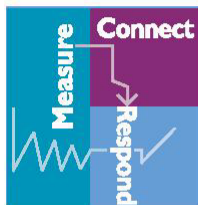**Telemonitoring Services**

Measure
Connect
Respond

Pulse Oximeter

Instructions for use/Instrucciones de uso

English

Spanish

PHILIPS

Notice

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Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085
(978) 687-1501

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New editions of this document will incorporate all material updated since the previous edition. The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed. (Minor corrections and updates which are incorporated at reprint do not cause the date to change.) The document part number changes when extensive technical changes are incorporated.

Revision A   August 2004

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Table of Contents

Introduction

WELCOME

Welcome to Philips Telemonitoring Services.

This **Pulse Oximeter Instructions for Use** explains how to use the Pulse Oximeter to measure your blood oxygen level ($\%SpO_2$) and pulse rate from the comfort and convenience of your home. It also explains how to maintain, clean, and troubleshoot the Pulse Oximeter and gives a number of safety precautions you should follow to assure safe, reliable and accurate measurements.

In only a few minutes every day you can provide these measurements to your healthcare provider so that he/she can make better decisions about your care. In this way, you are providing information that can help improve your health care and quality of life.

How the System Works

With this system, the Pulse Oximeter measurements are immediately sent to your Home Hub or TeleStation, which then automatically transmits them over your telephone line to your healthcare provider's computer. While the system uses your telephone to transmit the measurement, feel free to talk on you phone at any time -- the system is "smart" enough to know when the phone line is open. It will wait and then send the information after you hang up.

Keeping the System Working

If at any time you suspect something is wrong with the Pulse Oximeter or any part of the Telemonitoring System, immediately contact your healthcare provider. Philips will replace any defective device. You can also cross-check your results with another Pulse Oximeter if additional measurement devices of the same type are available to you.

Thank You!

Thank you for taking an active role in your home healthcare plan. Philips and your healthcare provider applaud your efforts to actively participate in you health care plan.

Safety and Precautions

Safety

Follow Instructions

Follow your doctor's instructions about symptoms that require you to contact your healthcare provider. This system does not take the place of medical care. Remember, only your healthcare provider is trained to interpret the results. He or she will tell you when and how often to take your vital signs. Please read all of the instructions in this guide before using the Pulse Oximeter and follow the instructions carefully.

Symbols

Type B Patient Applied Parts as defined in IEC 60601-1-1. Not suitable for direct cardiac application.

Attention: Consult accompanying documents.

Meets IEC-60950 standards

Meets Class B standards.

Meets Part 15 standards.

Precautions

Warnings

The word **Warning** is used for a hazard that could result in severe injury or death.

Observe the following **Warnings**:

The Pulse Oximeter is provided for **your use only**.

- **Do not** let anyone else use it.
- **Do not** swap devices with a neighbor or family member who has the same or similar system.

These devices are **not** intended to be used to call for emergency medical attention or response.

Cautions

The word **Caution** is used for a hazard that could result in personal injury or property damage.

Observe the following **Cautions**:

- Read this guide carefully before using this device.
- Use this device **only** as directed by your healthcare provider.
- Follow your physician's instructions regarding symptoms that require direct contact with your healthcare provider.

- This device is not intended for continuous monitoring.

- This device may not work properly on all patients. If you are unable to achieve stable readings within 3 or 4 attempts, discontinue use and contact your healthcare provider.

- Use of this device is not a substitute for medical care.

- If you have any questions regarding how to use your Pulse Oximeter, please contact your healthcare provider.

- Dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin may affect accuracy.

Pulse Oximeter Components

The Pulse Oximeter is a plastic display case with a finger-clip sensor attached to it. The front of the case has the following elements, as shown in the figure below. The rear of the case has a compartment for batteries that power the device.

Display: an LED display window shows the blood oxygen level (%SpO2) and pulse rate (in beats per minute) measured from the end of your finger. LEDs below the display window light to indicate which measurement is being displayed -- %SpO2 or pulse.

START button: pushing this button causes the Pulse Oximeter to begin taking a measurement.

T **Radio Test button**: this button is used to test the transmission of measurements from the Pulse Oximeter to the Home Hub or TeleStation.

Finger-clip sensor: This sensor is used to measure your blood oxygen level and pulse rate. The sensor is clipped on the end of one of your fingers.

The Finger-clip contains an LED light source that shines light on your finger. Light transmitted through the blood in your finger is received by a photo sensitive element and electronics in the display case uses the transmitted light to determine your blood oxygen level and pulse rate.

Display

Radio Test button

START button

Finger-clip sensor
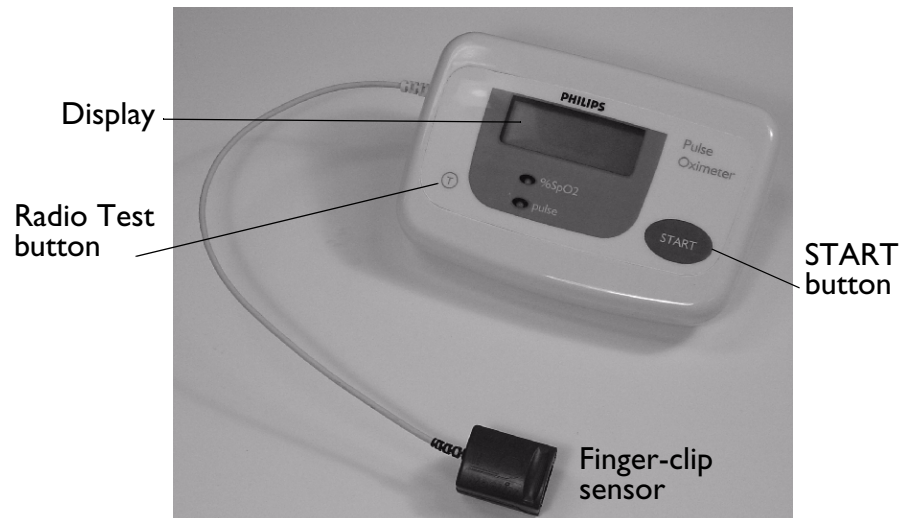
Measurement

The following steps describe how to use the Pulse Oximeter to measure your blood oxygen level (%SpO2) and pulse rate.

1. Sit **within 20 ft.** of the Home Hub or TeleStation with your hand resting on a flat surface and the Pulse Oximeter in front of you.

2. Open the sensor and fully insert your finger (index, middle, or ring, but not your thumb) until the end of your finger reaches the finger stop. The cable should extend over your finger toward your wrist as shown in the figure.
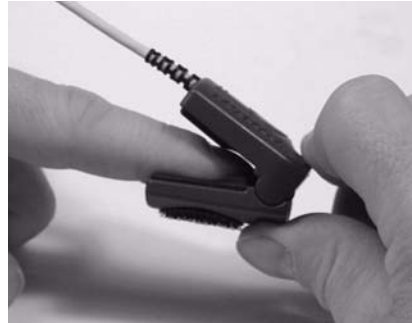
3. Sit comfortably with your hand resting on the surface so that it can remain still.

4. Press the START button and hold your hand still during the measurement.

Notes:

- Use the same finger each time you make a measurement unless your health care provider instructs otherwise.

- Do not use the sensor on a finger that has chronic poor circulation or is injured.

- Avoid wearing dark fingernail polish (particularly blues and blacks) that may reduce light transmission and affect measurement accuracy.

- Avoid using the sensor in sunlight or bright lights.

- Do not use the Pulse Oximeter with the battery door open

The measurement process is as follows:

- **Dashes** move across the display during measurement.
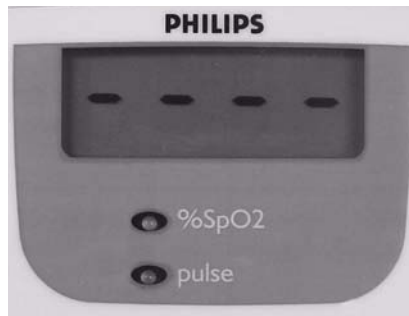
- A **double beep** sounds after a few seconds indicating that the measurement is complete.

- A **tick** sounds as the **% SpO2 measurement** displays and the yellow light next to % SpO2 illuminates.

- A **tock** sounds as the **pulse rate** displays and the green light next to **pulse** illuminates.

- The tick-tock sequence repeats several times and then turns off.

Note: If the measurement was not made, a long beep sounds and $rEdo$ displays.

Warm your hand or use a different finger and try again.

Maintenance

This section gives guidelines on how to maintain the Pulse Oximeter, including how to clean and store it and how to replace the batteries. Taking proper care of the devices will help keep it in good working order.

Cleaning

You generally need to clean the Pulse Oximeter only when it appears to be dirty. However, it is very important to keep the inside of the Finger-clip sensor clean, especially where the light shines through your finger.

Caution:

- Avoid spilling liquids on the device.
- Do not immerse this device in liquids to clean.
- Do not use harsh chemicals, caustic, or abrasive cleaning agents to clean the device.

The following steps describe how to clean the Pulse Oximeter and sensor.

1. Unplug the Home Hub or TeleStation from power and phone lines.
2. Remove the batteries from the Pulse Oximeter. For battery removal see the next section on **Replacing Batteries**.

3. Clean the case of the Pulse Oximeter with a dry, soft cloth. **Note:** If there are any bodily fluids, such as blood or mucus, use a cloth dampened with plain tap water (no soap).
4. Open the Finger-clip sensor and carefully wipe its inside surfaces with a cloth dampened with a mild detergent or rubbing alcohol. **Note:** Allow the sensor to dry thoroughly before using.
5. Replace the batteries in the Pulse Oximeter.
6. Plug the Home Hub or TeleStation into the power outlet and phone line.

Storing

The Pulse Oximeter must be stored within 20 feet of the Home Hub or TeleStation because it periodically sends updates to it. When storing the Pulse Oximeter, use the following precautions.

- Store the Pulse Oximeter so that the sensor cable is not twisted or kinked.

- Avoid tugging at the sensor cable or carrying the Pulse Oximeter by the sensor cable.

- Avoid storing the Pulse Oximeter where children or pets have access to it.

- Do not store the device inside a metal container or drawer, such as a file cabinet.

Replacing Batteries

The batteries should be replaced when the Low Battery indicator **bRtt** flashes on the Pulse Oximeter display.

Caution:

- Replace all 4 batteries with new ones at the same time.

- Only use Type AA (1.5 volt) Alkaline batteries.

- Do not use rechargeable batteries.

The following steps describe how to replace the batteries in the Pulse Oximeter.

1. Turn the Pulse Oximeter case over to expose the battery compartment.

2. Remove the battery cover by gently pushing in the direction of the arrow symbol to release the retaining tab and then remove the cover.

3. Remove the old batteries and dispose of them properly.

Note: Check with local authorities to determine the proper way to dispose of alkaline batteries.

4. Place new batteries into the compartment so that the positive (+) and negative (-) terminals match the diagram in the compartment. Make certain that the battery terminals make contact with the compartment terminals.

    Note: To prevent the batteries from popping out, insert the bottom row first.

5. Replace the cover by inserting its tabs into the slots and firmly pressing the cover tab into place.

Caution: Do not use the Pulse Oximeter with the battery cover removed.

Troubleshooting

The only user-serviceable parts of the Pulse Oximeter are the batteries.

Caution: Do not attempt to service or repair the Pulse Oximeter yourself. If a mechanical problem occurs, contact your healthcare provider for further instructions.

If an error message appears, check your equipment and retake your %SpO2 before contacting your healthcare provider. Remember to remain still during the measurement. Try reducing the surrounding light, try a different finger, warming you ahnds, and/or removing any dark nail polish.

You may be able to perform minor troubleshooting when one of the error messages below appears on the display.

If you are unabale to troubleshoot these error messages by following these corrective actions, contact your healthcare provider for further instructions.

Display Symbol	Condition or Cause	Corrective Action
Err.	Appears when a malfunction is detected	Contact your healthcare provider if the condition persists.
rEdo	Appears if a reading was not obtained.	Warm finger, keep hand still, reduce light, and try again. Contact your healthcare provider if the condition persists.
bAtt	Flashes during measurement when the batteries are too low for the Pulse Oximeter to work properly.	Replace all 4 batteries and perform a Radio Test.

Specifications

Model	• M3814A
Type	• Internally-powered equipment • Type B applied part • IPXO Ordinary Equipment • Continuous operation (does not imply continuous monitoring
Display	• Digital 0.7 in. (1.8 cm) character height • SpO2/pulse displayed alternately
Measurement Range	• SpO2: 70 - 100% • Pulse: 18 to 300 pulses per minute
Power source	• 4 type AA (1.5 volt) alkaline batteries connected in series (6.0 volts), included
Battery life	• Approximately 6 months with 1 daily measurement
Operating environment	• 50° to 104 ^{o}F (10° - 40 ^{o}C) • Less than 85% relative humidity • Atmospheric altitude pressure: 700 - 1060 kPa (0 - 15,000 ft. or 0 - 4,600 meters altitude) • **Warning: This equipment is not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.**
Transport and Storage environment (with batteries removed)	• 15° to 122 ^{o}F (-9° - 50 ^{o}C) • Less than 85% relative humidity • Atmospheric altitude pressure: 700 - 1060 kPa (0 - 15,000 ft. or 0 - 4,600 meters altitude)
Dimension (approx.)	• Length: 6.5 in. (16.5 cm) • Width: 4.4 in. (11.2 cm) • Height: 2.7 in. (6.9 cm)
Weight (approx.)	• 13 oz. (370 gm)

Electromagnetic Compatibility

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is the ability of equipment to function satisfactorily in the presence of radio frequency (RF) energy from devices such as cordless and cellular telephones or other RF transmitting equipment. The Pulse Oximeter was tested according to the international safety standards for EMC of medical electrical equipment. See the Manufacturer's Declaration for details.

EMC Testing

The M3814 Pulse Oximeter was subjected to both international standard and Philips proprietary tests. During the testing to the requirements of the medical safety standard IEC/EN 60601-1-2 (first edition), some anomalies were observed as described below. If you observe any abnormal operation of the devices, please see **Avoiding Electromagnetic Interference Problems** later in this section.

The M3814A Pulse Oximeter may also exhibit sensitivity to electrostatic discharges as low as $\pm$ x.xx kV to nearby objects or interconnecting cables. Electrostatic sensitivity does not put critical patient data at risk and normal operation is restored after approximately xxx minutes without user interaction. Measurements stored in the M3814A are retrieved following device recovery.

Telemonitoring Device	Interference Level (Volts per meter*)	Observed Performance Degradation Caused by the Stated Interference Level
Pulse Oximeter M3814A		
* Interference levels are measured in Volts per meter. A cellular telephone operating at a typical transmitting power of 0.1 watts will produce an interference level of 1 Volt per meter at a distance of 1 meter from the cellular telephone's antenna. Please see **Avoiding Electromagnetic Interference Problems** later in this section.		

Avoiding Electromagnetic Interference Problems

Possible sources of interfering radio frequency energy are cellular telephones, cordless telephones, and other products containing radio transmitters.

The M3814A has a Radio Test button that sends a reduced strength radio test signal to the M3184A Home Hub or the M3812B TeleStation and sounds an audio tone if the test signal is successfully received. This test can be used to determine whether sources of interference are present. These sources can be turned off or moved away to reduce their interference to your Pulse Oximeter.

In addition, the Pulse Oximeter and M3812A Home Hub or M3812B TeleStation can be placed closer to each other so that the radio transmission from the Pulse Oximeter to the M3812A Home Hub or M3812B TeleStation has less distance to travel and interfering radio signals have less effect. The radio transmissions from the Pulse Oximeter are repeated periodically, so an intermittent source of interference should only delay reception.

Recommended separation distances between portable and mobile RF communications equipment and the Philips Telemonitoring System		
The Philips Telemonitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Philips Telemonitoring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Philips Telemonitoring System as recommended below, according to maximum output power of the communications equipment.		
Rated maximum output power of transmitter Watts	Separation distance (in meters) according to frequency of transmitter	
	26 to 800 MHz	800 MHz to 2.5 GHz
0.01	3.5	7
0.1	11	22
1	35	70
10	110	220
100	350	700
These guidelines may not always apply. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people		

FCC Regulations

The M3814A Pulse Oximeter has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits provide reasonable protection against harmful interference in a residential installation. The M3814A Pulse Oximeter generates, uses, and can radiate radio frequency energy. If not installed and used according to instructions, it may interfere with radio communications. However, there is no guarantee that interference will not occur if the equipment is properly installed.

If the M3814A Pulse Oximeter causes interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct it by:

- relocating the Home Hub or TeleStation,
- increasing the separation between the Pulse Oximeter or the Home Hub or TeleStation and the device being interfered with, for example, a TV,
- consulting your healthcare provider.

Note: Any changes or modifications to the equipment not expressly approved by Philips could void the user's authority to operate it.