SmartMonitor® 2

Circadiance™
Pediatric Care

Checkout Procedure Manual

Table of Contents

INTRODUCTION

This manual provides procedures to determine if the Circadiance Model 4000 series SmartMonitor 2 and its accessories are suitable for use in patient applications. These procedures require the use of a calibrated Model 5000 Simulator or a Fluke Biomedical ProSim™ 2 Simulator, which is the source of ECG and respiratory test signals. 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 SmartMonitor 2 can be found in the *Professional Operator's Manual*.

The SmartMonitor 2 must perform within the specifications of the procedures in this manual before use on patients.

REQUIRED EQUIPMENT

- Model 4000 series SmartMonitor 2
- Model 5000 ECG/Respiration Simulator or Fluke Biomedical ProSim™ 2 Simulator
- Model 9520-1 Safety Lead Wires
- Model 4005 Patient Cable
- Model 990 Remote Alarm (optional)
- Stopwatch
- PCMCIA Memory Card

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 SmartMonitor 2 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 cable 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 SmartMonitor 2 should be made through the menu display located on the bottom panel of the SmartMonitor 2
- 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 SmartMonitor 2's memory should be cleared before performing the checkout procedures.
- The 990 Remote Alarm may be verified throughout the checkout procedures. The Remote Alarm 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.

ESTABLISHING INITIAL ALARM SET POINTS

1. Remove the Menu Display Cover from the bottom of the SmartMonitor 2. Note the three buttons to the right of the LCD display - UP arrow ▲ button, the DOWN arrow ▼ button, and the ENTER button.
2. Access the Menu Mode for the SmartMonitor 2 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 SmartMonitor 2 will beep every 10 seconds. This is to remind you that the SmartMonitor 2 is not monitoring and to power off the SmartMonitor 2 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.
   f. Press the UP arrow to display CLEAR MEMORY? then clear the memory.
4. For this checkout procedure, set the SmartMonitor 2 parameters as follows:

Table 1

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

To change STD Record Parameters to *not selected*, you must set the Apnea for Record parameter to 18 seconds.

5. After the designated checkout parameters are entered, turn the SmartMonitor 2 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 then release the RESET button.

THE FUNCTIONAL SELF-TEST

1. Plug the Battery Charger into a grounded, live wall outlet and connect the other end into the receptacle on the back of the SmartMonitor 2 Labeled DC POWER. The CHARGER light on the front of the SmartMonitor 2 should light and remain on continuously.
2. Insert the patient cable into the receptacle labeled Patient Input on the front of the SmartMonitor 2.
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. 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 you are using the Remote Alarm, connect it to the REMOTE ALARM output on the back of the Monitor at this time. Turn the Remote Alarm power to the on position. Each time the Monitor Alarms, verify that the sound can be heard through the Remote Alarm and that the Monitor light on the Remote Alarm comes on.

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

6. Press the POWER button to turn the SmartMonitor 2 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 SmartMonitor 2 battery pack is discharged. Turn the SmartMonitor 2 off using the correct power-off procedure (refer to pg. 4, step 5). Make sure the battery charger is plugged into a live power outlet and properly connected to the SmartMonitor 2. Allow the SmartMonitor 2 to recharge for 8 hours before performing the Checkout Procedure. This will provide fully charged battery power.
   - **FULL MEMORY** – The SmartMonitor 2's memory is 80% to 100% full. If the SmartMonitor 2 has been used on patients, the memory should be transferred to a Memory Disk, 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.
7. 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.
8. Approximately 20 seconds after 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.
9. Turn the Remote Alarm off.
10. Turn the SmartMonitor 2 off using the correct power-off procedure (refer to pg. 4, step 5). If the SmartMonitor 2 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 Battery Charger and the Patient Cable should remain connected to the SmartMonitor 2, as they were in the Functional Self-Test.

1. Disconnect the lead wires from the Self-Test connectors of the SmartMonitor 2.
2. Connect the RA and LA leads to the simulator as follows:
    a) For the Model 5000 simulator:
        i. Loosen the binding post caps (labeled “RA” and “LA”) under THREE LEAD ECG/RESP.
        ii. 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 simulator.
    b) For the Fluke ProSim™ 2 simulator, insert the leads into the RA and LA posts.
3. Set the simulator controls as follows:

Table 2

Control	Model 5000 Setting	Fluke ProSim™ 2 Setting
ECG Beats /Min	200	200
ECG AMPL / MV	0.5	0.5
RESP. Breaths / Min	10	15
Variation Ohms	0.5	0.5
Base Impedance Ohms	200	500

4. Turn the simulator POWER on.
5. Turn the SmartMonitor 2 power on and proceed to Verification of Respiration Signal Sensitivity.

VERIFICATION OF RESPIRATION SIGNAL SENSITIVITY FOR SMARTMONITOR 2

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 SmartMonitor 2 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: The last three tests require a simulator setting of 150 breaths per minute, and can only be performed when using the Model 5000 simulator, as indicated below.

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

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	

15	ECG BEATS/MIN.	200	-	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light. (Test case applicable only to the Model 5000)
	ECG AMPLITUDE/MV.	0.5	-	
	Resp. Breath / MIN	150*	-	
	Variation OHMS	2*	-	
	Base Impedance Ohms	200	-	
16	ECG BEATS/MIN.	200	-	No respiration detection Apnea light should illuminate and audible alarm should beep once per second 20 seconds (+/- 1) after last respiration is detected. (Test case applicable only to the Model 5000)
	ECG AMPLITUDE/MV.	0.5	-	
	Resp. Breath / MIN	150	-	
	Variation OHMS	0.2*	-	
	Base Impedance Ohms	200	-	
17	ECG BEATS/MIN.	200	-	No alarms 100% Detection Press **Reset** button to clear alarm faults and red light. (Test case applicable only to the Model 5000)
	ECG AMPLITUDE/MV.	0.5	-	
	Resp. Breath / MIN	150	-	
	Variation OHMS	2*	-	
	Base Impedance Ohms	200	-	

VERIFICATION OF THE ECG SIGNAL SENSITIVITY FOR SMARTMONITOR 2

There are 12 test points that require different simulator settings. For each test point, make the required changes as listed in Table 4 and verify the appropriate SmartMonitor 2 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 last respiration detection.

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 SmartMonitor 2 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.

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

1. Turn the SmartMonitor 2 off as follows:
   a. Press and hold the RESET button.
   b. Press and release the POWER button.
   c. Wait two seconds then release the RESET button.
2. Access the Menu Mode for the SmartMonitor 2 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 SmartMonitor 2 to accept the parameter value changes, turn the SmartMonitor 2 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 SmartMonitor 2.
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 SmartMonitor 2 off as described in step 1 above.
9. Access the Menu Mode for the SmartMonitor 2 as described in step 2 above.
10. Change the setting for **LOW BREATH ALARM** to **OFF.**
11. Turn the SmartMonitor 2 off as described in step 1 above.
12. Power on the SmartMonitor 2. (The SmartMonitor 2 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 SmartMonitor 2 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.

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 CARDIOGENIC ARTIFACT REJECTION

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

If a unit under test (UUT) emits an additional alarm during any of the steps in this test, where a "No Alarm" condition should exist, verify that the UUT has a good connection with the simulator. Once a good connection is confirmed, the audible alarm should stop. Press the reset button on the UUT to clear the Loose Connection light. If the alarm condition clears, resume testing at the next step. If the alarm condition continues, fail the UUT.

1. Disconnect the Patient Cable from the SmartMonitor 2. 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 9-10 only with the **Model 5000** simulator.

9. Change the Base Impedance Ohms to 2K. The audible alarm should sound continuously and the **LOOSE CONNECTION LIGHT** should illuminate.
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 SmartMonitor 2 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

1. Unplug the Battery Charger from the SmartMonitor 2.
2. Repeat the Functional Self-test to verify battery operation. Refer to page 5.
3. If the 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.

CLOCK CHIP BATTERY

Once every 15 years, the SmartMonitor 2 should be returned to Circadiance for replacement of the clock chip, which contains an internal lithium 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 if the monitor is over 15 years old.

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. 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 WATCHDOG TEST.
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 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 then repeat step 7.

8. Press the POWER button to turn the SmartMonitor 2 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 light should be blinking. The lights will continue to flash for about 45 seconds.

TRANSFERRING SMARTMONITOR 2 DATA TO A MEMORY CARD

The Memory Card is a credit-card-sized electronic memory transfer device that transfers monitor data. This is an optional feature of SmartMonitor 2 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 Setting Alarms and Recording Limits section of this manual. To transfer SmartMonitor 2 data to a PCMCIA Memory Card, follow the steps below:

1. Make sure the SmartMonitor 2 is OFF.
2. With the Memory Card facing you slide it into the slot provided on the side panel of the SmartMonitor 2. 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 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.
9. The display may show card full – overwrite?
10. Press the Enter button. The word NO will begin to blink. Press either arrow button to select YES.
11. Press the Enter button. The display will now show “Transferring data…” Once the transfer is complete the display will change to Data Transferred.

NOTE
The memory in the monitor will not be automatically cleared. The recorded data in the SmartMonitor 2 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 Synergy-E manual for more information.

COMPUTER RETRIEVAL OF SMARTMONITOR 2 DATA

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

CLEAR MEMORY

1. Access the Menu Mode for the SmartMonitor 2 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.
2. Use the UP or DOWN arrows to scroll to the CLEAR MEMORY? menu item.
3. Press ENTER.
4. Press the UP arrow button so that YES appears on the display screen.
5. Press ENTER. MEMORY CLEARED will appear on the display screen.
6. Power off the SmartMonitor 2.

CIRCADIANCE SMARTMONITOR 2 FUNCTIONAL CHECKOUT VERIFICATION CHECKLIST

Date Received: _____ Technician: _____ Cost Center: _____

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__**

Loose Connection Alarm Test Points
#1__ #2__ #3__ #4__ #5__ #6__ #7__ #8__ #9__ #10__ #11__ Note: Tests 10-11 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: _____

WARNING
If your SmartMonitor 2 does not pass all test points in all sections of this checkout manual, the SmartMonitor 2 must not be used for patient applications. For technical support or product service, please contact Customer Service at 1-888-825-9640.

This page intentionally left blank.

Circadiance™
Pediatric Care

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

1-888-825-9640
1-724-858-2837
orders@circadiance.com
www.Circadiance.com

Circadiance LLC
1010 Corporate Lane
Export, PA 15632 USA