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INTRODUCTION

The manual provides procedures to determine if the Circadiance SmartMonitor 2 PS/PSL and its accessories are suitable for use in patient applications. These procedures require the use of a calibrated Model 5000 Simulator or Fluke ProSim 2 Simulator which is the source of ECG and respiratory test signals. A Masimo Pulse Oximetry Tester is used to verify proper operation of the internal oximeter. No other simulators are acceptable for use while performing these procedures.

This manual is for performance testing and is not intended as a service or repair guide. The procedures contained in this manual are to be performed between each patient use or every 6-12 months. Monitors that have been used in a home environment should always be tested between patients. Operational information for the monitor can be found in the Professional Operator's Manual.

The monitor must perform within the specifications of the procedures in this manual before use on patients.

REQUIRED EQUIPMENT

- SmartMonitor 2PS or SmartMonitor 2PSL
- Respironics 5000 Simulator or Fluke ProSim 2
- Safety Lead Wires (9520-1 or 1000114)
- ECG Patient Cable (p/n 103019, 1030193 or 1030194)
- Oximeter Patient Cable (p/n H 5870)
- Stopwatch (optional)
- PCMCIA Memory Card (p/n 1017915)
- Masimo Tester
- Multimeter
- SmartMonitor 2 PS Nurse Call WYE Cable (p/n 1024837) or equivalent

IMPORTANT NOTES…READ CAREFULLY

As the checkout procedure is being performed, please remember the following:

- Complete all checkout procedures in one continuous operation and in the order presented in this manual. If you have not performed the checkout procedure before, please read and understand this manual before starting the checkout procedure.
- Do not place the monitor or the Simulator near electrical appliances that could cause interference (i.e., cordless or cellular telephones, air conditioners, vaporizers, computers, TVs, VCRs, microwave ovens, etc.)
- Coiling and/or manipulation of the patient cables or lead wires should be minimized.
- Once changes are made on the simulator, do not maintain hand contact with the simulator knobs or enclosure. It may affect the ECG and respiration signals.
- Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.
- In the section of Establishing Initial Alarm Set Points of the checkout procedure, the changes to the alarm parameters of the monitor should be made through the menu display located on the bottom panel of the monitor.
- The 5000 Simulator will not function correctly if the 9-volt battery is low. It should be replaced, minimally, once per month or more often with heavy use. The battery voltage can be too low for calibrated output signals before activation of the LOW BATTERY light.
- The monitor's memory should be cleared before performing the checkout procedures.

ESTABLISHING INITIAL ALARM SET POINTS

1. Remove the Menu Display Cover from the bottom of the SmartMonitor 2 PS or PSL. Note the three buttons to the right of the LCD display: the UP arrow ▲ button, the DOWN arrow ▼ button, and the ENTER button.
2. Access the Menu Mode for the monitor as follows:
   a. Press the POWER button ON.
   b. Within ten seconds, enter the following key code:
   c. Press the DOWN arrow once.
   d. Press the UP arrow twice.
   e. Press the ENTER button three times.

NOTE
While in Menu Mode, the monitor will beep every 10 seconds. This is to remind you that the monitor is not monitoring and to power off the monitor after parameters are set.

3. To set a specific parameter or series of parameters:
   a. Use the UP arrow button to move forward to the parameter to be changed.
   b. Select the parameter to be changed by pressing the ENTER key – this will cause the current value to flash.
   c. The value can be increased by pressing the UP arrow button and decreased by pressing the DOWN arrow button.
   d. To select the displayed value, press the ENTER button. The value displayed will continue to flash until you press the ENTER button.
   e. Press the UP arrow button to proceed to the next parameter to be selected.
4. For this checkout procedure, set the monitor parameters as follows:

Table 1

Parameter	Value	Parameter	Value
Menu Options	**All Menus**	Probe Off Function	**Do Events, Do Alarms**
View Prior Events?	**No**	Low SpO_2 Alarm*	**75%**
Patient Name	**Test ^**	High SpO_2 Alarm*	**OFF**
Patient ID Number	**00 ^**	Low SpO_2 Alarm Delay*	**5 Seconds**
STD Alarm Parameters	**Are Not Selected**	SpO_2 Record Limit*	**OFF**
STD Record Parms.	**Are Selected**	Record SpO_2?*	**YES**
STD System Parms.	**Are Not Selected**	Rec. Plethysmograph?*	**YES**
Apnea Alarm	**20 Seconds**	Record Pulse Rate?*	**NO**
Low Breath Alarm	**0FF**	Record Auxiliary 1	**OFF**
Bradycardia Alarm	**80 BPM**	Record Auxiliary 2	**OFF**
Brady Alarm Delay	**0 seconds**	Record Auxiliary 3	**OFF**
Tachycardia Alarm	**230 BPM**	Record Auxiliary 4	**OFF**
Tachy Alarm Delay	**5 Seconds**	Ext. Physio Trigger	**OFF**
Record Mode	**EVENT**	Ext. Equip. Trigger	**OFF**
Apnea Record Limit	**16 Seconds**	Date	**Current Date**
Brady Record Limit	**OFF**	Time	**Current Time**
Pre/Post Time	**30/15**	Rate Display	**ON**
Record Impedance?	**YES**	Computer Phone #	**(___-____)**
Record Resp Rate?	**YES**	When to Call	**(__/__/__ __:__)**
Record Heartrate?	**YES**	Dial if Memory Full?	**Yes**
Record ECG?	**YES**	Move Data to Card?	**NO**
Oximeter Enabled	**YES**	Memory Status	**0 Percent Full**
Enable Panel Display	**YES**	Clear Memory?	**YES**

*Available on SmartMonitor 2PS monitors only.

5. After the designated checkout parameters are entered, turn the monitor off using the proper Power-off procedure*. The proper power-off procedure is as follows:
   a. Press and hold the RESET button.
   b. Press and release the POWER button.
   c. Wait two seconds, and then release the RESET button.
6. For monitors used in locations where the mains power is 50 Hz, perform the following steps to ensure that the AC POWER INPUT setting is set to 50 Hz
   a. Turn the monitor on.
   b. When the LCD screen on the bottom of the monitor displays “MENU MODE? ENTER PROPER KEY SEQUENCE”, press the UP arrow button, DOWN arrow button, ENTER button, UP arrow button, DOWN arrow button, ENTER button. The monitor will now display SmartMonitor 2PS menu selection.
   c. Use the UP or DOWN arrows to scroll to the menu option labeled “AC POWER INPUT”. Verify that the menu displays 50 Hz. If the menu displays 50 Hz., power off the unit.
   d. If the menu displays 60 Hz., Press the ENTER button to make the 60 Hz. blink.
   e. Use either the UP or DOWN arrow button to select 50 Hz.
   f. Press the ENTER button.
   g. Power the monitor off.

NOTE

*If the Hospital Mode parameter is set to YES, the special power-off procedure described above is not required. Refer to the Professional Operator’s Manual for further details on setting the Hospital Mode parameter. Within this procedure, all functionality and stopwatch timing is based on the Hospital Mode Parameter being set to NO.

THE FUNCTIONAL SELF-TEST

1. Plug the power supply into a live wall outlet and connect the other end into the DC POWER receptacle on the back of the monitor. The CHARGER light on the front of the SmartMonitor 2 PS should light and remain on (continuous or blinking).
2. Insert the ECG patient cable into the ECG receptacle on the front of the monitor.
3. Insert the WHITE lead (RA) wire into the "RA" socket of the patient cable. Insert the BLACK lead wire into the "LA" socket of the patient cable. Make sure that both lead wires are fully inserted into the color-coded sockets of the patient cable.
4. Connect the lead wires to the Functional Self-Test receptacles on the right side of the SmartMonitor 2 PS. Insert the pin end of the WHITE lead wire into the receptacle labeled "RA". Insert the pin end of the BLACK lead wire into the receptacle labeled "LA".
5. If testing a SmartMonitor 2PS monitor,insert the Oximeter patient cable into the Oximeter receptacle on the front of the SmartMonitor 2 PS.
6. If testing a SmartMonitor 2PS, connect the Masimo Tester to the other end of the Oximeter patient cable.

NOTE

When using a stopwatch, timing should begin after the power button has been pressed.

NOTE

The LED on the Masimo Tester will blink when the SmartMonitor 2 PS is turned on. After a few moments, the tester LED will stop blinking and stay lit, during this time the display of the SmartMonitor 2 PS may display three dashed lines on the display and the alarm will sound. This is a normal condition. A few moments after the tester LED stays lit, the alarm will stop sounding and the SpO_2 display of the SmartMonitor 2 PS should display a reading of 81 ± 3%. This will occur each time the SmartMonitor 2 PS is turned on when this tester is being used throughout this procedure.

7. Press the POWER button to turn the monitor on. The alarm should beep and all the lights should come on for approximately 4 seconds. After all the alarm lights turn off, the CHARGER and POWER light should remain on and within 15 seconds, the green HEART and RESPIRATION light should be blinking. The lights will continue to flash for about 45 seconds.

NOTE

If the following lights remain on or are blinking, and/or the alarm sounds continuously, corrective action should be taken before continuing the Checkout Procedure.

- **LOW BATTERY** – The monitor battery pack is discharged. Turn the SmartMonitor 2 PS off using the correct power-off procedure. Make sure the Power supply is plugged into a live power outlet and properly connected to the monitor. Allow the monitor to recharge for 8 hours before performing the Checkout Procedure. This will provide fully charged battery power.
- **FULL MEMORY** – The monitor's memory is 80% to 100% full. If the monitor has been used on patients, the data should be transferred and then cleared using the procedure described in the Professional Operator's Manual.
- **LOOSE CONNECTION** – Indicates loose or bad lead wires or patient cable. Check all connections and/or replace lead wires first, then patient cable if necessary.

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

8. After approximately 45 seconds, the green HEART and RESPIRATION lights should stop blinking. The red LOW HEART light should illuminate within approximately seven seconds after the HEART light stops flashing, and the audible alarm should beep once every second.

9. Approximately 20 seconds after the last Respiration detection, the Red Apnea light should illuminate. (There should be no green HEART or RESPIRATION lights during this alarm.) When the APNEA light illuminates, the Functional Self-test is complete.
10. Turn the SmartMonitor 2 PS off using the correct power-off procedure. If the SmartMonitor 2 PS is not powered off correctly, the "sibling" alarm will sound. Repeat the proper Power-off procedure as described above until power is off.

CHECKOUT SET-UP

NOTE
The power supply and the Patient Cables should remain connected to the monitor as they were in the Functional Self-Test.

1. Disconnect the lead wires from the Self-Test connectors of the monitor.
2. If using a model 5000 simulator loosen the binding post caps (labeled "RA" and "LA") on the Model 5000 Simulator under THREE LEAD ECG/RESP.
3. Insert the white lead wire into the post-labeled "RA". Insert the black lead wire into the post-labeled "LA". Tighten both post caps on the 5000 Simulator. If using a Fluke ProSim 2 simulator, insert the lead wires into the appropriate connectors on the Fluke simulator".
4. Set the Simulator Controls as follows:

Table 2

Parameter	Value	Parameter	Value
Patient Name	**Test**	Record Heart Rate	**YES**
Patient ID Number	**1234**	Record ECG	**YES**
STD Alarm Parameters	**Are Selected**	Record Auxiliary 1	**OFF**
STD Record Parms	**Not Selected**	Record Auxiliary 2	**OFF**
STD System Parms	**Not Selected**	Record Auxiliary 3	**OFF**
Apnea Alarm	**20 Seconds**	Record Auxiliary 4	**OFF**
Low Breath Rate Alarm	**0FF**	External Physiological Trigger	**OFF**
Bradycardia Alarm	**80 BPM**	External Equipment Trigger	**OFF**
Bradycardia Alarm Delay	**0 seconds**	Date	**Current Date**
Tachycardia Alarm	**230 BPM**	Time	**Current Time**
Tachy Alarm Delay	**5 Seconds**	Rate Display	**ON**
Record Mode	**EVENT**	Phone Number For Computer	**(___-____)**
Apnea for Record	**16 Seconds**	Time to Call the Computer	**(__/__/__ __:__)**
Brady Limit Record	**OFF**	Dial if Memory Is Full	**NO**
Pre/Post Time	**30/15**	Move Data to Card	**NO**
Record Impedance?	**YES**	Memory Status	**0 Percent Full**
Record Respiration Rate	**YES**	Clear Memory	**NO**

NOTE

The LED on the Masimo Tester will blink when the SmartMonitor 2 PS is turned on. After a few moments, the tester LED will stop blinking and stay lit, during this time the display of the SmartMonitor 2 PS may display three dashed lines on the display and the alarm will sound. This is a normal condition. A few moments after the tester LED stays lit, the alarm will stop sounding and the SpO_2 display of the SmartMonitor 2 PS should display a reading of 81 ± 3%. This will occur each time the SmartMonitor 2 PS is turned on when this tester is being used throughout this procedure.

5. Turn the Simulator POWER on.
6. Turn the SmartMonitor 2 PS power on and proceed to Verification of Respiration Signal Sensitivity.

NOTE

If the Monitor Alarms at this point, check the Menu Display, if an Error Code is displayed, check to ensure the AAA backup batteries are installed and within voltage tolerances. If the AAA batteries are correctly installed and functional, then check the 5000 simulator battery or that the Fluke simulator is operating properly

VERIFICATION OF RESPIRATION SIGNAL SENSITIVITY FOR Monitor

There are 17 test points that require different simulator settings. For each test point, make the required changes as listed in Table 3 and verify the appropriate monitor response. Simulator Control setting values that change from the previous **Test Point** are marked with an asterisk (*). Press the **RESET** button on the SmartMonitor 2 to reset any alarm faults.

NOTE

Apnea should occur approximately 20 seconds after the last respiration detection.

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

Table 3

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	200	200	No Alarms 100% Detection
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	10	15	
	Variation OHMS	0.5	0.5	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	10	15	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	15*	15*	
	Variation OHMS	0.5*	0.5*	
	Base Impedance Ohms	200	500	
4	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	15	15	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
5	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30*	30*	
	Variation OHMS	0.2*	0.2*	
	Base Impedance Ohms	200	500	

6	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1) after last respiration is detected.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
7	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	50*	60*	
	Variation OHMS	0.2*	0.2*	
	Base Impedance Ohms	200	500	
8	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	50	40	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
9	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	75*	80*	
	Variation OHMS	0.5*	0.5*	
	Base Impedance Ohms	200	500	
10	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	75	80	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
11	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	100*	100*	
	Variation OHMS	0.5*	0.5*	
	Base Impedance Ohms	200	500	
12	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	100	100	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
13	ECG BEATS/MIN.	200	200	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	120*	120*	
	Variation OHMS	1*	1*	
	Base Impedance Ohms	200	500	
14	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	120	120	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	

VERIFICATION OF THE ECG SIGNAL SENSITIVITY FOR Monitor

There are 13 test points that require different simulator settings. For each test point, make the required changes as listed in Table 4 and verify the appropriate monitor response. Simulator Control setting values that change from the previous **Test Point** are marked with an asterisk (*). Press the **RESET** button on the SmartMonitor 2 PS to reset any alarm faults.

NOTE

Apnea should occur approximately 20 seconds after the last respiration detection.

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

Table 4

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	25	30	100% Detections **Low heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.2	0.3	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	85*	90*	100% Detections Audible alarm should stop. Press **Reset** to reset **Low Heart** light.
	ECG AMPLITUDE/MV.	0.2	0.3	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	85	90	No ECG Detections **Low heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.1*	0.1*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	

4	ECG BEATS/MIN.	100*	100*	100% Detections Audible alarm should stop. Press **Reset** to reset **Low Heart** light.
	ECG AMPLITUDE/MV.	0.2*	0.3*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
5	ECG BEATS/MIN.	100	100	No ECG Detections **Low Heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.1*	0.1*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
6	ECG BEATS/MIN.	150*	140*	100% Detections Audible alarm should stop. Press **Reset** to reset **Low Heart** light.
	ECG AMPLITUDE/MV.	0.2*	0.3*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
7	ECG BEATS/MIN.	150	140	No ECG Detections **Low Heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.1*	0.1*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
8	ECG BEATS/MIN.	200*	200*	100% Detections Audible alarm should stop. Press **Reset** to reset **Low Heart** light.
	ECG AMPLITUDE/MV.	0.5*	0.5*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
9	ECG BEATS/MIN.	200	200	No ECG Detections **Low Heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.1*	0.1*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
10	ECG BEATS/MIN.	240*	240*	100% Detections Press **Reset** to reset **Low Heart** light. **High Heart** light should illuminate and audible alarm should beep Twice per second.
	ECG AMPLITUDE/MV.	0.5*	0.5*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
11	ECG BEATS/MIN.	240	240	No ECG Detections **Low Heart** light should illuminate and audible alarm should beep once per second.
	ECG AMPLITUDE/MV.	0.1*	0.1*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
12	ECG BEATS/MIN.	200*	200*	100% Detection Press **Reset** button to reset High and Low Heart.
	ECG AMPLITUDE/MV.	0.5*	0.5*	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	

VERIFICATION OF THE APNEA ALARM AND DELAY

There are 3 test points that require different simulator settings. For each test point, make the required changes as listed in Table 5 and verify the appropriate monitor response. Simulator Control setting values that change from the previous **Test Point** are marked with an asterisk (*). Press the **RESET** button on the monitor to reset any alarm faults.

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

Table 5

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	200	200	No Alarms 100% Detections
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	15	15	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	200	200	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	15	15	
	Variation OHMS	0.1*	Apnea 22 seconds*	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	200	200	100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	15	15	
	Variation OHMS	0.5*	0.5*	
	Base Impedance Ohms	200	500	

VERIFICATION OF THE LOW BREATH RATE ALARM

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

The LED on the Masimo Tester will blink when the SmartMonitor 2 PS is turned on. After a few moments, the tester LED will stop blinking and stay lit, during this time the display of the SmartMonitor 2 PS may display three dashed lines on the display and the alarm will sound. This is a normal condition. A few moments after the tester LED stays lit, the alarm will stop sounding and the SpO_2 display of the SmartMonitor 2 PS should display a reading of 81 ± 3%. This will occur each time the SmartMonitor 2 PS is turned on when this tester is being used throughout this procedure.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

1. Turn the monitor off as follows:
   a. Press and hold the RESET button.
   b. Press and release the POWER button.
   c. Wait two seconds, and then release the RESET button.
2. Access the Menu Mode for the monitor as follows:
   a. Press the POWER button ON.
   b. Within ten seconds, enter the following key code:
   c. Press the DOWN arrow once.
   d. Press the UP arrow twice.
   e. Press the ENTER button three times.
3. Change the entry for **LOW BREATH ALARM** from **OFF** to **16 BrPM** for the Model 5000 or **18 BrPM** for the Fluke ProSim™ 2 Simulator.
4. In order for the monitor to accept the parameter value changes, turn the SmartMonitor 2 PS off as described in step 1 above.
5. Set the Simulator Controls as shown in Test Point 1 in Table 6.
6. Power on the monitor.
7. Test the SmartMonitor per Table 6.

Table 6

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	100*	100*	No Alarms 100% Detections
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30*	30*	
	Variation OHMS	1*	1*	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	100	100	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1)
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	10*	15*	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	100	100	The audible alarm should stop within approximately 7 seconds, but the **Apnea** light should remain flashing. Press **Reset** button to clear alarm and faults.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30*	30*	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	

8. Turn the monitor off as described in step 1 above.
9. Access the Menu Mode for the monitor as described in step 2 above.
10. Change the setting for **LOW BREATH ALARM.**
11. Turn the monitor off as described in step 1 above.
12. Power on the monitor. (The monitor must be powered off and then on for the changed parameter values to be accepted.)

VERIFICATION OF THE LOW AND HIGH HEART ALARMS

NOTE

Due to large signal changes that result when Simulator settings are initially changed, the off-scale signal recognition circuitry of the monitor may activate and cause brief pauses in detection once the normal signal is detected by the monitor. This would allow an additional 10 seconds for the circuitry to stabilize before proceeding with verifying the operation of the SmartMonitor 2 PS.

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

Table 7

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	85*	90*	No Alarms 100% Detections
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	75*	60*	Red **Low Heart** light should illuminate and audible alarm should sound once per second. **Green Respiration** should flash.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	85*	90*	The audible alarm will stop and the red **Low Heart** light will remain on. Press **Reset** button to **Low Heart** light
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
4	ECG BEATS/MIN.	240*	240*	Red **High Heart** light should illuminate and the audible alarm should beep twice per second.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
5	ECG BEATS/MIN.	200*	200*	The audible alarm will stop and the red **High Heart** light will remain on. Press **Reset** button to **High Heart** light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	

VERIFICATION OF THE SpO_2 ALARMS (Only performed on SmartMonitor 2PS monitors)

1. Disconnect the Masimo Tester from the Oximeter patient cable.
2. After a short delay, the SpO_2 light will turn red, the SpO_2 display will show dashes, and the audible alarm will sound.
3. Reconnect the Masimo Tester to the Oximeter patient cable.
4. Verify that the SpO_2 light turns green, the SpO_2 display shows a value of 81 ± 3%, and the audible alarm stops sounding.
5. Turn the SmartMonitor 2 PS off using the proper Power-off procedure.
6. Turn the SmartMonitor 2 PS on, enter Menu Mode, and change the Low SpO_2 Alarm parameter to 85%.
7. Turn the SmartMonitor 2 PS on.
8. Verify that the SpO_2 display shows a value of 81 ± 3%. In addition, verify that the Low SpO_2 light comes on and the audible alarm beeps once per second.
9. Turn the SmartMonitor 2 PS off using the proper Power-off procedure.
10. Turn the SmartMonitor 2 PS on, enter Menu Mode, and change the Low SpO_2 Alarm parameter to 75%.

VERIFICATION OF CARDIOGENIC ARTIFACT REJECTION

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

Table 8

Test Point	Simulator Control	Model 5000 Setting	Fluke ProSim™ 2 Setting	Smart Monitor 2 Response
1	ECG BEATS/MIN.	100*	100*	No Alarms 100% Detections
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	30	30	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
2	ECG BEATS/MIN.	100	100	No respiration detection **Apnea** light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1) after last respiration is detected.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	100*	100*	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	
3	ECG BEATS/MIN.	100	100	100% Detection Press **Reset** button to clear alarm faults and red light.
	ECG AMPLITUDE/MV.	0.5	0.5	
	Resp. Breath / MIN	75*	80*	
	Variation OHMS	1	1	
	Base Impedance Ohms	200	500	

VERIFICATION OF LOOSE CONNECTION ALARM

NOTE

The Masimo Tester simulates a nominal % SpO_2 value of 81 ± 3%. Throughout this section of the checkout procedure, the displayed % SpO_2 value should remain within this range and SpO_2 alarms should not be generated.

NOTE

Because the signal from the simulator is interrupted by each change in the simulator setting, allow approximately ten seconds after each setting change for the monitor circuitry to stabilize.

1. Disconnect the Patient Cable from the monitor. The audible alarm should sound continuously and the **LOOSE CONNECTION LIGHT** should illuminate.
2. Reconnect the Patient Cable. The audible alarm should stop. Press the **RESET** button to reset the **LOOSE CONNECTION LIGHT**. The **GREEN HEART LIGHT** and **GREEN RESPIRATION LIGHT** should resume flashing.

3. Disconnect the White Lead Wire from the Simulator. The audible alarm should sound continuously and the **LOOSE CONNECTION LIGHT** should come on. Reconnect the White Lead Wire. The audible alarm should stop.
4. Press the **RESET** button to turn off the **LOOSE CONNECTION LIGHT**.
5. Disconnect the Black Lead Wire from the Simulator. The audible alarm should sound continuously and the **LOOSE CONNECTION LIGHT** should illuminate.
6. Reconnect the Black Lead Wire. The audible alarm should stop.
7. Press the **RESET** button to turn off the **LOOSE CONNECTION LIGHT**.
8. After reconnecting the lead wires, set the Base Impedance Ohms to 1.5K on the Simulator. There should be NO alarms.
   Note: Perform steps 9-11 only with the Model 5000 simulator.
9. 9.Change the Base Impedance Ohms to 2K. The audible alarm should sound continuously and the **LOOSE CONNECTION LIGHT** should illuminate.
10. 10.Change the Base Impedance Ohms back to 1.5K. The audible alarm should stop.
11. Press the **RESET** button to reset the **LOOSE CONNECTION LIGHT.**

VERIFICATION OF ACCIDENTAL POWER-OFF ALARM (SIBLING ALARM)

1. Press the **POWER** button to turn the monitor off (without pressing the **RESET** button). The audible alarm should sound continuously. The **POWER LIGHT** will illuminate.
2. Press the **POWER** button again, then press and hold down the **RESET** button. Press and release the **POWER** button, and continue to press the **RESET** button for 2 seconds. The audible alarm should stop and the **POWER LIGHT** should also go out. Release the **RESET** button.

OPERATIONAL VERIFICATION OF THE MAIN BATTERY PACK

The monitor uses two types of batteries. Rechargeable batteries are used for power during portable operation. Alkaline batteries provide a back-up alarm function if the rechargeable batteries fail. The rechargeable batteries are contained inside the main battery pack. Two alkaline, size AAA, batteries are placed into a AAA holder located on the side of the main battery pack.

1. Unplug the Power supply from the monitor.
2. Remove the battery cover to gain access to the main battery pack.
3. Replace the AAA alkaline batteries and safely dispose of the old batteries in accordance with your area's environmental laws.
4. Replace the battery cover.
5. Repeat the Functional Self-test to verify battery operation. Refer to page 7.

NOTE
If the main battery pack is not sufficiently charged, the alarm will sound continuously, and the **LOW BATTERY LIGHT** will turn on.

NOTE
The main battery pack has a life expectancy of 2-3 years and should be replaced on a preventative basis within this time frame.

NOTE
The alkaline batteries should be replaced at least once each year to ensure their function, if needed, for backup in the case of a main battery pack failure.

CLOCK CHIP BATTERY

Once every 10 years, the monitor should be returned to Circadiance for replacement of the clock chip battery. If this battery is depleted, the monitor will sound a constant alarm, the LCD display will read "ERROR 2," and the memory may possibly be cleared, causing the alarm and record parameters to be set to standard values.

Circadiance recommends that you consider replacement of the clock chip battery if the monitor is over 10 years old.

OPERATIONAL VERIFICATION OF THE NURSE CALL FEATURE (OPTIONAL)

Interface of the monitor device with a Nurse Call system is possible via the jack located on the rear panel of the monitor. Two sets of relay contacts (one Normally Open and one Normally Closed) are available via the three contacts of the stereo phone plug. These contacts are as follows: tip-NO, ring-NC and sleeve-Common.

The monitor internal relay is de-energized when the monitor is OFF, or when the monitor is ON and an alarm condition exists. The relay is energized when the monitor is ON and no alarm condition exists. The appropriate set of relay contacts for interfacing varies based on the make and model of the Nurse Call system used. The following test verifies proper operation of the SmartMonitor 2 PS internal relay.

1. Connect p/n 1024837 or equivalent to the rear panel Nurse Call jack of the SmartMonitor 2 PS. This allows access to the three contacts of the internal relay.
2. Connect a multimeter between the sleeve terminal and either the tip or ring terminal.
3. Place the multimeter in Resistance mode. The multimeter will indicate either an open circuit (infinite resistance) or a short circuit (<1 ohm resistance). This is the de-energized state of the relay.

NOTE
When using a stopwatch, timing should begin after the power button has been pressed.

NOTE
Set up the monitor as per the Functional Self Test.

4. Turn the monitor on. The alarm should beep and all the lights should come on for approximately 4 seconds. After all the alarm lights turn off, the CHARGER and POWER light should remain on, within 15 seconds the green HEART and RESPIRATION lights should be blinking. The lights will continue to flash for about 45 seconds.

NOTE
If the following lights remain on or are blinking, and/or the alarm sounds continuously, corrective action should be taken before continuing the Checkout Procedure.

   - **LOW BATTERY** – The monitor battery pack is discharged. Turn the monitor off using the correct power-off procedure. Make sure the Power supply is plugged into a live power outlet and properly connected to the SmartMonitor 2 PS.
   - **FULL MEMORY** – The monitor's memory is 80% to 100% full. If the monitor has been used on patients, the data should be transferred and then cleared using the procedure described in the Professional Operator's Manual.
   - **LOOSE CONNECTION** – Indicates loose or bad lead wires or patient cable. Check all connections and/or replace lead wires first, then patient cable if necessary.
5. After approximately 45 seconds, the green HEART and RESPIRATION lights should stop blinking. The red LOW light should illuminate within approximately seven seconds after the HEART light stops flashing, and the audible alarm should beep once every second.
6. Approximately 20 seconds after the last Respiration detection, the Red Apnea light should illuminate. (There should be no green HEART or RESPIRATION lights during this alarm.)

7. Verify that the multimeter indication switches between open circuit and short circuit once every second.
8. Turn the monitor off.

WATCHDOG TEST

NOTE
The Watchdog test must be performed only when the main PCA has been replaced.

1. Insert the WHITE lead (RA) wire into the “RA” socket of the patient cable. Insert the BLACK lead wire into the “LA” socket of the patient cable. Make sure that both lead wires are fully inserted into the color-coded sockets of the patient cable.
2. Connect the lead wires to the Functional Self-Test receptacles on the right side of the SmartMonitor 2 PS. Insert the pin end of the WHITE lead wire into the receptacle labeled “RA”. Insert the pin end of the BLACK lead wire into the receptacle labeled “LA”.
3. Access the menu mode as follows.

NOTE
To perform the Watchdog test, you must press the buttons in the following sequence to enter menu mode.

   a. Press the POWER button ON.
   b. Within ten seconds, enter the following key code.
   c. Press the UP arrow once.
   d. Press the DOWN arrow once.
   e. Press the ENTER key.
   f. Press the UP arrow once.
   g. Press the DOWN arrow once.
   h. Press the ENTER key.
4. Using the DOWN arrow, scroll down until you come to TEST WATCHDOG.
5. Push the ENTER button, the “No” will flash, press the DOWN arrow to change “NO” to “YES”. Press enter button to start test.
6. After a few moments the alarm will sound, the test is now complete.
7. Hold the RESET and POWER buttons together for 6 to 8 seconds, and then release the POWER button while still holding the RESET button until the alarm stops sounding.

NOTE
If the alarm does not stop ringing after a few moments, repeat step 7.

NOTE
Monitor may display Error 0002 on Menu Display at this point.

8. Press the POWER button to turn the monitor on. The alarm should beep and all the lights should come on for approximately 4 seconds. After all the alarm lights turn off, the CHARGER and POWER light should remain on, and within 15 seconds the green HEART and RESPIRATION light should be blinking. The lights will continue to flash for about 45 seconds.

TRANSFERRING Monitor DATA TO A MEMORY CARD & CLEAR MEMORY

The Memory Card is a credit-card-sized electronic memory transfer device that transfers monitor data. This is an optional feature of monitor and may not be installed on every unit. All data in the memory card at the time of a download will be over written. For more information, refer to the Setting Alarms and Recording Limits section of this manual. To transfer monitor data to a PCMCIA Memory Card, follow the steps below:

1. Make sure the monitor is OFF.
2. With the Memory Card facing you, slide it into the slot provided on the side panel of the SmartMonitor 2 PS. The location of the memory card logo will be on the bottom edge facing you.
3. Press the POWER button ON. After a short delay, the display will read: INITIALIZING PLEASE WAIT, then, MENU MODE? ENTER PROPER KEY SEQUENCE.
4. Press the following key sequence within 10 seconds:
    a. Press the DOWN arrow once.
    b. Press the UP arrow twice.
    c. Press the ENTER button three times.
5. The display will read SmartMonitor 2 PS or SmartMonitor 2PSL MENU SELECTION.
6. Press the DOWN arrow until you see Move Data To Card?
7. Press the ENTER button. The word NO will begin to blink. To select YES press either arrow button.
8. Press the ENTER button. The display will now show Transferring Data… Once the transfer is complete, the display will change to Data Transferred. If the card has data on it, the following is displayed after selecting YES to move data to the card:
    a) The display may show card full – overwrite?
    b) Press the ENTER button. The word NO will begin to blink. Press either arrow button to select YES.
    c) Press the ENTER button. The display will now show “Transferring data…” Once the transfer is complete, the display will change to Data Transferred.
9. Use the UP or DOWN arrow to scroll to the CLEAR MEMORY? menu item.
10. Press ENTER.
11. Press the UP arrow button so that yes appears on the display screen.
12. Press ENTER. “It is Cleared” will appear on the display screen.
13. Power off the monitor.

NOTE
The memory in the monitor will not be automatically cleared. The recorded data in the monitor will be “Flagged” as downloaded information and, if it is not cleared before the next download, the Synergy-E software will exclude those duplicated events. Synergy-E has the ability to retrieve all the data if desired. Refer to the Synergy-E manual for more information.

COMPUTER RETRIEVAL OF Monitor DATA

For information on viewing data and printing reports, refer to the Synergy™-E Manual.

Circadiance SmartMonitor 2 PS/PSL Apnea Monitor Verification Checklist

Date Received: _____ **Technician:** _____

Serial Number: _____ **Model:** _____

NOTE
Indicate completion of each item below with an "X".

Initial Checkout
Visual Inspection: _____ Functional Self-test: _____

Respiration Sensitivity Test Points
#1__ #2__ #3__ #4__ #5__ #6__ #7__ #8__ #9__ #10__ #11__ #12__ #13__ #14__ #15__ #16__ #17__ Note: Tests 15-17 are only applicable with the Model 5000 Simulator.

ECG Sensitivity Test Points
#1__ #2__ #3__ #4__ #5__ #6__ #7__ #8__ #9__ #10__ #11__ #12__

Apnea Alarm and Delay Test Points	Low Breath Rate Alarm
#1__ #2__ #3__	**#1__ #2__ #3__**

Low and High Heart Alarm Test Points	Cardiogenic Artifact Rejection Test Points
#1__ #2__ #3__ #4__ #5__	**#1__ #2__ #3__**

Verification of SpO_2 Alarm*: _____

Loose Connection Alarm Test Points
#1__ #2__ #3__ #4__ #5__ #6__ #7__ #8__ #9__ #10__ #11__ Note: Tests 9-11 are only applicable with the Model 5000 Simulator.

Accidental Power-off Alarm (Sibling Alarm): _____

Battery Power Pack: _____

Watchdog Test (Perform only if the Main PCA has been replaced.): _____

Data Transfer to Memory Card: _____

Clear Memory: _____

WARNING
If your monitor does not pass all test points in all sections of this checkout manual, the monitor must not be used for patient applications. For technical support or product service, please contact Circadiance at 1-888-825-9640.

*Only performed on SmartMonitor 2PS units. Mark as N/A for SmartMonitor 2PSL units.

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For more information or to order SmartMonitor2 products and accessories, contact:

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