in the IBP Menu. The choices are: 37.5, 75, 150, or 300mmHg.
5. Flush arterial line at regular intervals per standard hospital procedure.

3.8 SEQUENCE FOR ESTABLISHING SpO₂ with DATASCOPE PULSE OXIMETRY

To obtain SpO₂ measurements, SpO₂ Heart Rate, and the plethysmographic waveform from the PASSPORT monitor with Datascope SpO₂:

1. Select the appropriate sensor for the patient.

Guidelines for the selection of a sensor are provided in the Sensor Selection Table page 3-24.

2. Plug the patient cable into the SpO₂ Connector (26) on the left side panel.
3. Apply sensor and connect to cable. **NOTE:** Do not place the sensor on an extremity with an invasive catheter or blood pressure cuff in place.

4. The digital SpO₂ values and SpO₂ heart rate will be displayed in the SpO₂ parameter Window.
5. If a pleth waveform is desired, enter the set-up menu as described in Section 3.4, Use of Menus, to display it as waveform 2.
6. To change the size of the waveform displayed select the SpO₂ menu and chose the desired size. Choices are: 1, 2, 3 or 4.
7. Press BEEP VOLUME (17) to set the volume of the SpO₂ beep.

3.8.1 Sensors

A. Introduction

A wide range of sensors are available for connection to the Datascope PASSPORT Monitor. The sensors cover both short-term and long-term monitoring needs on patients ranging from neonates to large adults.

The DATASENSOR is intended for short-term adult monitoring.

The FLEXISENSOR[®] SD, available in five different sizes, provides both short-term and long-term monitoring for large adults, adult ear, adults, pediatrics, infants, and neonates. The FLEXISENSOR[®] SD is used when the DATASENSOR is not convenient or suitable.

The ear sensor is intended for long-term adult monitoring.

A range of disposable bandages are available for use with the FLEXISENSOR[®] SDs. They are available in 3 styles, SENSOR GUARD™ (used for large adults, adults and pediatrics), Coban with SENSOR GUARD™ (used for infants) and LIGHTGUARD™ (used for neonates).

Use of the sensors does not cause any penetration of the skin, nor is there any electrical contact or transfer of excessive heat to the patient.

The sensor is composed of a light emitting diode (emitter) and a photodiode (detector). The emitter discharges two colors (wave lengths) of light into the patient's extremity (finger, toe, ear). The detector receives that amount of light not absorbed by the blood or tissue components. The PASSPORT then uses the relative absorption of the two light wavelengths to compute and display SpO₂ and Rate measurements.

The key benefits of the sensors are:

- | | |
|---|---|
| -electrocautery noise (ESU) rejection | -can be re-sterilized (ETO sterilization - 3 times) |
| -good motion artifact rejection | -patient isolation |
| -tracking of weak peripheral pulse levels | -ease of application and removal |
| -rejection of ambient light | -long term patient comfort |

- Electrocautery Noise (ESU) Rejection

The sensor configuration of both the DATASENSOR and the FLEXISENSOR[®] SD provide uninterrupted monitoring and absence of false alarms during the use of ESU (ESU can be set at any power level). This design prevents electro-surgical noise entering the monitor, via the sensor, and interfering with unit operation.

- Monitoring Restless Patients

Motion artifact rejection is achieved in several ways.

1. The sensor design used with their recommended bandages assures a snug fit of the sensor to the patient.
2. Light emitting diodes (LEDs) and detectors gather a strong signal from the patient.
3. Software in the PASSPORT evaluates the shape of each pulse and automatically rejects noisy and unreliable pulses.
4. When in the presence of motion, the software adjusts the "averaging-period", increasing it to a maximum of 15 seconds during motion, and automatically reducing it during quiet periods to obtain a fast response. This combination reduces the number of monitoring interruptions and false alarms from patient motion.

- Tracking of Weak Peripheral Pulse Levels

Many patients suffer poor peripheral perfusion due to hypothermia, hypovolemia, reduced cardiac output, etc. The PASSPORT is designed to automatically increase its gain to track patients with poor peripheral perfusion.

- Rejection of Ambient Light

Many monitoring situations involve high levels of ambient light, ie., operating room lights, neonatal phototherapy, heat warmers, etc. The PASSPORT Monitor, sensors, and bandages each contribute to the rejection of ambient light. The monitor automatically measures and corrects for high levels of ambient light. The enclosed design of the DATASENSOR prohibits the interference of high levels of ambient light on adults with sensor operation. And the opaque material used in the composition of the bandages, which are used with the FLEXISENSOR[®] SD, helps keep out ambient light.

- Patient Comfort

The FLEXISENSOR[®] SD line is designed to work with a disposable bandage of three styles (SENSOR GUARD[™], Coban and LIGHTGUARD[™]) which conform comfortably and safely to the particular patient's anatomy.

B. Sensor Selection and Application

Selection of a specific sensor is based on the patient's size, physical condition, and expected monitoring duration.

General guidelines for the selection of a sensor are provided in the Sensor Selection Table, page 3-24.

Instructions for the application of a sensor to a patient are provided in each sensor package.

C. Sensor Connection to the PASSPORT Monitor

1. Align the cable connector on the sensor assembly with the SpO₂ Patient Connector (26) on the PASSPORT Monitor.
2. Push the cable connector into the SpO₂ Patient Connector (26). Confirm that the cable connector is securely in place.

NOTE: To obtain maximum cable use, do not twist the cable connector when attaching to or disconnecting from the PASSPORT Monitor.

D. Sensor Inspection

Before use, always inspect sensors, cables, and connectors for damage, ie., cuts and abrasions. Do not use the sensor, cable or connector if damaged. Replace with a good working sensor.

For long sensor life:

- Do not drop on the floor, or give other sharp shocks to the sensor(s).

Between use, store the sensors in the optional FLEXISENSOR SD Organizer, accessory pouch, or coil the sensor cable and store on the side of the PASSPORT using the optional cable retainer.

For accessory part number information see Section 5.2, "Optional Accessories".

- Avoid running any cart, bed, or any piece of equipment over the sensor cable.
- Avoid strong pulls on the sensor cable (10 lbs/4kg).
- Watch for cracks in the DATASENSOR housing.
- Watch for cracks, cuts, rips, fogging, or signs of moisture in the FLEXISENSOR[®] SD.

E. Sensor Performance

For the BEST performance of all Datascope sensors:

- DO NOT PLACE any sensor on an extremity with an arterial catheter or blood pressure cuff in place. Placement of an arterial catheter or blood pressure cuff on an extremity may obstruct normal blood flow. False pulse rate information may result if the FLEXISENSOR SD is placed on that same extremity. Place the sensor on the limb opposite the site of the arterial catheter or blood pressure cuff.
- Encourage the patient to remain still. Patient motion may affect the sensor's performance. If it is not possible for the patient to remain still, replace the sensor bandage on the FLEXISENSOR SD to assure good adhesion, or change the site of the DATASENSOR.
- **Check the DATASENSOR site every 2 hours and check the FLEXISENSOR site every 8 hours on adults and every 4 hours on neonatal patients for indications of skin abrasions, sensor displacement, sensor damage, or circulation impairment. Check the sensor site every 4 hours if the ear clip is used.** If necessary, remove and reapply the sensor. If any of the above mentioned indications occur, immediately remove the sensor and find an alternate site.

NOTE: Check the sensor site more frequently on infant and active patients.

- Incorrect placement can also reduce the acquired sensor signal, and therefore compromise performance. Select an alternate site (toe) or use a FLEXISENSOR SD if the sensor can not be placed on the patient's finger correctly or if the fingernails interfere with the acquisition of a reliable signal.
- Use of the DATASENSOR is not recommended for long-term monitoring (4-6 hours). For monitoring situations exceeding 4-6 hours, either reposition the DATASENSOR every 2-4 hours to a different site (finger/toe) or use a FLEXISENSOR SD with its appropriate bandage.
- Do not over-tighten the sensor bandages. Excessive pressure on the monitoring site can affect SpO₂ readings and may reduce readings below true SpO₂. Excessive pressure can also result in pressure necrosis and other skin damage.
- Sensor configuration provides uninterrupted monitoring in the following situations:

Electrocautery Noise - ESU rejection is designed into the sensors.

Motion Artifact - The monitor's software adjusts the "averaging period" increasing it during motion and reducing it during inactivity. This decreases the number of monitoring interruptions and false alarms.

Weak Peripheral Pulses - The monitor's gain is automatically increased to track pulses on patients with decreased peripheral perfusion.

| Patient Group Sensor Type | Approximate Patient Weight kg/lbs | Where to be used | Long or Short Term Monitoring | ESIS | Reusable | Bandage Type | Sensor | Part Numbers** Bandages |
|---------------------------|-----------------------------------|-------------------------|-------------------------------|----------|----------------------|---------------------------|---|-------------------------|
| Large Adult (LA) | > 80kg/ > 176 lbs | Fingers, Toes | Long & Short Term | Included | Yes Up to 20 uses | Adhesive, Disposable | 0998-00-0076-06 | 0683-00-0409-01 |
| Adult (A) | 30 - 90kg/ 66 - 198 lbs | Fingers, Toes | Long & Short Term | Included | Yes Up to 20 uses | Adhesive, Disposable | 0998-00-0076-05 | 0683-00-0409-02 |
| Pediatric (P) | 10 - 40kg/ 22 - 88 lbs | Fingers, Toes | Long & Short Term | Included | Yes Up to 20 uses | Adhesive, Disposable | 0998-00-0076-04 | 0683-00-0409-03 |
| Infant (I) | 4.5 - 10kg/ 10 - 22 lbs | Feet, Palms, Big Toes | Long & Short Term | Included | Yes Up to 20 uses | Non-Adhesive*, Disposable | 0998-00-0074-03 | 0683-00-0415 |
| Neonate (N) | Up to 5kg/ Up to 11 lbs | Feet, Palms, Heel, Calf | Long & Short Term | Included | Yes Up to 20 uses | Non-Adhesive*, Disposable | 0998-00-0074-04 | 0683-00-0440 |
| Adult Ear (AE) | > 40kg/ > 88 lbs | Adult Ear | Long & Short Term | Included | Yes Up to 20 uses | N/A | 0998-00-0074-05 | N/A |
| DATASENSOR | 40 + kg/ 90 + lbs | Fingers, Toes | Short Term | Included | Yes 6- months | N/A | 0600-00-0026-01 (3' sensor cable) 0600-00-0026-02 (10' sensor cable) 0020-00-0071-01 (3' sensor cable plus 7' extension cable) | N/A |

*Non-adhesive bandages are recommended for premature infants to minimize prenatal skin damage.

**See Accessories, Chapter 5, for more detailed information.

TABLE 3 - Sensor Selections

3.9 RESPIRATION MONITORING

The PASSPORT utilizes an impedance pneumography technique to measure respiration. In using this method, standard ECG electrodes apply a low amplitude, high frequency current through the chest and return a voltage for calculation of impedance. Changes in the size of the chest cavity, during inhalation and exhalation, create variations in the electrical characteristics of the chest. These changes or variations are measured in ohms.

The PASSPORT measures impedance through the RA - LA ECG electrodes. Changes in electrical characteristics of the chest, from the heart filling and emptying (diastole and systole), can create artifact that can appear as respirations. This is called CVA or cardiovascular artifact. The PASSPORT has automatic CVA rejection.

Using thoracic impedance for respiration monitoring is most effective in detection of central apnea. This apnea is characterized by cessation of breathing. In infants, episodes of apnea can result from a failure of effort in restarting breathing. In adults, medications given intravenously for conscious sedation can cause cessation of breathing.

In obstructive apnea there are breathing efforts, but there is no air exchange because of an obstruction in the airway. These breathing efforts can create artifacts that may be detected as respirations. The clinician should routinely use pulse oximetry in conjunction with respiration monitoring in order to quickly recognize desaturation.

3.10 CO₂ MONITORING

The PASSPORT has a CO₂ option which can be used to monitor respiratory rate and ETCO₂ values. CO₂ is measured with a mainstream, or in line, sensor which is placed between the endotracheal tube and the breathing circuit. The sensor consists of two parts: a U-shaped sensor containing the infrared source and detector and the snap-in airway adapter.

3.10.1 Sequence for Establishing CO₂

1. Plug the CO₂ sensor into the PASSPORT connector. The "Sensor Warming Up" message is displayed.
2. Select CO₂ as the Resp. Source in the Setup Menu.
3. Snap a clean airway adapter into the U-shaped sensor. Align the line on the bottom of the adapter with the line on the bottom of the sensor.
4. Position the airway adapter between the endotracheal tube and the Y-piece of the breathing circuit.

5. After the PASSPORT has detected valid breaths, it will display numbers for ETCO₂, Inspired CO₂ and Respiratory Rate.
6. Select the CO₂ waveform to be displayed on Waveform 2 or Waveform 3 using the Setup Menu.
7. If desired the CO₂ waveform scale can be changed by entering the CO₂ menu. See Section 3.4, "Use of Menus" for details.
8. The CO₂ menu also has provisions for N₂O and O₂ compensation.

NOTE: See "User Configuration", Section 3.14 for Barometric Pressure and CO₂ Units selection.

NOTE: See "CO₂ Messages", Section 3.11.5 for more details on messages.

3.10.2 Adapter Calibration

Adapter calibration compensates for the optical differences between the adult and neonatal airway adapters.

Adapter calibration needs to be performed each time the type of airway adapter is switched. For example: if switching from using an adult to a neonatal or neonatal to an adult adapter a calibration is needed (not if switching from an adult adapter to another adult adapter). Adapter calibration should also be performed if the message "Check Adapter" displays.

To perform an adapter calibration:

1. Place the sensor and airway adapter away from all sources of CO₂ (including the patient's and your own exhaled breath, and ventilator exhaust valves).
2. Choose Start Adapter Cal - Yes from the CO₂ menu. (See Section 3.4, "Use of Menus".)

NOTE: If the monitor detects changing CO₂ levels (breaths) during an adapter calibration, an "Adapter Cal Failure" message displays. Remove the source of CO₂ and repeat the calibration.

3.10.3 Adapter Selection

Selection of an airway adapter is based on the diameter of the patient's endotracheal tube. There are two sizes of airway adapters available:

- Adult Airway Adapter (P/N 0103-15-0003). For use on patients with endotracheal tube diameters greater than 4.0 mm.
- Neonatal Airway Adapter (P/N 0103-15-0013). For use on patients with endotracheal tube diameters less than or equal to 4.0 mm.

3.10.4 Use of Adult Airway Adapter

The adult airway adapter should be used when monitoring patients with endotracheal tube diameters greater than 4.0 mm.

1. Verify the windows are clean and dry. Clean or replace the adapter if necessary.
2. Snap the airway adapter into the Capnostat[®] sensor. Align the line on the bottom of the airway adapter with the line on the bottom of the Capnostat[®]. Press the sensor and airway adapter together until they "click".
3. If necessary, perform an adapter calibration. See Section 3.10.2.
4. Place the Capnostat[®] / airway adapter assembly between the elbow and the ventilator circuit wye.

NOTES:

For optimal results, DO NOT place the airway adapter between the endotracheal tube and the elbow, as this may allow patient secretions to block the adapter windows.

Position the airway adapter with its windows in a vertical and NOT a horizontal position. This helps keep patient secretions from "pooling" on the windows.

To prevent "rain-out" and moisture from draining into the airway adapter, DO NOT place the airway adapter in a gravity dependent position.

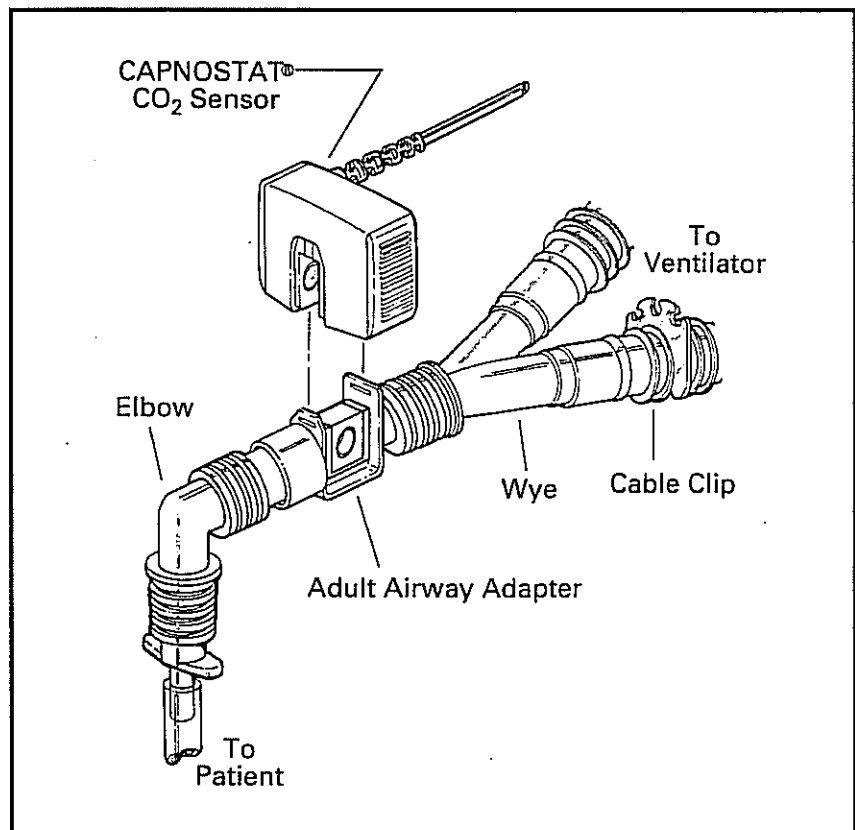


FIGURE 17 - Adult Airway Adapter

5. Check that the connections have been made correctly by verifying a proper CO₂ waveform (capnogram) on the monitor display. **NOTE:** The CO₂ waveform is displayed by choosing CO₂ as Waveform 2 or 3 and the Resp. Source in the Setup menu
6. The sensor cable should face away from the patient. To secure the sensor cable safely out of the way, attach the sensor cable holding clips to the airway tubing, then connect the sensor cable to the clips.

3.10.5 Use of Neonatal Airway Adapter

The neonatal airway adapter should be used when monitoring patients with endotracheal tube diameters less than or equal to 4.0 mm.

1. Verify the windows are clean and dry. Clean or replace the adapter if necessary.
2. Snap the airway adapter into the Capnostat[®] sensor. Align the line on the bottom of the airway adapter with the line on the bottom of the Capnostat[®]. Press the sensor and airway adapter together until they "click".
3. If necessary, perform an adapter calibration. See Section 3.10.2.
4. Place the Capnostat[®] / airway adapter assembly between the elbow and the ventilator circuit wye.

NOTES:

Position the airway adapter with its windows in a vertical and NOT a horizontal position. This helps keep patient secretions from "pooling" on the windows.

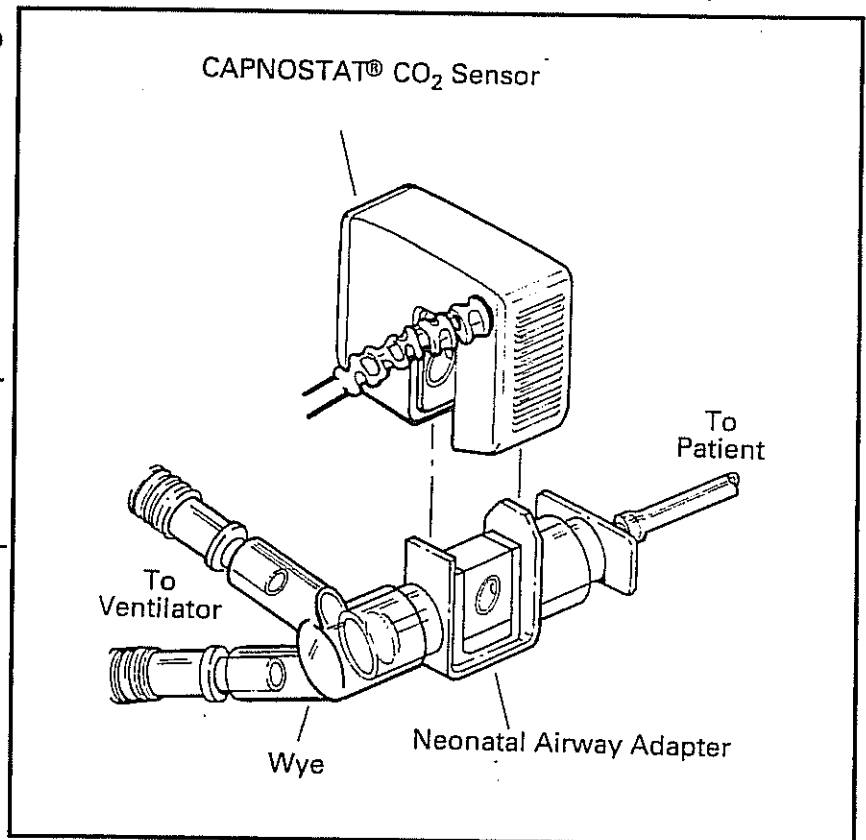


FIGURE 18 - Pediatric Airway Adapter

To prevent "rain-out" and moisture from draining into the airway adapter, DO NOT place the airway adapter in a gravity dependent position.

For routine maintenance of airway adapter, separate the system between the endotracheal tube and the airway adapter. Lavage and suctioning of the airway can then be performed without fluids and mucous accumulating on the neonatal airway adapter window.

5. Check that the connections have been made correctly by verifying a proper CO₂ waveform (capnogram) on the monitor display. **NOTE:** The CO₂ waveform is displayed by choosing CO₂ as Waveform 2 or 3 and the Resp Source in the Setup menu.
6. The sensor cable should face away from the patient. To secure the sensor cable safely out of the way, attach the sensor cable holding clips to the airway tubing, then connect the sensor cable to the clips.

3.10.6 CO₂ Sensor Calibration Verification

Calibration can be verified at anytime and should be verified at least once a week.

To verify calibration:

1. Verify the PASSPORT is turned on and the Capnostat[®] is connected and warmed-up.
2. Place the Capnostat[®] sensor onto the REF (reference) cell. The reference cell is the one farthest from the side of the monitor. The sensor cable should face away from the PASSPORT.
3. The "Sensor on Reference Cal" message is displayed and the reference value is displayed in the ETCO₂ window. The value should be between 36 and 40 Torr.

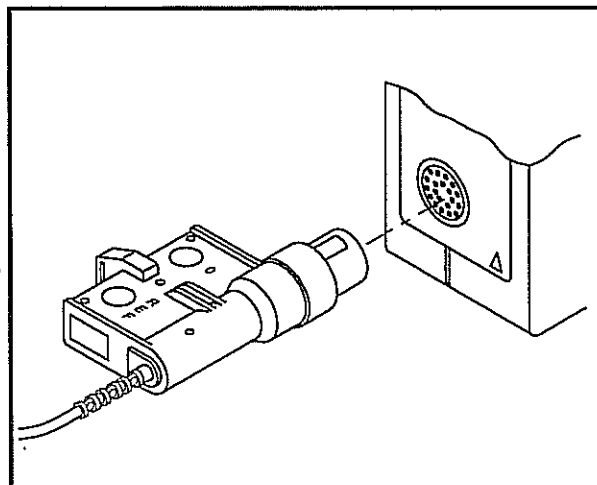


FIGURE 19 - Reference Cell

3.10.7 CO₂ Sensor Calibration

The Capnostat[®] CO₂ sensor does NOT need to be calibrated at each monitor power up.

Calibration of a sensor is required the first time a particular sensor is connected to a particular monitor and when the monitor requests it.

Once a sensor is calibrated, the PASSPORT can be turned off and on, the sensor can be unplugged and reconnected, without having to recalibrate. However, if a second sensor is connected in place of the original, the second sensor must be calibrated and if the original sensor is used again, it too will have to be recalibrated.

To perform a Capnostat[®] sensor calibration:

1. Verify the PASSPORT is turned on and the Capnostat[®] is plugged in and warmed-up.
2. Place the Capnostat[®] onto the ZERO cell.
3. The "Sensor on Zero Cell" message is displayed.
4. Select Start Zero Cal - Yes from the CO₂ menu. The "Zero Cal in Progress" message is displayed. The "Zero Cal Complete" message is displayed when complete and a 0 value is displayed.
5. Remove sensor from the zero cell and place onto the airway adapter.

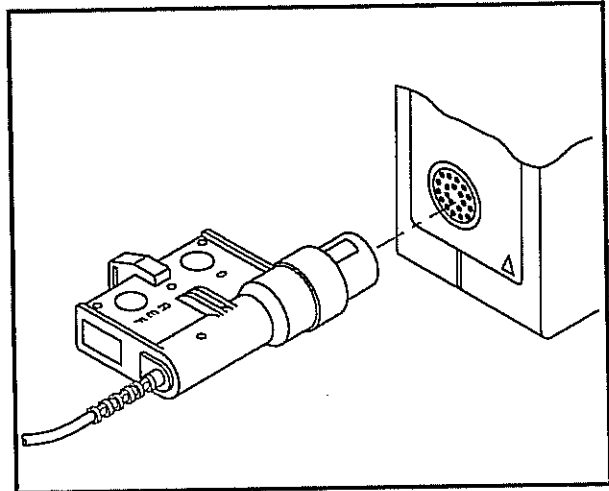


FIGURE 20 - Zero Cell

3.11 STATUS MESSAGES

The monitor uses the Message Display Area to provide messages to the user relating to monitor status. The following lists these messages and a description of the message. The messages are grouped by function.

3.11.1 NIBP Measurement Messages

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|--------------------|--|--|
| NIBP: IDLE | Displayed while system is idle. | Press START to take a single measurement. Press INTERVAL to select an interval and start timed measurements. |
| NIBP: DEFLATE | Displayed while the timer mode is stopped, usually by pressing the DEFLATE key. | Press START to take an immediate measurement and resume timed measurements. |
| NIBP: INTERVAL | Displayed in the interval between two timed measurements. | Press DEFLATE to suspend timed measurements. Press INTERVAL to change timer to OFF to stop timer. |
| NIBP: INITIALIZING | The NIBP system is being initialized. | Wait until initialization is complete, indicated by NIBP: IDLE message. Initialization may take up to 3 minutes from power up. |
| NIBP: FAILURE | The NIBP system has detected a potential error. | Power cycle unit. If message reappears, call Service. |
| MEASURING CUFF | Displayed during a measurement to show the cuff pressure. | Press DEFLATE to suspend a measurement and deflate the cuff. |
| RETRY: MOTION | Measurement has been attempted but no reading was possible due to detected motion and the retry limit has not been reached. | Retry will be attempted. Have patient remain still. |
| RETRY: PUMP HIGHER | A measurement has been attempted but no reading was possible due to pulse detection at highest cuff pressure and the retry limit has not been reached. | Retry will be attempted. Check that appropriate patient size is set. Preset initial inflation pressure. |

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|-----------------------|---|--|
| RETRY | A measurement has been attempted but no reading was possible. | Retry will be attempted. Check for leaks and quality of peripheral pulses. Decrease patient movement. Switch cuff to another limb. |
| UNABLE TO MEASURE* | An unsuccessful measurement cycle has been completed. | Switch cuff to another limb. Decrease patient movement. Press START to retry. Be prepared to auscultate BP manually. |
| CUFF OVERPRESSURE | The internal hardware cuff pressure check valve has been tripped. | Power cycle unit. If message reappears, call Service. |

- Always have an alternate method of BP verification available.
- On vasoconstricted patients, failure to evacuate air from the cuff can distort BP measurement.
- Do not place cuff on extremity that has an IV.
- Arm should be at heart level.

* The presence of arrhythmias may increase the time required to complete a measurement and may extend this time to a point where a measurement cannot be completed.

3.11.2 SpO₂ Messages

The following messages pertain to Datascope SpO₂ Operation.

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|-------------------------------|---|---|
| SpO ₂ NO SENSOR | No sensor is connected to the monitor. | Attach sensor cable to the monitor. |
| SpO ₂ SENSOR OFF | Sensor may not be connected to the patient. | Check patient connection. |
| SpO ₂ INTERFERENCE | Noise detected on the pulse signal prevents pulse discrimination. | Decrease patient motion, check sensor. |
| SpO ₂ PULSE SEARCH | Hardware settings are being adjusted in order to discriminate a pulse waveform. | Change to site where pulse is stronger if patient is vasoconstricted. Change or readjust sensor if loose. |

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|-------------------------------|---|--|
| SpO ₂ WEAK PULSE | Detected patient pulse is marginal. | Change site. |
| SpO ₂ NO PULSE | No detectable pulse is measured. | |
| CHECK SpO ₂ SENSOR | Insufficient light is received by the sensor detector, or the sensor has a malfunction. | Check alignment of emitter and detector or change sensor. |
| SpO ₂ PR UNDER 30 | Detected pulse rate is below thirty beats per minute. | Check patient status. Check alignment of sensor. Reapply sensor. |
| SpO ₂ PR OVER 250 | Detected pulse rate is above 250 beats per minute. | Check patient status. Decrease patient motion. Reapply sensor. |
| SpO ₂ UNCALIBRATED | Detected SpO ₂ falls below calibrated range. | Check patient status. Check sensor. |
| SpO ₂ SYSTEM CHECK | Self test is being performed. | Wait for completion of self test. |
| SpO ₂ FAILURE | ROM checksum fail. RAM test fail. Filter mismatch. Offset mismatch. | Power cycle unit. If message reappears, call Service. |

The following messages pertain to NELLCOR[®] SpO₂ Operation.

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|-------------------------------|---|---|
| SpO ₂ SYSTEM CHECK | Self test is being performed. | Wait for completion of self test. |
| SpO ₂ NO SENSOR | No sensor is connected to the monitor. | Attach sensor cable to the monitor. |
| SpO ₂ PULSE SEARCH | Hardware settings are being adjusted in order to discriminate a pulse waveform. | Change to site where pulse is stronger if patient is vasoconstricted. Change or readjust sensor if loose. |
| SpO ₂ NO PULSE | No detectable pulse is measured. | |
| SpO ₂ FAILURE | ROM checksum fail. RAM test fail. Filter mismatch. Offset mismatch. | Power cycle unit. If message reappears, call Service. |

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|---|---|-------------------------------------|
| SpO ₂ DIAGNOSTICS | PASSPORT is in NELLCOR [®] Diagnostics Mode. | Wait for completion of diagnostics. |
| <ul style="list-style-type: none"> • Administration of certain vasoconstrictive drugs, i.e. norepinephrine, may reduce peripheral perfusion to a level that prevents SpO₂ measurements. • Arterial compression, tricuspid regurgitation, or irregular heart rhythms may reduce perfusion and prevent SpO₂ measurement. • Intravascular dyes, depending on concentration, may affect SpO₂ measurements. • SpO₂ measurements may be difficult on patients undergoing IABP treatments. • This monitor measures functional hemoglobin. | | |

3.11.3 Recorder Messages (only units equipped with recorder)

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|--------------------|---|-----------------------------------|
| RECORDER DOOR OPEN | The door of the recorder is not closed. | Close recorder door. |
| RECORDER PAPER OUT | The roll of recorder paper is used up. | Replace with a new roll of paper. |

3.11.4 CO₂ Messages (only units equipped with CO₂)

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|-------------------------------------|--|---|
| CO ₂ : INITIALIZING | This message usually appears at power up. The CO ₂ subsystem has been reset and is performing internal self tests prior to operation. | Wait for the message to go away. It takes about 15 seconds for the CO ₂ subsystem to initialize. |
| CO ₂ : NO SENSOR | No CO ₂ sensor is connected to the monitor. | Attach the CO ₂ sensor to the CO ₂ connector (30). |
| CO ₂ : SENSOR WARMING UP | The CO ₂ sensor has not reached its operating temperature. Either the monitor was just turned on or the sensor was recently plugged in or the sensor was removed from the adapter or calibration cells. | Wait for the message to go away. It takes up to five minutes for the sensor to warm up. |

| | | |
|--|---|---|
| CO ₂ : CHECK ADAPTER | The CO ₂ sensor is not correctly placed on the airway adapter or a different type of airway adapter has been connected or the adapter is dirty or damaged. | Check the installation and condition of the airway adapter. Clean or replace the adapter if necessary. An adapter calibration should be performed if the message persists. This is accessed through the CO ₂ menu. |
| CO ₂ : CHECK SENSOR | The CO ₂ sensor is out of calibration or damaged. | A zero calibration should be performed if the message persists. This is accessed through the CO ₂ menu. |
| CO ₂ : SENSOR ON REFERENCE CELL | The CO ₂ sensor is positioned on the reference cell. This is located on the sensor cable adjacent to the connector. The ETCO ₂ reading should range from 36 to 40 Torr when on this cell. | The sensor should be removed from the reference cell and placed back on the airway adapter. |
| CO ₂ : SENSOR ON ZERO CELL | The CO ₂ sensor is positioned on the zero cell. This is located on the sensor cable adjacent to the connector. The ETCO ₂ reading should be 0 when on this cell. | After completing the calibration, the sensor should be removed from the zero cell and placed back on the airway adapter. |
| CO ₂ : ZERO CAL IN PROGRESS | The CO ₂ sensor is placed on the zero cell and a CO ₂ calibration is in progress. | Wait for the zero calibration to complete. Zero calibration takes less than 30 seconds. |
| CO ₂ : ADAPTER CAL IN PROGRESS | A CO ₂ adapter calibration has been requested and is in progress. | Wait for the adapter calibration to complete. Adapter cal takes less than 30 seconds. |
| CO ₂ : ZERO CAL FAILURE | The zero calibration was not completed successfully. The zero calibration may have been requested when the sensor had not completed warming up. | Wait for the unit to complete warming up. Repeat the zero calibration. |
| CO ₂ : ADAPTER CAL FAILURE | The adapter calibration was not completed successfully. The adapter calibration may have been requested when the sensor had not completed warming up or the sensor was not correctly installed on the airway adapter. | Wait for the unit to complete warming up or check the installation of the sensor on the airway adapter. Repeat the adapter calibration. |

| | | |
|--|---|---|
| CO ₂ : CAL FAILED - INSERT ZERO CELL | A zero calibration was attempted while the sensor was not attached to the zero cell. | Attach the sensor to the zero cell and repeat the zero calibration. The zero cell is located on the sensor cable adjacent to the connector. |
| CO ₂ : CAL FAILED - INSERT ADAPTER | An adapter calibration was attempted while the sensor was attached to the zero or reference cell. | Remove the sensor from the zero or reference cell and attach it to the air-way adapter. Repeat the adapter cal. |
| CO ₂ : ZERO CAL COMPLETE | The zero calibration has been successfully completed. | Remove the CO ₂ sensor from the zero cell and place back on the adapter to continue monitoring. |
| CO ₂ : ADAPTER CAL COMPLETE | The adapter calibration has been successfully completed. | Normal operation. The message is removed after a few seconds. |
| CO ₂ : FAILURE | The CO ₂ subsystem has failed. | Cycle the power on the monitor to determine if the problem persists. If the message returns then the unit needs to be serviced. |

3.11.5 Monitor Operation Messages

The following messages pertain to the operation of the monitor.

| <u>Message</u> | <u>Reason</u> | <u>Solution</u> |
|----------------------------|-------------------------------|--|
| DIAGNOSTICS IN PROGRESS | Self test is being performed. | Wait for completion of self-test. See Section 3.2. |
| SELF TEST COMPLETE | Diagnostics OK. | |

3.12 MONITOR PROBLEM SOLVING

This guide is provided to establish the possible causes and solutions to some monitoring problems.

| <u>Problem</u> | <u>Reason</u> | <u>Solution</u> |
|--|---|--|
| No trace for a desired parameter | -Improper attachment of transducer to monitor. -Faulty transducer. | -Check transducer connection. -Try a different transducer. |
| Wandering ECG | -Respiration artifact. | -Try a different baseline lead configuration. |
| Noisy ECG traces | -Loose or dry electrodes. -Defective electrode wires. -Patient cable or leads are routed too close to other electrical devices. | -Apply new electrodes. -Replace wires as necessary. -Eliminate 60Hz interference. -Use ECG cable with built-in filter block. |
| Low Amplitude ECG | -Electrode could be positioned over a bone or muscle mass. | -Reposition electrodes. -Press ECG SIZE key. |
| Excessive Electrosurgical Interference | -Inadequate skin prep prior to application of electrode. | -Repeat skin prep and electrode placement procedures. -Add additional gel to electrodes. |
| AC Noise | -Gain set too high (set through SIZE key). -Electrodes dry. -Patient cable entwined with cables of other electrical devices. | -Readjust as necessary. -Re-prepare skin and apply fresh, moist electrodes. -Separate patient cable from all other cables. |
| Intermittent Signal | -Connections not tight and properly secured. -Electrodes dry. -Cable or lead wires damaged. | -Ensure proper connection. (Electrode to lead, lead to cable, cable to monitor.) -Re-prepare skin and apply fresh moist electrodes. -Check with continuity tester. |
| Excessive alarms: heart rate, lead fault | -Electrodes dry. -Alarm limits set too close to patient's normal heart rate. -R-wave wrong size. | -Re-prepare skin and apply fresh, moist electrodes. -Readjust. -Must be twice the amplitude of other part of waveform. |



| <u>Problem</u> | <u>Reason</u> | <u>Solution</u> |
|--|---|--|
| | -Excessive patient movement or muscle tremor. | -Reposition electrodes and secure with tape if necessary. |
| Low Amplitude ECG Signal | -Gain set too low. (Set through SIZE key.) -Skin improperly prepared. -Possibly not patient's normal complex. -Electrode could be positioned over a bone or muscle mass. | -Readjust as required. -Abrade skin. -Check with 12 lead electrocardiogram. -Reposition electrodes. |
| Trace Not Moving | -FREEZE key may have been pressed. | -Press the FREEZE key to unfreeze the trace. |
| Temperature Probes not Working | -Poor contact from probes to body. | Check the body surface contact at the probe tip. Reposition or apply thermo-conductive gel. |
| Display Appears to be Off | -Mains power switch may not be on. -Unit may not be plugged into an AC outlet. -If used as a portable, battery pack may be drained. | -Check mains power switch on side panel. -Check power cord (is it plugged in?). -If battery pack is drained, plug into an AC outlet to recharge the battery. A period of 16 hours is required for a full charge. |
| Disabled Alarm Tone, QRS Tone, or Other Function | -Mute key pressed. -Beep volume low. | -Check for alarm mute symbol. -Increase beep volume. |
| ECG Baseline With No Waveform | -Gain control not set high enough. Set through SIZE key. -Lead wires and patient cable not fully inserted into proper receptacle. -Cable or lead wires damaged. | -Readjust as required. -Check insertion. -Check with lead continuity tester. |
| Baseline Wander | -Patient moving excessively. -Patient's respiration. -Electrodes dry. -Static build up around patient. | -Secure lead wires and cable to patient. -Reposition electrodes. -Re-prep skin and apply fresh moist electrodes. -Check with hospital engineer. |

| <u>Problem</u> | <u>Reason</u> | <u>Solution</u> |
|---------------------------------------|--|--|
| Damped Invasive Waveform | <ul style="list-style-type: none"> -Air bubbles in tubing. -Kinked catheter. -Catheter against wall of blood vessel. -Blood in tubing. | <ul style="list-style-type: none"> -Eliminate air from tubing. -Slightly alter position of catheter. -Check for leaks at connector. -Pump pressure bag up to 300mmHg. |
| Recorder Report Appears Totally Blank | <ul style="list-style-type: none"> -Thermal paper may be installed incorrectly. (up-side down) | <ul style="list-style-type: none"> -Remove paper and re-install with paper feeding off of the spool from the bottom. |
| Resp. Waveform Too Large | <ul style="list-style-type: none"> -Scales set inappropriately. | <ul style="list-style-type: none"> -Change scale via menu. |
| Resp. Waveform Too Small | <ul style="list-style-type: none"> -Patient breathing shallow or turned on side. -Scale set inappropriately. | <ul style="list-style-type: none"> -Change lead position to better detect respirations. -Change scale. |
| False Apnea Alarm | <ul style="list-style-type: none"> -Apnea delay may be improperly set. -Patient may be having frequent episodes of CVA. -Scale size may be too low. | <ul style="list-style-type: none"> -Choose another apnea delay. -Reposition electrodes to better detect respirations. |
| "CK Lead" Message | <ul style="list-style-type: none"> -Due to increased impedance. -Chest hair under electrodes. -Dried electrode gel. -Electrode off. -Lead off. -Cracked lead wires -Poor skin prep. | <ul style="list-style-type: none"> -Prep chest. -Change electrodes. -Replace electrode. -Replace lead. -Replace lead wires. -Clean and abrade skin before applying electrodes. |
| CVA Message | <ul style="list-style-type: none"> -Can be caused by shallow breathing or an apnea event. | <ul style="list-style-type: none"> -Check the patient-adjust scales or leads if necessary. |
| No Resp. Waveform or Rate Displayed | <ul style="list-style-type: none"> -Patient not connected to a patient safety cable. -Respiration parameter is "OFF". -Patient connected using Patient ESIS Choke/Cable. | <ul style="list-style-type: none"> -Turn respiration on ("OFF" will be displayed in resp. window). Check that proper patient cable is used. -Use 3-lead Patient Cable - non ESIS. (See Accessories, section 5.1.) |



3.13 ALARMS

The Datascope PASSPORT Monitor provides high and low alarm limits for heart rate (HR), systolic pressure (BP1/NIBP Sys), diastolic pressure (BP1/NIBP Dia), mean pressure (BP2 Mean), respiration rate, ETCO₂, and SpO₂. An alarm for apnea delay is also provided.

3.13.1 Setting Parameter Alarm Limits

- Using the UP  & DOWN  (1) keys select ALARM from the menu window.

When ALARM is highlighted an ALARM MENU is displayed in the multi-function area. A sample of this alarm menu is shown in Figure 21.

- Using the UP  and DOWN  (1) and SELECT (2) keys (as described in section 3.4, Use of Menus) set parameter limits as desired.

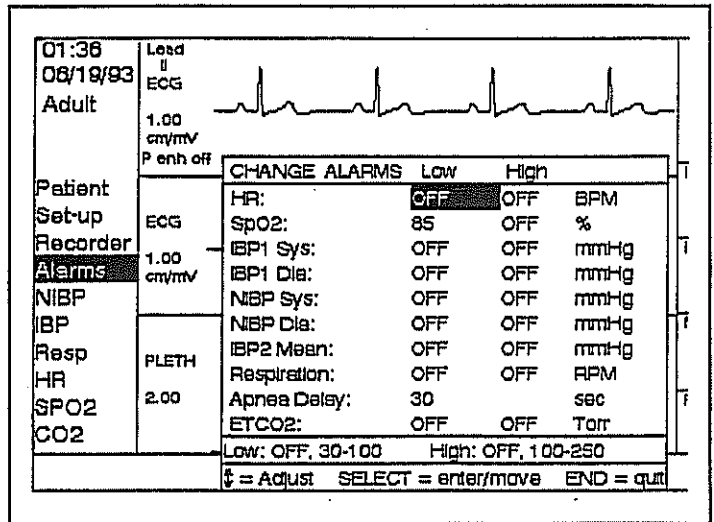


FIGURE 21 - Alarm Menu

3.13.2 Alarm Limits

All of the alarm limits have an "OFF" position with the exception of low SpO₂ and apnea in the neonate mode. A separate table of alarm limit settings are maintained for each patient size. When the patient size is changed the appropriate table is automatically used. See table below for alarm ranges.

| ALARM PARAMETERS | | | | |
|--------------------------|----------------|----------------------------------|-------------|-------------|
| Parameters | HIGH | | LO | |
| | Adult | Ped/Neonate | Adult | Ped/Neonate |
| Heart Rate (BPM) | Off, 100-250 | Off, 100-250 | Off, 30-100 | Off, 30-100 |
| IBP1 Sys (mmHg) | Off, 70-240 | Off, 40-180 | Off, 40-180 | Off, 40-180 |
| IBP1 Dia (mmHg) | Off, 40-130 | Off, 50-100 | Off, 5-90 | Off, 5-50 |
| NIBP Sys (mmHg) | Off, 70-240 | Off, 40-180* | Off, 50-150 | Off, 15-130 |
| NIBP Dia (mmHg) | Off, 40-130 | Off, 50-100 | Off, 30-120 | Off, 10-50 |
| IBP2 Mean (mmHg) | Off, 5-150 | Off, 5-100 | Off, 2-100 | Off, 2-50 |
| SpO ₂ (%) | Off, 80-100 | Off, 80-100 | 50*-99 | 50*-99 |
| Resp Rate (RPM) | Off, 30-200* ● | Off, 30-200* ● | Off, 5-50 | Off, 5-50 |
| Apnea Delay (sec) | Off, 10-40 | Off, 10-30 (Ped) / 10 - 20 (Neo) | | |
| ETCO ₂ (Torr) | Off, 20-100 | Off, 20-100 | Off, 0-60 | Off, 0-60 |

TABLE 4 - Alarm Limits

NOTE: The alarm parameters that are highlighted in grey are available only in models that are equipped with the invasive pressure option.

The ETCO₂ alarm is available only in models that are equipped with the CO₂ option.

*These alarm parameters may be set outside the accurate measurement range. Refer to the specifications, Chapter 6, for accuracy ranges.

●Respiration rate measurement range is limited to 2 - 150 RPM when CO₂ is selected as the rate source. Values above 150 RPM will be displayed as 150 RPM.

3.13.3 Alarm Violations

There are three types of alarm situations. They are Parameter Alarms, a Heart Rate Fault Alarm, and an Apnea Alarm. **NOTE:** The heart rate alarm tone has a different pitch than other alarms.

A. Parameter Alarms

An alarm condition exists if the parameter is equal to or is outside the high/low limit range. When an alarm limit is violated, the following actions occur:

- The alarm LED (12) flashes.
- The alarm tone is sounded (unless it is muted with the MUTE key (14)).
- The recorder prints the currently selected waveform (if Record On Alarm is selected from the Recorder menu).

NOTE: On the waveform printouts that are caused by alarm situations, a bar is printed above the alarming area. On trend printouts, the value that has caused an alarm is printed with square brackets around it. If the recorder is printing a waveform and an alarm situation occurs, the currently printing waveform will be completed and then the alarm waveform printout will be printed.

- The violated parameter is displayed in reverse graphics in the parameter window.

B. Heart Rate Fault Alarm

The Heart Rate Fault Alarm occurs if the selected heart rate source is no longer able to detect a heart rate. This may be due to an ECG lead fault, a problem with an SpO₂ sensor, or various other reasons. This alarm is only active if a low heart rate limit is set. The alarm operation is the same as for a parameter alarm. The heart rate value will be dashes ("----") and inverted. A further message from a lead fault or SpO₂ fault may be present to help diagnose the problem.

NOTE: Only the value displayed in the heart rate window is used to determine heart rate alarm conditions.

C. Apnea Alarm

The Apnea Alarm is active when the respiration function is enabled. The Apnea alarm is violated when a breath is not detected for a longer period of time than the apnea delay specified in the Alarm Menu. The alarm operation is the same as for a parameter alarm.

- **ALARMS OFF** - If alarms are not set on any one parameter, an alarm bell off symbol will be displayed next to the numerical data for that parameter.



Alarm Bell
Symbol

NOTE: Both the high and low alarm must be set for a particular parameter for the bell symbol to go away.

- **VOLUME KEY** - Increases or decreases the intensity of the alarm.

- **MUTE** - Pressing the MUTE key (14) silences all currently alarming parameters for 2 minutes. Any new alarms that occur while the alarm tone is muted will disable the mute and sound the alarm tone. An alarm mute symbol (a loudspeaker with an "X" through it) is displayed next to each muted parameter. The word **MUTE** is displayed above the menu selections.



All set alarms may be suspended for 2 minutes by pressing and holding the MUTE key (14) for 3 seconds. This mode is indicated by the Alarm Mute Symbol displaying in reverse graphics. The words **ALL MUTE** are displayed above the menu selections.

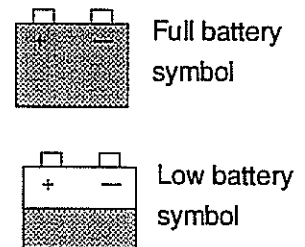
If the MUTE key is pressed and held for 4 seconds, all audio alarms are indefinitely suspended. (**NOTE:** To enable this function the "Audio Alarms Standby" option in the User Configuration must be on, see section 3.14.) This is indicated by a flashing reverse graphics loudspeaker with an "X" through it in all parameter windows. The words **Aud Alm Sby** are displayed above the menu selections and flash in reverse graphics.

The All Mute and Audio Alarms Standby functions can be exited by pressing the mute key once.

3.13.4 Battery Indicators

When the monitor is powered from the battery, a battery symbol will display.

When the battery charge is low, but not below the cutoff voltage, the low battery symbol will display and a beep is generated every 3 seconds. **NOTE:** A minimum of 15 minutes of operating time remains when the low battery symbol displays.



Battery recharge time is 16 hours.

3.14 USER CONFIGURATION MODE

The Trend Configuration, Time/Date, Temperature Scale, Heart Rate/SpO₂ Size Select, Alarm Audio Delay, Audio Alarm Standby, Serial Output Type and CO₂ settings may be set in the User Configuration Mode. This function is only available at power up and not during normal operation. The User Configuration Mode is accessed via a special power-up sequence.

To enter the User Configuration Mode:

1. Turn the POWER switch (35) ON.
2. After the "DIAGNOSTIC IN PROGRESS" message is displayed, press and hold the FREEZE key (6) until a second beep is heard (approximately 2 seconds). The User Configuration Mode will display.

The operation of the menu system is the same as the operation of the menu system during normal operation (See Section 3.4). To access normal operation when user configuration is complete, either time-out (no Set-Up key pressed within 1 minute) or press the END (3) key for 3 seconds. The following table describes the User Configuration Mode menu structure:

| USER CONFIG. ITEM | MENU ITEM | CHOICES |
|--------------------------|-----------------------|---|
| Date | Year | 0 to 99 |
| | Month | 1 to 12 |
| | Day | 1 to 31 |
| Time | Hours | 0 to 23 |
| | Minutes | 0 to 59 |
| Trend | Trigger | Interval, NIBP, Alarms, |
| | | Interval & NIBP & Alarms, |
| | | Interval & NIBP |
| | | Interval & Alarms |
| | | NIBP & Alarms* |
| | | Interval |
| Temperature | Scale | Fahrenheit, Centigrade |
| CO ₂ | Barometric Pressure | 500 to 800 mmHg |
| | CO ₂ Units | TORR, kPa, % |
| HR SpO ₂ Size | Size Change | HR Large/SpO ₂ Small*, HR Small/SpO ₂ Large |
| Alarm Audio Delay | Delay | Off*, 4, 6, 8 sec. |
| Audio Alarm Standby | Function | Off*, On |
| Serial Output Type | Protocol | VISA*, ACCUTORR, Message, DIAP |

The Trend Trigger setting is what causes new data to be stored in the trend memory. It may be set to trigger whenever there is an alarm, an NIBP measurement is performed, the trend timer expires (interval), or may be set to trigger at any combination of these items. The trend interval is only used when trend is triggering on interval, and it is used to set the time between interval triggers. The trend interval is independent of the NIBP interval.

The HR SpO₂ size change option allows the user to select a large SpO₂ reading compared to HR or vice versa.

The Alarm Audio Delay allows the user to select a pre-determined time interval whereby the audio portion only of a heart rate, SpO₂ or respiration rate alarm would be delayed. This option is useful when monitoring active patients, such as neonates.

The Audio Alarm Standby allows the user to enable (or disable) this feature (see section 3.13.3).

The Serial Output Type allows the user to select the communication protocols for interfacing with other specialized equipment: VISA*, ACCUTORR (sends data the same way as an ACCUTORR), or message (for diagnostic purposes).

Once the unit is in the User Configuration Mode, the time and/or date can be changed using the set-up keys as described in Section 3.4, "Use of Menus".


*Factory default settings.

3.15 RECORDER (optional)



The DATASCOPE PASSPORT Recorder can provide a permanent record of a patient's: systolic pressures, diastolic pressures, mean pressures, heart rate, SpO₂, CO₂, respiration and temperature. It is a two trace thermal strip chart recorder with an integral paper spool. The recorder uses plain white thermal paper 5 cm wide (see Section 4.7 for replacement instructions).

All grid patterns and data are printed by the recorder.

3.15.1 Operation of Printer

1. Using the UP  & DOWN  (1) keys select RECORDER from the main menu.

When RECORDER is highlighted a RECORDER MENU is displayed in the multi-function area. A sample of this menu is show in Figure 22.

2. Press SELECT (2) to enter the RECORDER MENU.
3. Using the UP  & DOWN  (1) and SELECT (2) keys (as described in Section 3.4, Use of Menus) set the desired waveforms or trend to be printed.
4. Press RECORD (18) to initiate a printing or stop a printing when one is in progress.

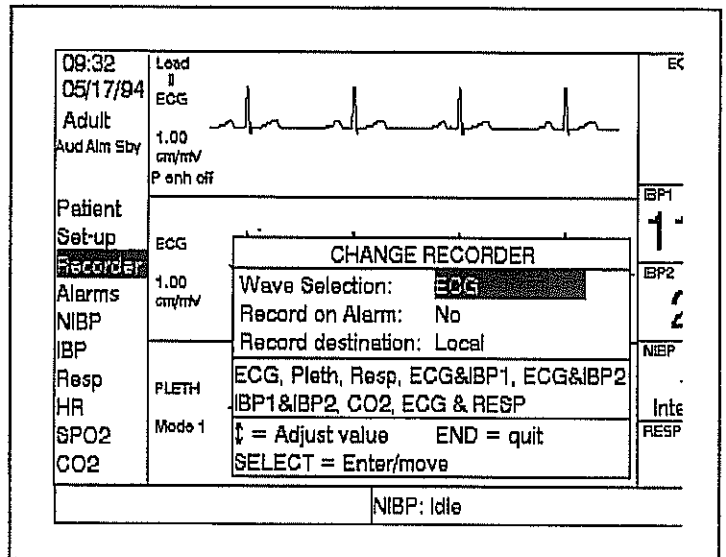


FIGURE 22 - Recorder Menu

When RECORD (18) is pressed to initiate a printing, a 16 second strip is printed. The 16 second strip consists of 8 seconds of prior and 8 seconds of post waveform from when RECORD (18) is pressed. If a continuous printing is required, press and hold RECORD (18) for 3 seconds (until a beep is heard). Press RECORD again to stop a real time printing.

Record Destination allows the user to generate a recording at the PASSPORT (local), at the VISA Central Station (remote, no recording at the PASSPORT), or at both the PASSPORT and the VISA (local and remote).

NOTES:

- When the ECG is frozen and RECORD (18) is pressed, the recorder prints the frozen displayed ECG.
- If the RECORD key (18) is pressed for 3 seconds while the ECG is frozen, the recorder prints a continuous real-time ECG waveform.
- If the RECORD key (18) is pressed while List Trend is displayed (and the ECG waveform is not frozen), the recorder prints the list trend report.
- The content of the recordings produced at the VISA Central Station is determined by the VISA, not the PASSPORT.
- See Section 4.7 of paper installation.

3.15.2 Printer Formats

Single waveform format:

ECG and pleth waveforms are automatically positioned in the center of the chart paper. Invasive pressure and respiration waveforms are relative to the lower border. The four centimeter waveform area has a grid pattern printed as follows: 100% darkness on 1 cm grid with 50% darkness on 2 mm grid.

The upper and lower borders have the date, time and physiologic parameters currently available as well as the ECG size and lead configuration the recorder is printing. All parameters include their units.

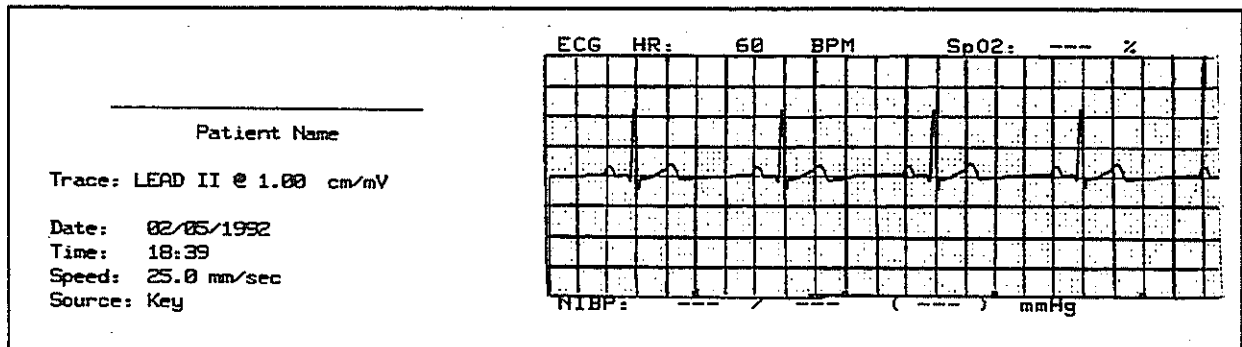


FIGURE 23 - Sample Printout, Single Waveform

Two waveforms separate field format:

The two waveforms are printed in a separate field format with two centimeters assigned to each waveform. The waveforms do not overlap. Grids are printed as for one waveform.

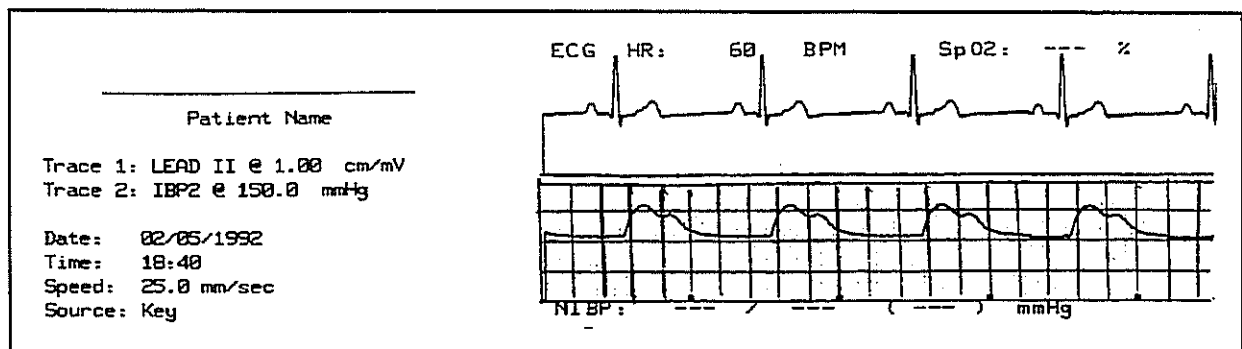


FIGURE 24 - Sample Printout, Two Waveforms

The upper and lower borders are printed as for the single waveform.

Trend list format:

The list trend data is printed with text running along the length of the strip. If more than one page of data is available then all additional pages are printed along the length of the strip.

| | Time | HR BPM | SpO2 % | NIBP s / d (m) mmHg | Resp |
|------------------------------|-------|-----------|-----------|--------------------------|------|
| Patient Name | 18:47 | 80 | 100 | — / — (—) | OFF |
| Date: 02/05/1992 Time: 18:47 | 18:46 | [60] | 100 | — / — (—) | OFF |
| ECG HR: 80 BPM SpO2: 100 % | 18:46 | 73 | 100 | — / — (—) | OFF |
| Resp: OFF Temp: — ° C | 18:45 | 60 | — | — / — (—) | OFF |
| IBP1: 119 / 79 (95) mmHg | 18:44 | 60 | — | — / — (—) | OFF |
| IBP2: 119 / 79 (95) mmHg | 18:43 | 60 | — | — / — (—) | OFF |
| NIBP: — / — (—) mmHg | 18:43 | [60] | — | — / — (—) | OFF |
| Interval: OFF ET: min | 18:38 | 45 | — | — / — (—) | OFF |

FIGURE 25 - Sample Printout, Trend List Format

NOTE: On waveform printouts that are caused by alarm situations (Record on Alarm must be selected YES in the Recorder menu), a bar is printed above the alarming area. On trend printouts and in annotations, the value that has caused an alarm is printed with square brackets around it. If the recorder is printing a waveform and an alarm situation occurs, the currently printing waveform will be completed and then the alarm waveform printout will be printed.

NOTE: IBP1 and IBP2 data is printed only when models are equipped with the invasive pressure option.

3.16 SEQUENCE FOR ESTABLISHING SpO₂ WITH NELLCOR[®] PULSE OXIMETRY

1. Select the appropriate sensor for the patient (see Table 5, page 3-49).
2. Plug the sensor directly into the SpO₂ connector located on the side panel of the monitor or if necessary, use a NELLCOR[®] EC-4 or EC-8 sensor extension cable.
NOTE: Do not place the sensor on an extremity with an invasive catheter or blood pressure cuff in place.

WARNING: When equipped with NELLCOR[®] SpO₂, use only NELLCOR[®] oxygen transducers including NELLCOR[®] OXISENSOR[™] patient dedicated adhesive sensors. Use of other oxygen transducers may cause improper oximeter performance.

WARNING: Tissue damage or inaccurate measurements may be caused by incorrect sensor application or use, such as wrapping it too tightly, applying supplemental tape, failing to inspect the sensor site periodically, or failing to position it appropriately. Carefully read the sensor directions for use, the PASSPORT operating instructions, and all precautionary information before use.

WARNING: Excessive ambient light may cause inaccurate measurements. Cover the sensor site with opaque material.

WARNING: Inaccurate measurements may be caused by incorrect sensor application or use; significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin); or intravascular dyes such as indocyanine green methylene blue; exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight; excessive patient movement; venous pulsations; electro-surgical interference; and placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.

3. The digital SpO₂ value will be displayed in the Parameter Window.
4. If a pleth waveform is desired, enter the set-up menu as described in Section 3.4, Use of Menus, to display it as Waveform 2.
5. Press the BEEP VOLUME (17) to set the volume of the SpO₂ beep.

NOTE: NELLCOR[®], OXIBAND[®] and DURASENSOR[®] are registered trademarks of NELLCOR[®] Incorporated.

OXISENSOR[™] and DURAFORM[™] are trademarks of NELLCOR Incorporated.

3.16.1 NELLCOR[®] Sensors

NELLCOR[®] provides a family of sensors suitable for a wide variety of clinical settings and patients. Specific sensors have been developed for neonates, infants, children, and adults. OXISENSOR[™] oxygen transducers are sterile adhesive sensors with optical components mounted on adhesive tape. OXIBAND[®] oxygen transducers and the DURAFORM[™] oxygen transducer system are reusable sensors that are applied with disposable adhesive. The DURASENSOR[®] DS-100A adult digit oxygen transducer is a reusable sensor with its optical components mounted in a plastic casing. The NELLCOR[®] RS-10 reflectance oxygen transducer is an adhesive sensor for application to forehead or temple.

SELECTING A SENSOR

Sensors are designed for specific sites on patients with designated weight ranges. To select the appropriate sensor, consider the patient's weight, level of activity, adequacy of perfusion, which sensor sites are available, whether sterility is required, and the anticipated duration of monitoring.

CLEANING AND RE-USE

Do not immerse any OXISENSOR[™], DURASENSOR[®], OXIBAND[®], or DURAFORM[™] oxygen transducer, the NELLCOR[®] RS-10 oxygen transducer, or any NELLCOR[®] adhesive in water or cleaning solution. Clean DURASENSOR[®], OXIBAND[®], and DURAFORM[™] oxygen transducers, and the NELLCOR[®] RS-10 oxygen transducer by wiping with a disinfectant such as 70% alcohol. Do not sterilize by irradiation, steam, or ethylene oxide. Use a new OXIBAND[®] adhesive wrap or FORM-A adhesive bandage for each patient. Do not re-sterilize OXISENSOR[™] oxygen transducers.

PERFORMANCE CONSIDERATIONS

To ensure optimal performance, use an appropriate sensor, apply it as directed, and observe all warnings and cautions.

If excessive ambient light is present, cover the sensor site with opaque material. Failure to do so may result in inaccurate measurements. Light sources that can affect performance include surgical lights, especially those with a xenon light source, bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight.

If poor perfusion affects instrument performance, and the patient weighs more than 50 kg (110 lbs.), consider using the OXISENSOR[™] R-15 adult nasal oxygen transducer. Because the R-15 obtains its measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid, this sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the NELLCOR[®] RS-10 reflectance oxygen transducer, which is applied to the forehead or temple.

If patient movement presents a problem:

- Verify that the sensor is properly and securely applied.
- Use a new sensor with fresh adhesive backing.
- Move the sensor to a less active site.
- Use a type of sensor that tolerates some patient motion, such as the OXISENSOR™ D-25, D-20, N-25, or I20 oxygen transducer.

| NELLCOR SENSOR FAMILY | | | | | | |
|-----------------------|---|---|--------------------------------------|--|---|-------------------------------------|
| SELECTION GUIDE | D25/D25L Adult | R-15 Adult | N-25 Neonatal | I-20 Infant | D-20 Pediatric | RS-10 Adult |
| Patient Size | >30 kg | >50 kg | <3 kg >40 kg | 1-20 kg | 10-50 kg | >40 kg |
| Duration of Use | Short or Long Term | Short or Long Term | Short or Long Term | Short or Long Term | Short or Long Term | Short Term |
| Sterility | Sterile ¹ | Sterile ¹ | Sterile ¹ | Sterile ¹ | Sterile ¹ | Non-sterile |
| Patient Activity | Limited Activity | Inactive | Limited Activity | Limited Activity | Limited Activity | Limited Activity |
| | OXISENSOR adult digit oxygen transducer | OXISENSOR adult nasal oxygen transducer | OXISENSOR neonatal oxygen transducer | OXISENSOR infant digit oxygen transducer | OXISENSOR pediatric digit oxygen transducer | RS-10 reflectance oxygen transducer |

TABLE 5 - NELLCOR Sensor Selections

¹In an unopened, undamaged package.

All NELLCOR® accessories and sensors must be purchased from NELLCOR® Inc., 25495 Whitehall Street, Hayward, Ca. 94545. To contact NELLCOR, call 1-800-NELLCOR.

3.16.2 Special Features

Automatic Calibration

The oximetry subsystem incorporates automatic calibration mechanisms. It is automatically calibrated each time it is turned on, at periodic intervals thereafter, and whenever a new sensor is connected. Also, the intensity of the sensor's LEDs is adjusted automatically to compensate for differences in tissue thickness.

Each sensor is calibrated when manufactured; the effective mean wavelength of the red LED is determined and encoded into a calibration resistor in the sensor plug. The instrument's software reads this calibration resistor to determine the appropriate calibration coefficients for the measurements obtained by that sensor.

Oximetry Operating Modes

The PASSPORT's three operating modes for SpO₂ enable it to make accurate measurements despite differing levels of patient activity. In all three modes, the PASSPORT updates its measurements with every pulse beat. Data from the most recent beat replaces data from the earliest beat and new averages are determined and displayed. The three modes are: 1 (default setting), 2, and 3.

1: the default operating mode, uses a 5 to 7 second averaging time and is useful in situations in which the patient is relatively inactive.

2: this mode uses a 2 to 3 second averaging time and therefore is more affected by patient motion. It is useful for special applications that require a fast response time, such as sleep studies.

3: this mode uses a 10 to 15 second averaging time and consequently is least affected by patient motion. In this mode, pulse rate is not displayed and there is no pulse tone.

Pleth Auto Scaling

The Pleth waveform is automatically scaled when using NELLCOR[®] SpO₂. There is no adjustment that can be made to the pleth waveform size.

Changing Operating Modes

To change from 1 to 2 or 3, select SpO₂ in the menu and toggle through the choices of 1, 2, and 3 using the up and down arrow keys. Press SELECT (2) then END (3) to lock the choice in and return to monitoring mode. See section 3.4 "Use of Menus" for details on using menus.

The operating mode will be displayed in the pleth waveform window.

3.17 CONNECTION TO EXTERNAL DEVICES

The PASSPORT provides a high level ECG waveform output from the J1 connector (34). The output specifications are listed in section 6.1. To facilitate connection of the PASSPORT to external devices requiring an ECG waveform for synchronization, Datascope provides two interface cables. They are:

- The 0012-00-0753-01 cable which is terminated with a Hewlett Packard (HP) 8 pin round connector, commonly used for ECG input on HP defibrillators.
and
- The 0012-00-0732 cable which is terminated with a standard AAMI 6 pin round connector, commonly found on many defibrillators and intra-aortic balloon pumps.

These cables attenuate the high level ECG waveform output from the PASSPORT monitor to a low level output and are intended to provide a means to synchronize compatible external devices with an ECG signal. Examples of such devices include defibrillators for cardioversion synchronization and intra-aortic balloon pumps for inflation timing.

PRECAUTION: It is the users responsibility to confirm correct operation of the PASSPORT with external devices. Before using these cables it is essential that a biomedical engineer verify correct operation of the PASSPORT with an external device using these cables. Testing should include verification that the maximum delay for cardioversion synchronization does not exceed 60m Sec (monitor and defibrillator). Cables should be labeled with the devices they have been tested for use with.



4.0 USER MAINTENANCE

4.1 INTRODUCTION

This section of the manual outlines routine maintenance that should be performed by the user.

The PASSPORT Monitor is designed for stable operation over long periods of time and under normal circumstances should not require technical maintenance beyond that described in this section. However, it is recommended that routine maintenance calibration and safety checks be performed at least once a year, or more often as required by local statutory or hospital administration practice.

4.2 CARE AND CLEANING OF MONITOR

The monitor enclosure may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the monitor. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

WARNING: Do not clean monitor while it is on and/or plugged in.

To prevent scratches on the front panel display screens, blow or carefully brush dust and dirt particles with a soft sponge moistened with cleaner solution; or a fine, soft-haired brush. DO NOT use abrasive cleaning materials. Fingerprints and stains may be removed by using a liquid lens cleaner and a soft cloth. DO NOT wipe a dry screen or use alcohol or chlorinated hydrocarbon solvents.

4.3 CARE AND CLEANING OF DATASCOPE FLEXISENSORS and DATASENSORS

NOTE: If your unit is equipped with NELLCOR SpO₂, refer to the individual instruction sheets that are packaged with each sensor.

- Daily, check the sensors and cables for signs of damage. Replace as required.
- Check for the proper sensor connection to the pulse oximeter.
- Check for proper operation of the spring mechanism on the DATASENSOR.
- Disconnect the sensor from the pulse oximeter.
- The sensors should be cleaned before and after each patient's use.
- Clean and disinfect the sensors. Wipe the patient contact area with a soft cloth and mild soap and water solution or isopropyl alcohol. Hydrogen peroxide can be used to remove dried blood on all accessible surfaces.
- Let the sensor completely dry before using.

PRECAUTION: When cleaning sensors do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with the cleaning solution.

4.4 STERILIZATION OF SENSORS

The DATASENSOR can be sterilized by using 12% ETO/88% Freon 12 at a humidification level of 80% RH and a temperature level of 130 F max. Refer to the Operator's Manual of the actual sterilization unit used for the correct sterilization procedure.

4.5 BATTERY REPLACEMENT AND MAINTENANCE

Battery Replacement:

1. Open battery compartment door, on left side of unit, by sliding the tab down.
2. Press the release button, located above the battery, to eject the battery. Slide out old battery.
3. Slide in replacement battery until it clicks into place.
4. Close battery compartment door.

Battery Maintenance:

Due to the self-discharge characteristics of this type of battery, it is imperative that it is charged after 6 to 9 months of storage (or unit not in use). If not, permanent loss of capacity may occur as a result of sulfation. Charge retention at 20°C is 6 months to 83%.

The batteries used in the PASSPORT Monitor are of sealed lead acid construction. This battery type may be subject to local regulations regarding disposal. At the end of the battery life, dispose of the batteries in accordance with any local regulations.

4.6 STERILIZATION OF DISPOSABLE CUFFS

Disposable cuffs may be sterilized if desired. Use ETO sterilization procedures.

4.7 RECORDER PAPER REPLACEMENT

Instructions are provided below to describe the periodic replacement of chart paper. Use only recommended chart paper, Part Number 0083-00-0422 to ensure that the print quality will be acceptably dark and reduces print head wear.

1. Open recorder door by pressing the paper eject button (upper right corner with paper roll icon on it).

NOTE: If the recorder's door does not open completely, carefully pull it until it is completely open.

2. Remove empty paper spool by pulling it out gently.
3. Insert new paper roll between the two rounded tabs of the paper holder with the sensitive (shiny) side of the paper facing the print head at the top of the recorder (paper feeding off of the spool from the bottom).
4. Unroll approximately 4 inches of paper.
5. Align the paper across the top of the metal bar.
6. Holding the paper in place, close recorder door.
7. To ensure that the paper is aligned properly and has not been pinched in the door, pull the loose edge out a couple of inches. If the paper jams, open the door and return to step 5.

4.8 CLEANING CO₂ SENSORS AND ADAPTERS

CO₂ Sensor:

The Sensor, Calibrator and Cable Assembly can be damp wiped with soapy water, Cidex, Sproiciden, 70% isopropyl alcohol or a 10% bleach solution. It should then be wiped dry with a soft cloth. Immersion into any liquid bath is not recommended. ETO and steam autoclaving is not recommended.

Adult and Neonate Reusable Adapters:

These adapters can be disinfected by soaking in any of the above mentioned solutions. In addition, they can be ETO and steam autoclave sterilized following the sterilizer manufactures' recommended procedures.

5.0 ACCESSORIES

5.1 STANDARD ACCESSORIES

Description

Part Numbers

Domestic Kit (LCD units)

0020-00-0068-01

Power Pack AC/DC (120Vac)

0014-00-0027-02

Operating Instructions

0070-00-0236

Service Manual

0070-00-0237

3 Lead Patient Cable (domestic - non-ESIS)

0012-00-0620-05

Lead Wires

0012-00-0622-01

NIBP Cuff 12cm Diameter (adult)

0998-00-0003-24

NIBP Hose, 1.5M

0683-00-0189-81

NIBP Hose, 3.5M

0683-00-0189-80

Recorder Paper (1 roll)

0683-00-0422-01

AC Line Cord

0012-25-0001

Battery (2)

0146-00-0043

Passport Video

0061-00-0588

Domestic Kit (EL units)

0020-00-0068-21

Power Pack AC/DC (120Vac)

0014-00-0027-22

Operating Instructions

0070-00-0236

Service Manual

0070-00-0237

3 Lead Patient Cable (domestic - non-ESIS)

0012-00-0620-05

Lead Wires

0012-00-0622-01

NIBP Cuff 12cm Diameter (adult)

0998-00-0003-24

NIBP Hose, 1.5M

0683-00-0189-81

NIBP Hose, 3.5M

0683-00-0189-80

Recorder Paper (1 roll)

0683-00-0422-01

AC Line Cord

0012-25-0001

Battery (2)

0146-00-0043

Passport Video

0061-00-0588

Domestic Kit (EL/CO₂ 120V units)

0020-00-0068-41

Power Pack AC/DC (120Vac)

0014-00-0027-22

Operating Instructions

0070-00-0236

Service Manual

0070-00-0237

3 Lead Patient Cable (domestic - non-ESIS)

0012-00-0620-05

Lead Wires

0012-00-0622-01

NIBP Cuff 12cm Diameter (adult)

0998-00-0003-24

NIBP Hose, 1.5M

0683-00-0189-81

NIBP Hose, 3.5M

0683-00-0189-80

Recorder Paper (1 roll)

0683-00-0422-01

AC Line Cord

0012-25-0001

Battery (2)

0146-00-0043

CO₂ Sensor Kit

0600-00-0025

Passport Video

0061-00-0588

Britain/Ireland**0020-00-0068-02**

Power Pack AC/DC (240 V UK/BSI) 0014-00-0027-04
Operating Instructions(English) 0070-00-0236
Service Manual(English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (UK/Ireland) 0012-25-0003

Britain/Ireland (EL Units)**0020-00-0068-22**

Power Pack AC/DC (240 V UK/EL) 0014-00-0027-24
Operating Instructions(English) 0070-00-0236
Service Manual(English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (UK/Ireland) 0012-25-0003

Britain/Ireland (EL/CO₂ 240V Units)**0020-00-0068-42**

Power Pack AC/DC (240 V UK/EL) 0014-00-0027-24
Operating Instructions(English) 0070-00-0236
Service Manual(English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (UK/Ireland) 0012-25-0003
CO₂ Sensor Kit 0600-00-0025

Scandinavia/Netherlands**0020-00-0068-03**

Power Pack AC/DC (220 V German/TUV) 0014-00-0027-03
Operating Instructions (English) 0070-00-0236
Service Manual (English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (Cont. Europe) 0012-25-0002

Scandinavia/Netherlands (EL 220V Units)**0020-00-0068-23**

Power Pack AC/DC (220 V German/EL) 0014-00-0027-23
Operating Instructions (English) 0070-00-0236
Service Manual (English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (Cont. Europe) 0012-25-0002

Scandinavia/Netherlands (EL/CO₂ 220V Units)**0020-00-0068-43**

Power Pack AC/DC (220 V German/EL) 0014-00-0027-23
Operating Instructions (English) 0070-00-0236
Service Manual (English) 0070-00-0237
3 Lead Patient Cable (Int'l) 0012-00-0620-07
Lead Wires 0012-00-0622-03

NIBP Cuff 12cm Diameter (adult) 0998-00-0003-24
NIBP Hose, 1.5M 0683-00-0189-81
NIBP Hose, 3.5M 0683-00-0189-80
Battery (2) 0146-00-0043
Chart Paper 0683-00-0422-01
Line Cord (Cont. Europe) 0012-25-0002
CO₂ Sensor Kit 0600-00-0025

Mexico (EL units)**0020-00-0068-28**

| | |
|--|-----------------|
| Power Pack AC/DC (120Vac) | 0014-00-0027-22 |
| Operating Instructions (Spanish) | 0070-00-0269 |
| Service Manual (English) | 0070-00-0237 |
| 3 Lead Patient Cable (domestic - non-ESIS) | 0012-00-0620-05 |
| Lead Wires | 0012-00-0622-01 |
| NIBP Cuff 12cm Diameter (adult) | 0998-00-0003-24 |
| NIBP Hose, 1.5M | 0683-00-0189-81 |
| NIBP Hose, 3.5M | 0683-00-0189-80 |
| Recorder Paper (1 roll) | 0683-00-0422-01 |
| AC Line Cord | 0012-25-0001 |
| Battery (2) | 0146-00-0043 |

Mexico (EL/CO₂ 120V units)**0020-00-0068-48**

| | |
|--|-----------------|
| Power Pack AC/DC (120Vac) | 0014-00-0027-22 |
| Operating Instructions (Spanish) | 0070-00-0269 |
| Service Manual (English) | 0070-00-0237 |
| 3 Lead Patient Cable (domestic - non-ESIS) | 0012-00-0620-05 |
| Lead Wires | 0012-00-0622-01 |
| NIBP Cuff 12cm Diameter (adult) | 0998-00-0003-24 |
| NIBP Hose, 1.5M | 0683-00-0189-81 |
| NIBP Hose, 3.5M | 0683-00-0189-80 |
| Recorder Paper (1 roll) | 0683-00-0422-01 |
| AC Line Cord | 0012-25-0001 |
| Battery (2) | 0146-00-0043 |
| CO ₂ Sensor Kit | 0600-00-0025 |
| Passport Video | 0061-00-0588 |

Spanish (EL 220V Units)**0020-00-0068-27**

| | |
|--|-----------------|
| Power Pack AC/DC (220 V German/TUV) | 0014-00-0027-23 |
| Operating Instructions (Spanish) | 0070-00-0269 |
| Service Manual (English) | 0070-00-0237 |
| 3 Lead Patient Cable (Domestic - non-ESIS) | 0012-00-0620-05 |
| Lead Wires | 0012-00-0622-01 |
| NIBP Cuff 12cm Diameter (adult) | 0998-00-0003-01 |
| NIBP Hose, 1.5M | 0683-00-0189-81 |
| NIBP Hose, 3.5M | 0683-00-0189-80 |
| Battery (2) | 0146-00-0043 |
| Chart Paper | 0683-00-0422-01 |
| Line Cord (Cont. Europe) | 0012-25-0002 |

Spanish (EL/CO₂ 220V Units)**0020-00-0068-47**

| | |
|--|-----------------|
| Power Pack AC/DC (220 V German/TUV) | 0014-00-0027-23 |
| Operating Instructions (Spanish) | 0070-00-0269 |
| Service Manual (English) | 0070-00-0237 |
| 3 Lead Patient Cable (Domestic - non-ESIS) | 0012-00-0620-05 |
| Lead Wires | 0012-00-0622-01 |
| | |
| NIBP Cuff 12cm Diameter (adult) | 0998-00-0003-01 |
| NIBP Hose, 1.5M | 0683-00-0189-81 |
| NIBP Hose, 3.5M | 0683-00-0189-80 |
| Battery (2) | 0146-00-0043 |
| Chart Paper | 0683-00-0422-01 |
| Line Cord (Cont. Europe) | 0012-25-0002 |
| CO ₂ Sensor Kit | 0600-00-0025 |

5.2 OPTIONAL ACCESSORIES

Description

Part Number

5.2.1 NIBP Accessories

Hoses

| | |
|-------------------------------|-----------------|
| ACCUTORR Hose, 1.5 m | 0683-00-0189-81 |
| ACCUTORR Hose, 3.5 m | 0683-00-0189-80 |
| ACCUTORR hose, neonatal 1.5 m | 0683-04-0001 |
| ACCUTORR hose, neonatal 3.5 m | 0683-04-0002 |
| Accessory Pouch | 0202-03-0001 |

Reusable Cuffs

Arm Pressure Cuff:

| | |
|--------------------------------------|-----------------|
| Adult (24 - 36 cm arm circumference) | 0998-00-0003-01 |
| Large Adult (30 - 45 cm...) | 0998-00-0003-02 |
| Child (18 - 27 cm...) | 0998-00-0003-03 |
| Small Child (16 - 25 cm...) | 0998-00-0003-04 |
| Infant (11 - 19 cm...) | 0998-00-0003-06 |
| Newborn (6 - 11 cm...) | 0998-00-0003-07 |

| | |
|--|-----------------|
| Thigh Pressure Cuff, Adult (45-65cm thigh circumference) | 0998-00-0003-05 |
|--|-----------------|

Color Coded Reusable Cuffs*

| | |
|---|-----------------|
| Adult, Tan (24 - 36 cm arm circumference) | 0998-00-0003-24 |
| Large Adult, Grey (30 - 47 cm...) | 0998-00-0003-25 |
| Child, Red (18 - 27 cm...) | 0998-00-0003-23 |
| Infant, Green (10 - 19 cm...) | 0998-00-0003-22 |
| New Born, Blue (6 - 11 cm...) | 0998-00-0003-21 |
| Adult Thigh, Brown(45 - 66 cm...) | 0998-00-0003-26 |

Disposable Cuffs (box of 10)

Arm Pressure Cuff:

| | |
|--------------------------------------|-----------------|
| Adult (24 - 32 cm arm circumference) | 0683-07-0002-01 |
| Large Adult (32 - 42 cm...) | 0683-07-0001-01 |
| Child (17 - 25 cm...) | 0683-07-0003-01 |

Disposable Neonatal Cuffs (box of 10)

Approximate Limb Circumference:

| | |
|--------------------|-----------------|
| Size 0: 5 - 8 cm | 0683-03-0004-01 |
| Size 1: 7 - 10 cm | 0683-03-0001-01 |
| Size 2: 9 - 13 cm | 0683-03-0002-01 |
| Size 3: 12 - 17 cm | 0683-03-0003-01 |

*The limb circumferences of the Color Coded Cuffs adhere to the AHA guidelines for size.

5.2.2 SpO₂ Accessories

| Description | Part Number |
|---|-----------------|
| DIGISENSOR reusable adult finger sensor | 0998-00-0088-02 |
| DATASENSOR w/ 3' cable | 0600-00-0026-01 |
| DATASENSOR w/ 12' cable | 0600-00-0026-02 |
| DATASENSOR Starter Kit | 0020-00-0071-01 |

FLEXISENSOR S.D. Series Starter Kits

Each starter kit includes one instrument cable, one FLEXISENSOR SD sensor and (with exception of Adult Ear sensor) one package of SENSOR GUARD bandages .

| | |
|------------------|--------------|
| Large Adult (LA) | 0998-00-0094 |
| Adult (A) | 0998-00-0093 |
| Pediatric (P) | 0998-00-0092 |
| Infant (I) | 0998-00-0083 |
| Neonate (N) | 0998-00-0090 |
| Adult Ear (AE)* | 0998-00-0091 |

Replacement FLEXISENSOR SD 3 Packs: - 3 sensors of the same size.

| | |
|------------------|-----------------|
| Large Adult (LA) | 0998-00-0076-06 |
| Adult (A) | 0998-00-0076-05 |
| Pediatric (P) | 0998-00-0076-04 |
| Infant (I) | 0998-00-0074-03 |
| Neonate (N) | 0998-00-0074-04 |
| Adult Ear (AE) | 0998-00-0074-05 |
| Ear Clip | 0380-00-0169 |

Replacement SENSOR GUARD or LIGHT GUARD Bandages - 72 in each package

| | |
|------------------------------|-----------------|
| Large Adult (LA) | 0683-00-0409-01 |
| Adult (A) | 0683-00-0409-02 |
| Pediatric (P) | 0683-00-0409-03 |
| Infant (I) (36 bandages) | 0683-00-0415 |
| Neonate (N) (LIGHT GUARD) | 0683-00-0440-03 |
| Replacement Instrument Cable | 0012-00-0516-02 |
| FLEXISENSOR SD Organizer | 0683-00-0421 |

5.2.3 CO2 Accessories

| Description | Part Number |
|-------------------------------------|--------------|
| CO ₂ Sensor Kit | 0600-00-0025 |
| Adult Airway Adapter | 0103-15-0003 |
| Neonate Airway Adapter | 0103-15-0013 |
| Adult Airway Adapter (package of 5) | 0103-15-0001 |

5.2.4 Temperature Probes

| | |
|-------------------------------|--------------|
| YSI 700: | |
| Adult Rectal / Esophageal | 0206-00-0701 |
| Pediatric Rectal / Esophageal | 0206-00-0702 |
| Skin Surface | 0206-02-0003 |

5.2.5 Pressure Transducers

| | |
|-------------|--------------|
| Gould P-50 | 0682-00-0032 |
| Gould P231D | 0682-00-0040 |

5.2.6 Power Packs

| | |
|---------------------------------|-----------------|
| Power Pack AC/DC (120Vac) (LCD) | 0014-00-0027-02 |
| Power Pack AC/DC (120Vac) (EL) | 0014-00-0027-22 |

5.2.7 ECG Accessories

| | |
|--|-----------------|
| Patient Cable 3-lead (Domestic 10') | 0012-00-0620-05 |
| Skin Electrodes - case of 300 disposable electrodes | 0681-00-0070-02 |
| Pediatric ECG Electrodes - box of 25 pouches, 3 electrodes per pouch (including lead wires) | 0681-00-0082-01 |
| Package of Lead Wires | 0012-00-0622-05 |
| Limb Electrode Leads - package of 3 | 0012-00-0622-01 |
| Limb Electrode and Strap | 0681-00-0016 |
| Precordial Suction Electrode | 0681-00-0017 |
| Patient Cable 3-Lead (International 10') | 0012-00-0620-07 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors and Choke Block (Domestic 10') | 0012-00-0722-05 |

| Description | Part Number |
|--|--------------------|
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors and Choke Block (Domestic 20') | 0012-00-0722-06 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors and Choke Block (International 10') | 0012-00-0722-07 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors and Choke Block (International 20') | 0012-00-0722-08 |
| Patient Cable 3-Lead, w/ Internal Resistors and Choke Block (Domestic 10') | 0012-00-0723-05 |
| Patient Cable 3-Lead, w/ Internal Resistors and Choke Block (Domestic 20') | 0012-00-0723-06 |
| Patient Cable 3-Lead, w/ Internal Resistors and Choke Block (International 10') | 0012-00-0723-07 |
| Patient Cable 3-Lead, Internal Resistors and Choke Block (International 20') | 0012-00-0723-08 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors (Domestic 10') | 0012-00-0724-05 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors (Domestic 20') | 0012-00-0724-06 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors (International 10') | 0012-00-0724-07 |
| Patient Cable 3-Lead, Right Angle, w/ Internal Resistors (International 20') | 0012-00-0724-08 |

5.2.8 Mounting Accessories

| | |
|-------------------------|-----------------|
| Wall Mount Kit | 0040-00-0121-03 |
| Bed Mount Kit | 0040-00-0121-04 |
| Rolling Pole Stand Kit | 0040-00-0121-02 |
| Bed Rail Hook Mount | 0020-00-0070 |
| Ohmeda Mounting Bracket | 0406-00-0663 |

5.2.9 Miscellaneous Accessories

| | |
|---|-----------------|
| Recorder Upgrade Kit | 0040-00-0114 |
| Chart Paper (10 rolls) | 0683-00-0422-02 |
| Battery Pack (1) | 0146-00-0043 |
| PASSPORT Carry Bag | 0202-00-0095 |
| 6-Pin AAMI Defib. Cable, w/ Internal 1000 to 1 attenuator | 0012-00-0732 |
| 8-Pin HP Defib. Cable, w/ Internal 1000 to 1 attenuator | 0012-00-0753-01 |
| CO ₂ Upgrade Kit | 0040-00-0144 |
| Corometrics Fetal Monitor 116 Interface Kit | 0020-00-0078 |
| EL Display Upgrade Kit (Service Installed) | 0040-00-0132 |

6.0 APPENDIX

6.1 PERFORMANCE SPECIFICATIONS

- **ECG**

| | |
|-------------------------------|---|
| Leads: | I,II,III |
| Gain: | 0.25, 0.5, 1.0, 2.0, 3.0, 4.0 cm/mV |
| Frequency Response to Screen: | 0.5-20 Hz (with filter in) 0.5-30 Hz (with filter out) to diagnostic ECG output with pace circuit disabled 0.5-40 Hz |
| CMRR: | 100 dB min, at 50/60 Hz with 5K imbalance and zero DC offset. |
| Defibrillator Protection: | Fully protected against 500 Joule charge |
| Recovery Time: | 2 sec. maximum |

- **IBP**

| | |
|--------------------------------|--|
| Range to Digital Display: | Systolic/Diastolic/Mean -20 to +300 mmHg |
| Accuracy: | 2 mmHg or 2%, whichever is greater |
| Scales to Display: | 0 to +37.5 mmHg 0 to +150 mmHg 0 to +75.0 mmHg 0 to +300 mmHg |
| Zero Range: | 120 mmHg |
| Calibration Input Sensitivity: | 5uV/V/mmHg |
| Frequency Response: | DC to 15 Hz, +/-2 Hz (+0/-3db) |

- **HEART RATE METER**

| | |
|------------------|---|
| Range: | 30-220 bpm Adult/Child 30-250 bpm Neonatal |
| Accuracy: | 3 bpm or 3%, whichever is greater |
| Pacer Rejection: | Rejects all pulses of amplitude $\pm 2.0\text{mV}$ to $\pm 700\text{ mV}$ and duration 0.1ms to 2 ms with no tail. Rejects all pulses $\pm 2.0\text{mV}$ to $\pm 700\text{mV}$ and duration 0.1ms to 2 ms with 100ms T.C. tail < 0.8mV or 25 ms T.C. tail < 0.4mV. |

- **NON-INVASIVE BP**

| | |
|-----------------|---|
| Technique: | Oscillometric |
| Systolic Range: | Adult/Ped mode: 50 to 250 mmHg Neonatal mode: 15 to 150 mmHg |

Diastolic Range: Adult/Ped mode: 30 to 200 mmHg
Neonatal mode: 10 to 150 mmHg

Accuracy: Mean error less than 5 mmHg, standard deviation less than 8 mmHg (complies with voluntary Standard ANSI/AAMI SP10-1987 paragraph 3.4.2 "Overall System Efficacy")
Mean error less than 4 mmHg, standard deviation less than 7 mmHg (neonatal)

Heart Rate Meter Range: 30-250 bpm

Heart Rate Meter Accuracy: 3 bpm or 3%, whichever is greater

• **PULSE OXIMETRY (SpO₂)**

Accuracy: 70-100%, <+/-2% SpO₂ (1 S.D.)
60-69%, <+/-4% SpO₂ (1 S.D.)
0-59% Unspecified

Response Time: 8 seconds to 95% of final step change of % SpO₂ value from 60-95% (at 72 bpm)

• **PULSE OXIMETRY (with NELLCOR[®] SpO₂)**

Saturation Accuracy: Nellcor[®] determines module accuracy by comparisons with NELLCOR[®] N-100 and N-200 pulse oximeters, using NELLCOR[®] OXISENSOR[™] OXIBAND[®], and DURASENSOR[®] oxygen transducers only. For accuracy specifications when used with each of the above sensors, refer to the sensor's labeling and instructions. Accuracy, when used with the OXISENSOR[™] D-25 and N-25 sensors, is as follows:

| Sensor | Patient | Range | Accuracy |
|--------|---------|------------|-------------|
| D-25 | Adult | 70 to 100% | ±2 digits |
| D-25 | Adult | 50 to 69% | ±3 digits |
| D-25 | Adult | 0 to 49% | unspecified |
| N-25 | Neonate | 70 to 95% | ±3 digits |

• **PLETHYSMOGRAPH**

Display Range: 30-230 bpm Adult/Child
30-250 bpm Neonate

Pulse Rate Accuracy: 3 bpm or 3%, whichever is greater

Response Time: 8 seconds to 95% of final step change of pulse value (rate from 60-120 bpm)

- **TEMPERATURE**

Scale: Selectable °C or °F
Range: 15°C to 45°C
59°F to 113°F
Accuracy: +/-0.2°C, +/-0.4°F

- **RESPIRATION (ECG)**

Rate Range: 0-200 bpm
Rate Accuracy: 2 bpm or 2%, whichever is greater

- **RECORDER**

Speed: 25 mm/sec 5%
12.5 mm/sec 5%

- **CO₂**

Range: 0 - 100 TORR
Accuracy: +/-4 Torr (0 - 40 Torr)
10% of reading (41 - 100 Torr)
Respiration Rate Range: 0 - 150 bpm
Respiration Rate Accuracy: +/-2 bpm

- **BATTERY PERFORMANCE**

Run Time: 2 hours from full charge of new battery
at 25°C with SpO₂, 1 NIBP/ 15 minutes
and no recording.
Cycle Service Life: 150 cycles, 100% to 20% of capacity
400 cycles, 100% to 40% of capacity

- **HIGH LEVEL ECG OUTPUT (J1 Pin 9 referenced to pin 4 or 5)**

Delay From Input: 15.2 msec typical, 24.1 msec worst case
Overall Gain: 1000 ±5%, RTI
Frequency Response: .5 Hz to 30 Hz, -3db monitor quality
Output Lead: Same as displayed lead, no output
under "Lead Fault) condition.

6.2 INDIRECT BLOOD PRESSURE MEASUREMENTS AND ASSOCIATED ERRORS

Place the patient in a supine position to obtain true physiological pressure. If the cuff is not at the patient's heart level, the pressure values obtained will not reflect the true physiological pressure. Instead, the readings will be decreased by 1.86mmHg for every inch the cuff is placed above the heart level and increased by 1.86mmHg for every inch the cuff is placed below the heart level. This effect is due to hydrostatic pressure.

Blood has weight and it is this weight that influences these blood pressure readings. The value of the weight of blood depends on where the measurement is taken with respect to the heart. When the patient is supine, on a flat surface, the arm is near enough to the heart level so no adjustment of the NIBP readings will be necessary.

6.3 PRECAUTIONS WITH USING AUTOMATICALLY CYCLED BLOOD PRESSURE CUFFS

Reports have been made of nerve injury occurring during use of automatically cycled blood pressure cuffs. The authors recommend the following practices when using automatically cycled blood pressure cuffs:

- Position and support the limb in such a way as to minimize stretching of and weight exertion on affected nerves.
- Avoid cuff placement that applies pressure on the ulnar nerve. Cuff tubing should not exit the cuff over the course of the ulnar nerve at the elbow.
- Select a measurement interval that provides adequate venous drainage during cuff deflation.
- Periodically inspect the limb bearing the cuff in order to detect venostasis.

Cuff Size

Using a narrow cuff gives erroneously high pressure readings. If a standard cuff is applied to an obese patient or a patient with large biceps, the extra tissue and fat will dissipate the applied pressure, requiring an additional pressure increase to collapse the artery. On the other hand, over-wrapping a slender arm gives erroneously low pressure readings. Too much force per unit area is exerted. This requires less pressure to collapse the artery.

Other Factors

An accurate determination of blood pressure by the PASSPORT can be difficult if cardiac rhythm is very irregular. Irregular cardiac rhythm changes the stroke volume from beat to beat. This changing stroke volume may increase the time it takes the PASSPORT to make a measurement. All four PASSPORT models make up to four succes-

6.4 CUFF BLEED RATE SELECTION

The PASSPORT has 3 independent bleed valves and a larger valve to vent the cuff at the end of each measurement. The selection of the bleed valve for each measurement is determined and adjusted if necessary, from the measured bleed rate of the previous measurement. The bleed rate is set by valve selection such that at least 8 pulses but no more than 40 pulses, are detected between the systolic and diastolic phases of the measurement.

6.5 USER VERIFICATION OF PASSPORT MEASUREMENTS

Regular service to blood pressure equipment will help insure accurate measurements. Consult your service manual for appropriate information.

If you question the accuracy of the PASSPORT check it (the PASSPORT) with a manometer. See the Calibration Section of the PASSPORT Service Manual.

Auscultatory verification can be made at the same time the PASSPORT is taking a measurement. Apply a bell stethoscope over the brachial artery. Do not allow the stethoscope to touch either the patient's clothing or the pressure cuff.

6.6 NEWBORN NIBP TECHNIQUE

Newborn patients present unique obstacles to NIBP measurement. Their vital signs can change from moment to moment, and their tiny physiologic signals are very prone to noise interference. The following suggestions will help you to obtain the best possible NIBP measurement.

- **Try to measure infants when they are calm.** A kicking/crying baby may disturb or jiggle the cuff, causing noise within the system and, as a result, yielding unstable blood pressure readings. If necessary, hold the cuffed limb steady, but do not impede circulation; do not hold onto the cuff and do not "pat" the cuffed limb to comfort the child.
- **Try the calf.** Irritable newborns will react to the cuff pressure but may tolerate the calf better than the arm. Place the cuff just above the ankle.
- **Use the correct size cuff.** Datascope offers Newborn and Infant size cuffs. When applying verify the cuff's "Index" line falls between the "Range" lines.
- **Try disposable cuffs.** Disposable cuffs are more pliant than the reusable ones. They generally fit really tiny infants better.
- **Place the cuff lightly.** If the cuff is too snug, it won't work properly. On infants, you should be able to easily move the cuff over the limb.

Remember NIBP cannot be taken under all conditions. Even manual methods employing a sphygmomanometer and stethoscope will not work on unstable or active patients.

6.7 HOW TO GET HELP

Datascope maintains a network of service representative and factory-trained distributors. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist contact the Datascope Service Department (800) 288-2121 for assistance in determining the nearest field service location.

Please include the instrument model number, the serial number, and a description of the problem with all requests for service.

Any questions regarding the warranty should be directed to:

Domestic Office:

Service Manager
Datascope Corp.
580 Winters Ave.
Paramus, NJ 07652
(800) 288-2121

International Offices:

Service Manager
Datascope B.V.
Dr. W van Royenstraat 8
P.O. Box 26
3870 CA Hoevelaken
Holland
Phone: 31(3495)44911
Fax: 31(3495)34280

Service Manager
Datascope GmbH
Wiesenstrasse 4
6140 Bensheim
Germany
Phone: 49(6251)6060
Fax: 49(6251)67877

Service Manager
Datascope Medical Co., Ltd.
Lakeview Court
Spitfire Close
Ermine Business Park
Huntingdon, England
Cams PE186XR
Tel: 44(480)433477
Fax: 44(480)434051

Service Manager
Datascope S.A.R.L.
Rond Point 93
65 Avenue DU General Gallieni
93100 Montreuil-sous-Bois
France
Phone: 33(1)48599844
Fax: 33(1)48599845

6.8 REFERENCES

The following bibliography provides several articles and books of interest on pulse oximetry and issues affecting SpO₂ accuracy (carboxyhemoglobin, methemoglobin, dyes, variation in calibration of algorithms between manufacturers, and excessive sensor pressure).

Recommendations for Human Blood Pressure Determination by Sphygmomanometers. American Heart Association.

Adams, Jose A. M.D. *Respiratory Monitoring in Infants and Newborns.* The Journal for Respiratory Care Practitioners.

Clancy, Fred. *Factors Affecting Correlation Between Direct and Indirect Arterial Blood Pressure Measurements.* Journal of Clinical Engineering, 3:49, 1978.

Hazard of Automatic Non-Invasive Blood Pressure Monitoring. Anesthesiology 55:717-718, 1981.

Sy, W.P. *Ulnar Nerve Palsy Possibly Related to Use of Automatically Cycled Blood Pressure Cuff.* Anesthesia and Analgesia 60:687-688, September 1981.

Harrison, G., G. Roth, and E. Hines. *Bilateral Indirect and Direct Arterial Pressure.* Circulation, 22:419, September 1960.

Harrington, D. *Disparities Between Direct and Indirect Arterial Systolic Blood Pressure Measurements.*, CVP, pg. 40-44, August/September 1978.

Hanning, C.D. *Oximetry and Anesthetic Practice (Pre-Operative, Intra-Operative, Post-Operative, and Critical Care).* Ohmeda, BOC Health Care, 1985, Form #8601M.

Hay, William W. Jr. *Application of Pulse Oximetry in Neonatal Medicine.* Ohmeda, BOC Health Care, 1986, 1-13 pp.

Jennis, Michael S. and Joyce L. Peabody. *Pulse Oximetry: An Alternative Method for the Assessment of Oxygenation in Newborn Infants.* Pediatrics. 79:4, April 1987, 524-28 pp.

Nelson, Cynthia M., Everett N. Murphy, James K. Bradley, and Robert H. Durie. *Clinical Use of Pulse Oximetry to Determine Oxygen Prescriptions for Patients with Hypoxemia.* Respiratory Care, 31:8, August 1986, 673-80 pp.

Payne, J.P., and J.W. Severinghaus, editors. *Pulse Oximetry.* London: Springer-Verlag. 1986.

Rasanen, Jukka, John B. Downs, Donald J. Malec, Kenneth J. Oates. *Oxygen Tensions and Oxyhemoglobin Saturations in the Assessment of Pulmonary Gas Exchange.* Critical Care Medicine, 15:11, 1058-51 pp.

Scheller, MS and R.J. Unger. *The Influence of Intravenously Administered Dyes on Pulse Oximetry Readings.* Anesthesiology, 65:3A, September 1986, A161 pp.

Sidi, A., W.R. Rush, D.A. Paulis, N. Gravenstein, R.F. Davis. *The Effect of Fluorescein, Indocyanine Green, and Methylene Blue of the Measurement of Oxygen Saturation by Pulse Oximetry*. *Anesthesiology*, 65:3A, September 1986, A132 pp.

Staewen, William CCE. "Apnea Monitoring Basics". *Biomedical Instrumentation and Technology*, July/August 1991.

Toledo, Laura Worthington. *Pulse Oximetry: Clinical Implications in the PACU*. *Journal of Post Anesthesia Nursing*, 2:1, February 1987, 12-17 pp.

Yount, John E. M.D. *Optimal Detection Sensitivity: A Clinical Perspective*. AAMI 1984.

6.9 WARRANTY

Datascope Corp. warrants that its products will be free from defects in workmanship and materials for a period of one year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner.

Datascope Corp. shall not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Datascope Corp's option at the factory or at an authorized Datascope Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Datascope Corp. has any authority to bind Datascope Corp. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Datascope Corp. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Datascope, freight prepaid to Datascope Corp., Paramus, New Jersey 07652. Datascope Corp. shall not have any responsibility in the event of loss or damage in transit.

The warranty for the SpO₂ Datasensor is six months. Other accessories may also be warranted for less than one year; contact your local Datascope representative for specific information.

6.10 DATASCOPE'S RESPONSIBILITY

Datascope is responsible for the effects on safety, reliability and performance of the equipment only if:

- a. assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Datascope; and
- b. the electrical installation of the relevant room complies with IEC requirements (VDE 0107); and
- c. the equipment is used in accordance with the instructions for use.

6.11 EXTENDED WARRANTY

Datascope Corp. warrants that components within the monitor unit will be free from defects in workmanship and materials for the number of years shown on the Datascope invoice. Under this extended warranty, Datascope Corp. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as, but not limited to batteries, displays, external cables and sensors.

Recommended preventative maintenance, as prescribed in the service manual, is the responsibility of the user, and is not covered by this warranty.

Except as otherwise provided herein, the terms, conditions and limitations of Datascope Corp.'s standard warranty shall remain in effect.