



Nellcor™

**Portable SpO₂ Patient Monitoring System
PM10N**

Home Use Guide



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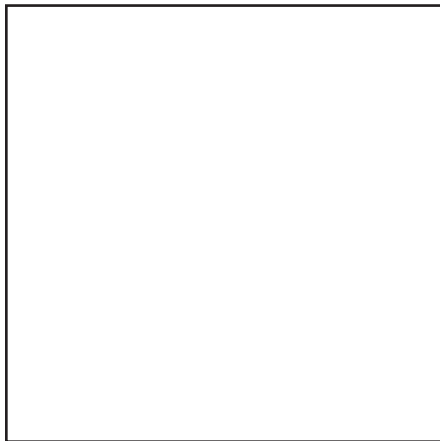
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Write your clinician's contact information here.



Notes:

1 Welcome

This manual is for the home caregiver—the person who provides care in the home for a patient monitored by the Nellcor™ portable SpO₂ patient monitoring system (PM10N). Read this entire guide before using the monitoring system.

What Does the Monitoring System Do?

The monitoring system measures the patient's pulse rate and the percentage of oxygen circulating in the blood (*functional oxygen saturation*). When either the patient's pulse rate or the percentage of oxygen goes below or above a pre-set alarm limit, the monitoring system warns you by sounding an alarm, showing an indicator, and flashing a number.

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The monitoring system can be used for patients of all ages—infants, children, and adults. Your clinician will assist you with the selection and use of the appropriate Nellcor™ sensor, based on the size and age of the patient.

What Is Your Role As Caregiver?

The clinician will instruct you in:

- Turning the monitoring system on and off
- Attaching the sensor to the patient
- Responding to alarms
- Contacting the clinician with questions or concerns



What Is the Clinician's Role?

The clinician is a trained health care professional who:

- Orders a monitoring system and sensors for use in your home
- Sets up the monitoring system for you
- Assists you with monitoring the patient and answers any questions you have
- Reviews the monitored results and the patient's condition
- Ensures that the monitoring system is working correctly
- Follows up with you on a regular basis to make sure the monitoring system is meeting your needs



If you have any questions about the information provided in this guide, ask your clinician.



2 Safety Information

Read this chapter thoroughly. If you have questions, contact your clinician.

Safety Symbols

	WARNING Alerts you to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.
	Caution Identifies conditions or practices that could result in damage to the equipment or other property.



WARNINGS

- Explosion hazard—Do not use the monitoring system in the presence of flammable substances.
- Shock hazard—Use only AA size batteries. Do not use different types or models of batteries, such as lithium-ion and nickel-metal hydride batteries, together.
- Shock hazard—Firmly close the battery cover to prevent moisture from entering the monitoring system.
- Shock hazard—Do not operate the monitoring system with the battery cover open or removed.

- Shock hazard—Do not immerse or apply liquid to the sensor.
- Carefully route the cabling to reduce the possibility of patient entanglement or strangulation.
- The LCD panel (display) contains toxic chemicals. Do not touch broken LCD panels.
- Do not reuse any sensor intended for single use. If in doubt, ask your clinician.
- Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor. Do not apply the sensor too tightly or by using excessive pressure. Do not wrap the sensor, apply supplemental tape, or leave the sensor too long on one place.
- Do not cover or obstruct the holes for the speaker or silence or decrease the volume of the audible alarm if patient safety could be compromised.
- Do not use any monitoring system or sensor that appears damaged.
- Pulse oximetry readings and pulse signal can be affected by patient conditions, excessive patient movement, sensor application errors, and certain ambient environmental conditions.
- To ensure accurate measurements in bright ambient light, cover the pulse oximetry sensor site with opaque material.
- For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to their respective instructions for use.
- Do not crimp the pulse oximetry cable, which could cause damage to the cable.

- The only user-serviceable parts inside the monitoring system are the four AA batteries. While you can open the battery cover to change the batteries, only qualified service personnel should remove the cover or access internal components for any other reason. Do not modify any components of the monitoring system.
- To avoid damage, do not throw, hit, drop, impact, or apply pressure to the batteries.
- Keep the monitoring system and batteries out of reach of children to avoid any accidents.
- Remove batteries from the monitoring system before cleaning.



Cautions

- The monitoring system may not work if it is operated or stored at conditions outside the ranges stated in this manual, or if it is subjected to excessive shock or dropping.
- Be aware of possible interference from sources of electromagnetic interference, such as cellular phones, radio transmitters, motors, telephones, lamps, electrosurgical units, defibrillators, and other medical devices. If pulse oximetry readings are not as expected for the patient's condition, remove the sources of possible interference.

- The use of accessories, sensors, and cables other than those specified may result in inaccurate readings of the monitoring system and increased emission and/or decreased electromagnetic immunity of the monitoring system.
- To avoid short-circuiting the batteries, do not let the batteries come in contact with metal objects at any time, especially during transport.
- Follow local government ordinances and recycling instructions regarding disposal or recycling of the monitoring system and its components, including batteries and accessories.

3 Set Up the Monitoring System

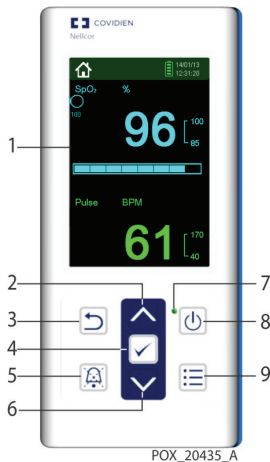
Perform the following steps to prepare the monitoring system for use with your patient:

- Identify the parts of the monitoring system
- Insert the batteries
- Turn on the monitoring system
- Attach a sensor to the monitoring system and to the patient

Operating Environment

To ensure reliability, the monitoring system must be operated within temperatures of 5° C to 40° C (41° F to 104° F), humidity of 15% to 95% (non-condensing), and at altitudes of -390 to 5,574 m (-1,280 to 18,288 ft).

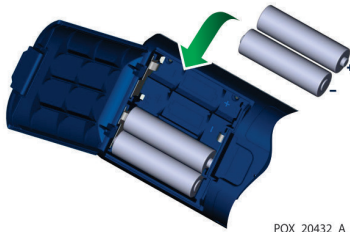
Parts of the Monitoring System



- 1 Display
- 2 Up button
- 3 Return button
- 4 OK (Select) button
- 5 Silence Alarm button
- 6 Down button
- 7 Power-On indicator
- 8 Power On/Off button
- 9 Menu button

Insert the Batteries

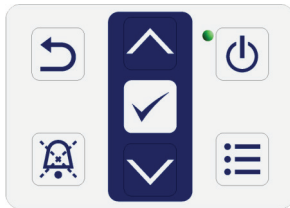
1. Use 4 Lithium AA batteries.
2. Make sure to orient each battery correctly.



Turn On the Monitoring System

1. Press the power button for about 1 second.
2. Make sure you hear a beep (this is a test for the alarm sound) and that the monitoring system's main screen appears.

The light next to the power button turns green.



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Turn Off the Monitoring System

1. Press and hold the power button for about 1 second.
2. Make sure the screen and green light turn off.



Identify Connectors

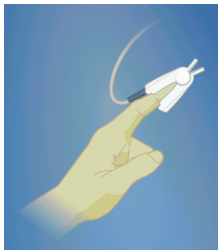
1. Sensor Connector
2. Service Connector (Do not use unless instructed by your clinician.)



Attach the Sensor to the Patient

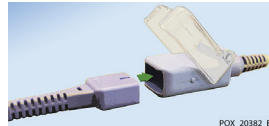
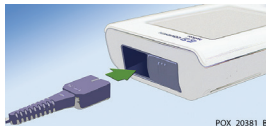
1. Attach the sensor to the appropriate location on the patient (for example, finger, forehead, nose, or foot).

If the sensor is not attached to the patient, you will see this picture on the screen.

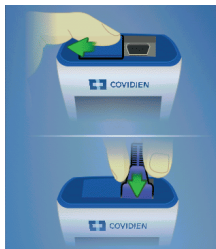


Connect the Sensor to the Monitoring System

1. Insert the sensor connector firmly.
2. If you use an extension cable, make sure it is firmly connected to the sensor's connector.

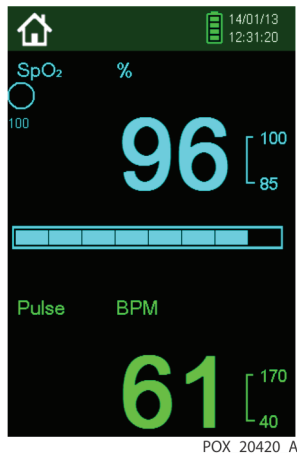


If the sensor or extension cable are missing or not connected firmly, you will see this picture on the screen.



Verify Operation

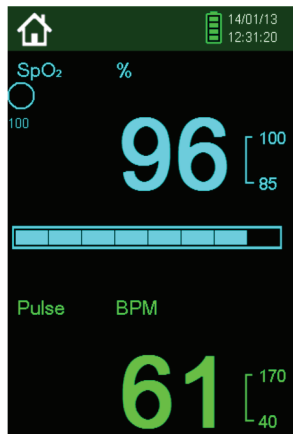
1. Look at the display to see if it is showing oxygen saturation (SpO₂ %) and pulse rate values in the expected range.
2. If you are not sure, contact your clinician.



4 Monitor the Patient

Once you have completed the setup tasks, you are ready to monitor the patient. As you monitor the patient, you will perform the following tasks:

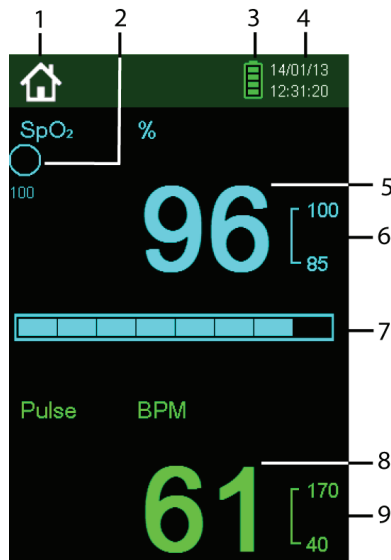
- Recognize what the main screen looks like under normal conditions
- Verify that the monitoring system is receiving a good signal from the sensor
- Identify alarms, alerts, and indicators
- Change monitoring system settings, such as brightness and sound, if desired
- View and report monitoring history as requested by your clinician



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Identify Main Screen Components

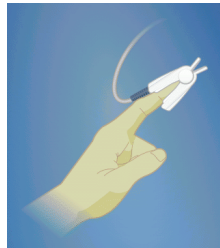
1. Homecare Mode indicator
2. SatSeconds™ indicator (your clinician will explain this feature if necessary)
3. Battery power level
4. Date and time
5. Current SpO₂ % (oxygen) reading
6. SpO₂ % upper and lower alarm limits
7. Pulse indicator (blip bar)
8. Current pulse rate (beats per minute, BPM)
9. Pulse rate (BPM) upper and lower alarm limits



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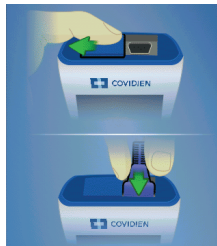
Identify Sensor Detached from Patient

1. Place sensor back on patient (finger, forehead, or nose).
2. If you have trouble, contact your clinician.



Identify Sensor Disconnected from Monitoring System

1. Firmly insert the sensor connector into the plug at the top of the monitoring system.
2. If you have trouble, contact your clinician.

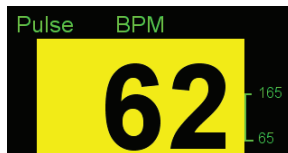


Identify Pulse Rate Alarm

High or Low pulse rate

Contact your clinician.

Pulse Rate Low

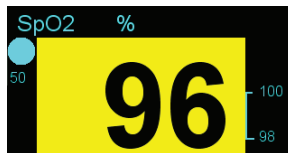


Identify SpO₂ Alarm

High or Low SpO₂ %

Contact your clinician.

SpO₂ Low



Identify Alarm Silence

Temporarily silence an alarm by pressing the Silence Alarm button.



The Alarm Silenced symbol appears on the screen with the time remaining for the alarm to be silenced.



Identify Signal Interference

1. Turn off other nearby electronics.
2. Encourage patient to be still.
3. If the interference symbol continues to appear on the screen, contact your clinician.



Identify Low Battery

Battery OK

Fewer bars indicates less power.



Low Battery symbol

If monitoring continuously, replace the batteries within 15 minutes. If monitoring for spot checks, replace the batteries before the next use.



Critically Low Battery symbol

Replace the batteries as soon as possible.



Operate Buttons

1. **Power:** Press and hold to turn monitoring system on or off.



3. **Menu:** Press once to view the list of available settings.



5. **Up/Down:** Press once to move up or down the menu or to increase or decrease a value by one. Press and hold to move faster through the menu or to increase or decrease a value by more than one.



2. **Silence Alarm:** Press once to temporarily silence the alarm sound.



4. **Return:** Press once to go back to the previous screen.



6. **OK:** Press once to select a menu item or value. On the Monitoring History screen, press to change the interval of readings displayed from every 1, 5, 100, or 500.



Identify Menu Items

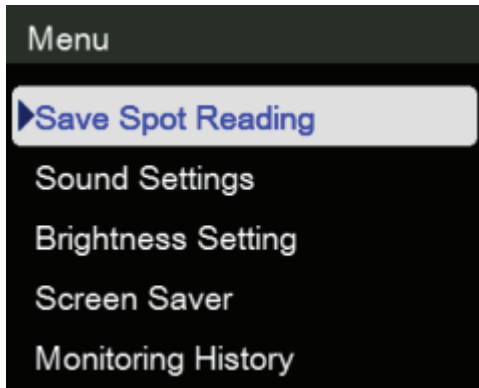
Save Spot Reading allows you to capture the reading that is currently displayed.

Sound Settings allows you to adjust the volume for alarms, pulse beep, and key beep.

Brightness Setting allows you to adjust the screen's brightness.

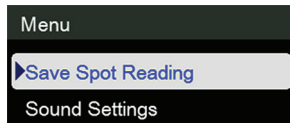
Screen Saver allows you to set the time interval when the screen will go dark after the monitoring system keys have not been pressed.

Monitoring History allows you to view the readings saved.



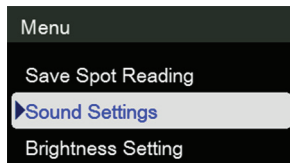
Save Spot Reading

1. Press the Menu button.
Save Spot Reading (top item) is highlighted.
2. Press OK to select Save Spot Reading.
3. Message "Spot Reading Saved" appears.



Adjust Volume

1. Press the Menu button.
2. Press Down Arrow until Sound Settings is highlighted.
3. Press OK to select Sound Settings.
4. Select the sounds setting you want to change.
Alarm Volume is shown as an example on the next page.

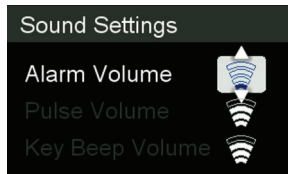
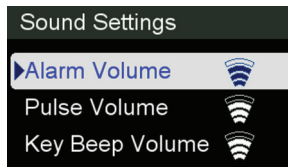


Alarm Volume Example

For example, to change the alarm volume:

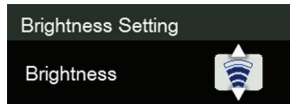
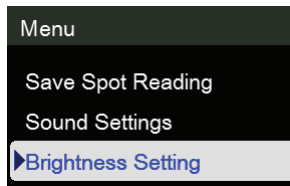
1. Press OK when Alarm Volume is highlighted.
2. Press the Up Arrow or Down Arrow to select a volume.
3. Press OK to select the volume.

Note: You can also adjust the Pulse Volume by pressing Up Arrow or Down Arrow when the main monitoring screen is displayed.



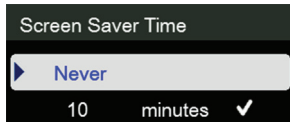
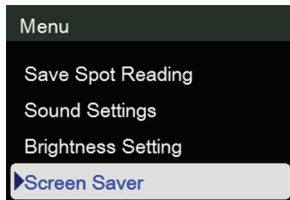
Adjust Brightness

1. Press the Menu button.
2. Press Down Arrow until Brightness Setting is highlighted.
3. Press OK to select Brightness Setting.
4. Press Up or Down Arrow to adjust to the brightness you want.
5. Press OK to select the brightness setting.

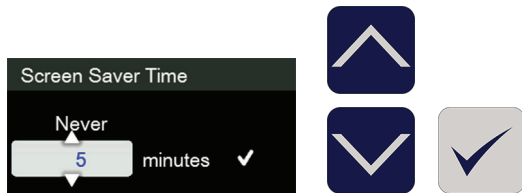


Set Screen Saver

1. Press the Menu button.
2. Press Down Arrow until Screen Saver is highlighted.
3. Press OK to select Screen Saver.
4. Choose from two options:
 - Press Up Arrow to highlight Never and press OK.

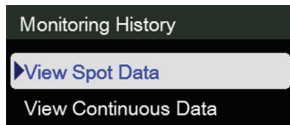
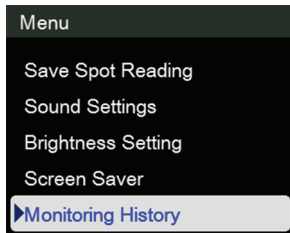


- Or, press OK to change the number of minutes of idle time before Screen Saver activates.
 - To change the number of minutes, press Up or Down Arrow.
 - Press OK to select the number of minutes indicated on the display.



View Monitoring History

1. Press the Menu button.
2. Press Down Arrow until Monitoring History is highlighted.
3. Press OK to select Monitoring History.
4. Select View Spot Data or View Continuous Data.
5. Press OK.



6. When viewing Continuous Data, press OK again to adjust the interval of the displayed readings to every 1, 5, 100, or 500 data points.

History Table		(1)	
Time	SpO ₂	Pulse	Status
13/11/17			
11:37:27	97	63	
11:37:26	97	61	
11:37:25	97	61	
11:37:24	97	60	



History Table		(100)	
Time	SpO ₂	Pulse	Status
13/11/17			
11:46:38	98	61	
11:44:58	98	66	
11:43:18	---	---	SO

Interpret Status Codes

Status	Description
LM	Loss of pulse, patient motion
LP	Loss of pulse
CB	Critically low battery
LB	Low battery
SO	Sensor off patient
SD	Sensor disconnected from monitoring system
AO	Alarm audio off
AS	Alarm audio silenced
MO	Signal interference, patient motion
PS	Pulse search

History Table		(100)	
Time	SpO ₂	Pulse	Status
13/11/17			
11:46:38	98	61	
11:44:58	98	66	
11:43:18	---	---	SO
11:41:38	97	69	
11:39:58	---	---	SO
11:38:18	98	62	

Notes:

5 Change the Sensor

Your clinician can help you determine when the sensor needs changing or moving to another location on the patient. Look for the following characteristics in sensors that have been applied to the patient for a period of time:

- Patient is developing dryness, redness, or soreness on the skin underneath the sensor. **Contact your clinician immediately, and change the location of the sensor.**
- Adhesive on the sensor is not sticking very well.
- Sensor falls off easily, or falls off immediately after you have attached it to the patient.

Examples of Sensor Placement



Sensor Information

Some of the sensors are provided in sterile packaging, and some are not. If you have questions about the sensors you are using on the patient, contact your clinician.

6 Clean the Monitoring System and Sensor

You can clean the monitoring system periodically to keep it looking fresh and so that you can readily see the display. In addition, if there is any type of fluid spill on the monitoring system, you should clean it immediately.

Recommended Cleaning Materials

- Soft cloth
- Tap water
- Isopropyl alcohol
- A pre-moistened wipe (ask your clinician)



Clean the Monitoring System

1. To avoid possible shock, remove the sensor from the patient, turn off the monitoring system, and remove the batteries.

2. Dampen a soft cloth with tap water or isopropyl alcohol. If the cloth becomes soaked with liquid, start again with a dry cloth.

Or, use a pre-moistened wipe recommended by your clinician.

3. Gently wipe all surfaces of the monitoring system.
4. Allow the monitoring system to dry.



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Clean the Sensor



1. If the sensor is reusable, ask your clinician how to clean it.
2. If the sensor is disposable, periodically dispose of it and replace it with a new one.

Your clinician will provide guidance on the frequency of replacement.

3. After you clean a reusable sensor, allow it to dry.

Restart the Monitoring System

- 1.** Turn the monitoring system on. Ensure it powers on correctly.
- 2.** Listen for the audible beep that indicates the sound is working.
- 3.** Look at the display and ensure that it turns on and that you see the SpO₂ and pulse rate areas.
- 4.** If the monitoring system is operating correctly, attach the sensor to the monitoring system and to the patient.
- 5.** Monitor the patient as usual.

Notes:

7 Accessories

The monitoring system has a few accessories. Ask your clinician if they are available for your use.

Extension Cable

(DEC-4)



Protective Cover









Carrying Case











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8 Symbols

The symbols that appear on the labels attached to the monitoring system are described in this chapter.

Symbol	Description
	Prescription only device
	Must consult instructions for use
	China RoHS (no hazardous substances)
	Proper waste disposal for electrical and electronic equipment

Symbol	Description
IP22	Ingress protection (IP) rating: Protected against access to hazardous parts by a finger or solid object greater than 12.5mm in size. Protected against falling drops of water with the device tilted up to 15 degrees from normal position.
	Type BF applied part
	UL classified (tested by Underwriters Laboratories to specific requirements for USA and Canada)
	CE Mark - Approved for sale and use in Europe

Symbol	Description
	European Union representative
	Reference code (part number)
	Manufacturer
	Serial number
	Date of manufacture

Glossary

ambient light The light in the area of the patient sensor. High ambient light sources, such as bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO₂ sensor.

BPM See *pulse BPM*.

caregiver The person who attends to the patient and check the monitoring system readings and sensor placement.

clinician The trained healthcare professional who assists you with monitoring the patient and using the monitoring system in your home. This person can be the doctor, or nurse, treating the patient, or some other trained healthcare professional.

heart rate

The number of times the heart beats, usually as a per-minute value.

monitoring system

The device, described in this home use guide, used to measure SpO₂ and pulse rate for a patient.

oxygen saturation (saturation)

A measurement of the percentage of oxygen circulating in the blood. Also identified as %SpO₂.

pulse BPM

Pulse rate. A measurement of the number of times the heart beats per minute. Pulse rate is also called heart rate, beats per minute, or BPM.

sensor

An accessory used to collect and send patient information to the monitoring system. One end of the sensor attaches to the patient's finger, toe, ear lobe, or forehead and the other end of the sensor connects to the monitoring system.

The sensor collects measurements by sensing the patient's pulse rate and percentage of oxygen in the blood and sending this information to the monitoring system.

sensor site

The place on the patient's body where the sensor is applied, such as a finger, the forehead, or the nose.

SpO₂ (%SpO₂)

An estimation of the oxygen saturation level as measured by the monitoring system.

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