HOME USE GUIDE

for the

NELLCOR® N-200 Pulse Oximeter

Your local *NELLCOR* ® Home Care Provider is:

24-hour hotline:_____

EDENTEC
A Nellcor Company

Edentec Corporation
10252 Valley View Road
Eden Prairie, MN 55344
U.S.A.

To contact Edentec's representative: in the United States, call 612 941-3006; outside the United States, call Edentec's local representative.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

023466A-0492

EMERGENCY PHONE NUMBERS

Post this list near your telephone.

Ambulance	911_____
Police	911_____
Fire Department	911_____
Doctor	_____

Other Telephone Numbers

Caregiver/Home Care Provider	_____
_____	_____
_____	_____
_____	_____

Table of Contents

Table of Contents (continued)

IMPORTANT

It is essential that you, the Home User of this monitor, read and understand this Home Use Guide completely before using the monitor. This Home Use Guide provides you with basic reference information for proper use of the monitor. This manual is not a replacement for the N-200 Operator's Manual or for the training your home care provider or home provider company will provide for you.

Read this manual carefully *BEFORE* using the monitor. Read all warnings and cautions (in boldface type). If you do not understand any part of the manual or the warnings and cautions, ask your home care provider or home provider company before using the monitor.

Intended Use

This monitor can be used for patients of all ages. It measures blood oxygen saturation levels and pulse rate continuously. It sounds an alarm and an alarm light blinks when detected oxygen levels or pulse rate are above or below the alarm settings. The N-200 monitor may be used with or without ECG synchronization.

This monitor does not distinguish between normal hemoglobin and abnormal hemoglobin. Therefore, this monitor should not be used in cases of carbon monoxide poisoning or any other situation that may decrease the hemoglobin's capability to carry oxygen.

The N-200 monitor is not intended for use as an infant apnea (stopped breathing) monitor. If required, your patient's doctor will prescribe special equipment for detecting apnea.

Federal law restricts this device to sale by or on the order of a physician.

Your Home Care Provider

A qualified health care professional (called a *home care provider*) is essential for providing adequate care for your patient. Your home care provider will:

- Provide you with a monitor, pulse sensors, and accessories
- Train you how to use your monitor, sensors, and accessories
- Teach you how to respond to alarms

If you have any questions, ask your home care provider.

Definitions

Alarm	The tone you hear from the monitor and the indicator that flashes when an abnormal condition is detected.
Battery Charger	A device built inside your monitor that allows you to plug the monitor into a standard wall socket (3 prong) and recharge the monitor's internal battery.
ECG Monitor	A monitor that displays electrical signals from the heart, through electrocardiogram (ECG), as heart rate (not pulse rate).
Hemoglobin	The part of the red blood cell that carries oxygen.
Home Care Provider	Health care professional who supplies the monitor, provides training on its use, and does follow-up and maintenance checks.
Interface/Powerbase	The section of the monitor that allows AC electrical power to be used to run the monitor.
Monitor	The part of the pulse oximetry system that receives signals from the detector on the pulse sensor. The system then measures, displays, and compares the readings to the alarm settings. The monitor sounds an alarm when the oxygen saturation level or pulse rate are outside the alarm settings.
Oxygen Saturation	A measure of the amount of oxygen actually carried in the blood, compared to the amount it *could* carry.
Oxygen Transducers	See *pulse sensor.*

Patient Module	The connecting cable between the pulse sensor and the monitor. If using ECG equipment, the patient module may also be used to synchronize the saturation measurement with the ECG signal.
Perfusion	The amount of blood in a particular area, such as the arm or leg. Poor perfusion indicates that very little blood flow occurs in the area.
Pulse Oximetry	A method of determining oxygen saturation levels.
Pulse Sensor	The part of the pulse oximetry system that actually sends and receives the light.
Synchronization	Using signals from more than one source and using them to synchronize the pulse oximeter's oxygen measurement. This enhances oxygen measurement, especially when the patient has poor perfusion or is moving around.
Standby	A condition controlled by the ON/STDBY switch that turns off monitor functions, but allows battery charging and retains data stored in memory.

What You Need to Know About the N-200 (Safety Information)

Read this manual carefully *BEFORE* using the monitor. Read all warnings and cautions (in boldface type).

NEVER USE A MONITOR THAT YOU SUSPECT IS NOT WORKING CORRECTLY. Contact your home care provider immediately to have the monitor tested or replaced.

The N-200 should be plugged into a wall outlet at all times. The battery is only for backup in case of power failure. The battery provides operation for up to 90 minutes if fully charged. After the battery has discharged, the monitor turns itself off automatically.

Always use *NELLCOR* pulse sensors. Using any other pulse sensor may cause the monitor not to work correctly.

Incorrect application or use of the pulse sensors may cause tissue damage or false readings. Do NOT wrap the pulse sensors too tightly or apply extra tape. Check the sensor site every 4 hours for redness or swelling. Do not place the sensor somewhere it is not intended to be used.

Excessive light (such as fluorescent lamps or direct sunlight) may cause the monitor not to work correctly. If this happens, cover the sensor area with a piece of dark cloth to block the extra light.

DO NOT reuse disposable pulse sensors. Dispose of them as instructed.

DO NOT get pulse sensors wet or they may not work correctly.

DO NOT change the alarm settings that your home care provider has directed you to use. Check the settings at least once a day or whenever you turn the monitor on. When the monitor is turned off and then back on, all alarm settings return to their standard values (see Appendix A). If necessary, return settings to the values directed by your home care provider.

Never turn the audio alarm off when you are not in the room with the patient. If you do so you may not know when an alarm condition occurs. If you disable the alarm, be sure to turn it back on before leaving the room.

Be sure you can hear the alarm from wherever you are in the house.

For continued protection from fire, replace fuses only with those of the same type and rating.

Shock hazard. DO NOT remove the cover of the monitor.

DO NOT place the monitor in water or any other liquid. Do NOT use abrasive or caustic cleaners on the monitor or pulse sensors.

Remove the pulse sensor before bathing the patient.

How the N-200 Works

Your patient's doctor has decided to place your patient on a device called a *pulse oximeter*. This device uses a technique called *pulse oximetry* to measure the amount of oxygen in the blood continuously.

Pulse oximetry requires three parts: an *oxygen transducer (called a pulse sensor in this manual)* , a patient module, and an *oximeter (called a monitor in this manual)*. Refer to Figure 1.

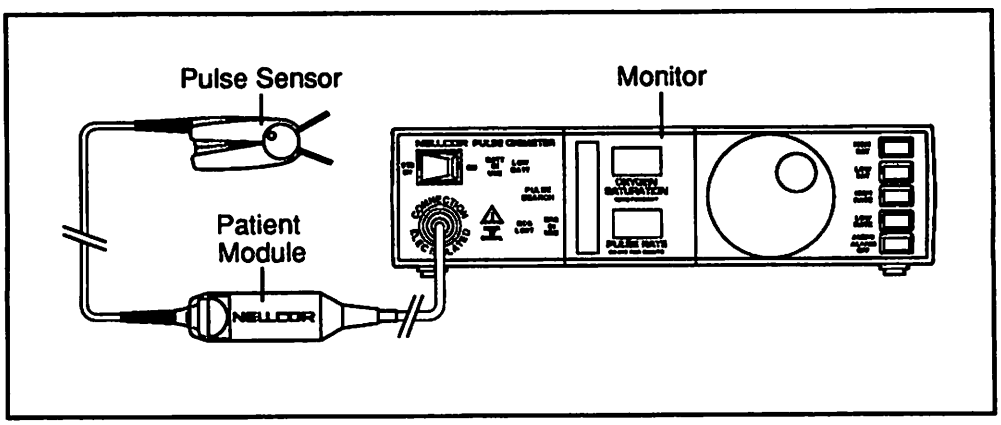

Figure 1: The pulse sensor, patient module, and monitor are the three parts of a pulse oximetry system. ECG equipment is optional.

The plastic reusable sensor gently sandwiches an area of the body that has a lot of blood flow near the surface. Reusable plastic sensors may be used on a finger or an adult's toe. Disposable adhesive sensors may be used on the bridge of the nose, a toe, or a baby's foot.

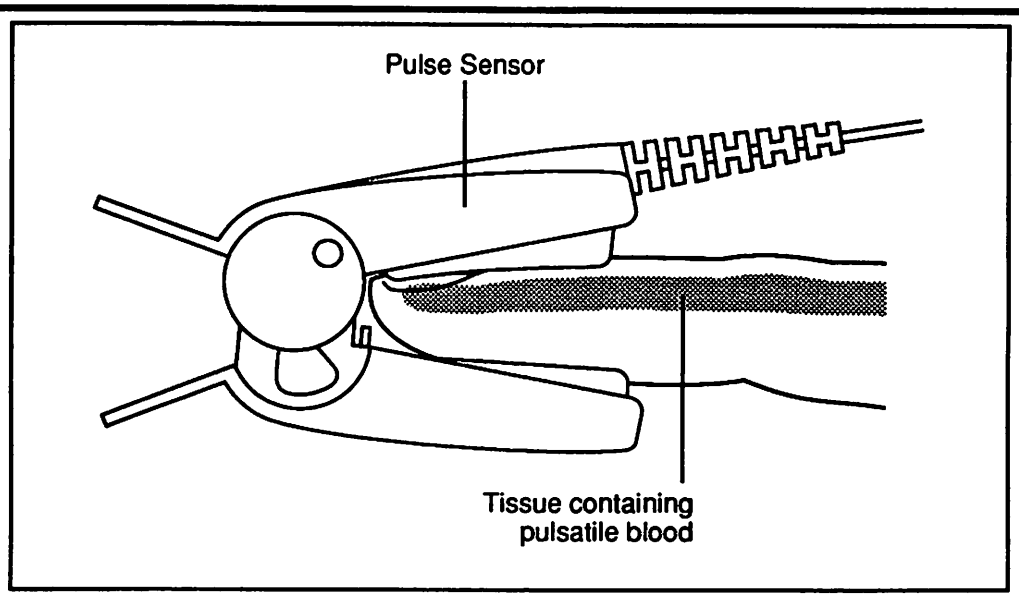

Figure 2: The pulse sensor gently sandwiches an area of the body that has a lot of blood flow near the surface. A typical application of the reusable plastic sensor is shown above.

Infrared light (which you cannot see) and red light are sent from one side of the pulse sensor to the other side through the skin. When this light passes through the blood, some light is absorbed by the *hemoglobin* (the part of the blood cell that carries oxygen). The light not absorbed is measured by a detector on the other side of the sensor (see Figure 3).

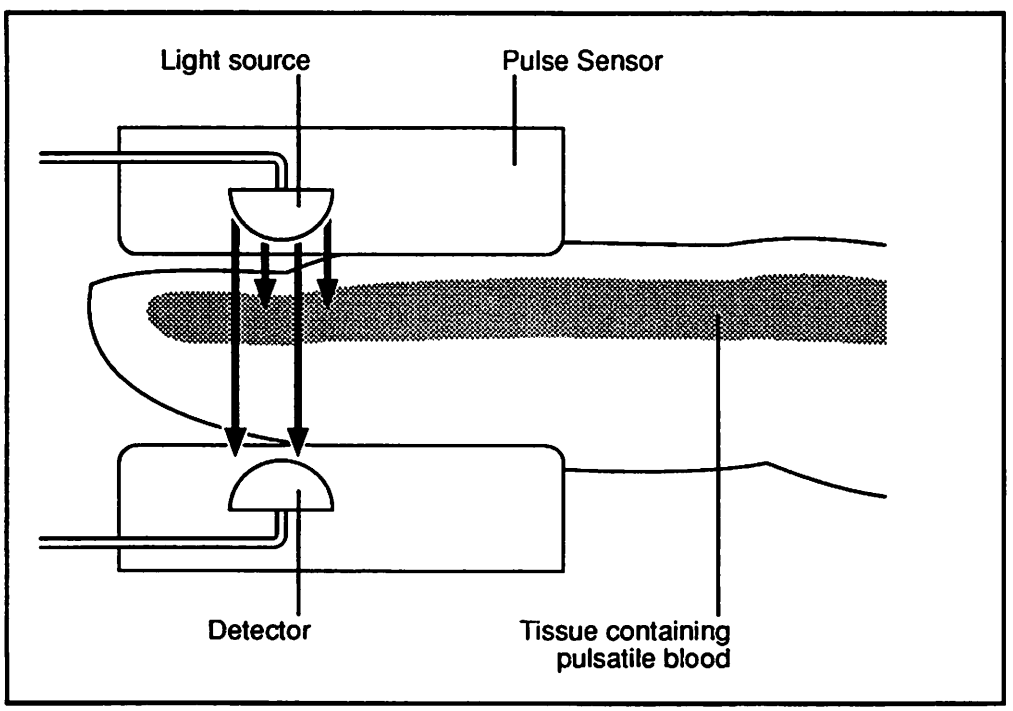

Figure 3. Some of the light is absorbed when it passes through the blood. The remaining light reaches the detector on the other side of the sensor.

The pulse sensor then sends information on the amount of light not absorbed through the patient module to the monitor (see Figure 4). The monitor calculates the oxygen saturation level and the pulse rate, displays the readings, and compares them to the alarm settings.

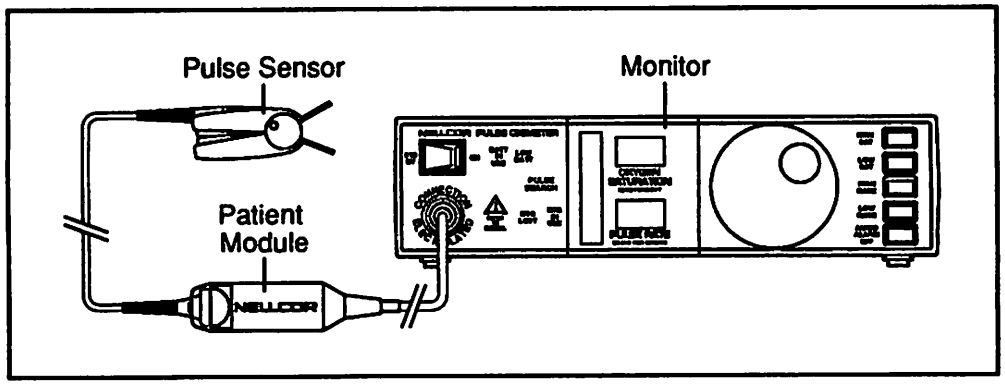

Figure 4: The sensor sends information to the monitor through a patient module. The monitor then computes the amount of oxygen in the blood and compares it to the alarm settings.

If either the oxygen saturation or the pulse rate goes above or below the alarm settings, an *alarm* sounds from a loudspeaker in the bottom of the monitor and a light flashes on the monitor's front panel. (see Figure 5). Your patient's doctor determines these alarm settings. If you turn the monitor off and back on, be sure that you check the alarm settings and adjust them if necessary.

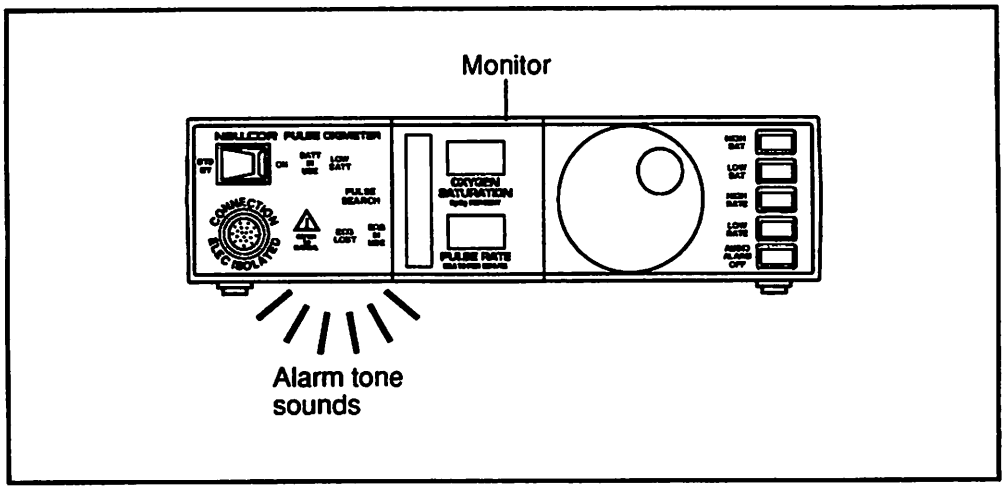

Figure 5: An alarm occurs when either the oxygen saturation in the blood or the pulse rate goes above or below the limits.

The monitor may have problems making measurements if your patient has poor blood flow or is moving around a lot. Your home care provider will help to determine this and obtain the correct patient module for ECG synchronization (see Figure 6).

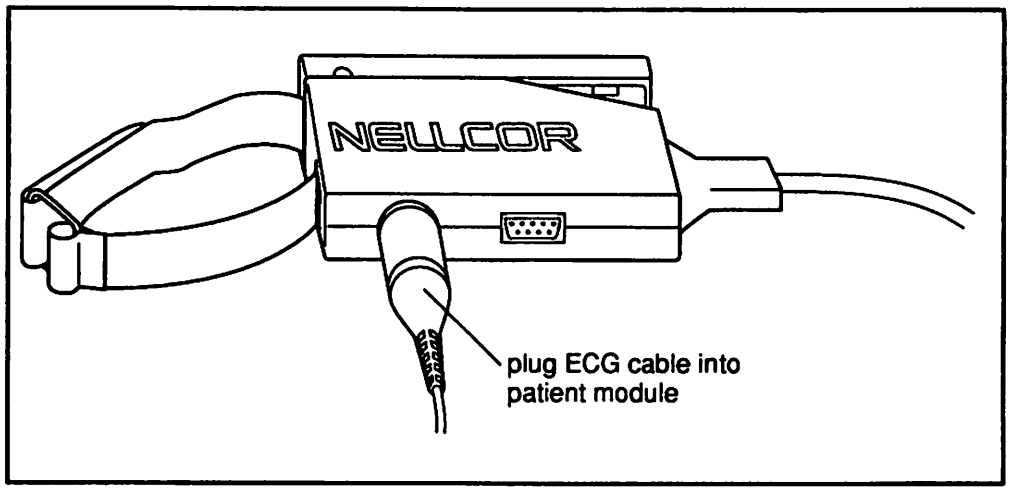

Figure 6: A three-lead ECG cable may be connected to the patient module to allow ECG and pulse sensor signals to be synchronized.

If you are using an ECG monitor in addition to the N-200, it may be possible to use a synchronization signal from the ECG monitor to synchronize the N-200's measurements to the patient's heartbeat. Ask your home care provider to determine if this can be done.

WARNING: This monitor acts as an early warning device. You must ACT when the alarm sounds. The monitor cannot act for you.

The monitor cannot prevent your patient's oxygen saturation levels from falling below a safe level or your patient's heart from stopping. It will, however, warn you of situations that may be life-threatening. You must respond to alarms immediately.

Setting Up

Unpacking and Inspection

Caution: Notify the carrier if the monitor shipping carton is damaged. Do NOT use a damaged monitor.

Carefully unpack the monitor and its accessories. The packages should contain:

- one N-200 monitor
- one interface/powerbase
- one hospital-grade power cord
- one patient module (N-200 mini patient module or N-200 patient module with ECG)
- pulse sensors (also called *oxygen transducers*)
- this home use guide

If any of these items is missing, contact your home care provider immediately.

Note: Always have an extra pulse sensor available. If you do not have an extra, contact your home care provider.

Where Not to Place Your Monitor

Follow these guidelines for placing your monitor:

WARNINGS

DO NOT place the monitor in the crib or bed with your patient.

DO NOT place the monitor on a carpeted floor. The alarm may be muffled by the carpeting.

DO NOT place the monitor on or near electrical equipment such as television sets, radios, microwave ovens, or electric heaters. These may affect the monitor and cause it to work improperly.

DO NOT place containers of liquid on or near the monitor. Liquids spilled on the monitor may cause it to work improperly.

DO NOT place the monitor on or near a vaporizer. Moisture in the air may condense on the monitor and cause it to work improperly.

Place the monitor where the pulse sensor can reach your patient easily.

Be sure that you can hear the monitor alarm from anywhere in the house.

Pulse Sensors

WARNINGS

Always use *NELLCOR* pulse sensors. Using any other pulse sensor may cause the monitor not to work correctly.

Incorrect application or use of the pulse sensors may cause tissue damage or false readings. DO NOT wrap the pulse sensors too tightly or apply extra tape. Check the sensor site every 4 hours for redness or swelling. DO NOT place the sensor somewhere it is not intended to be used.

Excessive light (such as fluorescent lamps or direct sunlight) may cause the monitor not to work correctly. If this happens, cover the sensor area with a piece of dark cloth to block the extra light.

Remove the pulse sensor before bathing the patient. DO NOT allow the pulse sensor to get wet.

Using a Pulse Sensor

Nellcor provides several types of pulse sensors (also called *oxygen transducers*). Some pulse sensors are disposable and others can be reused. Your home care provider has determined which is the best type of pulse sensor for your patient.

Follow your home care provider's instructions on how to use the pulse sensor.

Cleaning Your Pulse Sensor

If you are using a reusable pulse sensor:

- Clean the pulse sensor with a disinfectant, such as 70% isopropyl alcohol.
- Gently wipe the sensor with a damp cloth.

If you are using disposable pulse sensors:

- DO NOT clean disposable pulse sensors.
- DO NOT get disposable sensors or the tape wet.
- Dispose of pulse sensors as directed by your home care provider.

The Parts of the Monitor

The N-200 monitor can be used with any model *NELLCOR* pulse sensor. The monitor should be run only on AC electrical power by plugging the hospital-grade power cord into a standard, grounded wall outlet (3 slots). In case of power failure, the monitor may be run on its internal battery for up to 90 minutes. The internal battery is recharged when the monitor is connected to AC power. It takes 14 hours to recharge fully after operating on battery power.

The N-200 monitor must be used with one of the following patient modules:

- N-200 patient module with ECG
- N-200 mini patient module

The monitor will not work with any other kind of patient module or without one. Do not attempt to connect a pulse sensor to any connector on the monitor's rear panel. The N-200 patient module with ECG may be connected to ECG leads connected to the patient; N-200 mini patient module cannot. (If you wish to use an ECG signal with the N-200 mini patient module, an ECG lead from a bedside ECG monitor must be connected to the ECG IN/OUT connector on the back of the N-200 monitor.)

No matter which patient module is used, the monitor will sound an audible alarm and flash a light when the oxygen levels (detected by light absorption) fall below or go above the alarm settings. The monitor will also alarm if the pulse rate goes above or falls below the alarm settings.

Besides the alarm functions, the N-200 monitor saves 12 hours of trend information. This information can be printed on a printer having a serial input.

Battery Capacity Testing for *NELLCOR*® Pulse Oximetry Products

Nellcor Technical Updates are intended to inform Biomedical and Clinical Engineers of timely service and maintenance issues regarding Nellcor products. These updates are distributed to customers who own the identified products. Additional copies may be requested by contacting Nellcor Technical Services at 1-800-NELLCOR (inside the U.S.A.), or Nellcor corporate offices at 510 887-5858.

Instruments: *NELLCOR* N-100, N-200, and N-250 pulse oximeters and N-1000 multifunction monitor.

Description: *NELLCOR* monitors are equipped with sealed lead-acid batteries. Electrical specifications for each monitor can be found in the operator's manuals. Battery capacity decreases over time due to several factors such as temperature, depth of discharge and number of charge/discharge cycles. Replacing the battery periodically ensures battery operation when needed. A periodic battery capacity check is also recommended. The time interval for this check is left to the discretion of the customer. Depending on how the unit is used, the customer may wish to perform a battery check as often as every 6 months. This check should also include inspection of the batteries' physical condition. Any batteries with signs of leakage or corrosion should be replaced. Refer to the applicable "Battery Capacity Test" below for instructions on testing battery capacity. Regardless of periodic test results, Nellcor recommends replacement of lead-acid batteries every 2 years. Replacement batteries can be purchased through Nellcor Technical Services.

Battery Capacity Test, N-200: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-200 in either ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet. (If an N-200 220-240 V monitor is being tested, the MAINS switch on the powerbase rear panel must be on.)

2. Charge the battery for a minimum of 14 hours.

3. Test the N-200 for operation in the battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 45 minutes.

Battery Capacity Test, N-250: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-250 in either ON or STDBY mode, ensuring that the N-50 interface/ECG monitor is plugged into an operational, properly grounded AC outlet and the mains switch on the N-50 rear panel is in the ON position.
2. Charge the battery for a minimum of 14 hours.
3. Test the N-250 for operation in the battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 45 minutes.

Battery Capacity Test, N-100: This test requires that the unit be fully charged for 8 hours. Use the following procedure:

1. Place the N-100 in either the ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet. (If an N-100 220-240 V unit is being tested, the MAINS switch on the rear panel must be on.)
2. Charge the battery for a minimum of 8 hours.
3. Test the N-100 for operation in battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 60 minutes.

Battery Capacity Test, N-1000: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-1000 in either ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet.
2. Turn on the N-1000 MAINS switch and verify that the rear-panel AC power indicator illuminates.
3. Charge the battery for a minimum of 14 hours.
4. Test the N-1000 for operation in battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 15 minutes before the monitor powers down.

Note: The message "WARNING: POWER DOWN IS IMMINENT DUE TO LOW BATTERY VOLTAGE" appears before actual power-down; the 10-minute battery test period applies to monitor power-down, not appearance of message.

If any unit does not meet the specified battery operating time, further testing or repair may be necessary. Only qualified service personnel or Nellcor repair facilities are recommended for testing or repair. If you encounter problems or have questions regarding this update, contact Nellcor Technical Services at 1-800-NELLCOR.

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Battery Capacity Test, N-200: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-200 in either ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet. (If an N-200 220-240 V monitor is being tested, the MAINS switch on the powerbase rear panel must be on.)

2. Charge the battery for a minimum of 14 hours.

3. Test the N-200 for operation in the battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 45 minutes.

Battery Capacity Test, N-250: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-250 in either ON or STDBY mode, ensuring that the N-50 interface/ECG monitor is plugged into an operational, properly grounded AC outlet and the mains switch on the N-50 rear panel is in the ON position.
2. Charge the battery for a minimum of 14 hours.
3. Test the N-250 for operation in the battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 45 minutes.

Battery Capacity Test, N-100: This test requires that the unit be fully charged for 8 hours. Use the following procedure:

1. Place the N-100 in either the ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet. (If an N-100 220-240 V unit is being tested, the MAINS switch on the rear panel must be on.)
2. Charge the battery for a minimum of 8 hours.
3. Test the N-100 for operation in battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 60 minutes.

Battery Capacity Test, N-1000: This test requires that the unit be fully charged for 14 hours. Use the following procedure:

1. Place the N-1000 in either ON or STDBY mode, ensuring that the instrument is plugged into an operational, properly grounded AC outlet.
2. Turn on the N-1000 MAINS switch and verify that the rear-panel AC power indicator illuminates.
3. Charge the battery for a minimum of 14 hours.
4. Test the N-1000 for operation in battery mode (unplugged from AC power). The operating time in battery mode must be a minimum of 15 minutes before the monitor powers down.

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NELLCOR®

June 1, 1992

Dear N-200 User:

Subject: Component update for the *NELLCOR®* N-200 pulse oximeter.

Nellcor Incorporated has elected to change the battery pack in the monitor portion of the N-200. Although the new battery pack has a lower charge capacity, it was chosen for its consistent performance. The effect of this lower capacity is a reduction in the instrument's battery operation from 120 minutes to 90 minutes.

The charge capacity of lead-acid batteries is highly variable. Testing has shown that the actual performance of a battery in good condition may exceed the new specification by as much as 45 minutes. Nellcor has specified 90 minutes as the typical battery operation period at the time of shipment. Storage may decrease battery capacity, and several complete charge cycles may be required to restore the battery to its rated capacity.

Nellcor monitors are equipped with sealed lead-acid batteries. Battery capacity decreases over time due to several factors such as temperature, depth of discharge, and number of charge/discharge cycles. Replacing the battery periodically ensures battery operation when needed. A periodic battery capacity check is also recommended. The time interval for this check is left to the discretion of the customer. Depending on how the unit is used, the customer may wish to perform a battery check as often as every 6 months. This check should also include inspection of the batteries' physical condition. Any batteries with signs of leakage or corrosion should be replaced. Regardless of periodic test results, Nellcor recommends replacement of lead-acid batteries every 2 years. Replacement batteries can be purchased through Nellcor's Technical Services Department.

This notification must be included with the information in the N-200 operator's manual. Attach it accordingly.

If you have any questions or concerns regarding the N-200 pulse oximeter, contact Nellcor's Technical Services Department at 1-800-NELLCOR or 510 887-5858. In Europe, contact Nellcor B.V., +31.73.42.6565.

Sincerely,

Technical Services

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