

STUDY OF OSTEOPOROTIC FRACTURES

# Manual of Procedure for Oximetry

# **SOF Sleep/Cognition Study**

Case Sleep and Epidemiology Research Center Triangle Building Suite 290-B 11400 Euclid Avenue Cleveland, OH 44106 This Manual of Procedure provides step instructions to acquire field data in a uniform fashion and is not intended to replace the Rad-8 Operator's manual. All users should read and refer to the manufacturer's operator manual for more extensive information on the Rad-8 oximeter.





#### Rad-8 specifications

PERFORMANCE
Measurement Bange

SpO <sub>2</sub> i	1-100%
Pulse Rate:	25-240 beats per minute (bpm)
Perfusion:	0.02% - 20%
ACCURACY	
Saturation	70% to 100%
No Motion1	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Mation <sup>2</sup>	
Adults <sup>1</sup> , Pediatrics <sup>1</sup>	±3 digits
Neonate	±3 digits
Low Perfusion <sup>3</sup>	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Pulse Rate Accuracy	× ×
Pulse rate:	25-240 bpm
No Motion <sup>1</sup>	
Adults, Pediatrics, Neonate	±3 digits
Motion <sup>2</sup>	
Adults, Pediatrics, Neonate	±5 digits
Low Perfusion <sup>3</sup>	
Adults, Pediatrics	±2 digits
Neonate	±3 digita
Resolution	
Saturation (%SpO2)	1%
Pulse Rate (bpm)	1 bpm
ELECTRICAL	
AC Power requirements:	90-240 VAC, 47-63 Hz
Power consumption:	15VA
Batteries	
Type:	Sealed lead acid
Capacity:	8 hours4
Charging time:	8 hours
ENVIRONMENTAL	
Operating Temperature:	41°F to 104°F (5°C to 40°C)
Storage Temperature:	-40°F to 158°F (-40°C to +70°C)
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	500 mbar to 1060 mbar messure
chorand carrier	-1000 ft to 18,000 ft (-304 m to 5,496 m)

Dimensions:	8.2" x 6.0" x 3.0" (20.8 cm x 15.2 cm x 7.6 cm)
Weight:	2.1 lbs. = .908 Kg. = 32 oz
Rad-8 Modes	
Rad-8 Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds <sup>5</sup>
Rad-8 Sensitivity:	Normal, Maximum and APOD
Alarms	
Sensor condition, system failure and lo	w battery alarms
Audible and visual alarms for high and	low saturation and pulse rate
(SpO <sub>2</sub> range 1-100%, pulse rate	e range 25-240 bpm)
High Priority:	800 Hz tone, 5 pulse burst, pulse spacing: 0.250s
	0.250s, 0.500s, 0.250s, repeat time:10s
Low Priority:	500 Hz tone, 3 pulse, repeat time: 5
Alarm Volume:	High Priority: 80 dB, Low Priority: 78 dB
DisplayIndicators	
Data display: %SpO <sub>2</sub> , p	pulse rate, alarm status, alarm silenced status, AC power, Signal
IQ / pleth	bar, perfusion index bar, battery status, no sensor, sensor off
APOD, Norm, Max, FastSat, Trauma	LED
Туре:	LED
Compliance	
EMC Compliance:	EN60601-1-2, Class E
Equipment Classification:	IEC 60601-1/ UL 60601-1
Type of Protection	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Par
Rad-8 Mode of Operation:	Continuous
<ol> <li>Maxino SET technology with UNOP Ad/ Neo a add/ volumieors in induced hyposis attalies in fi- variation equals plus or minus one standard do neonatal sensors were validated on adh/ volumies 2 Maxino SET technology with UNOP Ad sensor volumears in induced hyposis studies while part mon-septitive noticin between the 4-bat ana a laboratory OD-consister and EO-3 monitor. This technology Diversities and EO-3 monitor.</li> </ol>	encombas been wilded for no notion accuracy in human blood statises on healty so range of 70-100% SpO <sub>2</sub> against a bioentory co-coinester and ECG monitor. This written which encompasses 68% of the population. The saturation accuracy of the so and 1% was acticable account for the properties of field hemoglobin. It is not been validated for motion a councey in human blood statises on healthy adult orming nobling and tapping motions, at 2 to 4 Heat at an amplitude of 12.02 cm and applicable 0.21x 3 cm initiatured hyposis statis in the range of 70-100% SpO <sub>2</sub> agains is variation equals place or minus one standard divisition which encompasses 68% of could statise use within the outdu values and 1% was added to accur it for the
properties of letal hemoglobil. 3 Masimo SET technology has been validated for	Now pelfusion accuracy in bench too testing against a Biotek Index 2 simulator and
<ol> <li>Masino SET technology has been validated in Masino SET technology has been validated for Masino's simulator with signal strengths of great 70 to 100%. This variation equals plus or minus</li> </ol>	rlow perfusion accuracy in bench top tealing against a Biotek Indax 2 simulator and Fer than 0.02% and a % transmission of geater than 5% for astutations anging from one standard classifion which encompasses 68% of the population.

5 With FastEat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-8 seconds, respectively.

#### 5

## **Front Panel Buttons**



## **Rear Panel**



AC Power Entry Module

Masimo Technical Support: 1-800 326-4890

Before first use, fully charge the battery by attaching the power cord to the AC power entry Module in the back of the unit. Plug the power cord receptacle into an AC power source. The green battery charging light (front panel) will illuminate.

There will be 2 oximetry collections for SOF V9:

• One short daytime "baseline" at the time of the sensor placement. This daytime collection will be performed with the Rad8 in the standard (STD) collection mode and serves to verify good sensor placement as well as a resting baseline values. The sensor will be placed on the participant for the baseline collection and remain on the participant until the following morning.

• Nighttime oximetry for which the Rad8 will be set to the sleep (SLP) mode. The participant will connect the Rad8 to a power source in the bedroom and then connect the sensor to the oximeter before bedtime. If the participant needs to leave the bed in order to use the bathroom, the power cord will be unplugged from the AC power entry module then re-plugged when returning to bed. In the sleep mode, alarms will not sound to disturb sleep, and values will not be displayed on the unit.

## Setting Up the Rad8 for the 3 minute baseline collection

- 1. Attach the power cord to the back of the oximeter and the other end to an AC wall outlet.
  - The green battery-charging indicator will illuminate.
- 2. Turn on the unit by pressing the Power key. The oximeter will beep once then cycle through to display its current settings.
  - If in the STD mode, the colored indicator lights will be illuminated. If in the SLP mode, only the green charging and amber silence alarm indicators will be illuminated. If in SLP, change to STD mode.

#### If Necessary, Change from SLP to STD mode (Needed to Synchronize Time/Date to Actigraph):

- 1. Press and hold NEXT and MODE ENTER at the same time until "No Sen" is displayed on the screen.
- 2. Release NEXT and MODE ENTER.
- 3. While "No Sen" is still displayed, again press and hold NEXT and MODE ENTER at the same time until the mode is displayed. If the mode reads "SLP" press NEXT until STD is displayed.
- 4. Press ENTER to execute the command for the mode change.

When in STD mode, the indicator lights will be illuminated for FastSat, Silence Alarm, No Sensor and battery charging.

#### Set Averaging Time:

- 1. Press MODE ENTER once
- 2. Cycle through the menu (AL VOL, SIL 120, AL ON, AL 05) by pressing NEXT 4 times. It is not necessary to adjust these settings since they are not active for the SLP mode.

3. After the pressing NEXT 4 times, the averaging time will be displayed. Make sure the averaging time is set to 02 SEC.

• If 02 Sec is not displayed, adjust the averaging time by pressing the  $\uparrow\downarrow$  buttons until 02 is displayed.

• Press MODE ENTER to lock in the 02 averaging time.

#### Synchronize Time and Date to the Actigraph:

- 1. Press MODE ENTER 4 times, SEt CL will be displayed.
- 2. Press NEXT to set the year (Yr)
- 3. Press NEXT to set the month (nn)
- 4. Press NEXT to set the day (dAY)
- 5. Press NEXT to set the hour (Hr)
- 6. Press NEXT to set the minute (nn)
- 7. After adjusting the date and time press MODE ENTER to execute any changes.
  - Set the time and date as closely to the actigraph as possible.

#### With the Participant, Review the Conditions Within the Home:

- 1. It will be necessary to plug in the Rad 8 once the participant returns home. It is necessary that the wall plugs within the home have grounded receptacles (i.e.: 3-pin receptacle which will take a standard ground pin). The use of "cheater adaptors" in order to convert at 3 pin plug on the oximeter to a 2 pin wall outlet is not advised.
- 2. The Rad 8 should be plugged in close to the bed in which the participant sleeps. Ask the participant which side of the bed she occupies during the night and which side of the bed the Rad 8 will be placed in order to provide AC power. Once the Rad 8 is plugged-in it can be placed either on the floor near the bed or on a bedside nightstand providing the oximeter and power cord are out of the path of the participant and others. Keep in mind which side (hand) the finger sensor should be applied based on the location of the Rad 8 in the bedroom.

#### Attach the Finger Sensor for Baseline Oximetry:

The finger oximeter records pulse and oxygen saturation using a small light that shines through the finger. When possible, the finger sensor should be placed on the ring finger of the non-dominant hand (preferably the 4<sup>th</sup> or 5<sup>th</sup> digit). Colored nail polish defeats the function of the oximeter. Colored nail polish must be removed from the finger prior to sensor attachment.

Placing the LNCS Neo sensor:

1. Open the package and remove the sensor.

- 2. Remove the sensor from its protective backing.
- 3. With the fingers spread, support the participant's hand by placing it on a flat surface. Align the sensor onto the desired finger so that the diode (grey rectangle with the word "Neo") is on the pad of the fingertip, the center line of the receiver (with the \*) is midline of the fingernail and the gray sensor cord runs the length of the finger.
- 4. Lightly tape the sensor wire to the finger, and then thread the wire through the web space to the side of the hand, providing additional tape to hold in place.
- 5. Lastly, securing the cord once more to the forearm, between the wrist and elbow, can provide additional strain relief. Coban works nicely for this.

Add a new picture here

#### **Connect the sensor to the cable:**

- 1. Flip open the clear connector cable-lock on the receptacle of the grey oximeter cable.
- 2. Hold the cable receptacle with the hinged lock cover on top.
- 3. Hold the connector of the finger sensor with the name "Masimo" on top.
- 4. Firmly insert the sensor connector into the cable receptacle and close the cable-lock cover.

#### Acquire baseline oximetry recording:

- 1. Allow the readings to settle, with participant sitting and at rest, acquire data for 3 minutes.
- 2. During this 3-minute collection, fill in the baseline oximetry form, note values for
  - SpO2
  - Pulse
  - Signal IQ (SIQ)
  - Perfusion Index (PI)

For oximetry (SpO2) readings <90%:

1. Check sensor on your own finger

- a. If the reading is what you would expect, then reposition sensor on participant using a different digit.
  - i. If reading on different digit remains below 90%, see "Medical Alert" below.
- b. If reading is not what you would expect, use a new sensor.
  - i. If new sensor is applied, start a new form. Record failure of sensor in your equipment log and tag sensor to return to vendor.

#### Medical Alert:

- 1. If SpO2 <90% but >85%:
  - a. Ask the participant about a known history of anemia, heart disease, peripheral vascular disease and annotate form.
  - b. Ask participant about symptoms: shortness of breath, dizziness and chest discomfort.
    - i. If symptoms are denied, annotate form.
    - ii. If symptoms are confirmed, call participant's physician with information on history and current symptoms.
- 2. If SpO2  $\leq 85\%$ :
  - a. Call participant's physician, regardless of symptoms.
  - b. Ask participant about history and symptoms, and report this information to physician.
  - c. Physician will decide course of action.
  - d. Annotate form.

#### Place the Rad 8 into the SLP Mode:

- 1. Press MODE ENTER and NEXT at the same time
- 2. Hold for 3 secs until the bottom screen displays the current mode (STD).
- 3. Press the NEXT till display reads SLP
- 4. Press MODE ENTER to execute the SLP command.
  - In the SLP mode the displays, indicator lights and alarms are deactivated. The green battery level and amber silence alarm lights remain illuminated.
  - While in the SLP Mode pressing any key will activate the display for %SpO2, BPM, SIQ and PI for 10 secs.

#### Disconnect the finger sensor from the cable.

- 1. Leave the oximeter powered on
- 2. Flip open the clear plastic cable-lock on the receptacle of the gray interface cable.
- 3. Firmly grasp the connector of the finger sensor at the strain- relief and gently rock the connector side-to side while pulling from the interface receptacle.
- 4. After disconnection provide a form of cable management for the tail end of the finger sensor.
  - This must be able to be easily removed by the PPT at bedtime.

#### **Provide instructions to participant:**

- How to keep the finger sensor in place and dry until bedtime.
- How to re-connect and lock the sensor in place before bedtime.

• How to plug in the oximeter as soon as the participant arrives home, in a grounded outlet (Note: see instructions for driver below)

• How to unplug (and re-plug) the power cord from the back of the unit when leaving bed in order to use the bathroom or how to unplug the oximeter once the participant gets into bed, to

avoid having to unplug (and re-plug) during the evening

- That pressing any key on the front panel will display values for 10 secs.
- How to remove the finger sensor and unplug unit from wall AC power after morning awakening (if oximeter was plugged in during the night).
- How the unit will be retrieved from the home.

### **Provide Instructions for Driver:**

- How to plug in the oximeter as soon as the participant arrives home, in a grounded outlet
  - If there is no grounded outlet in the participant's bedroom, the oximeter may be plugged into an outlet in another room (eg, the kitchen or the bathroom)
  - If there is no grounded outlet anywhere in the participant's home, use a power surge outlet strip.
- How to re-connect and lock the sensor in place before bedtime.
- How to unplug (and re-plug) the power cord from the back of the unit when leaving bed in order to use the bathroom or how to unplug the oximeter once the participant gets into bed, to

avoid having to unplug (and re-plug) during the evening

- That pressing any key on the front panel will display values for 10 secs.
- How to remove the finger sensor and unplug unit from wall AC power after morning Awakening (if oximeter was plugged in during the night).

How the unit will be retrieved from the home.

### **Upon Morning Retrieval:**

Power off the unit

- 1. Press and hold the Power ON/OFF key for 3 secs.
- 2. Remove and discard the used finger sensor.
- 3. Clean the Rad 8 by wiping with a soft cloth damped with 70% isopropyl alcohol, or a commercially prepared disinfectant wipe.
- 4. Remove all sticky reside of tape from the grey interface cable by wiping with a cloth saturated with adhesive remover such as Goo-Gone or Detachol.
- 5. Before downloading data from the Masimo Change from SLP to STD mode:
  - Plug in the Masimo to an AC supply.
  - Power on the Masimo.
  - Press and hold NEXT and MODE ENTER at the same time until "No Sen" is displayed on the screen.
  - Release NEXT and MODE ENTER.
  - While "No Sen" is still displayed, again press and hold NEXT and MODE ENTER at the same time until the mode is displayed. If the mode reads "SLP" press NEXT until STD is displayed.
  - Press ENTER to execute the command for the mode change.

• When in STD mode, the indicator lights will be illuminated for FastSat, Silence Alarm, No Sensor and battery charging.

6. Connect the download cable that is connected to the computer with the ProFox software to the back of the Masimo Unit.

If the computer you are going to use does not have a serial communication port, not uncommon with new equipment, we recommend a Keyspan USB to serial converter model number USA-19HS. You can find where to buy this and pricing at <u>www.keyspan.com</u>. This device will replicate a 9 pin serial or COM port to allow downloading of the oximeters.

#### Download Procedures from Masimo to Profox for sending to Reading Center:

The Trend files on the Masimo only contain the dates and times of recording and the following procedures will be done to remove the data from the Masimo:

- 1. Download files from Masimo to ProFox
- 2. Name the File with Study ID
- 3. Save the File
- 4. Create a Zip File
- 5. Place Zip File on Reading Center FTP Server
- 6. Complete necessary paperwork during the download to Profox.

#### **Dowloading Files**

To Begin -Click on the PROFOX Icon on your Desktop



The Main Menu will appear with the information filled in

• Select Oximetry data (transfer)

🛃 PROFO	OX Associates, Inc. Oximetry Software version Standard			
<u>F</u> ile <u>E</u> dit	t Utilities About Case Sleep and Epidemiology Research Center			
Main Menu				
	Current Patient			
	PATIENT NAME: Patient Name			
	ID NUMBER: Patient I.D. Number			
	REQ. PHYSICIAN: Physician Name			
	REPORT COMMENTS: Overnight sleep study breathing room air.			
	Oximetry Test: 01/12/03 22:00. Duration: 07:56 hours,original memory, repo Datex-Ohmeda 3800 with 6 second resolution.	rted.		
	The current data path is: C:\Program Files\PROFOX 0XIMETRY\tests			
	<u>N</u> ew Patient	Data (transfer)		
	Select Another Patient	review Reports		

• Select Masimo Rad8 then select Next



ᄰ PROFOX: Access Oximetry Data		×
	Please select an oximeter:	
C BCI 3302	C Invacare 750	O Nellcor N-595
BCI 3303	C Invacare 775	Nellcor N-3000
BCI 3304	🔿 Invivo 4500 plus 4	O Nonin 2500 PalmSAT
BCI 3402	Invivo Scout ES	O Nonin 3100 WristOx
Burdick 0XY-200	C Masimo Rad-5	Nonin 8500M
Criticare 504	C Masimo Rad-9	Nonin 8600M
C Criticare 504D×	Masimo Radical	O Nonin 8800
🔿 Datex-Ohmeda 3500 TruSat	C Minolta Pulsox 3 Series	O Nonin 9600 Avant
C Datex-Ohmeda 3700	O Nellcor N-45	O Nonin 9700 Avant
Datex-Ohmeda 3740	Nellcor N-200	Philips M4529A
Datex-Ohmeda 3800	C Nellcor NPB-290	🔿 Quartz Q-400
Datex-Ohmeda 3900	O Nellcor NPB-295	C Respironics 920M
O Dolphin 2100	C Nellcor N-395	C Respironics 920M Plus
O Draeger MicrO2+	Nellcor N-550	<ul> <li>Respironics WristOx</li> </ul>
Nev	t Cancel	

• Select transfer new memory data from a Maximo

😽 PROFOX: Access Oximetry Data - M	lasimo Rad-5	
	Current Patient: Patient Name	
The prior memory transformed to the prior memory transformed t	Current Patient: Patient Name  sr: Ending time 01/01/00 00:00 Extract oximetry from the prior transfer. Iransfer new memory data from a Masimo Rad-5. Cancel	
	<u>C</u> ancel	

It will immediately begin transferring the data if your cable is connected

🔮 PROFOX: Access	Oximetry Data - I	Masimo Radical			_ 🗆 🗙
The selected COM poi	rt is: 1	Current F	Patient: 51111JR		
TI	he prior memory transl	fer:			
Time transferred	Starting time	Ending time			
11/07/05 17:46	No data	No data			
		Status: Collecti	ing oximetry data, bytes tran	sferred: 7503	
			Stop		

Oximetry\_Visit9

If you get an error message check cable connection and/or check your output selection on the Masimo is set correctly. Instructions for the proper settings will appear if the program is unable to find the connection.

PROFOX: Access Oximetry Data -	- Masimo Radical Current Patient: Patient Name	
The selected component. T		
The prior memory tran	nsfer:	
10/17/05 14:23 01/01/90 00:00	01/01/00 00:00	
	Status: Attempting to read the Radical There is no serial data on the selected COM port. Please make sure you are using a serial (modem) cable, and that the COM port is selected that has the cable attached. Also, please ensure that the Radical is in ASCII 2 mode. To put it into ASCII 2 mode, please do the following: Press the menu access button (icon looks like 3 sheets of paper). Using the arrow buttons, scroll to "Output" and then press the select button. The mode will be highlighted, so select it by pressing the select button. Change the mode to "ASCII 2." by pressing the up and down buttons. With "ASCII 2" highlighted, press the select button.	
	<u>C</u> ancel	
	Change COM <u>P</u> ort.	

If you have not deleted previous files on the Masimo, or if you have collected several files before downloading, you will need to select which file matches the Study ID you set up. This is why the Masimo Log is so important to identify correct participant.

• Select correct file based on date and start time of recording then select OK

				1=1-11
PROFOX: Access Oximetry Data - Masimo Radical				
Options		_		
Current Patie	ent:  51111JR			
The prior memory transfer:	<u> </u>	Record	ling sessions:	
Time transferred Starting time Ending time		Start time	End Time	Duration
11/07/05 17:46 11/04/05 09:22 11/07/05 17:46		1 11/04/05 09:22	11/04/05 09:55	00:33
		2 11/04/05 09:55	11/04/05 11:52	01:57
		3 11/07/05 08:05	11/07/05 17:46	09:41
	Ple	ase note that the first se	ssion is the oldest, and	d the last
	ses	sion is the most recent.		
Diagon calent the reporting car	cion with the starting	timo vou wich	to outract	
Please select the recording ses	sion with the starting	y unie you wish	to extract.	
ОК	ZZ Back	Can		
<u></u> ^	C D dok			

In cases where there are multiple files respond no when it asks if you want to include this data. This keeps the files separate, as you do not want to join participant files.



19

• Select save this test - confirm that the hours of recording you have are appropriate for the time the participant had the unit.



• Confirm it belongs to the correct participant



• It will display patient info and you can correct any fields needed

Please	e complete the patient information.
Patient Information:	
PATIENT NAME:	51111JR
ID NUMBER:	51111
REQ. PHYSICIAN:	
REPORT COMMENTS:	PSG file

If more than one file downloaded and you need to name the other files continue by

	PROFOX Associates, Inc. Oximetry Software version Standard	_ 🗆 X
	File Edit Utilities About	
	Lase Sleep and Epidemiology Research Lenter	
	Main Menu	
	Current Patient	
	PATIENT NAME: 51111JR	
	ID NUMBER: 51111	
	REQ. PHYSICIAN:	
	REPORT COMMENTS: PSG file collected 4 Nov 05	
	Oximetry Test: 11/04/05 09:55. Duration: 01:34 hours,original memory, not reported.	
	Masimo Hadical with 2 second resolution.	
	The current data path is:	
	C:\Program Files\PR0F0X 0XIMETRY\tests	
	New Patient	
	Select Another Patient	
la stin a "Ori	materia Data (teanafaa)" again	
pen radical 8	metry Data (transfer) again/	
nen select oxi	imetry from prior transfer	
ien seleet om	initially nom prior dumora	
	$\mathbf{h}$	
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Visit9		
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🔮 PROFOX: Access Oximetry Data - Masimo Radical	
Current Pa	tient: 51111JR
The prior memory transfer.           Time transferred         Starting time         Ending time           11/07/05         17:46         11/04/05         09:22         11/07/05         17:46	
<u>E</u> xtr	act oximetry from the prior transfer.
Iransf	er new memory data from a Radical.
	Cancel

Now you can select a different recording, select OK, then Save

🛃 PROFOX: Access	Oximetry Data - N	Masimo Radical					
Options							
		Current F	atient: 51111JR				
					_		
T	ne prior memory transf	er:			Record	ing sessions:	
Time transferred	Starting time	Ending time			Start time	End Time	Duration
11/07/05 17:46	11/04/05 09:22	11/07/05 17:46			04/05 09:22	11/04/05 12:06	02:44
				2 11/1	/04/05 09:55	11/04/05 19:38	09:43
				1 3 1 17	-07703-08.03	11/03/03 08.23	40.24
				Please note	e that the first ses be most recent	sion is the oldest, and	d the last
				3033101113 (Th	io most recent.		
	Please select	t the recordina	session with the startir	na time vo	ou wish to e	extract.	
	,· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·					
		1	1				
	<u>0</u> K		<< <u>B</u> ack		<u>C</u> ano	el	
		-					

🛃 PROFOX: Access Oximetry Dat	a - Masimo Radical				×
	Current Patie	nt <mark>51111JR</mark>			
The prior memory tra	insfer:		Reco	ding sessions:	
Time transferred Starting time	e Ending time		Start time	End Time Duration	1
11/07/05 17:46 11/04/05 09:	22 11/07/05 17:46		1 11/04/05 09:22	11/04/05 12:06 02:44	
			2 11/04/05 09:55	11/04/05 19:38 09:43	
			3 11/07/05 08:05	11/09/05 08:29 48:24	
Start of data: 11/04/05_11:22	Duration: 00:41 hours				
End of data: 11/04/05 12:04	Valid data: 00:41 hours.				
Sp02: 100-					
3p02. 100-					
80-					
60-					
40-					
40 <u></u>					
Pulse: 220-					
140-					
140-					
60 - <del></del>					
20-					
4 hours:	10	11	12	13	
<u>Save this</u>	test	<< <u>B</u> ack		Lancel	

When prompted if this is the correct ID – answer "No" and then complete the Patient Info screen with the correct information.



PR	DFOX										
Please complete the patient information.											
[	Patient Information:										
	PATIENT NAME:	51111JR									
	ID NUMBER:	51111									
	REQ. PHYSICIAN:										
	REPORT COMMENTS:	PSG file									
		<u>ο</u> κ									

After all downloaded files have been named correctly and accurate comments have been entered you can exit the ProFox software.

#### **Re-Set Rad 8 in order to Clear Trend:**

- 1. After download is completed disconnect cable from the back of the unit.
- 2. Power the unit off by pressing and holding the Power key for 3 secs.
- 3. Re-power the unit.
- 4. The unit will beep and cycle through its settings and end with NO SEN displayed.

#### **Clear Trend:**

- 1. Press MODE ENTER 4 times
- 2. CLR Trd will be displayed
- 3. Press the  $\uparrow$  or  $\downarrow$  button until YES is displayed
- 4. Press MODE ENTER to execute the CLR command
- 5. There will be no confirmation that the trend has cleared but the display will advance to SET CL
- 6. If no keys are pressed the display will revert to NO SEN
- 7. Fill in paperwork

MESSAGES

The Rad-8 will indicate other data or system errors. Message conditions for the Rad-8 follow:

DISPLAY	TYPE	SOLUTION			
LEDS FLASH HORIZONTAL BARS	Pulse Search	Wait for found pulse. (This Search should occur whenever a sensor is first applied to a patient).			
PULSE BAR TURNS RED (Bottom two LEDs only:)	Low Signal 1Q	<ol> <li>Rule out occlusion of blood flow.</li> <li>Verify placement of sensor.</li> </ol>			
PERFUSION BAR TURNS RED (Bottom	Low Perfusion	<ol> <li>Rule out occlusion of blood low.</li> <li>Attempt to warm patient.</li> <li>Move sensor to better perfused site.</li> </ol>			
two LEDs only:)		Note: Masimo recommends using an adhesive sensor whenever low perfu- sion is expected or evident.			
Sp02 NUMBER FLASHES	Saturation limit alarm	Assess /address patient condition. Re-set alarm limits if indicated			
PULSE RATE NUMBER FLASHES	Pulse Rate limit alarm	Assess laddress patient condition. Re-set alarm limits if indicated.			
Err ##	System Fault	Return for service There are several error codes, all error codes require return of the unit to an authorized service center for repair. See Section 9. Service and Repair.			
688 SEN	Defective sensor	Replace sensor			
SEN	Unrecognized sensor	Connect appropriate cable			
۳۵۶ ۲۳۶	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.			

#### Troubleshooting

The following chart describes what to do if the Rad-8 system does not operate properly or fails.

DISPLAY	TYPE	SOLUTION		
UNIT DOES NOT POWER ON	Low battery/ not plugged into AC power supply	Check / plug into AC power supply.		
CONTINUOUS SPEAKER TONE	Internal Failure	Unit requires service. Press the Alarm Silence button. If alarm continues to sound, power down unit. If the power button does not turn the unit off, press and hold the sensitivity and alarm susperd buttors simultaneously. Return the unit for service.		
NO SPEAKER TONE	Pulse tone set to "mule"	Press Up Arrow (Rad-8) or Alarm Volume Adjust (Rad-8).		
NO OF LARCE TONE	Alarm Suspend Enabled	Inspect Alarm Suspend Indicator. See Section 4, <i>Alarm Suspend</i> . Press Alarm Suspend button until Alarm Suspend Indicator is no longer illumi- nated or flashing.		
BUTTONS DON'T WORK WHEN PRESSED	Internal Failure	Use auxillary power down method by pressing and holding sensitivity and Alarm Suspend buttons simultaneously. Return for service.		

### **IV. CREATE ZIP FILE BACKUPS**

After you have downloaded and saved the Masimo oximetry files you need to make a backup copy (create a zip file) and transmit the "zip" file via FTP to the Reading Center.

Go the directory containing the POD files:

C:\\Program Files\PROFOX OXIMETRY\Tests

			/							
🗁 PROFOX OXIMETRY										
Eile Edit View Favorites Iools Help										
🕞 Back 🔹 🕥 🖂 🏂 Search 🔊 Folders 🔛										
Address 🗁 C:\Program Files\I	PROFOX O	XIMETRY				💌 🄁 Go				
		Name 🔺	Size	Туре	Date Modified	▲				
File and Folder Tasks	×	🛅 452+drv		File Folder	10/14/2005 2:47 PM					
		🛅 ASCII Data		File Folder	11/7/2005 5:30 PM					
Other Places	*	🛅 Manuals		File Folder	11/2/2005 5:36 PM					
		Reports		File Folder	11/7/2005 5:30 PM					
Details	×	🛅 Tests 📕		File Folder	11/7/2005 6:07 PM					
Details	•	🔟 CD-SYS1	1 KB	DAT File	8/25/2005 3:35 PM					
		🛂 Convert	64 KB	Application	11/24/2003 8:34 AM					
		🔤 EnhControls.lic	1 KB	LIC File	11/7/2005 5:30 PM					
		🖄 EnhControls.ocx	384 KB	ActiveX Control	2/9/2002 2:41 PM					
		MFC40.DLL	903 KB	Application Extension	2/6/1999 11:00 PM					
		MSVCRT40.DLL	319 KB	Application Extension	1/28/1999 8:59 PM					
		NDQCOM32.OCX	255 KB	ActiveX Control	7/24/1998 10:29 AM					
		PDQTAPI.OCX	60 KB	ActiveX Control	11/25/1996 2:36 PM					
		DFWCPT	1 KB	DAT File	11/7/2005 6:13 PM					
		🖬 PFWMM32	43 KB	DAT File	11/7/2005 5:47 PM	•				

A list of all the "pod" files that have been downloaded, named, and saved will be displayed. The program names the test files using the participant name, the starting date and time of the test, the duration of the test in hours, the status of the test and the entered comments. In the example below, 51111JR was done on November 4, 2005, it started at 9:55 am and the recording was for 1 hour 34 minutes.

There will be one ".pod" file for every data collection.

Name 🛆		Size	Туре	Modified	
33333	21 Oct 2005 16_30 Dur 00_06 .pod	3 KB	POD File	10/21/2005 4:38 PM	
🗖 51111JR	04 Nov 2005 09_55 Dur 01_34 .pod	8 KB	POD File	11/7/2005 6:55 PM	
52222	04 Nov 2005 11_22 Dur 00_41 .pod	3 KB	POD File	11/7/2005 7:03 PM	
52222	07 Nov 2005 17_56 Dur 00_00 .pod	3 KB	POD File	11/7/2005 6:57 PM	
55089	06 Sep 2005 12_02 Dur 02_40 .pod	5 KB	POD File	10/21/2005 4:19 PM	
GCRC_Cert1	10 Feb 2006 09_17 Dur 02_26 .pod	11 KB	POD File	3/10/2006 12:26 PM	▾
				•	
19 object(s)		80.	5 KB	🖳 My Computer	//

Once you are in this directory you will create a zip file for all Masimo collections that need to be sent to the Reading Center. Select "File" -> New -> then WinZipFile.



Name the zip file as follows:

SOF01-05Apr06.zip (SOF-indicating study name, your site ID, and date DDMonthYY)

				/			<u> </u>	_						
🔁 C:\Tests					_	🗐 WinZip -	M01-05A	pr06.zip						
File Edit View	Favorit	es Tools	Help			File Action:	s Options	Help						
🔃 Back 🔹 🔿 👻	1	Search 🗗	Folders 🛞 🎼	-≣ α X ≌•		2		(4)		ſĜ			2	
Address 🔂 C:\Tes	ts					New		Equaritad	کی ا	V.	View	CheckOut	Wizard	
Name 🛆		Size	Туре	Modified	Pati		Open	rayunces	Auu	LAUIDUU	VIGVV	CHELNOUL	Wizdiu	
33333		3 KB	POD File	10/21/2005 4:38 PM		Name 🔇					Туре		Modified	
■51111JR		8 KB	POD File	11/7/2005 6:55 PM										
52222		3 KB	POD File	11/7/2005 7:03 PM										
52222		3 KB	POD File	11/7/2005 6:57 PM										
55089		5 KB	POD File	10/21/2005 4:19 PM										
GCRC_Cert1		11 KB	POD File	3/10/2006 12:26 PM										
GCRC_Cert2		12 KB	POD File	3/10/2006 12:43 PM										
Patient Name		12 KB	POD File	12/9/2002 3:55 PM										
I X.txt		1 KB	Text Document	3/1/2001 10:16 AM										
M01-05Apr06.zip		0 KB	WinZip File	5/5/2006 4:12 PM										
•						•								Þ

Once it has been named Click on the zip file to open it.

Check the Masimo Log and determine which studies are to be sent.

Highlight the studies in the "Tests" folder that need to be placed in the zip file (Hold down Control Key and click on studies that need to be included). Once highlighted click on any one of the studies and drag them into the winzip window.



Once you see the files displayed you can close the Winzip file. As long as the Winzip file window is open you can continue to add files. If after you close the file you want to add more, just double click on the winzip file to open it again and add more files by highlighting and dragging. (Confirm all "Names" - "Participant IDs" are accurate)

<b>(</b> )	/inZip - N	101-05Ap	or06.zip						
<u>F</u> ile	<u>A</u> ctions	Options	<u>H</u> elp						
1	0	1	<b>(</b>	<b>()</b>	1	<b>@</b>	<b></b>	<b></b>	
P	lew	Open	Favorites	Add	Extract	View	CheckOut	Wizard	
Nam	ie 🔇				· · · · ·	Туре		Modified	
5	1111JR		04 Nov 200	)5 09_55 Dur	01_34 ]	POD File		11/7/2005 6:55	PM
5	2222		04 Nov 2005	5 11_22 Dur I	00_41	POD File		11/7/2005 7:03	PM
									Þ
Selec	ted 0 files	, 0 bytes			Total 2 fil	es, 11KB			● ● //.

This zip file becomes your backup copy of your data and should be kept on some media or computer other than the computer used to download the data to Profox. Do not delete the files from PROFOX.

### BE SURE TO RECORD ON THE MASIMO LOG SHEET THE FILE(S) HAVE BEEN DOWNLOADED AND BACKED UP.

This will confirm to the next person using the Masimo that the files can be deleted before proceeding to collect additional data.

### IV. FTP DATA TO READING CENTER

Create a folder on the computer used to send data via ftp called: "FTPSends\_SOFV8 Place the zip file containing the Masimo files in this directory.

Using your web browser, enter the following ftp address:

			ftp://			(1	Nate will send once set up)
	User nan	nes assigned	are:	SOF01 - SOF02 -	Minnea Pittsbu	apolis rgh	
Login As	Either the serve e-mail address w FTP Server: User Name: Password: After you login, by adding it to y	r does not allow vas not accepted 129.22.254.14 sac01 you can return t rour Favorites Lis	anonymous loo o this FTP serv t.	gins or the	X		Assigned passwords have been sent via e-mail to the invididual sites and may be changed for security reasons from time to time. Please contact Susan Surovec 216-844-6272 if you are having problems accessing the FTP server.
	🔲 Login Anony	mously	Save Pas	sword	el		

🔁 \\dceweb1\Incoming_PSG\Sickle	\\dceweb1\Incoming_PSG\Sickle_Cell\sac01											
<u>File E</u> dit <u>Y</u> iew F <u>a</u> vorites <u>T</u> ools	<u>H</u> elp	/										
$\Leftrightarrow \text{Back} \bullet \to \bullet  \textcircled{log}   \textcircled{Q} \text{Search}   \textcircled{B} \text{Folders}   \textcircled{G}   \textcircled{P}   \textcircled{P}   \leftthreetimes ) \boxtimes \bullet   \blacksquare \bullet$												
Address 🔄 \\dceweb1\Incoming_P5G\Sickle_Cell\sac01 ⊭ 🖉 @Go												
Name 🛆	Size	Туре	Modified	Patient Name								
C_021006.ISF	41 KB	ISF File	3/3/2006 1:21 PM									
C_021006.LCK	0 KB	LCK File	3/3/2006 1:21 PM									
C_021006.MSR	64,458 KB	MSR File	3/3/2006 1:21 PM									
C_021006.SET	7 KB	SET File	3/3/2006 1:21 PM									
C_021006.svr	64 KB SVR File 3/3/2006 1:21 PM											
C_021006.TMP	1 KB	TMP File	3/3/2006 1:21 PM									
C_021006.WEB	8 KB	WEB File	3/3/2006 1:21 PM									
GCRC certif 2 022406.MSR	69,024 KB	MSR File	3/3/2006 1:25 PM									
GCRC certif 2 022406.SET	7 KB	SET File	3/3/2006 1:25 PM									
GCRC certif 2 022406.WEB	8 KB	WEB File	3/3/2006 1:25 PM									
I sac01_ftp_readme.txt	1 KB	Text Document	2/22/2006 4:45 PM									
<u>                                     </u>				► E								
11 object(s)			130 MB 🔠 Loc	al intranet								

Place the "zip" file on the server in the appropriate folder:

Be sure you have closed the zip file and or any files before placing them on the server. "Folders" cannot be placed on the server.

Enter data on the appropriate forms and send an e-mail to susan.surovec@case.edu that a Masimo data zip file was placed on the FTP server. Please make every attempt to send data to Cleveland every week.

Remember to delete the files from the Masimo!