

PRO 1000
PRE-SERVICE AND
CALIBRATION
MANUAL



C R T I K O N
VITAL ANSWERS**

DINAMAP® PRO 1000 Monitor

Pre-Service & Calibration Manual



GE Medical Systems *Information Technologies*

List of Effective Pages

Part No./Rev. Page No. Date of Latest Revision 2008384 All Original (Oct. 2001)

U.S. Patent 5,170,795
U.S. Patent 4,349,034
U.S. Patent 5,052,397
U.S. Patent 4,754,761
U.S. Patent 4,501,280
U.S. Patent 4,638,810
U.S. Patent 4,546,775
U.S. Patent 4,543,962
U.S. Patent 5,518,000
U.S. Patent 5,704,362
Patents Pending

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a health care practitioner

The content of this document, including all figures and drawings, is proprietary information of General Electric Medical Systems *Information Technologies*, provided solely for purposes of operation, maintenance or repair of PRO Series 1000 Monitors.

Dissemination for other purposes or copying thereof without the prior written consent of General Electric Medical Systems *Information Technologies*, Tampa, Florida, is prohibited. Illustrations may show design models; production units may incorporate changes.

©2001 TAMPA, FL 33614 Printed in the U.S.A. All rights reserved.

United States

General Electric Medical Systems *Information Technologies* 4502 Woodland Corporate Boulevard Tampa, FL 33614

EU Representative

General Electric Medical Systems *Information Technologies* GmbH Munzinger Strasse, Freiburg, Germany

SECTION 4. GENERAL MAINTENANCE

Contents	
4.1. Introduction	4-3
4.2. Configuring the PRO 1000 Monitor for the First Time	4-3
4.2.1 Unpacking and Preparation for Installation	4-3
4.2.2 Set the Date and the Clock	4-5
4.2.3 Parameter Level Functional Testing	4-6
4.3. Periodic Maintenance	4-7
4.3.1. As Required	4-7
4.3.1.1 Integrity of Cuffs and Hoses	4-7
4.3.1.2 External DC Supply and Battery	
4.3.1.3 Cleaning of Accessories	
4.3.1.4 Long Term Storage	
4.3.2 Annual Procedures	
4.4. Care of Storage Batteries	4-9
4.4.1. Procedures for First Use	
4.4.2 Battery Charging	4-9
4.5 Safety Resistance Testing	4-12
4.6. Alarm Code Interpretation	
4.6.1. System Failures	
4.6.2. Hardware Errors	4-15
4.6.3. Parameter Failures	4-15
4.6.3.1 ECG/RESP Errors	4-15
4.6.3.2 NIBP Messages	4-15
4.6.3.3 Temperature Messages	4-16
4.6.3.4 SpO2 Messages	
4.7. Service Mode Operation	4-16
4.7.1 SpO2 Tests	4-19
4.7.2 NIBP Tests	4-20
4.7.2.1 Leak Test	4-21
4.7.2.2 NIBP Calibration Check	4-23
4.7.2.3 Pressure Recalibration	4-24
4.7.2.4 Overpressure Test	4-25
4.7.3 ECG Tests	4-27
4.7.4 Temp Tests	4-28
4.7.5 Recorder Tests	
4.7.6 Battery Tests	4-31
4.7.7 Test Failsafe Logic	4-32
4.7.8 Keypad LED Test	4-33
4.7.9 Keypad Key Test	
4.7.10 Sound Test	
4.7.11 Turn off the System	
4.8 Service Mode Exit	
Appendix A - Test Record	
Appendix B – Monitor Configuration Log	

This page intentionally left blank.

SECTION 4. GENERAL MAINTENANCE

4.1 INTRODUCTION

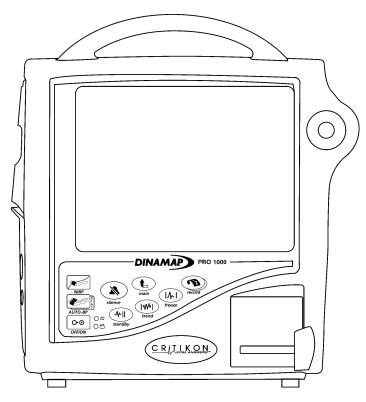
This section contains general Monitor service procedures, including alarm code interpretation, service mode operation, and periodic maintenance and battery care. Refer to Section 5 for disassembly and reassembly procedures and related component service information.

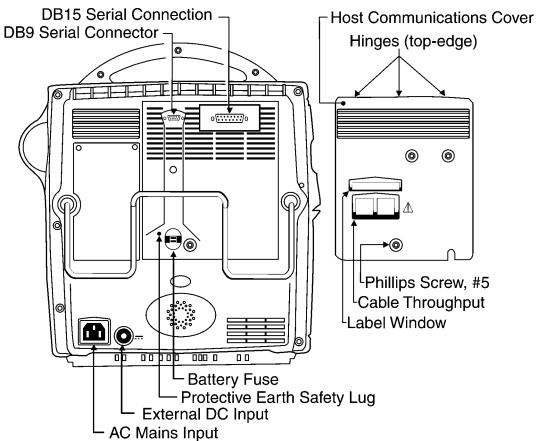
4.2 Configuring the PRO 1000 Monitor for the First Time

4.2.1 Unpacking and Preparation for Installation

- 1. Unpack and identify the contents of all shipping materials.
- 2. Remove the PRO 1000 monitor.
- 3. Unpack the AC cord but do not plug the monitor in at this time.
- 4. Turn the monitor for access to the Host Comms Cover.
- 5. Use a Phillips-head screwdriver to remove the single screw that secures the Host Comms cover.
- 6. The Battery fuse and the Fuse Holder are not connected at time of shipment. Locate and remove the fuse and fuse holder from the protective plastic bag.
- 7. Identify the Battery Fuse holder located within the Host Comms well, near the lower left side.
- 8. Insert the Battery Fuse into the Battery Fuse holder
- 9. Press the Battery Fuse Holder into the Battery Fuse mount using thumb pressure until it is securely snapped in place.
- 10. Replace the Host Comms cover; refasten the Phillips screw. Tighten using hand-tools only.
- 11. Plug the AC cord into the AC Mains input at the back of the monitor.
- 12. Plug the AC cord into a Hospital Grounded AC receptacle. A green LED will illuminate on the front of the monitor indicating that an AC source is available.

Prior to usage it is necessary to charge the monitor for 12 hours. This charge calibrates the battery charging circuitry with the charge status of the battery.

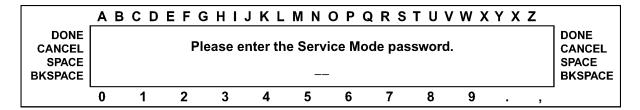




4.2.2 Set the Date and the Clock

The DINAMAP® PRO 1000 monitor uses a rotor knob to navigate through the menu systems. Rotating the rotor moves the arrow cursor, and pressing the rotor makes the selection.

- 1. Power on the PRO monitor using the **OFF/ON** key
- 2. Choose **no** when the monitor prompts to admit a new patient
- 3. Press or turn the rotor to access the main menu.
- 4. Turn the rotor and press to select **other system settings** option.
- 5. Turn the rotor and press to select **go to config mode** option.
- 6. Turn the rotor and press **yes** to continue to Configuration Mode.
- 7. The PRO Monitor will now prompt for the Configuration Mode password.



- 8. Turn the rotor and press to select after each numeral of the password is selected.
- 9. The password to enter the configuration mode is **2-5-0-8**.
- 10. Following the password entry, turn the rotor and press to select **done**.
- 11. In the process of entering the Configuration Mode, the PRO 1000 monitor will reset. Successful entry into the Configuration Mode can be noted by the words CONFIGURATION MODE in red capital letters at the top-center of the screen.
- 12. Turn the rotor and press to select **other system settings**.
- 13. Turn the rotor and press to select config settings...

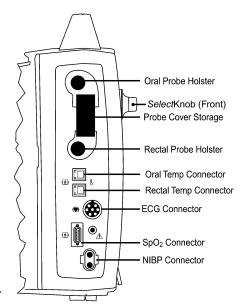
The Options available within this menu are:

- Select Date Format Press the rotor to choose the order Month, Day, and Year appears
- Select Time Format Press the rotor to choose either a 12-hour clock or a 24-hour clock.
- Adjust Date & Time Press the Select Knob to enter the correct Date and Time. After setting the date and the time, make sure to press set new time and date to save.
- Language Press the rotor to choose a different language.
- Display Units Choose yes to display all units of measure.
- Display Limits Choose yes to display all alarm units.
- Reset all to Factory CAUTION: resets all user-set options to the factory defaults. Yes enables.
- Send all defaults Choose this option sends all defaults to another connected PRO 1000 monitor through the Host Communications ports.

4.2.3 Parameter Level Functional Testing

After the initial configuration is complete, perform functional testing of each of the parameters. Using the accessories supplied with the PRO Monitor, initialize the monitor in such a way that only one parameter is functioning at a time.

- Perform a blood pressure by connecting the supplied hose and cuff together, then attaching to the left side of the PRO Monitor. Press the Start Key on the front to begin the NIBP cycle.
- Connect the supplied temperature probes to the corresponding connections (see right). A predictive temperature will begin once one probe is removed from its' holster. Replace the probe after completion of the Temp cycle.
- The SpO₂ sensor is an assembly consisting of two parts: the DS-100A, and the extender cable SCP-10. Connect the cables prior to attaching to the monitor. A SpO₂ reading will be displayed within moments of attaching the sensor to either a Nellcor simulator or to your finger.



Left Side View of the Monitor Showing Patient Connections

- Connect the ECG lead connector to the ECG trunk cable prior to connecting to the monitor. The simplest way to function test the ECG circuits is through the usage of an ECG simulator.
 - 1. Set your simulator to normal heart rate.
 - 2. Set ECG amplitude to 1.5mV, BPM to 80.
 - 3. Set respirations to 20 RPM, delta ohms to 1.0.
 - 4. Verify that the ECG waveform is displayed.
 - 5. Remove and reattach leads I, II, and III sequentially, and verify that **LEAD OFF** is displayed.
 - 6. From the ECG menu, select turn parameter off.

4.3 PERIODIC MAINTENANCE

4.3.1 As Required

Perform the following maintenance procedures as required.

4.3.1.1 Integrity of Hoses and Cuffs

When the pneumatic integrity of any NIBP cuff and hose is in doubt, replace the cuff and hose, and discard the questionable accessories.

4.3.1.2 Cleaning of Monitor

CAUTION: Do not clean Monitor with isopropyl alcohol or other solvents.

Wipe the exterior of the Monitor with a cloth slightly dampened with mild detergent or normal hospital bactericides. Use dishwashing detergents such as IVORY and JOY (registered trademarks of Procter & Gamble Corp.), or PALMOLIVE (registered trademark of Colgate-Palmolive Corp.)

Do not immerse unit.

4.3.1.3 Cleaning of Accessories

Clean the adult cuffs supplied for use with the monitor by hand washing in warm, soapy water. However, take care to avoid entry of water into the cuff and hoses at any time. If water enters the cuff, dry the cuff by passing air through it.

The neonatal cuffs are for single patient use - discard if they become soiled.

Clean cuffs and hoses with a cloth slightly dampened with mild detergent.

Do not immerse hoses.

Do not immerse cuffs without prior application of cuff hose caps.

Clean SpO2 sensor surface before and after each patient use. Clean SpO2 sensor with a cloth slightly dampened with a mild detergent. Wipe SpO2 sensor to ensure all detergent residue has been removed.

Follow manufacturer's instructions for cleaning ECG lead wires and cable. Compatible cleaning and disinfecting solutions are:

Dishwashing detergents such as IVORY and JOY (registered trademarks of Procter & Gamble Corp.), or PALMOLIVE (registered trademark of Colgate-Palmolive Corp.)

Chlorine bleach disinfectant, 5.25%, 0.75 cup per gallon of water

CAUTION: Do not apply isopropyl alcohol to the Monitor - some parts can become marred and cracked.

Isopropyl alcohol (for accessories only)

Cidex Formula 7 (registered trademark of Johnson & Johnson Medical Products, Inc.) or pHisoHex (registered trademark of Winthrop-Breon Laboratories)

Quaternary-based germicidal detergents like VESTAL INSURANCE (registered trademark of the Vestal Corp.), HI-TOR PLUS (registered trademark of the Huntington Corp.), or VIREX (registered trademark of S.C. Johnson & Son Corp.)

For the above, follow manufacturers' recommendations for dilution rate and use. These recommendations are not an endorsement of the manufacturers or of the effectiveness of these materials for cleaning or disinfecting.

4.3.1.4 Long-Term Storage

If it becomes necessary to store the Monitor for an extended period of time, remove all attached accessories. Attach the original packing inserts, and place the monitor into the original shipping container.

Generally, long-term storage of a nickel-metal hydride battery in either a charged or discharged condition has no permanent effect on capacity. Capacity loss due to self-discharge is reversible, and nickel-metal hydride batteries can recover to full capacity by proper recharging. For example, cycling through repeated charge/discharge cycles can restore a full capacity of a nickel-metal hydride battery that was stored at room temperature for up to one year.

Long-term storage at high temperatures can lead to deterioration of seals and separators and should be avoided.

4.3.2 Annual Procedures

Perform the test procedures described in paragraph **4.7** every twelve months, or whenever the accuracy of any reading is in doubt.

Note: An internal, 3.6V NiMh battery acts as an alarm backup and maintains the nonvolatile RAM memory when the Monitor is off or away from AC mains. A system alarm message will be generated if backup battery replacement is required.

4.4 CARE OF STORAGE BATTERIES

The Monitor uses one nickel-metal-hydride (NiMH) storage battery. The battery can be charged at any time without reducing the charging capacity.

4.4.1 Procedures For First Use

Follow these procedures to condition a new NiMH battery and optimize its performance:

The internal battery will automatically charge when the AC power supply is in use. When the battery is charged for the first time, the charger may indicate prematurely that charging is incomplete. This is normal and can happen with all rechargeable batteries when first charged.

4.4.2 Battery Charging

The Monitor charges the NiMH battery whenever the AC power supply is in use. The Monitor automatically senses if the battery needs recharging. Battery charging will continue as long as the Monitor is connected to the AC power supply, even when the Monitor is turned off.

- Batteries should be charged before first use or after prolonged periods of storage.
- The battery should be charged before use, as a charged battery loses some charge when left in storage.
- The battery should be charged at room temperature (59° F 86° F; 16° C 30° C).
- It is normal for the battery to become warm during charging or after use.
- Batteries can be charged or topped-off at any time. It is not necessary to wait until they are fully discharged.
- If the monitor is idle for extended periods, it should be fully charged once a month to ensure optimum performance.

Table 4-1. Battery Alarms

Alarm Type	Indication	Probable Cause			
BATT WRONG TYPE - REMOVE or INTERNAL BATT - WRONG TYPE -REMOVE	Message appears in alarm message field	Unapproved battery engaged			
BATT CHECKING or INTERNAL BATT - CHECKING	Message appears in alarm message field	Noncommunicating battery engaged			
INTERNAL BATT FAIL - REPLACE NOW	Message appears in alarm message field	Internal battery loses voltage or communication or is not accepting proper charge			
< 00:30 BATTERY	Message appears in alarm message field and in SelectBox	30 minutes remaining in battery life			
< 00:10 BATTERY	Message appears in alarm message field	10 minutes remaining in battery life			
SHUTTING DOWN	Message appears in alarm message field	< 1 minute remaining in battery life. Monitor may shut down anytime after 45-60 seconds			
AC FAIL - < 00:30 BATTERY	Message appears in alarm message field and procedural alarm sounds	Upon loss of AC power, the internal battery is engaged with less than 30 minutes of life (but more than 10 minutes) remaining			
CHECK COOLING FAN	Message appears in the alarm message field	Monitor's internal temperature is too high. Cooling fan may be blocked or inoperative			
AC FAIL - < 00:10 BATTERY	Message appears in alarm message field and crisis alarm sounds	Upon loss of AC power, the internal battery is engaged with less than 10 minutes of life remaining			

Table 4-2. Battery Troubleshooting

Trouble	Probable Cause	Remedy
Battery inoperative	Battery not fully	Charge and discharge battery up
or does not last very	charged.	to three times for optimum
long.		performance.
	Battery in long-term	Remove and reinstall battery so
	storage or nonuse.	connector is properly seated.
Battery charged for		When charging battery for first
only a short period	Improper procedure for	time, charger may indicate
of time before	charging battery for first	prematurely that charging is
indicating full	time use.	completed. Discharge battery and
charge.		repeat charging procedure.
Battery will not charge.	Charging battery in unusually cold or hot temperatures.	Charge at basic room temperature of 59° F (16° C) to 86° F (30° C). Slowly bring battery to basic room temperature before recharging. Batteries cannot be fully charged unless internal temperatures between 57° F (15° C) and 109° F (40° C).

4.5 SAFETY RESISTANCE TESTING

Using a safety analyzer (Dynatech Nevada Model 235A or equivalent), check the ground resistance of the PRO 1000 Monitor; refer to the Rear View graphic for locations of test points.

Earth-To-Secondary Continuity

Verify that the resistance between the AC Mains ground pole and the External DC connector ground is less than or equal to 1Ω .

AC Mains Leakage – Normal Polarity

For the following tests, 260 VAC is applied at the Monitor's AC Mains input in normal polarity.

No Fault

Verify that the leakage from the Line pole to the Ground pole is less than or equal to $500 \mu A$.

Open Ground

Disconnect the Monitor's ground lead from earth ground (for the duration of this test only) and verify that the leakage from the Line pole to the Ground pole is less than or equal to 500 μ A.

Open Neutral

Open the Monitor's neutral lead (for this test only) and verify that the leakage from the Line pole to the Neutral pole is less than or equal to $500 \, \mu A$.

AC Mains Leakage – Reverse Polarity

For the following tests, 260 VAC is applied at the Monitor's AC Mains input in reverse polarity (inputs to Line pole and Neutral pole reversed).

No Fault

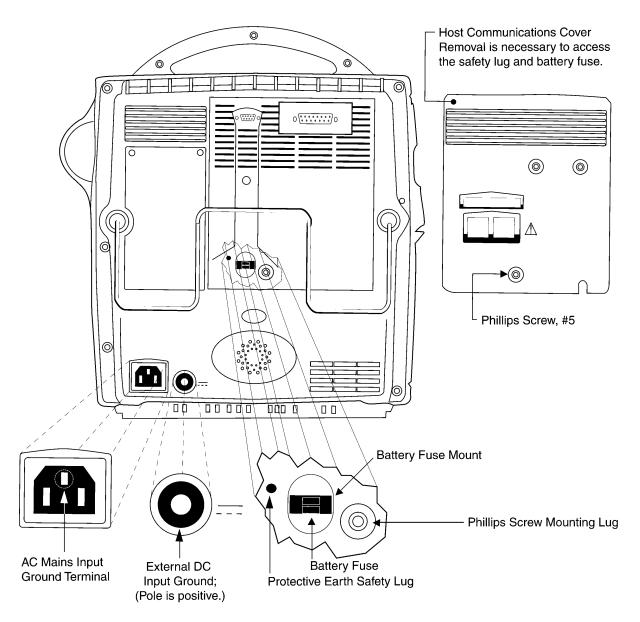
Verify that the leakage from the Line pole to the Ground pole is less than or equal to 500 μ A.

Open Ground

Disconnect the Monitor's ground lead from earth ground (for the duration of this test only) and verify that the leakage from the Line pole to the Ground pole is less than or equal to $500~\mu\text{A}$.

Open Neutral

Open the Monitor's Neutral lead (for the duration of this test only) and verify that the leakage from the Line pole to the Neutral pole is less than or equal to $500~\mu A$.



Rear View of Monitor with safety connection exposed

4-13

4.6 ALARM CODE INTERPRETATION

Refer to Table 4-1 for information about procedural alarms that involve battery operation. If any other alarms appear that are not listed in the paragraphs that follow, record the error message and report the failure to Customer Support. Refer to the Operation Manual for information about patient alarms and general procedural alarms.

4.6.1 System Failures

When a system failure is encountered, the error code is displayed on the screen for five seconds and the system enters failsafe mode. The error code is logged in the history log.

General system error codes are listed below. If any other **SY** or similar code appears, report it to Customer Support.

Error Code	Explanation	Possible Cause(s)
SY-16	Power fail signal true time is too long	Circuit that drives POWERFAIL* signal is defective
SY-19	Software detected power supply out of limits	 Go to service mode to observe current values for power supplies Digital to analog converter is defective
SY-20	Checksum of code in flash memory is not valid	 Defective flash memory chip. Error during programming of flash memory.
SY-43	Real time clock running too slow	 RTC chip running too slow or not at all. System clock running too fast.
SY-44	Real time clock funning too fast	 Noise getting into RTC chip crystal input. Defective or wrong crystal on clock chip. System clock running too slow.

4.6.2 Hardware Errors

These error codes, which are common to all parameters, indicate some internal self-check test of the hardware has failed, and service is required.

Error Code	Description
8193	HW, Time base failure
8202	HW, Power supply, System
8222	HW, RAM test failure
8232	HW, ROM checksum failure
8242	HW, Isolation interface comm failure
8252	HW, Secondary processor not
	compatible

4.6.3 Parameter Failures

4.6.3.1 ECG/ TEMP Errors

Fail Code	Description
101	ECG board data rate error.
201	ECG board cmd queue overrun

4.6.3.2 NIBP Messages

Fail Code	Description
110	Overpressure circuit failure
112	Overpressure watchdog error
120	FPT test failure
130	EEProm read failure
131	EEProm write failure
140	Transducer initialization failure
141	Calibration of a transducer channel's zero failed
142	Calibration of a transducer channel's span failed
150	Auto zero failure
151	Auto Zero. Verify failed.
160	PT1 reference failure
161	PT2 reference failure
162	OVC reference failure
170	Pump current failure
171	Pump current value out of range
180	Excessive leakage

Fail Code	Description
190	Commands out of sequence
200	OVP setpoint not found
210	Pump stuck on during idle
220	Valve in illegal state
221	Pressure too high for too long

4.6.3.3 Temperature Messages

Fail Code	Description
114	Temp data line out of sync with clock
115	Temp date frames out of sync

4.6.3.4 SpO2 Messages

In operate mode, the Fail Code is reported as described in section 4.6.3. In service mode, the Service Mode Code (hex) is displayed on the screen as a Parameter Fatal Error (hex).

Fail Code	Description
125	Too many reset requests
126	Nellcor has posted a "serious" FE error
127	Nellcor FE requests power cycle
128	Nellcor over-current error
129	FE data OK – processing stalled

4.7 SERVICE MODE OPERATION

The Monitor service mode exercises the built-in diagnostic features of the Monitor and the installed parameters. Access the service mode from a cold start by proceeding as follows:

- Momentarily press the on/off button at the front of the Monitor. Observe that a beep sounds and that the power up screen displays.
- 2. Press the Rotor to answer **no** to the **admit patient** prompt, rotate the *Rotor*, and observe the main menu is displayed on the left side of the screen.
- 3. Rotate the Rotor to select **other system settings**.

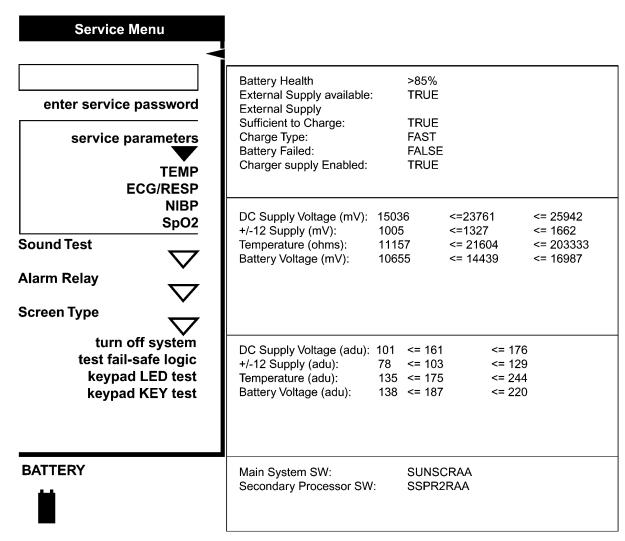
Select **go to service mode**. Rotate and press the knob again to answer **yes** at the prompt. Note that the menu changes to what is shown below.

	Α	В	С	DΕ	F G	ΗΙ	JKL	. M N	O P (QRS	TUV	w x	XYX	Z	
DONE CANCEL SPACE					Ple	ase e	enter th	ne Serv	ice Mo	ode pas	sword	i			DONE CANCEL SPACE
BKSPACE									-						BKSPACE
	0		1		2	3	4	5	6	7	8	9		,	-

- 4. Observe that a row of numbers is displayed at the bottom of the screen. Turn the rotor and press to select after each numeral is selected.
- 5. The password to enter service mode is: **2213.** Following completion of the password entry, turn the rotor and press to select **DONE**.
- 6. In the process of entering the Service Mode, the PRO 1000 Monitor will reset. Successful Entry into Service Mode can be noted by the Service Menu title display on the upper left side of the display.

NOTE: The service mode can also be entered directly from a cold start by pressing and holding the following three keys until full power-up: OFF/ON, AUTO-BP, ands GO/STOP. To make any changes to the Service Menu, the password will still have to be entered: press the rotor to **enter service password.**

7. At this point the Service Mode main screen should be present in the main display, as shown below. The service menu service parameters area displays a list that corresponds to the number and type of parameters that have been detected by the Monitor. If the service mode was entered directly (as described in the NOTE above), enter service password appears above the service parameters on the service menu. If recalibration of any component is required, the password MUST be entered (as described in steps 5 and 6) before any changes to calibration can be made.

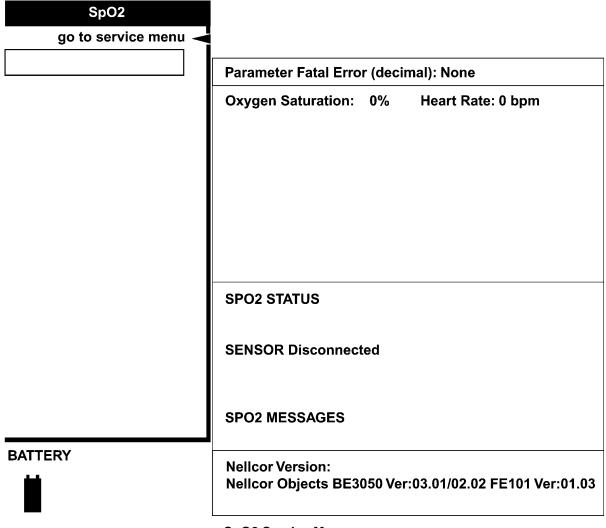


Main Service Menu

For each parameter, there are one or more service screens that display operating values and tests that are applicable to the parameter type. Refer to the following paragraphs for information about each parameter. At the conclusion of the tests, select **go to service menu** at the top of the screen to return to the Service Menu main screen.

4.7.1 SpO2 Tests

- 1. Disconnect all sensor cables from the SpO2 Parameter, and ensure that the SpO2 parameter is listed within the main Service menu.
- From the Service Menu, Turn and press the rotor to select the SpO2 service parameter. The SpO2 service menu should appear, with the SpO2 STATUS displaying SENSOR Disconnected and the SPO2 MESSAGES display empty. Example shown below.

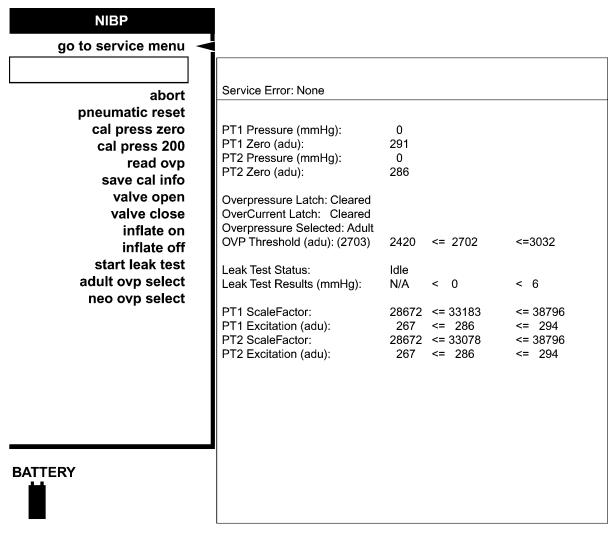


SpO2 Service Menu

3. Insert the Nellcor SRC-2 pocket tester into the Parameter front panel SpO2 sensor socket (use the extender cable SCP-10), and press until fully seated in the socket.

- 4. After a few seconds, the two red LEDs should light on the pocket tester. The SpO2 service menu should soon display a saturation of 80±1 and also displaying the heart rate as set on the SRC-2 pocket tester. Cycle through the 3 *RATE* settings and verify that the monitor responds accordingly.
- 5. Remove the SRC-2 pocket tester from the extender cable and verify that the monitor reports a **SENSOR Disconnected** message in the **STATUS** box.

4.7.2 NIBP Tests



NIBP Service Menu

Perform the following tests to determine that the NIBP parameter is functioning normally.

4.7.2.1 Leak Test

CAUTION

Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the monitor and/or the accessories.

 Using the calibration kit (part number 320-246), an adult cuff and air hose, and a manometer, set up the equipment as shown in Figure 3-1. Connect the hose to the NIBP Parameter. Make sure all fittings are tight, and that the valve on the manual inflation bulb is fully closed.

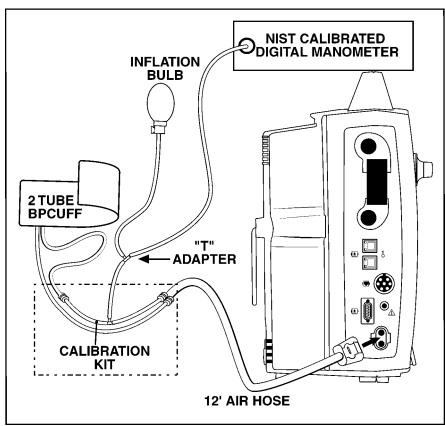


Figure 4-1. NIBP Test Setup

- 2. From the Service Menu, Turn and press the rotor to select the NIBP service parameter.
- 3. Turn and press the rotor to select **pneumatic reset**.
- 4. Turn and press the rotor to select valve close.

- 5. Turn and press the rotor to select **start leak test**. Observe that the **Leak Test Status** message on the menu indicates **Busy**.
- 6. Observe that the pump begins inflating the system to 200 ~ 210 mmHg, at which point the pump operation will cease. The Monitor will begin to calculate system pressure loss rate.
- 7. After about 60 seconds, the pressure is released, and the menu should display **Leak Test Status Passed**, and the **Leak Test Results** indication should be a value less than 6. **Service Error: None** should continue to display.
- 8. If the menu displays **Leak Test Failed**, continue to step 9.
- 9. Using the calibration kit (part number 320-246), an adult cuff and air hose, and a manometer, set up the equipment as shown in Figure 4-2.

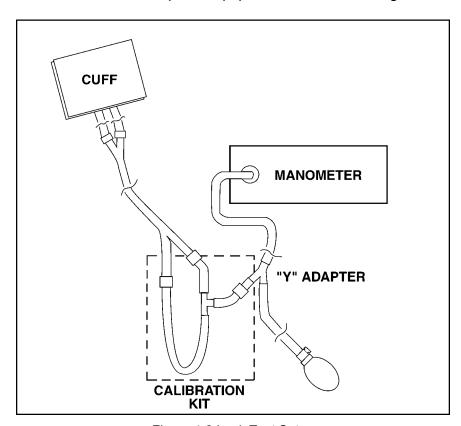


Figure 4-2 Leak Test Setup

10. Close the pressure release valve on the manometer inflation bulb and slowly increase the pressure to 200-mmHg ±1 mmHg.

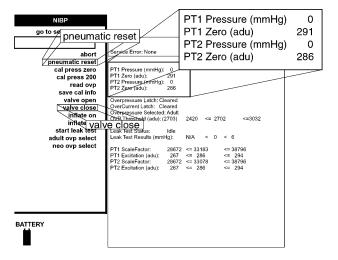
11. Verify the pressure indicated on the manometer remains within 5 mmHg of 200 mmHg for 60 seconds. If not, either the cuff or hose or both may be defective. If the cuff and hose pass this test, repeat steps 1 through 7 to try to isolate the leak. Repeat the leak test for all cuff and hose combinations to be used with the Monitor.

CAUTION

Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the monitor and/or the accessories.

4.7.2.2 NIBP Calibration Check

- Using the calibration kit (part number 320-246), an adult cuff and air hose, and a manometer, set up the equipment as shown in Figure 4-1. Connect the hose to the NIBP Parameter. Make sure all fittings are tight, and that the inflation bulb valve is closed tightly.
- 2. From the Service Menu, Turn and press the rotor to select the NIBP service parameter.
- 3. Turn and press the rotor to select **pneumatic reset**.
- 4. Turn and press the rotor to select valve close.
- Observe that both PT1 Pressure and PT2 Pressure equal initial values of zero mmHg (0 mmHg).
- 6. Connect the pneumatic hose to the Monitor's NIBP port.



- 7. Fold the adult cuff so the index line is aligned with the inner range mark on the inside of the cuff. Make sure all fittings are tight, and that the valve on the inflation bulb is closed tightly. If there is doubt about the integrity of the system, perform the leak test (paragraph 4.7.2.1) before continuing.
- 8. Close the pressure release valve on the manometer inflation bulb and manually pump up the pressure until the manometer indicates approximately 220 mmHg.

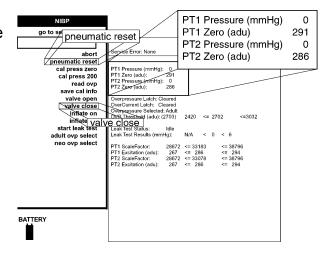
- 9. Allow the pressure to stabilize for at least a minute. Then open the pressure release valve on the manometer inflation bulb and carefully bleed off pressure until the manometer indicates 200 mmHg.
- 10. Observe that the values of **PT1 Pressure** and **PT2 Pressure** on the menu indicate within 1 mmHg of the pressure shown on the manometer.
- 11. Verify the system linearity by repeating steps 8 & 9 using manometer readings of 250 mmHg, 150 mmHg, and 50 mmHg. Observe that the **PT1** and **PT2 Pressures** are within 3 mmHg of manometer readings for each of these pressure indications.

4.7.2.3 Pressure Recalibration

CAUTION

Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the monitor and/or the accessories.

- 1. Always enter Service Mode with the password, as described in paragraph 4.7, before attempting to recalibrate equipment.
- 2. Using the calibration kit (part number 320-246), an adult cuff and air hose, and a manometer, set up the equipment as shown in Figure 4-2. Do not connect the pneumatic hose to the NIBP port yet.
- From the Service Menu, Turn and press the rotor to select the NIBP service parameter.
- 4. Turn and press the rotor to select **pneumatic reset**.
- 5. Turn and press the rotor to select **valve close**.
- 7. Observe that both PT1
 Pressure and PT2 Pressure
 display initial values of 0 on the menu.



- 8. Turn and press the rotor to select **cal press zero**. Observe that the message **Inflate System to 200 mmHg Then Hit 'Cal Press 200'** is displayed on menu.
- 9. Connect hose to NIBP Parameter.

- 10. Fold the adult cuff so the index line is aligned with the inner range mark on the inside of the cuff. Make sure all fittings are tight, and that valve on inflation bulb is closed tightly. If there is doubt about the integrity of the system, perform the leak test (paragraph 4.7.2.1) before continuing.
- Close the pressure release valve on the manometer inflation bulb and manually pump up the pressure until the manometer indicates approximately 220 mmHg.
- 12. Allow the pressure to stabilize for at least a minute. Then open the pressure release valve on the manometer inflation bulb and carefully bleed off pressure until the manometer indicates a little more than 200 mmHg.
- Turn and press the rotor to select cal press 200, but do not press the knob at first.
- 14. When the manometer indicates exactly 200 mmHg, press the Rotor. Observe that system pressure is released, and the message: !!!!! CAL INFO NOT SAVED!!!!! is displayed on menu.
- 15. Turn and press the rotor to select **save cal info**. If the system is operating normally, the menu displays **Service Error: None**, and the calibration setting is saved.
- 16. Repeat the calibration check procedure (paragraph 4.7.2.2) to confirm the calibration setting.

4.7.2.4 Overpressure Tests

CAUTION

Calibration equipment should always be kept dry and free of particulate matter. Moisture or foreign substances introduced to the pneumatic system will likely cause damage to the monitor and/or the accessories.

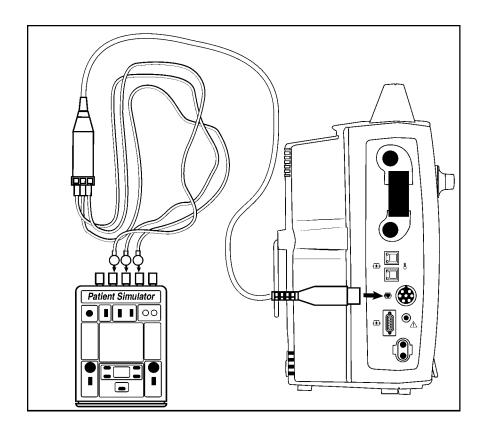
- Using the calibration kit (part number 320-246), an adult cuff and air hose, and a manometer, set up the equipment as shown in Figure 4-1. Connect the hose to the NIBP Parameter. Make sure all fittings are tight, and that valve on inflation bulb is closed tightly.
- 2. From the Service Menu, Turn and press the rotor to select the NIBP service parameter.
- 3. Turn and press the rotor to select **pneumatic reset**.

- 4. Turn and press the rotor to select **valve close**.
- 5. Observe that the menu displays **Overpressure Selected Adult**. If not, turn and press the rotor to select **adult ovp select**.
- 6. Turn and press the rotor to select **inflate on**. The pump should begin to inflate the system.
- 7. Watch the pressure indication increase on the manometer, and observe that the pump is shut down and the pressure is released when the manometer indicates in the range of 300 to 330 mmHg. Observe that the menu displays **Service Error: None**.
- 8. Turn and press the rotor to select **pneumatic reset**.
- 9. Turn and press the rotor to select **valve close**.
- 10. Turn and press the rotor to select **neo ovp select**. Observe that the menu displays **Overpressure Selected Neo**.
- 11. Turn and press the rotor to select **inflate on**. The pump should begin to inflate the system.
- 12. Watch the pressure indication increase on the manometer, and observe that the pump is shut down and the pressure is released when the manometer indicates in the range of 150 to 165 mmHg. Observe that the menu displays **Service Error: None**.
- 13. If the overpressure test results in an "out of tolerance" condition, contact Critikon Technical Support at 877-274-8456 for assistance.

4.7.3 ECG Tests

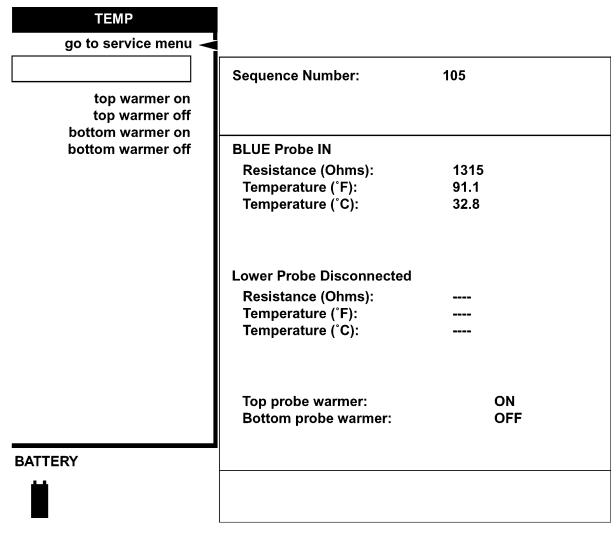
Connect the ECG leads to the ECG trunk cable prior to connection to the monitor. The simplest way to function test the ECG circuitry is through the usage of an ECG simulator with the monitor in normal monitoring mode.

- 1. Set your simulator to normal heart rate.
- 2. Set the simulator's ECG amplitude to 1.5 mV, BPM to 80.
- 3. Set respirations to 20 RPM, delta ohms to 1.0.
- 4. Remove and reattach leads I, II, and III sequentially, and verify that LEAD OFF is displayed in the main window.



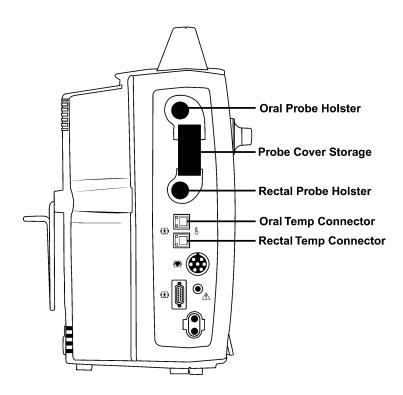
4.7.4 TEMP Tests

- 1. Disconnect the all sensor cables from the Alaris temperature connections.
- 2. From the Service Menu, Turn and press the rotor to select the TEMP service parameter. The TEMP service menu should appear as shown below.



Temperature Service Menu

- 3. Connect both the Oral and Rectal Temp probes to their respective connections, reference the graphic below.
- 4. Perform the following test to verify the integrity of the temperature parameter:
 - Verify top probe IN/OUT
 - Verify top probe warmer ON. Observe that the temperature reading rises to 105.0° F.
 - Verify top probe warmer OFF. Observe that the temperature reading drops slowly.
 - Verify bottom probe IN/OUT
 - Verify bottom probe warmer ON. Observe that the temperature reading rises to 105.0° F
 - Verify bottom probe warmer OFF. Observe the temperature reading drops slowly.



4.7.5 RECORDER tests (if fitted)

- Ensure that paper has been loaded into the Recorder Parameter, and you are presently in the Service Mode.
- 2. From the Service Menu, Turn and press the rotor to select the RECORDER test option. Turn and press the rotor to choose the 3 waveforms option. Verify that all printouts are of even tone and all pixels are present.
- 3. Select the 6.25mm/S option.
- 4. Allow for the paper to spool out a 12 inch printed section.
- 5. Select Vertical Text test. Verify that the printed text is legible and evenly spaced.
- 6. Select Horizontal Text test. Verify that the printed text is legible and evenly spaced.

This is a vertical text printer test spanning more than a single line.

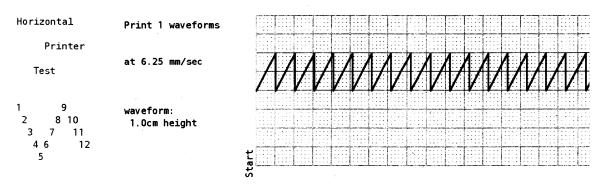
1 2 3
12345678901234567890123456789012

! "#\$%& '

40: ()^+, -. /01 50: 23456789:; 60: <=>?@ABCDE 70: FGHIJKLMNO 80: PQRSTUVWXY 90: Z[\]^_\abc 100: defghijklm 110: nopgrstuvw 120: xyz{|}- ○ 130: ->≥≤≈≠=√∞ 140: 3,55€ 474.€ 150: ≥12•♥!!€E° 160: i&feY|§"6 170: \$ **** * * * * * * * 180: 'u¶-190: ≰¿ÅÁÁÁÁÁAÆÇ 200: ÈÉÉËÌÍÎÏÐÑ 210: ბნბბნ×**მ**ბსს 220: ÜÝÞßàdáááá 230: acèéééiííi 240: đồ để để độ độ ở Đứ 250: úűűűýþý

30:

Vertical Text printout

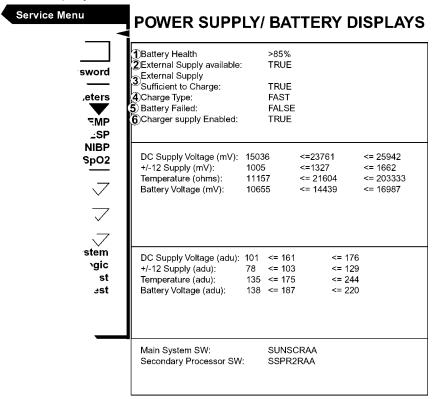


Horizontal Text print test

Sample 6.25 mm/sec – 1 waveform chosen

4.7.6 Battery Tests

From within the Service Menu, battery status information is displayed on the right upper 1/4th of the display.



Battery/ Power Supply menu

- 1. Battery Health: the Monitor's software approximates the true status of the battery's health. The value indicated is displayed as both a number (in percentage) and as an icon on the bottom-left area of the display.
- 2. External Supply available: True indicates a source other than the internal battery is providing power for the monitor, and a source to charge the internal battery.
- 3. External Supply Sufficient to Charge: If the voltage from the external supply is greater than that of the internal battery, the monitor will display the results as TRUE. False will result if either the voltage is equal to or lower than the power available from the internal battery.
- 4. Charge Type: Fast or Slow.
- 5. Battery Failed: Any result other than FALSE, indicates that the internal battery has suffered a failure and should be investigated.

6. Charger Supply Enabled: Should always be TRUE as the monitor consistently attempts to keep the battery at its' fullest capacity. A FALSE indicates the battery may be faulty or not installed, or the charge circuit may have failed. Also, if no external source of power is available, the monitor will register a FALSE result.

4.7.7 Test Failsafe Logic

- 1. From the Service Menu, turn the rotor to select **test fail-safe logic**. A dialogue box will appear:
- 2.

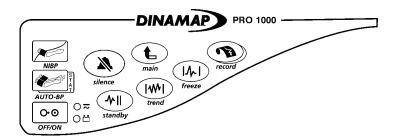
CAUTION! This will cause the system to freeze for approx. 2 seconds then enter fail-safe mode. Continue?

Answer **yes**.

2. After two seconds, the system will freeze and an alarm will sound. Recycle the system power using the on/off button. To return to the Service Mode, repeat the procedures as described in section **4.7.**

4.7.8 Keypad LED Test

From the Service Menu, rotate and press the rotor to select keypad LED test.
 Observe that each of the keys on the PRO 1000 monitor-face, illuminate one
 key at a time. With the exception of the ON/OFF key, observe whether any of
 the keys fail to illuminate.



2. After all keys have been tested, press the rotor again to stop the test.

4.7.9 Keypad KEY Test

Verify that the keypad LEDs are illuminated (except Main, Trend, and Standby)

4.7.10 Sound Test

Verify that the Monitor produces tones of various pitches when this option is selected.

4.7.11 Turn off system

Selection of this menu item will bring up a dialogue window requesting you to confirm your decision:

CAUTION! This will turn the system off. Are you sure you want to do this?

Selecting **yes** will power off the monitor; **no** will return you to the Service Menu.

4.8 SERVICE MODE EXIT

To exit the service mode and power off the Monitor, locate and press the key marked **ON/OFF** at the front of the Monitor.

This page intentionally left blank.

TEST RECORD (Appendix A) Model# Serial# Min Max Actual Pass Fail N/A Description Step SpO₂ Tests 4.7.1 Verify Pleth waveform 4.7.1 SpO₂ reading at 100% Saturation 96 100 SpO₂ reading at 90% Saturation 94 4.7.1 86 **Internal Tests (Perform in Service Mode)** 4.7.2.1 Leakage Test 4.7.2.2 UUT Pressure - 50 mmHg 46 54 4.7.2.2 UUT Pressure - 150 mmHg 145 155 4.7.2.2 UUT Pressure - 250 mmHg 244 255 4.7.2.4 Verify adult overpressure occurs between 300~350 mmHg 4.7.2.4 Verify neo overpressure occurs between 150~165 mmHg 4.7.4 Verify top probe IN/OUT 4.7.4 Verify top probe warmer ON 4.7.4 Verify top probe warmer OFF 4.7.4 Verify bottom probe IN/OUT 4.7.4 Verify bottom probe warmer ON 4.7.4 Verify bottom probe warmer OFF 4.7.5 Recorder Test 4.7.8 Keypad Test 4.7.10 Speaker Test **ECG Tests (Perform in Monitor Mode)** 4.7.3 Verify Waveform 76 84 4.7.3 Verify BPM (@ 80 BPM) 4.7.3 Verify Paced Signal 4.7.3 Verify Lead-Off **RESP Tests (Perform in Monitor Mode)** Verify Waveform Verify RESP (@ 20 RPM) 17 23 2 Verify RESP (@ 5 RPM) Verify alarm sounds & displays below 6 RPM **BPM Tests (Perform in Monitor Mode)** Verify low rate alarm at 45 BPM Heart Rate reading at 50 BPM (SpO₂) 46 54 Heart Rate reading at 120 BPM (SpO₂) 116 124 76 84 Heart Rate reading at 80 BPM (SpO₂) **NIBP Tests (Function test in Monitor Mode)** Initial cuff inflation (Adult cuff) 161 195

Heart Rate reading @ 80 BPM (NIBP)

Initial cuff inflation (Neonatal cuff)

Inflate/ Deflate cycle time <120 seconds

76

84

94 | 151

Appendix A (continued)

Temperature Test (service or monitor mode - requi	res Alaris T	emp S	imulato	r)	
Measured top Temp in °F (98.6° nominal)	98.4	98.8			
Measured top Temp in °F (80.2° nominal)	79.9	80.5			
Measured top Temp in °F (107.8° nominal)	107.5	108.1			
Measured bottom Temp in °F (107.8° nominal)	107.5	108.1			
Measured bottom Temp in °F (80.2° nominal)	79.9	80.5			
Measured bottom Temp in °F (98.6° nominal)	98.4	98.8			
Front Panel Key Tests (Perform in Service Mode)					
7.9 Verify appropriate responses to keypresses					
Battery System Test (Perform in Monitor Mode)					
Verify AC Mains indicator					
Remove AC, Verify uninterrupted battery operation	_				
Verify Battery LED is lit					⊥
Safety Testing					
External DC to GND Resistance (m)	0	1000			
SpO2 leakage (µA)	0	150			
Temp Leakage (μA)	0	50	d		
ECG Leakage (μA)	0	50			
Normal no-fault leakage (μA)	0	500			
Normal open-ground leakage (μA)	0	500			
Normal open-neutral leakage (μA)	0	500			
Reverse no-fault leakage (μA)	0	500			
Reverse open-ground leakage (µA)	0	500			
Reverse open-neutral leakage (µA)	0	500			
Tested by:		Date:			
Signature:		Facilit	y:		



MONITOR CONFIGURATION LOG - Appendix B

DINAMAP PRO 1000 Monitor Series

Note: Please refer to the I	PRO 1000 Pre-Serv	ice and Calibration Pro	ocedures for instru	ctions.
Date:	City:			
Hospital:				<u> </u>
Serial Numbers:				

How to Enter Configuration Mode

- 1. Choose other system settings from the Main Menu.
- 2. Choose go to config mode. The message This will initiate the sequence for entering Configuration Mode. Do you want to do this? appears.
- 3. Choose **Yes** to enter configuration mode.
- 4. The message Please enter the Config Mode password appears. Enter the password. FACTORY SET CONFIG PASSWORD: 2508
- 5. Choose Done.
- 6. The system will restart in configuration mode. Press the SelectKnob to access the Configuration Menu.

How to Configure Default Tables

- 1. Choose admit patient from the Configuration Menu.
- 2. Choose Choose patient settings. Select the table you wish to configure (default 1 through default 6).
- 3. A popup window appears: All unsaved changes to the current default will be lost! Are you sure you want to do this? Choose Yes.
- 4. Choose Patient type and select either Adult, pediatric, or neonate.
- 5. Change all other available settings as desired.
- 6. To save your changes for the selected table go to other system settings, choose save default changes.
- 7. A popup window appears: Enter the name for this default. Rename or accept the default table and choose DONE. Your data will be saved.
- 8. Repeat steps 1 through 7 for configuring the remaining five default tables.

How to Exit Configuration Mode

- 1. Choose other system settings from the Configuration Menu.
- 2. Choose exit config mode.
- 3. A popup window appears: This will exit configuration mode. All unsaved changes will be lost. Are you sure you want to do this? Choose Yes.
- 4. The system will automatically restart in patient monitoring mode.

Warning: All monitoring will cease when entering configuration mode. Do not enter this mode if actively monitoring a patient.

Default Table Name	Factory Default	Adult	Pediatric	Neonate	Adult2	Pediatric2	Neonate2
Adjust Alarms							
Adjust alarm volume (0 to 5)	4						
Choose autoset %	70%						
HR/Pulse	auto-set						
Config settings							
Alarm volume low range	1						
Alarm silence time (in min)	2						
Admit Patient							
Choose Patient settings	DEFAULT 1						
Patient type	adult						
enter bed number							
enter unit number							
View Patient Trends							
Choose graphs to print	0 chosen						
Display as	numbers						
View vitals every	NIBP						
Mini trends							
View trends on main screen?	yes						
Display as	numbers						
View vitals every	NIBP						
Config Settings							
Save previous patient data?	yes						
Trend key default	mini trends						
Setup HR/Pulse							
Select source	auto						
Adjust QRS volume	0						
Adjust limits	auto-set						
hi	150						
Ol	20						
Advanced settings							
Limit alarms priority	warning						
Change color based on source?	yes						
Select HR/Pulse's color	light green						
(A=adult. P=pec	(A=adult. P=pediatric. N=neonate. If no	at specified the	e factory default	setting is the s	same for adult.	If not specified the factory default setting is the same for adult, pediatric, and neonate)	neonate)

(A=adult, P=pediatric, N=neonate. If not specified the factory default setting is the same for adult, pediatric, and neonate)

Setup ECG			
Lead selection	Lead II		
Waveform size	1X		
Pacer off?	PACE OFF		
Arrhythmia detection	yes		
Advanced settings			
Cardiac sweep speed	25.0 mm/s		
Cascade ECG?	ou		
Display filter	0.5 to 40 Hz		
other alarm priorities			
VTACH	crisis		
lead fail	procedural		
Replace electrodes	procedural		
Artifact	essage		
Select EKG's color	light green		
Config settings			
Fixed ECG sweep speed?	ou		
Setup NIBP			
Auto BP	Manual		
setup custom series			
1st BP Series	q 10 mins		
repeat	£X		
2nd BP Series	d 30 mins		
repeat	£X		
3rd BP Series	d 60 mins		
repeat	x3		
4th BP Series	q 120 mins		
repeat	x3		
Adjust limits	auto-set		
systolic hi	A=200, P=150, N=100		
Ol	A=80, P=70, N=40		
diastolic hi	A=120, P=90, N=60		
Ol			
mean hi	A=140, P=100, N=70		
Ol	A=40, P=40, N=30		
Advanced settings			
Initial target pressure	auto		
(A=adult P=per	(A=adult, P=pediatric, N=neonate, If no	If not specified the factory default setting is the same for adult, pediatric, and neonate)	(č

(A=adult, P=pediatric, N=neonate. If not specified the factory default setting is the same for adult, pediatric, and neonate)

Setup NIBP (continued)			
Limit alarms priority	warning		
other alarm priorities			
No determination	procedural		
Overpressure	procedural		
Pump timeout	procedural		
Total timeout	procedural		
Level timeout	procedural		
Select NIBP's color	eldund		
Setup SpO2			
View Waveform?	yes		
Adjust limits	hi 100 lo 90		
Advanced settings			
View signal strength bar?	yes		
View SpO2 PR?	OU		
Spot check enable	yes		
Cardiac sweep speed	25.0 mm/s		
Limit alarms priority	warning		
other alarm priorities			
Lost pulse	procedural		
Sensor disconnected	procedural		
Replace cable	procedural		
Select SpO2's color	white		
Setup RESP			
Lead to analyze	A-LII, P-LII, N - L1		
View waveform?	yes		
Waveform size	1X		
Adjust limits hi	A=30, P=60, N=100		
Ol	A=6, P=10, N=15		
Advanced settings			
Resp sweep speed (mm/s)	A/P=12.5, N=6.25		
Cardiogenic filter	auto		
Limit alarms priority	warning		
other alarm priorities			
Resp approaching	warning		
Lead Fail	procedural		
Saturation	procedural		
Jan=4 Hilbe=4)	/A=adult P=nediatric N=neonate If no	If not specified the factory default setting is the same for adult, pediatric, and ne	and neonate)

(A=adult, P=pediatric, N=neonate. If not specified the factory default setting is the same for adult, pediatric, and neonate)

Setup RESP (continued)						
Artifact	procedural					
Select RESP's color	procedural					
Config settings						
Turn on RESP with ECG?	uo					
Setup TEMP						
Unit of Measure	Ⅎ。					
Choose mode	predictive					
Advanced Settings						
other alarm priorities						
Disconnected	procedural					
Two probes out	procedural					
Timed out	procedural					
Probes same type	procedural					
Check probes	procedural					
Select TEMP's color	yellow					
Config settings						
Allow °C units only?	no					
Setup RECORDER						
print on alarm	no					
vitals summary on printout	no					
Auto printout of vitals summary	OFF					
setup continuous						
Waveforms to record	1 chosen					
setup timed						
Chart speed	25.0 mm/s					
Length of strip (in seconds)	8					
Record key printout	at bedside					
Config settings						
setup continuous						
Delayed memory (in seconds)	8					
Length of strip (in seconds)	20					
setup timed						
Delayed memory (in seconds)	4					
(A=adult P=ned	(A=adult P=pediatric N=peopate If p	If not specified the factory default setting is the same for adult pediatric	rv default s	etting is the	same for adult	and neonate)

(A=adult, P=pediatric, N=neonate. If not specified the factory default setting is the same for adult, pediatric, and neonate)

Other System Settings						
Always display battery icon?	no					
Advanced Settings						
Select color format	full color					
Adjust keyclick volume	2					
Adjust system volume	8					
Config settings						
Select date format	mm/dd/yy					
Select time format	military					
Language	english					
Display units?	yes					
Display limits?	yes					
Config HostComm						
Unit address	и и					
IP address	2.0.0.0					
Waveforms to send	2 chosen					
Remote access	OFF					
Serial 1 setup						
Startup mode	ASCII cmd					
Baud rate	9600					
Serial 2 setup						
Startup mode	ASCII cmd					
Baud rate	9600					
han=d #inhe=d)	(A=adult P=nediatric N=neonate If n	If not specified the factory default setting is the same for adult	default setting is t	the same for adult	nediatric and neonate)	

(A=adult, P=pediatric, N=neonate. If not specified the factory default setting is the same for adult, pediatric, and neonate)

Notes Columns that are grayed out are non-configurable.