Telemonitoring Services

Patient Telemonitoring Set

Instructions for use/Instrucciones de uso

English

Spanish

PHILIPS

Notice

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Document number:
M3810-90096

Issue number 5, October 2008

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085
USA

Published in the United States of America

Printing History

New editions of this document will incorporate all material updated since the previous edition. Update packages may be issued between editions and contain replacement and additional pages to be merged by a revision date at the bottom of the page. Note that pages which are rearranged due to changes on a previous page are not considered revised.

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.

All Editions and Updates of this manual and their publication dates are listed below.

First Edition. . . . . October 2002

Second Edition . . . . . July 2006

Third Edition. . . . . May 2007

Fourth Edition . . . . . May 2008

Fifth Edition . . . . . October 2008

Personal Health Information Security

Telehealth equipment collects personal information in the form of vital sign measurements and survey responses that help your health care organization manage you health care effectively. These data are stored and protected on a secure network and will not be disclosed for purposes other than for the management of your healthcare. Any unintentional disclosure of your personal information will be reported to your health care organization.

Contents/Tabla de contenidos

1 Introduction

Welcome

Welcome to Philips Telemonitoring Services.

When you use this product, you'll take a few minutes every day to measure your weight, vital signs, and/or glucose.

These measurements will help you and your healthcare provider make better decisions about your care. You are providing information that can help improve your quality of life.

How the System Works

With this system, it's easy to take your measurements from the comfort of your home. The measurements are sent over your phone line to your healthcare provider's computer

Feel free to talk on your 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 any of the devices, immediately contact your healthcare provider. Philips will replace any defective device. You can also cross-check your results with another device if additional measurement devices of the same type are available to you.

This Instructions for Use contains easy-to-follow steps for taking your measurements. It also shows you how to maintain the devices so that they will continue to take accurate readings.

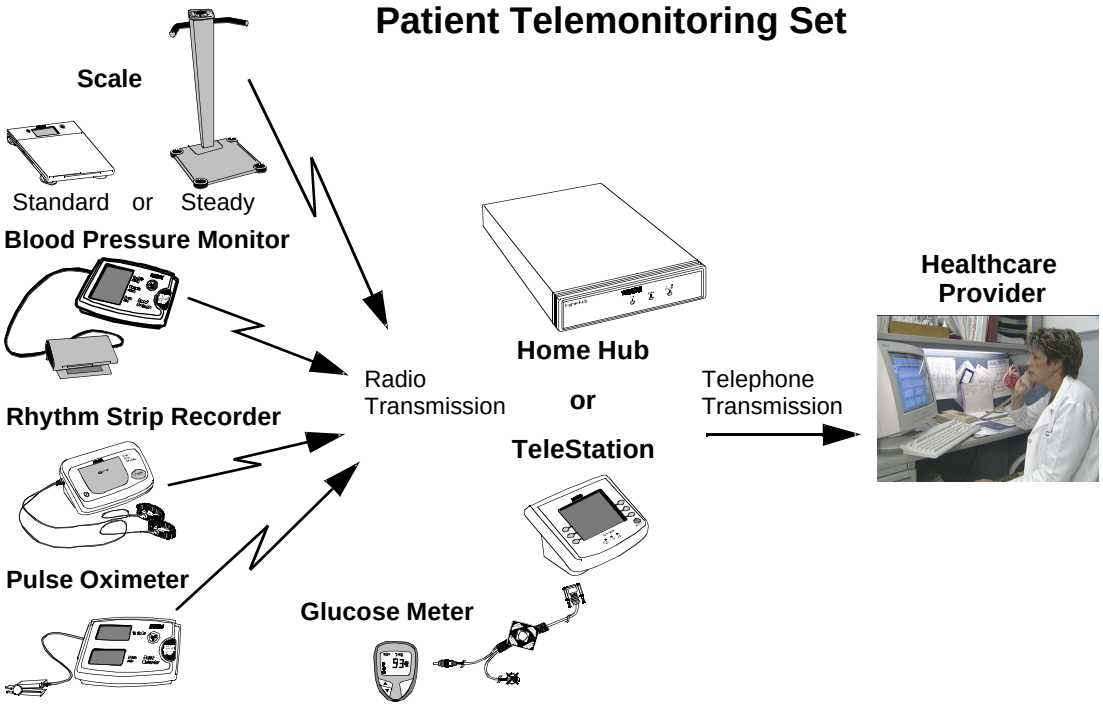
Thank You!

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

Philips Telemonitoring Services System

Your Philips Telemonitoring Services system includes a set of measurement devices known as the **Patient Telemonitoring Set**. Each device takes an important measurement -- such as weight, blood pressure, pulse rate, heart rhythm, $\%SpO_2$ -- and then wirelessly sends that measurement to the Home Hub or TeleStation. A patient's glucose meter can also send glucose measurements to a TeleStation using a special cable.

Your healthcare provider decides whether you will use one or all of the measurement devices below. The HomeHub/TeleStation is the "communications center." It receives your measurements from the devices and sends them over your phone line to your healthcare provider's computer. The computer keeps a record of all of your vital sign measurements for review by your healthcare provider.



Safety and Precautions

Follow Instructions

Follow your doctor's instructions about symptoms that require you to contact your healthcare provider. Use of these devices is not intended to replace your existing therapy or drug administration. 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 Philips Telemonitoring System and follow the instructions carefully.

Document Conventions

The following conventions will be used in this Instructions for Use to alert you to special or important information in the text.

Warnings

Warnings are information you should know to avoid a hazard that could result in severe injury or death.

Observe the following Warnings with all devices of the Philips Telemonitoring System.

Warning

- **Do not** let anyone else use these devices. They are provided for **your use only**.
- **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.
- **Do not** try to fix a device yourself. If there's a problem, call your healthcare provider.
- **Do not** use a device with the battery door removed.
- Avoid exposing the devices to extremes in temperature, humidity, direct sunlight, shock, dust spill, or standing water.
- **Do not** let children use the device.
- Throw away packing materials and plastic bags right away. They are a hazard for children.

- Be careful with small parts that can be removed from a device and swallowed, such as the Home Hub's rubber feet and power adapter clip. They are hazards for children and pets.
- To prevent shock, connect cables only as described in these Instructions for Use.
- **Do not** connect anything to this system other than Philips Telemonitoring Services devices or glucose meters approved by your healthcare provider.
- To prevent shock, do not use devices during a lightning storm.
- Call your healthcare provider if you are injured using any device.

Cautions

Cautions are information you should know to avoid a hazard that could result in personal injury or property damage.

Observe the following Cautions with all devices of the Philips Telemonitoring System.

Caution

- Read these Instructions for Use carefully before using devices.
- Use these devices **only** as directed by your healthcare provider.
- Follow your physician's instructions regarding symptoms that require direct contact with your healthcare provider.
- Use of these device is **not a substitute** for medical care.

Notes

Notes contain additional information on usage of the Patient Telemonitoring System and its devices.

Note

Bold Typeface

Objects of actions in procedures appear in **bold** typeface, as shown in the following example:

Step 1. Select the **Update** button.

Display Symbols

A number of symbols are displayed on various devices or in documentation of the Philips Telemonitoring System. Their meaning and the devices on which they may appear are given in the following table.

Symbol	Description	Applicable Devices
	Type B Patient Applied Parts as defined in IEC 60601-1. Not suitable for direct cardiac application.	Scale (M3813A, M3813B) Blood Pressure Monitor Rhythm Strip Recorder Pulse Oximeter (M3814A)
	Type BF Patient Applied Parts as defined in IEC 60601-1. Not suitable for direct cardiac application.	Pulse Oximeter (M3814B)
	Attention: Consult accompanying documents.	Home Hub/TeleStation Scale (M3813A, M3813B) Blood Pressure Monitor Rhythm Strip Recorder Pulse Oximeter
	Meets UL-1950, CSA-950, IEC-60950 standards Meets CSA IEC-60950-1 standards	Home Hub/TeleStation TeleStation Scale (M3813A) Blood Pressure Monitor Rhythm Strip Recorder Pulse Oximeter
	In TelePort serial data port for connection to Philips devices only	TeleStation
	AC Power adapter connection (9.0VAC/500mA Use Philips-supplied adapter only)	TeleStation

Symbol	Description	Applicable Devices
	Telephone or telephone line	TeleStation
 **US**	Meets standards CSA 60601-1, UL 60601-1	Scale (M3813B)
	Meets Class B standards.	Home Hub/TeleStation Standard Scale Steady Scale Blood Pressure Monitor Rhythm Strip Recorder Pulse Oximeter
	Meets Part 15 standards.	Standard Scale Steady Scale Blood Pressure Monitor Rhythm Strip Recorder Pulse Oximeter
	Meets Part 68 standards	Home Hub/TeleStation

2
Philips Telemonitoring Set

Overview

Chapter 2 provides a detailed description of the devices of the Philips Telemonitoring Set and how to use them. It includes the following.

Device Descriptions

The **Philips Telemonitoring Set** consists of a Home Hub or TeleStation, which serves as the "communications center" of the system, and devices that measure important healthcare vital signs -- Scale (weight), Blood Pressure Monitor (blood pressure), Rhythm Strip Recorder (heart rhythm), Pulse Oximeter (%SpO_2, pulse rate), Glucose Meter (glucose level).

Note: The PTS system provides only a cable for connecting the patient's glucose meter to the system.

This section provides a brief description of each of these devices. More detailed descriptions of how to use each device to make its measurement are given in the sections that follow.

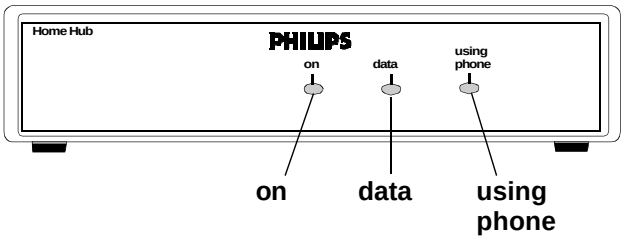
Home Hub/ TeleStation

You will have either a **Home Hub** or a **TeleStation**, depending on the home healthcare plan designed for you.

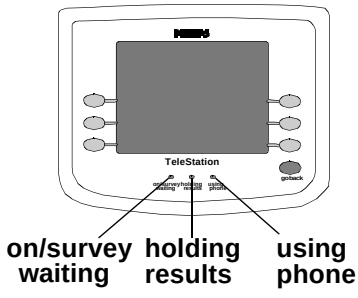
After you take a measurement, such as weight, the Home Hub/ TeleStation receives the result. It then sends the result to your healthcare provider's computer when both telephone lines (yours and the computer's) are free.

If you pick up your telephone while the Home Hub/TeleStation is dialing or sending the result, you will not hear a dial tone. Hang up the phone and wait for 5 seconds. Then make your call. The Home Hub/ TeleStation will send the result when the phone line is open. Your healthcare provider will call you if your results are not received.

Home Hub (M3812A)



TeleStation (M3812B)



Indicators

The Home Hub and TeleStation have lights on the front that indicate what it is currently doing.

The **on** or **on/survey waiting** light stays lit as long as the Home Hub/ TeleStation is plugged in.

If you have the TeleStation and the **on/survey waiting** light is **flashing**, you have questions to answer. Your healthcare provider may activate the TeleStation to beep every 60 seconds to alert you that a survey is waiting.

The **data** or **holding results** light comes on when the Home Hub or TeleStation receives your measurement results and stays on until those results have been sent over the telephone.

The **using phone** light comes on when the Home Hub or TeleStation is sending your results to your healthcare provider's computer.

Warnings

The following **Warnings** apply to the use of Home Hub/TeleStations.

Warning

- Use **only** the Philips-supplied power adapter for the Home Hub/ TeleStation.
  - **Do not** place anything on top of the adapter.
  - **Plug** the adapter into an outlet near the Home/Hub Telestation for easy access.
  - **Unplug** the adapter from the outlet to disconnect.
- **Do not** place the Home Hub/TeleStation where anyone, especially children, can step on, trip over or get tangled in phone or power adapter cords.
- **Do not** place the Home Hub/TeleStation near running water or where liquids (for example, a cup of coffee or water in a vase of flowers) might spill onto it.
- **Unplug** power and phone cords before cleaning the Home Hub/ TeleStation.and prior to an impending lightning storm
- **Do not** put lighted tobacco products or candles on Home Hub/ TeleStations.
- **Do not** overload circuits where Home Hub/TeleStation are installed.

- If you have a personal response service (**except for LifeLine**® Systems), it must be installed on its own phone line (not just a separate telephone jack).
  If you **have a LifeLine**® System telephone, ensure that the Home Hub/Telestation is plugged into the phone jack labeled **AUX** on the back of the LifeLine® unit.
- **Do not** touch, use, clean, or handle the Home Hub/TeleStation or your connected glucose meter during a thunderstorm.

Cautions The following **Cautions** apply to using the HomeHub or TeleStation.

Caution

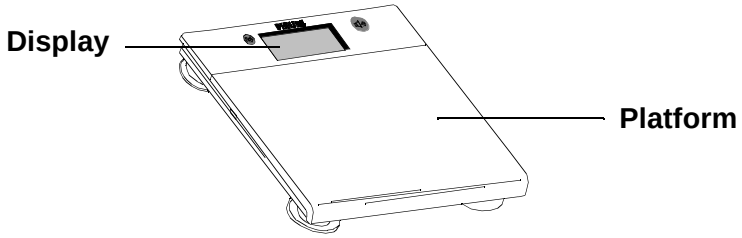
- Avoid placing the Home Hub/TeleStation on a metal surface or inside a metal enclosure as it can interfere with the radio signal.
- **Do not** use electronic devices, such as cordless and cellular phones and computers, near the Home Hub/TeleStation
- Avoid placing large appliances or metal furniture near the Home Hub/TeleStation as they can block radio signals from the measurement devices.
- High temperatures can affect the LCD screen of your TeleStation.
  – Choose a location away from direct sunlight.
  – Operate the TeleStation at room temperature.
- Make sure that the Home Hub/TeleStation is plugged into its telephone jack and electrical outlet at all times, except when cleaning or prior to an impending lightning storm.
- Make sure that a light switch or power strip does not turn off power to the Home Hub/TeleStation.
- Clear voice mail messages. Telephone services that modify the dial tone, such as voice mail, can interfere with transmissions made by the Home Hub/TeleStation.
- If you are using a glucose meter connected to your TeleStation:
  – Follow the glucose meter manufacturer's instructions.
  – Follow any additional instructions from your healthcare provider.
  – **Do not** take glucose measurements while your glucose meter is connected to your TeleStation.

Scale

You may have either a Standard Scale or a Steady Scale. Both scales speak your weight.

Standard Scale

The **Standard Scale** is for people who can get on and off the Scale without help. It has a maximum weight limit of **440 lbs (200 kgs)**.



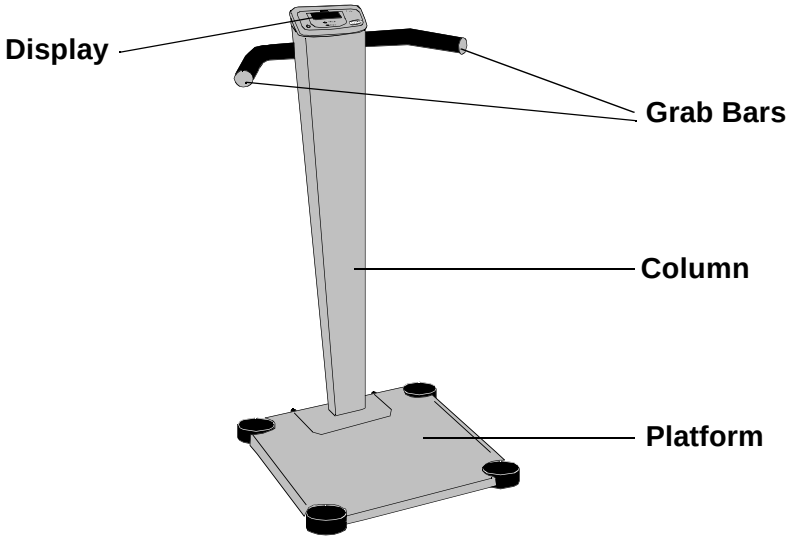
The scale announces your weight (in English or Spanish).

The front panel has a **Volume** control button and a **Radio Test** button .

Batteries are stored underneath the platform.

Steady Scale

The **Steady Scale** has a column with grab bars to help people keep their balance when using the Scale. It has a maximum weight limit of **365 lbs (166 kgs)**.



The Steady Scale announces your weight in English only.
The front panel has a **Volume** control and a **Radio Test** button  .
Batteries are stored underneath the display case.

Warnings The following **Warnings** apply to use of the Scale.

Warning

- **Do not** use the Scale in standing water.
- **Do not** store the Scale where children or pets could get hurt by playing with the grab bars and knocking the Scale over.

Cautions The following **Cautions** apply to use of the Scale.

Caution

- **Do not** use the **Standard Scale** if you weigh over **440 pounds (200 kilograms).**
- **Do not** use the **Steady Scale** if you weigh over **365 pounds (166 kilograms)**.
- Keep the Scale in a dry, temperature controlled place, **not in the bathroom**.
- Position the Scale away from metal objects, such as a refrigerator, as they can block transmission to your Home Hub/TeleStation.
- Place the Scale on the floor between 1 to 3 inches (2.5 to 7.5 cm) from a wall and facing it.
- Only one person should use the Scale.
- **Do not** use the Scale to measure anything other than yourself, such as a package or pet, because all measurements are sent to your healthcare provider.
- **Do not** drop or drag the Scale.
- **Do not** step on the Scale's corners.
- The scale should be used on a **flat, hard surface** if at all possible.
- If the scale is used on carpet, carpet feet may have to be installed.
- Traveling with the Scale is not recommended.

Note If you don't feel comfortable taking your weight using the Standard Scale, contact your healthcare provider.

Blood Pressure Monitor

You may have a Blood Pressure Monitor if your home healthcare plan includes measuring your blood pressure and pulse.

The **Blood Pressure Monitor** (also called a BP Monitor) is a plastic display case with a removable blood pressure cuff. The BP Monitor displays your blood pressure and pulse.

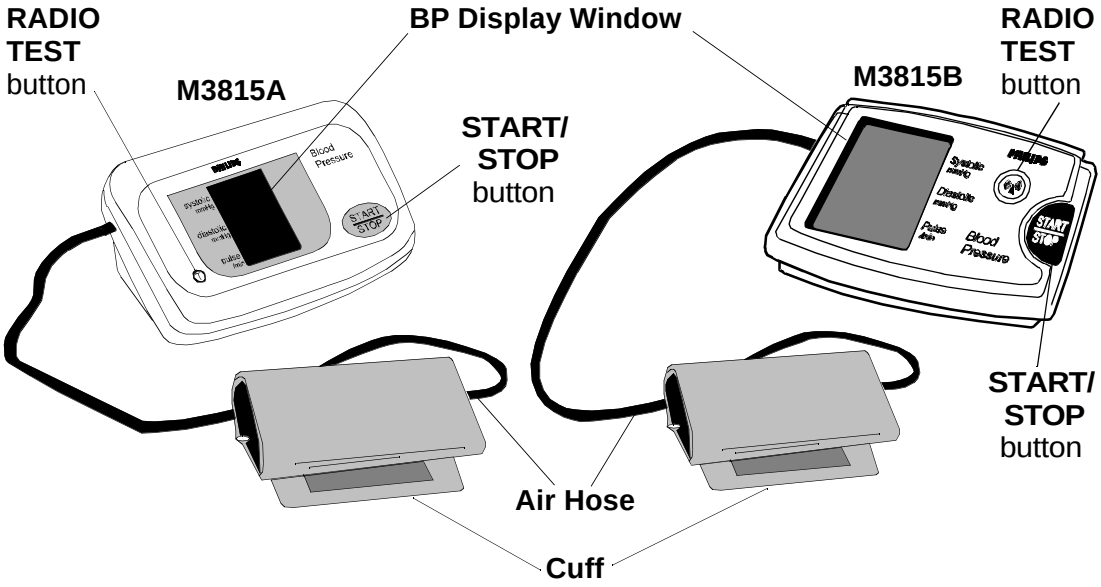
The BP Monitor has an air hose connector on the left side. The blood pressure cuff has a metal D-ring (a metal bar that the cuff slides through and loops over), an air hose, and an air connector. Batteries are stored underneath the display case.

Note

Two models of BP Monitor are available (**M3815A** and **M3815B**) and are shown below. Check your BP Monitor to determine which one you have. The part numbers are shown on the rear of the monitor.

BP Monitor Display Case

Both monitors have a display window that shows the systolic and diastolic blood pressure and pulse rate, a **START/STOP** button and a **RADIO TEST** button --  . (on **M3815A**) or  (on **M3815B**).



Warnings The following **Warnings** apply to use of the BP Monitor.

Warning

- Avoid storing the BP Monitor where children or pets can get at it. There is a risk of injury if they get tangled in the air hose or if the cuff inflates.

Cautions The following **Cautions** apply to use of the BP Monitor.

Caution

- If you get an error message when taking your blood pressure or think the reading may be wrong, take it again.
- **Do not** store the BP Monitor inside a metal drawer or container, such as a file cabinet. It will interfere with the radio signal to the Home Hub/TeleStation.
- **Do not** store the BP Monitor with the cuff assembly twisted or folded tightly.
- Avoid tugging at the air hose or using it to carry the BP Monitor.
- Watch the display when taking your blood pressure.
  - If the numbers go up to **330 mmHg**, press the START/STOP button immediately.
  - If the numbers drop down to **15 mmHg** and stay that way for more than 3 minutes, press the START/STOP button again.
  - If either of these conditions occur, contact your healthcare provider.

Rhythm Strip Recorder

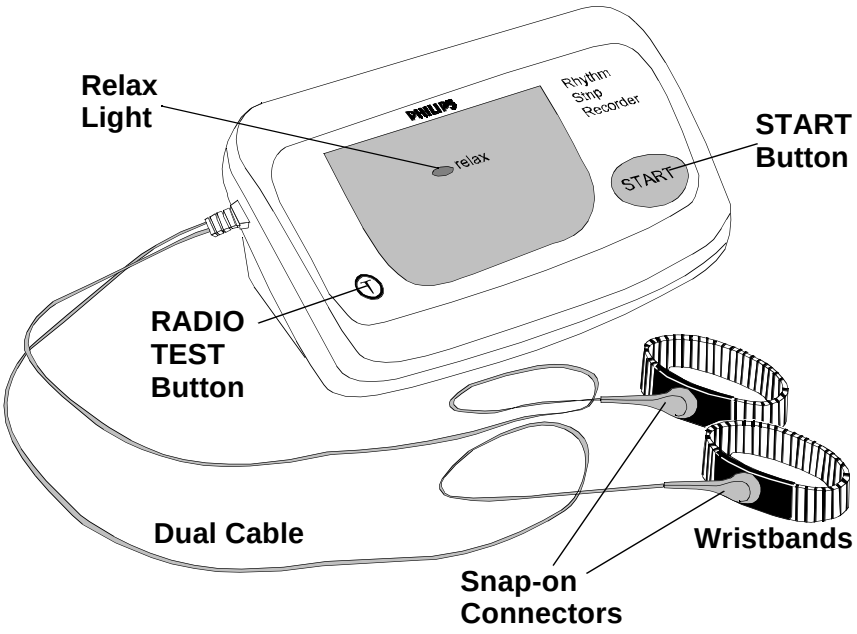
You may have a Rhythm Strip Recorder if your healthcare plan includes recording your heart rhythm.

The **Rhythm Strip Recorder** is a plastic display case with an attached dual cable with snap-on connectors. Each of the two metal wristbands has a black plastic pad. One side of the pad has a metal snap and the other side has a flat piece of metal. Batteries are stored underneath the display case

Rhythm Strip Recorder Display Case

The display case has a **START** button, a **RELAX** light, and a **RADIO TEST** button .

Rhythm Strip Recorder Display Unit



Warnings The following **Warnings** apply to use of the Rhythm Strip Recorder.

Warning

- **Do not** store the Recorder where children or pets can get tangled in the cables and the wristband.
- The wristbands may cause skin irritation, injury or an allergic reaction to metal.
  - Stop using the recorder if you have redness, rash, or other skin problems.
  - Contact your healthcare provider.

Cautions The following **Cautions** apply to use of the Rhythm Strip Recorder.

Caution

- **Do not** store the Recorder inside a metal drawer or container, such as a file cabinet. It will interfere with the radio signal to the Home Hub/TeleStation.
- Store the Recorder so that the dual cable is not twisted or kinked.
- Avoid tugging at the dual cable or carrying the Recorder by the cable.

Pulse Oximeter

The **Pulse Oximeter** measures blood oxygen level (%SpO_2) and pulse rate. It has a plastic display case with a finger-clip sensor attached to it. The front of the case is shown in the figure below. The rear of the case has a compartment for batteries that power the device.

Note Two models of Pulse Oximeter are available (**M3814A** and **M3814B**). Check your Pulse Oximeter to determine which one you have. The part numbers are shown on the rear of the device.

Pulse Oximeter Display Case

LED display windows show the blood oxygen level (%SpO_2) and pulse rate (in beats per minute) measured from the end of your finger.

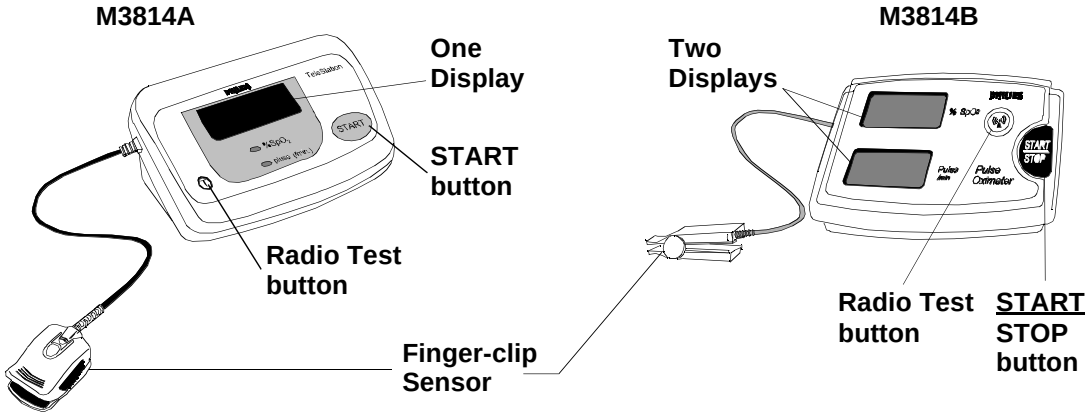
The **M3814A** has **1 display** in which **%SpO_2** and **pulse (/min.)** measurements alternate. LEDs below the display light to indicate which measurement is being displayed.

The **M3814B** has **2 displays**, one each for **%SpO_2** and **pulse (/min.)**.

Pushing the **START** button causes the Pulse Oximeter to begin taking a measurement.

The **Radio Test** button  . on **M3814A,**  on **M3814B** -- tests the transmission of measurements from the Pulse Oximeter to the Home Hub or TeleStation.

The **Finger-clip sensor** is clipped on the end of one of your fingers and measures your blood oxygen level and pulse rate.



Warnings The following **Warnings** apply to use of the Pulse Oximeter.

Warning

- **Do not** use a damaged sensor.
- **Do not** let children use the device.
- **Do not** apply the finger sensor to a finger on the same arm where a Blood Pressure cuff is present or has recently been used.
- Avoid excessive motion during measurements, this can lead to inaccurate measurements.
- Make sure the finger is not deeply pigmented with dark nail polish, artificial nails, dye, or pigmented cream. This could cause inaccurate measurements.
- Cover the sensor with opaque material under conditions of strong or excessive light (infrared lamps, photo therapy, etc.) Failure to do so can result in inaccurate measurements.
- Avoid exposing the devices to extremes in temperature, humidity, direct sunlight, shock, dust, spills, or standing water.
- The finger sensor can be comfortably clipped onto the finger (not thumb) of patients weighing > 90 lb. If the sensor is too tight, it may result in inaccurate measurements.
- The sensor may cause skin irritation, injury or an allergic reaction.
  - Stop using the Pulse Oximeter if you have redness, rash, skin tear, or other skin problems.
  - Contact your healthcare provider.
- **Do not** use the device with the battery door removed.
- To prevent shock, do not use devices during a lightning storm.

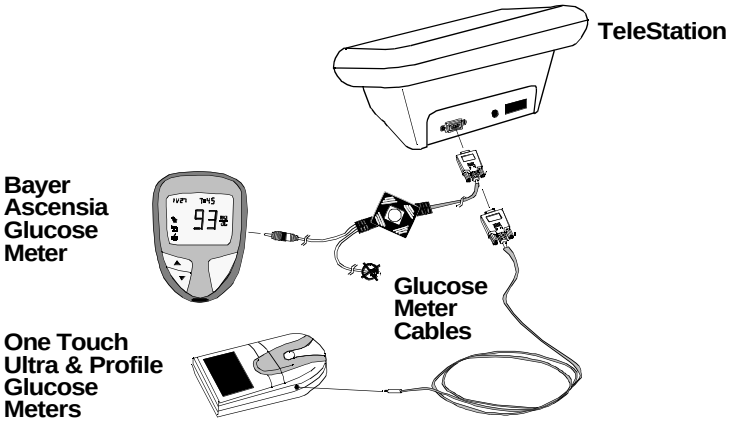
Cautions The following **Cautions** apply to use of the Pulse Oximeter.

Caution

- Read the procedures 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. The recommended maximum time for the sensor to be attached to a finger is no more than 4 minutes (more than enough time for a measurement to be obtained). Do not leave the finger sensor on the patients finger between measurements.
- This device may not work properly on all people. 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, contact your healthcare provider.
- Abnormal hemoglobin may affect accuracy.

Glucose Meter Cable

The Patient Telemonitoring Set may also provide a **Glucose Meter Cable** for connecting your Glucose Meter to a TeleStation to record your glucose measurements. The Cable for the *Bayer Ascensia Contour 7151B* glucose meter is different from the Cable for the *OneTouch Basic* and *OneTouch Profile* glucose meters..



Warnings

The following **Warnings** apply to the use of a Glucose Meter Cable.

Warning

Glucose Meter readings can *only* be recorded on a TeleStation. They cannot be recorded on a Home Hub.

The PTS System operates only with the *Bayer Ascensia Contour 7151B, OneTouch Basic* and *OneTouch Profile* glucose meters. The Bayer Ascensia Contour 7151B operates *only* with TeleStations with serial numbers SN: US4837 and higher. The serial number is on the label on the back of the TeleStation under the Philips logo. No other glucose meters should be connected to a TeleStation.

Do not measure your glucose while your Glucose Meter is connected to the TeleStation.

Clean your finger of blood before using the TeleStation.

Note

For procedures on how to measure your glucose with your Glucose Meter refer to its Instructions for Use manual.

Device Usage

This section describes how to use each of the devices of the Philips Telemonitoring Set -- HomeHub/TeleStation, Scale, Blood Pressure Monitor, Rhythm Strip Recorder, Pulse Oximeter, and the cable for your Glucose Meter.

Home Hub/ TeleStation

The **Home Hub** or **TeleStation** is the communications center for your Patient Telemonitoring Set. You may have either a Home Hub or a TeleStation depending on your healthcare plan.

Once the Home Hub/TeleStation is hooked up to your telephone and plugged into the wall, it will send your measurements to your provider when your phone line is free.

Note The Home Hub and TeleStation depend on your phone number to transmit results. They cannot be used with phones that have another number.

Home Hub

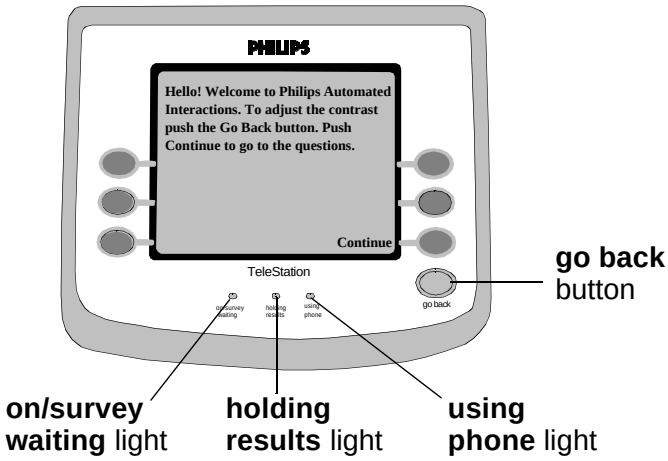
The **Home Hub** receives your measurement results from your measurement devices by radio signals and automatically sends them to your healthcare provider's computer. No actions are required by you after you have made your measurement.

TeleStation

TeleStations also have the additional capability of asking you questions about your health and sending your answers to your healthcare provider. Some TeleStations also have the ability to let you enter your measurements manually and to receive results from some Glucose Meters. Procedures for using these TeleStation features are given in the following sections

Answering Survey Questions

The front panel of the TeleStation has a number of buttons to assist you in answering questions and lights to indicate when questions have been sent, as shown in the following figure.



The **on/survey waiting** light flashes on the front of your TeleStation when there are questions from your healthcare provider waiting to be answered.

Your healthcare provider may activate the TeleStation to beep every 60 seconds to alert you that a survey is waiting.

To answer survey questions, use the following procedure

Step 1. Questions show on the screen with answer choices:

- Push the button next to the best answer.
- Choose only one. The answer will be highlighted.

If you make a mistake:

- Select the **go back** button and choose your answer again.

Step 2. After you select an answer, the next question is displayed.

- Answer it by pushing a button.
- Answer all of the questions.

Step 3. If you want to change your answer to an earlier question:

- Push the **go back** button until you see that question again.
- Then push the button next to the correct answer.

Note If you go back to change an answer to an earlier question, you will then need to answer all of the questions that follow again. The last question will confirm that your responses are complete.

Step 4. When you have finished the survey, the **holding results** light will come on followed in a few minutes by the **using phone** light. This indicates that your results are being sent to your healthcare provider's computer.

Entering Measurements Manually

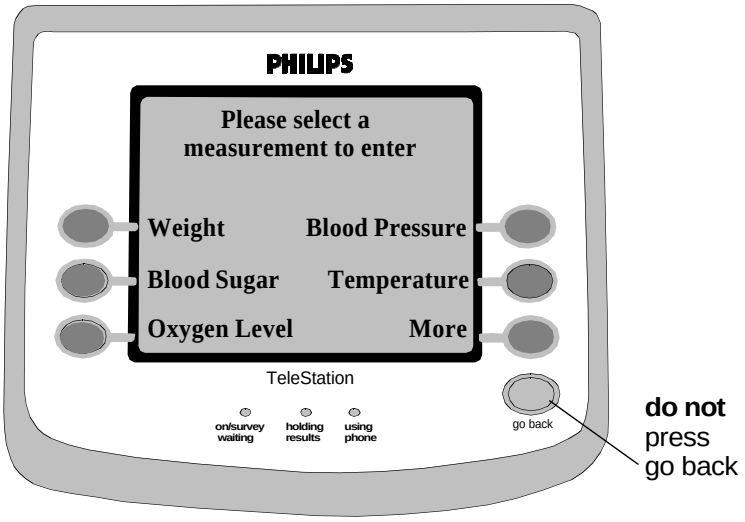
For TeleStations that permit manual entry of your measurements, the procedure is as follows.

Note Your TeleStation may not have this feature. Consult your healthcare provider if you want to use this feature.

Step 1. Take your measurements as directed by your healthcare provider and write down the results.

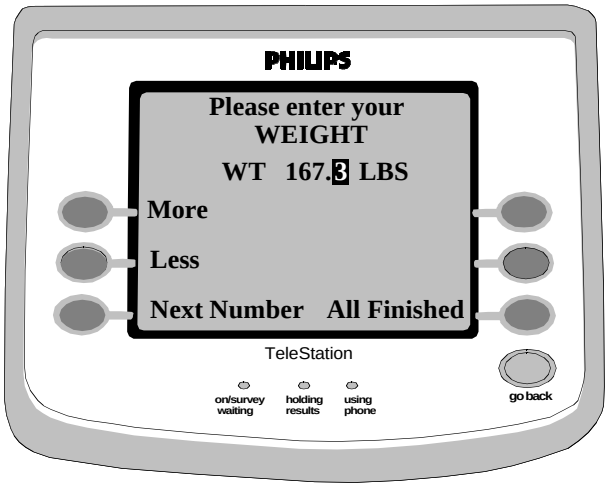
Step 2. Press any button – except **go back**.

A menu screen appears showing the measurements that can be entered.



Step 3. Press the button next to the measurement you want to enter,
or
press the **More** button to see other measurements.

The measurement entry screen appears, for example **WEIGHT** as shown below.



Note If you make a mistake, press the **go back** button before you press the **All Finished** button.

Step 4. Use the **More** and **Less** button to set the number on the screen to match the measurement you wrote down earlier.

Note To make big changes to a number, press the **Next Number** button one or more times, then use the **More** or **Less** buttons.

When entering **Blood Pressure** and **Oxygen Level** measurements, press **Continue** to move to the next part of the entry.

When you have finished entering your measurement:

Step 5. Press the **All Finished** button to store your measurement**.**

Step 6. Repeat **Steps 3-5** to enter any other measurements.

Several minutes after you store your last measurement, the screen will go blank and the **using phone** light will turn on indicating that your measurements are being sent to your healthcare provider's computer.

Note

If you get an invalid reading on your measurement device, do not enter it in the TeleStation.

If you accidently turn on the measurement screen, do not press any buttons. After a few minutes the screen will go blank.

Scale

Two types of scale are available:

Standard Scale for people who can get on and off without help

Steady Scale with a column and grab bar to help keep your balance.

Notes

If you have been given a Standard Scale and are having balance problems standing on it, contact your healthcare provider. A Standard Scale can be converted to a Steady Scale.

If you need the support of a walker, refer to the following section **Measuring Weight with a Walker**.

Measuring Weight

Procedures for measuring your weight on both the Standard and Steady Scales are as follows. Choose the procedure for your type of Scale.

Standard Scale

Step 1. Step on the Scale and stand on it without holding onto anything.

- Stand as much in the center of the platform as possible.
- Try not to step on the corners; you might damage the Scale.

Step 2. The Scale will say, "*Please stand still*". **Do not move**.
Walking "-" will show on the display during the measurement.

Notes

You will not hear the voice prompt if the volume is set to **0.**

After several seconds, the Scale will say *"Please step off the Scale"*.

Step 3. Step off the Scale.

About 5 seconds after you step off the Scale, the Scale will say your final weight (unless the volume is set to 0).
The Scale then turns off by itself.

Notes

If the batteries in the Scale are weak, the Scale's display will alternately flash **Lo** and **batt** and announce *"Please replace the scale batteries"* for 3 measurements and then the voice turns off.

If this message appears on the display or the voice is silent even though it is not set to 0, change the Scale's batteries following the **Replacing Batteries** procedure on page **3-4**.

Steady Scale

Step 1. Step on the Scale and stand on it holding the grab bars as shown opposite. You can continue holding the grab bars while taking your weight.

- Stand as much in the center of the platform as possible.
- Try not to step on the corners; you might damage the Scale.

Step 2. The Scale will say, "*Please stand still*", and the **Stand Still** light will come on.
Do not move.
Changing weight values will show on the display.
The final weight displayed is the correct weight.

Notes You will not hear the voice prompt if the volume is set to **0.**

After several seconds, the Scale will say *"Please step off the Scale"*, (unless the volume is set to 0) and the **Step Off** light will come on.

Step 3. Step off the Scale.

About 5 seconds after you step off the Scale, the Scale will say (unless the volume is set to 0) and display your final weight.
The Scale then turns off by itself.

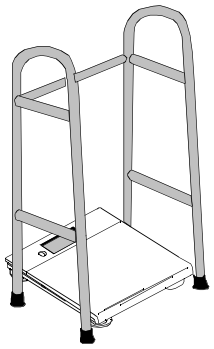
Notes If the batteries in the Scale are weak, the Scale's **Stand Still** light will flash instead of remaining on.

If this message appears on the display or the voice is silent even though it is not set to 0, change the Scale's batteries following the **Replacing Batteries** procedure on page **3-4**.

Measuring Weight with a Walker

If it is necessary to use a walker to steady yourself on the Scale, use the following procedure for either the Standard Scale or Steady Scale.

Standard Scale



Step 1. Place the walker so its legs are on either side of the Scale platform as shown opposite.

Step 1. Step on the Scale and use the walker arms for balance.

- Stand as much in the center of the platform as possible.
- Try not to step on the corners; you might damage the Scale.

Step 2. Remove your hands from the walker arms.

Note You must remove your hands from your walker for the Scale to take your true weight.

Step 3. The Scale will say, "*Please stand still*". **Do not move**.
Walking "-" will show on the display during the measurement.

Notes You will not hear the voice prompt if the volume is set to **0.**

After several seconds, the Scale will say *"Please step off the Scale"*.

Step 4. Grasp the walker arms.

Step 5. Step off the Scale.

About 5 seconds after you step off the Scale, the Scale will say your final weight (unless the volume is set to 0).
The Scale then turns off by itself.

Notes If the batteries in the Scale are weak, the Scale's display will flash **Lo** and **batt** alternately instead of Walking "-".

If this message appears on the display or the voice is silent even though it is not set to 0, change the Scale's batteries following the **Replacing Batteries** procedure on page **3-4**.

Steady Scale

Step 1. Place the walker so its legs are on either side of the Scale platform as shown opposite.

Step 2. Step on the Scale and stand using the walker

- Stand as much in the center of the platform as possible.
- Try not to step on the corners; you might damage the Scale.

Step 3. Move your hands from the walker arms to the Scale's **grab bars**. You can continue to use the Scale's grab bars for balance while you are taking your weight.

Note You must remove your hands from your walker for the Scale to take your true weight.

Step 4. The Scale will say, "*Please stand still*" and the **Stand Still** light will come on.
Do not move.
Changing weight values will show on the display. The final weight displayed is the correct weight.

Notes You will not hear the voice prompt if the volume is set to **0.**

After several seconds, the Scale will say *"Please step off the Scale"*, (unless the volume is set to 0) and the **Step Off** light will come on.

Step 5. Move your hands from Scale's grab bars to the **walker arms**.

Step 6. Step off the Scale.

About 5 seconds after you step off the Scale, the Scale will say (unless the volume is set to 0) and display your final weight.
The Scale then turns off by itself.

Notes

If the batteries in the Scale are weak, the Scale's **Stand Still** light will flash instead of remaining on and the voice prompt is quiet even though the volume is not set to **0**.

If this message appears on the display or the voice is silent even though it is not set to 0, change the Scale's batteries following the **Replacing Batteries** procedure on page **3-4**.

Changing Voice Volume

The Scale's voice has 4 volume settings, as follows:

Setting	Volume
0	Silent
1	Low
2	Medium
3	High

The volume of the Scale's voice can be changed as follows:

Note

The procedure for changing the volume is identical for both scales. The only difference is the label on the Volume button.

The **Standard Scale** has a speaker symbol  .

The **Steady Scale** has the word **Volume**.

Step 1. Step off the Scale when changing the volume.

Step 2. Firmly press and release the **Volume** button. The volume will move to the next setting. For example, the Scale may say *"one"* and display **1** for **Low**.

Step 3. Firmly press and release the **Volume** button again. The volume moves to the next setting. In this example, the Scale will say *"two"* and display **2** for **Medium**.

Each time your press the **Volume** button, the volume moves to the next setting.

Step 4. Stop the procedure when you reach the desired voice volume.

Note

If you set the volume to **0**, there will be no voice prompt and you must watch the Scale's display for instruction lights and your weight measurement.

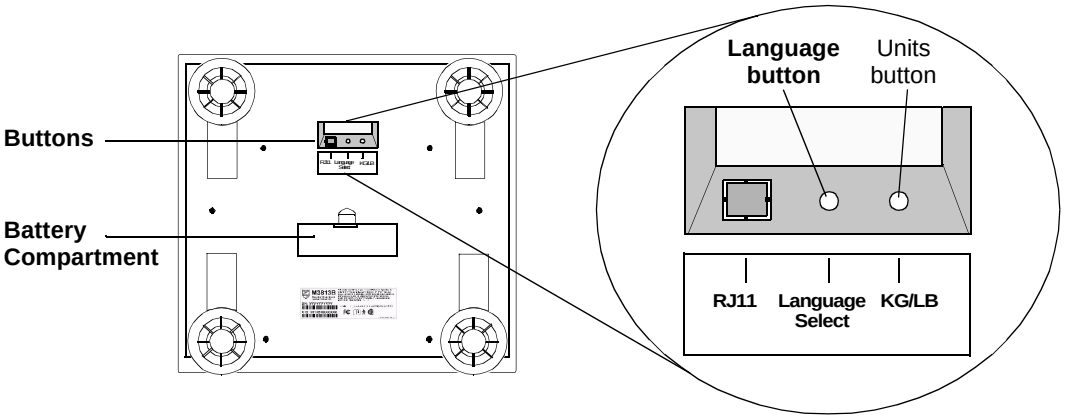
Changing Language

The Standard Scale (only) can speak your weight in either English or Spanish.

Standard Scale

The procedure for changing the language on the **Standard Scale** is as follows:

Step 1. Turn the Scale over to expose its under side, shown in the following figure.



Step 2. Locate the **Language Select** button in the opening above the Battery Compartment.

Step 3. Press and release the **Language Select** button to change the language.

The Scale will speak the next language - English or Spanish (Español).

Step 4. Repeat the press and release procedure until the desired language is spoken.

When the desired language is spoken, the procedure is completed and that language will be spoken by the scale during weight measurements.

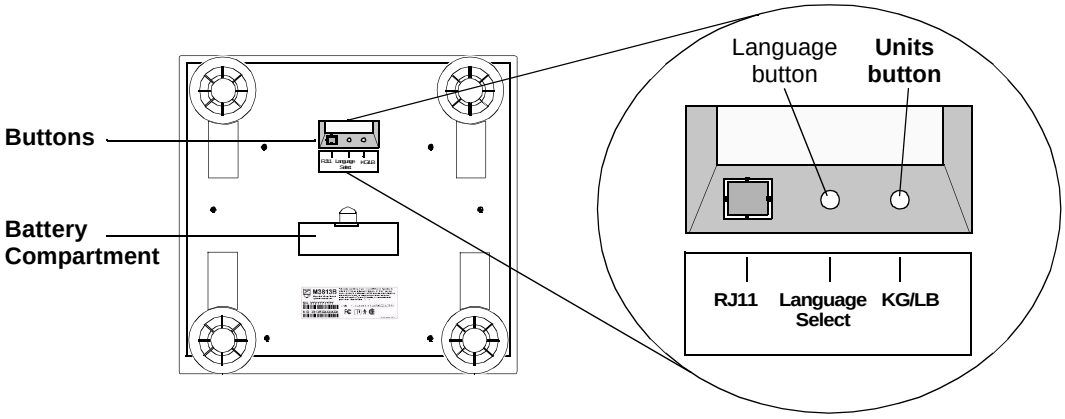
Changing Weight Units

The Scale can measure your weight in either pounds or kilograms. The procedure for changing the weight units is different for the Standard Scale and the Steady Scale.

Standard Scale

The procedure for changing the Weight Units on the **Standard Scale** is as follows:

Step 1. Turn the Scale over to expose its under side, shown in the following figure.



Step 2. Locate the **KG/LB Units** button in the opening above the Battery Compartment.

Step 3. Press and release the **KG/LB Units** button to change the weight units.

The Scale will speak the next unit -- Kilograms or Pounds.
[Kilogrammor Libra in Spanish (Español)]

Step 4. Repeat the press and release procedure until the desired unit is spoken.

Step 5. When the desired unit is spoken, the procedure is completed and that unit will be spoken by the scale during weight measurements.

Steady Scale

The procedure for changing the Weight Units on the **Steady Scale** is as follows:

Step 1. Step off the Scale when changing the weight units.

Step 2. Firmly press both the **Volume** button and the **Radio Test**  button **at the same time**.
Hold both buttons down for at least **3 seconds**.

If the Scale had been measuring pounds, the display will now show **Kgs.** 65. (for kilograms).

If the Scale was measuring kilograms, the scale will now show **Lbs**. 65. (for pounds).

The voice will also say the new weight units (unless the volume is set to 0).

Blood Pressure Monitor

To get the most accurate and reliable readings from you Blood Pressure Monitor observe the following guidelines.

- Check the cuff size.
  Small cuff fits upper arms 6.3 to 9.4 inches (16 to 24 cm) around.
  Standard cuff fits upper arms 9.4 to 14.2 inches (24 to 36 cm) around
  Large cuff fits upper arms 14.2 to 17.7 inches (36 to 45 cm) around.
- Take your blood pressure at the **same time** or times each day in a quiet place.
- **Rest 10 minutes** before taking your blood pressure.
- **Do not** take your blood pressure after exertion or drinking coffee or during conversation.
- **Sit within 20 feet** of the Home Hub/TeleStation.
- **Sit comfortably** with uncrossed legs.
- Use the **same arm** each time.
- **Remove any tight clothing** on the arm you will use to measure your blood pressure or roll up a loose garment sleeve.
  Do not measure with the cuff over clothing.
- Place the **cuff 1 inch above the elbow** with the air hose on the inside of your arm.
- Leave room for **two fingers under the cuff**.
- **Sit still** and do not move your arm during the measurement.

Notes

You can lie down while someone else takes your blood pressure, but it is important to take your blood pressure the same way every time (either sitting or lying down).

Report any changes in how you take your blood pressure to your healthcare provider.

If you travel with the BP Monitor, the **M3815A** will store up to 19 readings for up to 11 days with good batteries that remain in the device. The **M3815B** will store up to 25 readings.
When you return home to your Home Hub/TeleStation, the readings will be sent automatically to your healthcare provider’s computer.

Measuring Blood Pressure

Two procedures for measuring your blood pressure follow, one for each of the two Blood Pressure Monitor models available -- **M3815A** and **M3815B**. Select the procedure that matches your BP Monitor.

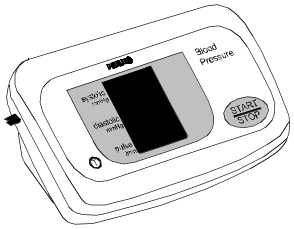
Note

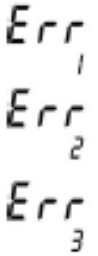
The BP's Model number is given on the back side of the monitor.

- **M3815A** - BP Monitor with the **Radio Test** button  symbol on the front of the display.
- **M3815B** - BP Monitor with the **Radio Test** button  symbol on the front of the display.

Procedure for M3815A Blood Pressure Monitor

The following table describes symbols you may see on the **M3815A** BP Monitor display during the measurement.



Symbol	Meaning
	The blood pressure measurement is taking place. The symbol blinks and beeps with each pulse beat. The symbol may also appear briefly at the start of your blood pressure measurement.
	The batteries need to be replaced. This symbol may also appear briefly at the start of your measurement.
	There may be a problem with your equipment. Take your blood pressure again. If there is still a problem, you may be able to fix the problem by looking in the Troubleshooting section. If not, call your healthcare provider.

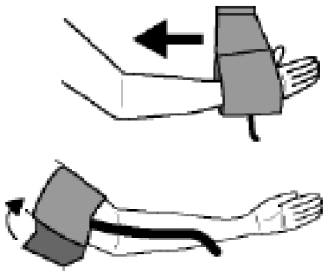
The procedure for measuring your blood pressure with the **M3815A** Blood Pressure Monitor is as follows:

Step 1. Sit comfortably with your forearm resting on a flat surface and your legs uncrossed. The center of your upper arm should be at about the same height as your heart.

Step 2. Put your hand through the cuff and slide the cuff up your forearm.

Step 3. Move the cuff so it is on your upper arm and the bottom of the cuff is abou 1 inch above your elbow

Step 4. Position the air hose so it dangles on the inside of your arm.



Warning **Do not allow the air hose to kink or twist.**

Step 5. Pull on the end of the cuff to tighten it. Then fold the cuff end back over the metal D-ring.

Note The cuff should be snug but not too tight. Leave room for two fingers to fit under the cuff.

Step 6. Fasten the end of the cuff to the Velcro® closure.

Step 7. Make sure that your hand is open and relaxed with the palm up.

Step 8. Press the **START/STOP** button. The cuff will inflate and feel tight.
Sit still and do not move your arm during the measurement.

Note

If it feels too tight or to stop the measurement at any time:

- Press the **START/STOP button**.
- Take your blood pressure again.

If you are concerned at any time about the measurement, contact your healthcare provider.

The BP Monitor will display numbers that go up to just beyond 150 mmHg for the initial pump. It may then resume pumping to higher pressures.

Warning

Watch the display. If the numbers go up to 330 mmHg, press the START/STOP button to immediately stop the measurement. Contact your healthcare provider.

Step 9. As the cuff pressure slowly decreases, watch the display window. The BP Monitor will beep as the pressure decreases.

Warning

Watch the display.
If the numbers drop down to 15 mmHg and stay there for more than 3 minutes, press the START/STOP button to stop the measurement. Contact your healthcare provider.

A long beep indicates that your blood pressure has been taken. The cuff will deflate. The display window shows your final blood pressure and pulse.

Note

If an error message was displayed, you stopped the reading, or you feel that the reading may be incorrect, take your blood pressure again.
If this happens a second time, contact your healthcare provider.

Step 10. Slide the cuff off you arm.
The BP Monitor will turn off by itself.

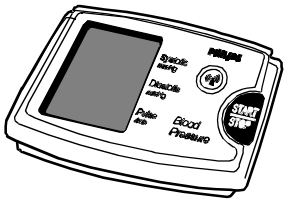
Note Once properly adjusted, the cuff can be slid off without undoing the Velcro.

Step 11. Store the BP Monitor within 20 feet of the Home Hub/ TeleStation so it can send your readings to the Home Hub/ TeleStation.

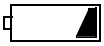
Note Refer to the **Maintenance** section for proper storage of your BP Monitor.

Procedure for M3815B Blood Pressure Monitor

The following table describes symbols that you may see on the **M3815B** BP Monitor display during the measurement.



.

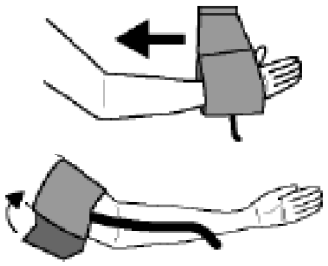
Symbol	Meaning
	Indicates that a measurement is in progress. It blinks when detecting the pulse
	Battery power full indicator
	Battery power low indicator. If it blinks, the batteries should be replaced
Err.	There was a problem with the measurement, such as: – Unstable blood pressure due to excessive body movement. – Pulse not detected correctly. – Systolic and diastolic values within 10 mmHG of each other. Take your blood pressure again, being sure to remain very still during the measurement.
Err CUF	Cuff is not fastened correctly. – Refasten the cuff – Take your blood pressure again.
If there is still a problem, consult the Troubleshooting section for corrective actions. If this does not resolve the problem, call your healthcare provider.	

The procedure for measuring your blood pressure with the **M3815B** Blood Pressure Monitor is as follows:

Step 1. Sit comfortably with your left arm resting on a flat surface and your legs uncrossed. The center of your upper arm should be at about the same height as your heart.

Step 2. Put your hand through the cuff and slide the cuff up your forearm.

Step 3. Position the cuff on your upper arm with the tube facing downward and toward the inside of your arm.



Warning **Do not allow the air hose to kink or twist.**

Step 4. Fasten the cuff securely with the hook and loop fastener strap.

Note The cuff should be snug but not too tight. You should be able to insert two fingers between the cuff and your arm.

Make sure that your hand is open and relaxed with the palm up.

Remain still and do not talk or move your arm during the measurement.

Step 5. Press the **START/STOP** button.

All display symbols appear briefly and the display then changes as the measurement begins.

The cuff starts to inflate to the correct level. It is normal for the cuff to feel very tight.

Note If it feels too tight or to stop the measurement at any time:

- Press the **START/STOP button**.
- Take your blood pressure again.

If you are concerned at any time about the measurement, contact your healthcare provider.

When the inflation is complete, the deflation starts automatically and the heart symbol  blinks, indicating that the measurement is in progress.

Once the pulse is detected, the symbol flashes with each pulse beat.

Note If an appropriate pressure is not obtained, the device automatically starts to inflate again.

When the measurement is complete, the systolic and diastolic pressure reading and pulse rate are displayed. The cuff will then deflate and the BP Monitor automatically shuts off after 45 seconds, or you can turn it off by pressing the **START/STOP** button.

Note If an error message was displayed, you stopped the reading, or you feel that the reading may be incorrect, take your blood pressure again.

If this happens a second time, contact your healthcare provider.

Step 6. Remove the cuff.

Step 7. Store the BP Monitor within 20 feet of the Home Hub/ TeleStation so it can send your readings to the Home Hub/ TeleStation.

Note Refer to the **Maintenance** section for proper storage of your BP Monitor.

Rhythm Strip Recorder

The following guidelines should be followed before you take your heart rhythm to assure an accurate reading.

- Sit down **within 20 feet** of the Home Hub/TeleStation.
- **Relax**.

Notes

It is important to be still and relaxed during the rhythm measurement.

You can lie down while you take your heart rhythm.

It is important to take your heart rhythm the same way every time (either sitting or lying down).

Report any changes in how you take your heart rhythm to your healthcare provider.

If you travel with your Recorder, it will store the most recent reading for up to 11 days with good batteries that remain in the device.
When you return home to your Home Hub/TeleStation, the most recent reading will be sent automatically to your healthcare provider's computer.

Caution

Do not talk or move during the measurement.

Measuring Heart Rhythm

The procedure for measuring your Heart Rhythm is as follows:

Step 1. Sit back in a chair with your arms at your sides or on the chair arms. Do not cross your legs. Keep your feet flat on the floor.

Step 2. Place the Recorder on the table next to you so you can see it and listen to it without moving. If you have to move to see or hear the Recorder, place the Recorder in your lap.

Step 3. Place the wristband with the **white** snap-on connector on your **right** wrist. Make sure that the flat metal inside of the wristband (on the other side of the black plastic pad) firmly touches the inside of your wrist.

Step 4. Place the wristband with the **red** snap-on connector on your **left** wrist. Make sure that the flat metal inside the wristband (on the other side of the black plastic pad) firmly touches the inside of your wrist.

Notes

If the wristbands are loose, push them up each forearm until they feel snug.

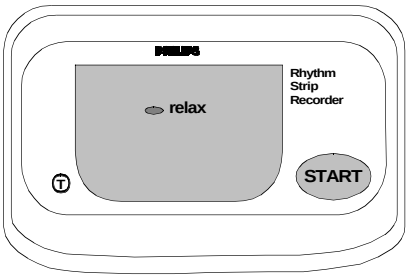
Be careful not to snag the hair on your arms.

Do not put the wristbands over clothing, bandages, or jewelry.

If you cannot fit the wristband on your arm, contact your healthcare provider.

Step 5. Let your hands rest on the tabletop or your chair's arms so that your hands are open relaxed, and palms up.

Step 6. Press the **START** button. The **relax** light will flash on and off, and the Recorder will beep for about 20 seconds as the measurement is being made.



Notes

If the Recorder beeps twice quickly before beginning the normal beeping, this means that the batteries are low. Replace the batteries within a week.

The beeps do not reflect your heart rate. They indicate that the Recorder is working.

After another short pause, the **relax** light flashes on and off twice and the Recorder will quickly **beep** twice. The Recorder has finished taking your heart rhythm.

Step 7. Remove the wristbands. The Recorder will turn off by itself.

Step 8. Store the Recorder within 20 feet of the Home Hub/TeleStation so it can send you measurements to the Home Hub/TeleStation.

Note

Refer to the Maintenance section for proper storage of your Rhythm Strip Recorder.

Pulse Oximeter

To get the most accurate readings from you Pulse Oximeter, observe the following guidelines:

- The Pulse Oximeter may not work properly with a finger thickness of less than 5/16 inches (0.8 cm) or more than 1 inch (2.5 cm).
- Dark colored nail polish or artificial nails will prevent the Pulse Oximeter from making accurate measurements. Remove dark nail polish and artificial nails from the finger you use to take your measurement.
- Avoid exposing the finger sensor to very bright or changing light while taking your measurement.
- Do not use your Pulse Oximeter on the same arm during or immediately after taking your blood pressure. Use your other arm or take your Pulse Oximeter measurement first.
- Use the same finger each time you make a measurement unless your healthcare provider instructs otherwise.
- Do not use the sensor on a finger that has chronically poor circulation or is injured.
- Be sure the inside of the finger sensor is dry before taking your measurement.
- Be sure your finger is warm when you take your measurement. If your finger is cold, warm or rub it before taking your measurement.
- Carefully place your finger in the sensor as far as it will comfortably go. Do not press in so far that you can feel your finger throbbing.
- Keep you finger relaxed and still while taking your measurement.
- If you have anemia, a low hemoglobin count, or arrhythmias, you may not be able to get a correct reading. Contact your healthcare provider.

Caution **Do not use the Pulse Oximeter with the battery door open.**

Measuring Blood Oxygen and Pulse Rate

Two procedures for measuring your blood oxygen level (%SpO2) and pulse rate follow, one for each of the two Pulse Oximeter models available -- **M3814A** and **M3814B**. Select the procedure that matches your Pulse Oximeter.

Note

The Pulse Oximeter Model number is given on the back of the device.

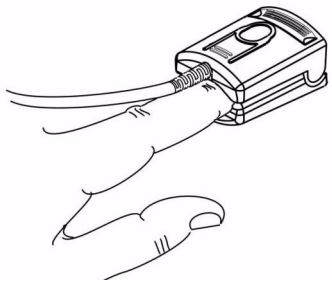
- **M3814A** - Pulse Oximeter with the **Radio Test** button symbol on the front of the display.
- **M3814B** - Pulse Oximeter with the **Radio Test** button symbol on the front of the display.

Procedure for M3814A Pulse Oximeter

The following steps describe how to use the **M3814A** Pulse Oximeter to measure your blood oxygen level (%SpO_2) and pulse rate. By default, pulse rate is turned off. To turn pulse on, press and hold both the **START** and **test** buttons for more than 3 seconds. Repeating this step will turn pulse off again.

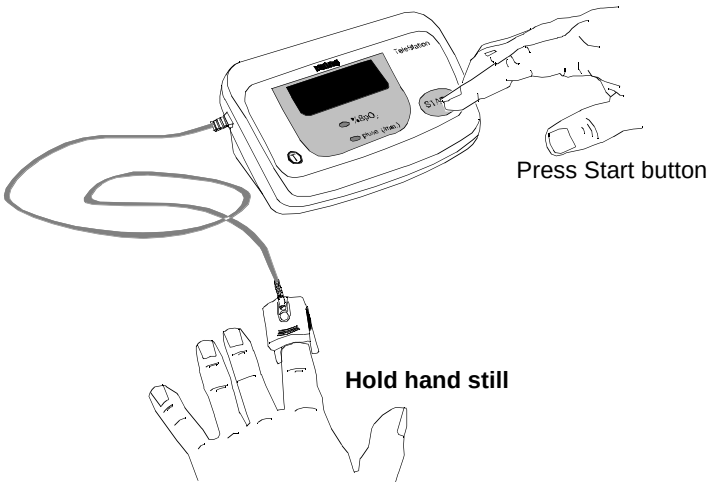
Step 1. Sit **within 20 ft.** of the Home Hub or TeleStation with your hand resting on a flat surface and the Pulse Oximeter in front of you.

Step 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.



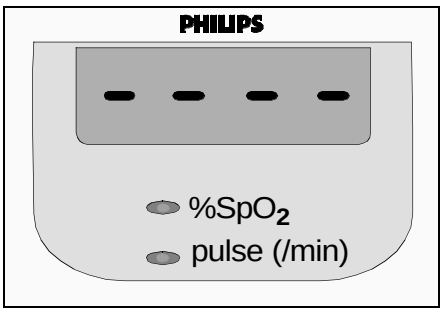
Step 3. Sit comfortably with your hand resting on the surface so that it can remain still.

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



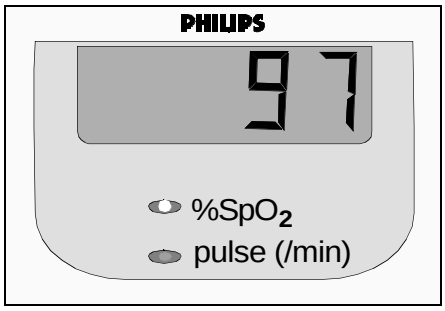
The measurement process is as follows:

- **Dashes** move across the display during measurement.



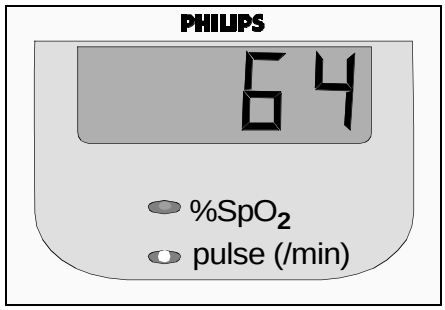
- A **double beep** sounds after a few seconds indicating that the measurement is complete

- A **tick** sounds as the **% SpO_2 measurement** displays and the yellow light next to **% SpO_2** illuminates.



- A **tock** sounds as the **pulse rate** displays and the green light next to **pulse (/min.)** 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.

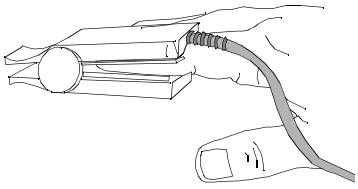
Procedure for M3814B Pulse Oximeter

The following steps describe how to use the **M3814B** Pulse Oximeter to measure your blood oxygen level (%SpO_2) and pulse rate. By default, pulse rate is turned off. To turn pulse on, press and hold both the **START/STOP** and **test** buttons for more than 3 seconds. Repeating this step will

turn the pulse rate display off again.

Step 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.

Step 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.



Step 3. Sit comfortably with your hand resting on the surface so that it can remain still. Press the **START/STOP** button and **hold your hand still** during the measurement

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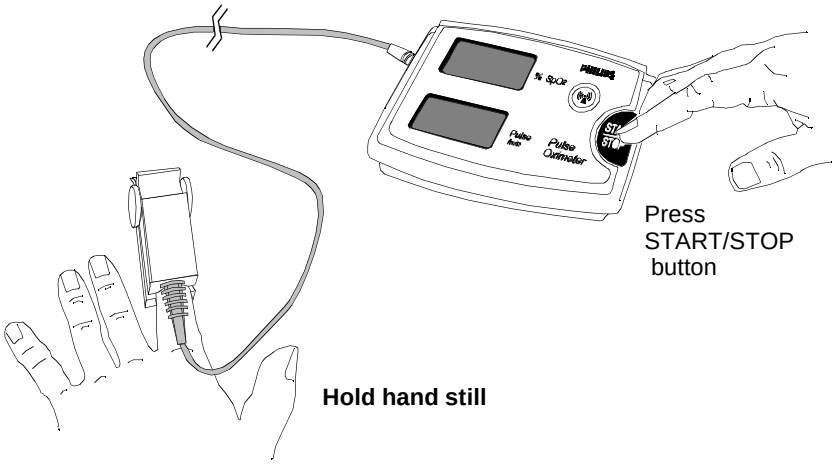
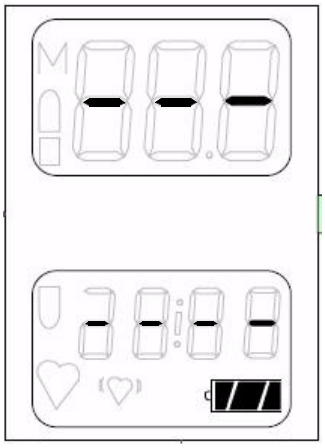


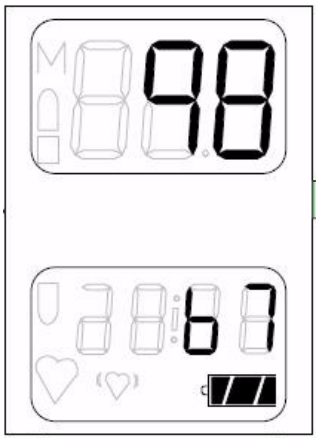
The measurement process is as follows:

- **Dashes** move across the display during measurement.



Note: If the depleted battery symbol  flashes on/off, replace the batteries and repeat the measurement. See Replacing Batteries on page **3-12**.

- After several seconds, the **%SpO2** measurement and **Pulse /min** rate display



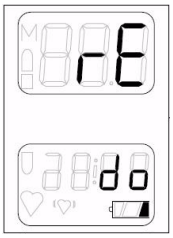
Note: The Pulse rate may not display if it was not turned on by your healthcare provider.

- After 15 seconds the Pulse Oximeter turns off.

Note

If the measurement was ***not*** made, the display shows

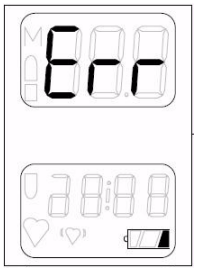
rEdo, as shown opposite.
Warm your hand or use a different finger and try again.



If there is a problem, the display shows

Err. as shown opposite and then goes blank.
Warm your hand or use a different finger and try again.

If it still shows Err, contact your healthcare provider.



Glucose Meter

The TeleStation can record results from some Glucose Meters. Glucose Meter readings cannot be made with a HomeHub. The following Glucose Meters are approved for use with the TeleStation:

- **Bayer Ascensia Contour 7151B**
- **OneTouch Basic**
- **OneTouch Profile**

Warning

Glucose Meter readings can be recorded only on a TeleStation. this function is not available with a Home Hub.

The *Bayer Ascensia Contour 7151B* operates only with TeleStations with serial numbers SN: US4837 and higher. The serial number is on the label on the back of the TeleStation under the Philips logo. No other glucose meters should be connected to a TeleStation.

Do not measure your glucose while your Glucose Meter is connected to the TeleStation.

Clean your finger of blood before using the TeleStation.

Note

For procedures on how to measure your glucose with your Glucose Meter refer to its Instructions for Use manual.

Recording Glucose Measurements

Follow these steps to send your Glucose Meter measurements to your healthcare provider's computer via the TeleStation:

Step 1. Measure your glucose with your Glucose Meter following the procedures given in its User Guide.

Step 2. Wait for the meter to turn off. The meter will turn off automatically when the strip is discarded.
For the *Bayer Ascensia Contour* meter, this can take 3 minutes.
OneTouch meters will stay on and should be left on.

Step 3. Clean your finger of any residual blood before the next step.

Step 4. Connect the **large** end of the Glucose Meter Cable to the. connector marked **| 0 | 0 |** on the back of the TeleStation. The Glucose Meter may already be connected.

Step 5. Connect the ***single*** **pin connector** on the other end of the Glucose Meter Cable into the data port on the Glucose Meter. Press firmly to make sure the connector is pushed in all the way. The TeleStation will not detect the Glucose Meter until the meter is turned on.

Note The Glucose Meter Cable for the ***Bayer Ascensia Contour 7151B*** glucose meter is different from the Cable for the ***OneTouch Basic*** and ***OneTouch Profile*** glucose meters**.** See the following figure

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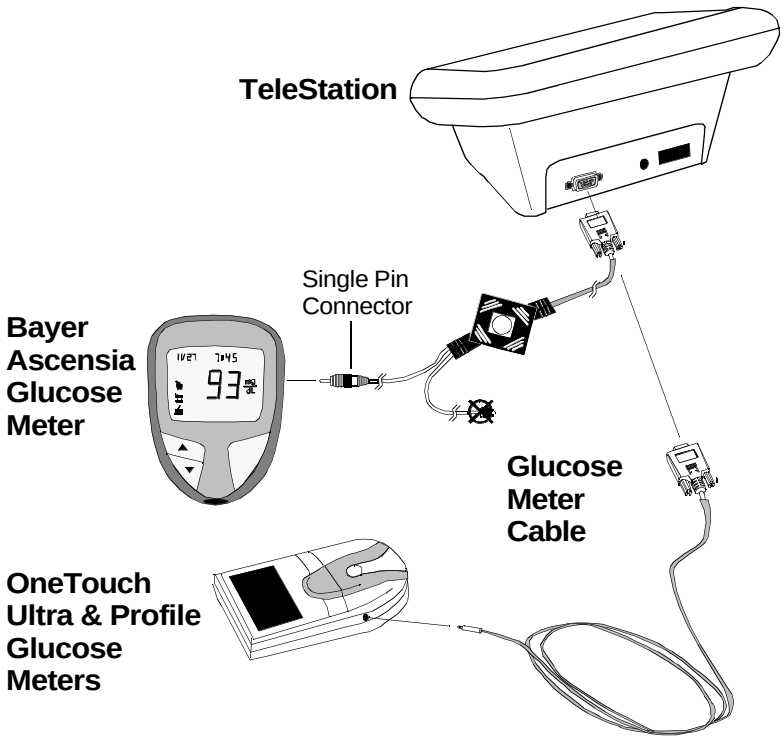


Step 6. Turn the Glucose Meter on (*OneTouch* meters should already be, see Step 2). The TeleStation will detect the Glucose Meter and

connect automatically. The Glucose Meter sends the results to the Telestation and then turns off automatically.

The TeleStation will display a message “Please Disconnect Glucose Meter”.

Step 7. Disconnect the cable from the Glucose Meter. If using the *Bayer Ascensia Contour 7151B,* the cable can be left connected to the TeleStation.

Changing Glucose Meter Time and Date

The TeleStation relies on the date and time set in the Glucose Meter. This gives the clinician the most accurate date and time of measurement. Therefore it is important for the Glucose Meter’s date and time to be set correctly. If it is necessary to correct the date or time in your Glucose Meter, follow the steps below to ensure that the date and time of your glucose measurements are accurate when you transmit them via the TeleStation.

Step 1. Connect your Glucose Meter to the TeleStation and transmit the results as described above.

Step 2. Clear the Glucose Meter’s memory of all readings.

Step 3. Change the time and/or date on your Glucose Meter following the procedure described for the unit.

3
Maintenance

Overview

Chapter 3 provides steps for cleaning and storing Patient Telemonitoring devices, replacing batteries, and general maintenance of the Patient Telemonitoring Set. You can help keep your devices in working order by taking good care of them.

This chapter includes the following sections:

Cleaning Devices

Telemonitoring devices should be cleaned only when necessary. The following procedure should be followed to clean the devices.

Note

Body fluids, such as blood or mucus, should be promptly removed using a cloth dampened with plain tap water (no soap).

Caution

Avoid spilling liquids on the devices.

Do not immerse devices in liquids to clean.

Do not use alcohol. harsh chemicals, caustic, or abrasive cleaning agents to clean devices.

Step 1. **Unplug** the Home Hub/TeleStation from power and phone lines.

Step 2. **Remove batteries** from the measurement devices following procedures given in the **Replacing Batteries** section.

Step 3. **Clean** all exposed device surfaces with a **dry, soft cloth**.

Note

When cleaning the Pules Oximeter:

- Open the Finger-clip sensor and carefully wipe its inside surfaces with a cloth dampened with a mild detergent.
- Allow the sensor to dry thoroughly before using.

Step 4. **Plug** the Home Hub/TeleStation back into power and phone lines.

Step 5. **Reinstall batteries** into the measurement devices following procedures given in the **Replacing Batteries** section.

Storing Devices

All measurement devices should be stored **within 20 feet** of the Home Hub or TeleStation so they can send their results to the Home Hub or TeleStation.

Caution

Do not store devices inside or next to a metal drawer or container, such as a file cabinet.

Do not store devices where children or pets could get tangled in the hoses, dual cables. or wristband assemblies.

Blood Pressure Monitor

- Store the BP Monitor so that the hose and cuff assembly are not bent, twisted, or folded tightly.
- Do not wrap the hose around the display case.

Rhythm Strip Recorder

- Store the Rhythm Strip Recorder so that the cable is not twisted or folded tightly.
- The Recorder can be stored with its connectors attached to the wristbands.

Pulse Oximeter

- Store the Pulse Oximeter so that its sensor cable is not twisted or kinked.
- Avoid tugging at the sensor cable or carrying the Pulse Oximeter by the sensor cable.

Replacing Batteries

Batteries in devices should be replaced as soon as the device indicates that they are low or need to be replaced.

Caution

When replacing batteries, replace all of the batteries with new ones at the same time.

Use only Type AA (1.5 volt) alkaline batteries

Do not use rechargeable batteries.

Warning

Do not use any device with its battery door removed.

Scale

Replace the batteries in the **Standard Scale** every **12 months** or sooner if:

- the voice prompt is absent even though the volume was not set to **0**
- the display screen alternately displays **Lo** and **batt** during a measurement
- the Scale announces *"Please replace the scale batteries"* during a measurement.

Replace the batteries in the **Steady Scale** every **6 months** or sooner if:

- the voice prompt is absent even though the volume was not set to **0**
- the normally steady **Stand Still** light display flashes.

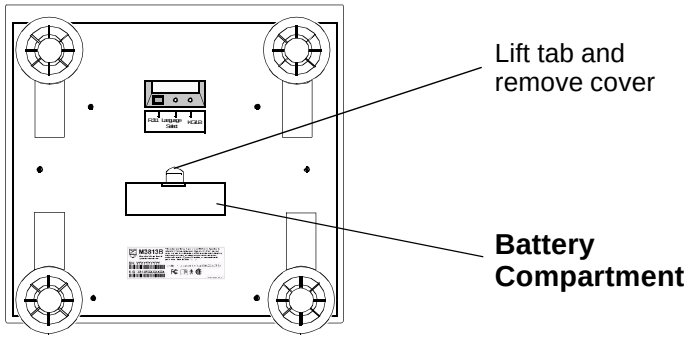
Both Scales use **4 AA alkaline batteries**.

Procedures

Procedures for replacing batteries in the Standard Scale and Steady Scale are as follows. Use the procedure for your type of scale.

Standard Scale

Step 1. Lift and gently turn the scale upside down on a flat surface to expose the Battery Compartment.

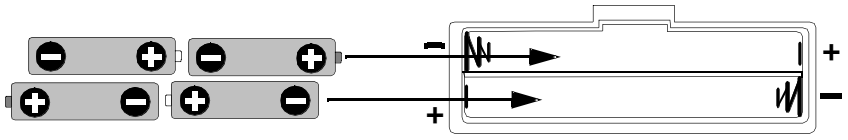


Step 2. Remove the cover of the Battery Compartment by lifting the tab.

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

Note Check with your local authorities for the proper way to dispose of batteries.

Step 4. Place the new batteries in the Battery Compartment so that the positive (+) and negative (-) terminals match the diagram in the compartment.



Notes Make sure that battery terminals are touching compartment terminals.

Step 5. Replace the cover by inserting its tabs into the slots and gently pressing the cover into place.

Step 6. Return the Scale to its original spot following proper lifting techniques given below.

Note

Lifting the Scale requires good balance, the ability to grasp and lift up to 10 pounds, and safe lifting techniques.

Do not lift the Scale if you are unsteady or unable to follow proper lifting techniques. Ask for assistance or contact your healthcare provider for help.

When you lift or lower the Scale:

- Wear shoes with nonslip soles.
- Keep your feet apart and one foot a bit in front of the other, if possible.
- Squat to lift and lower the Scale. **Never bend at the waist**.
- Keep the Scale close to your body.
- Lift with your legs, not your back.
- If you must turn, turn with your feet not your body.

Step 7. Perform the **Radio Test** described in the **Troubleshooting** section.

Step 8. Step on the Scale and verify that it is working properly.

Note

If the Scale does not seem to be operating properly or the **Radio Test** fails, contact your healthcare provider.

Steady Scale

Step 1. Firmly hold the display and pull it from the Scale to release it from the plastic fastener strips that hold it in place.

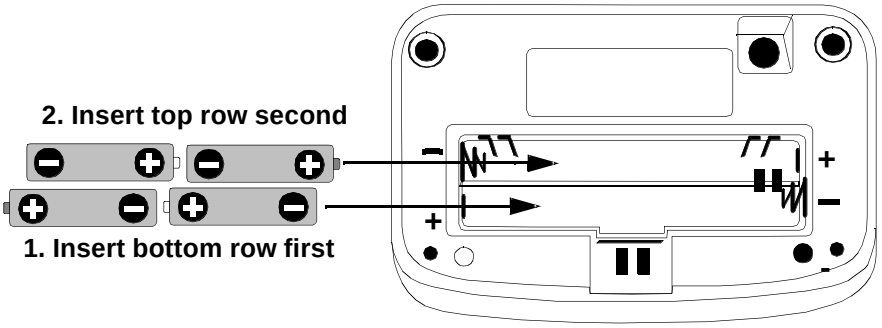
Step 2. Turn the display over and unplug the cord inside the top of the column.

Step 3. Gently push the Battery Compartment cover in the direction of the arrow symbol and lift it off.

Step 4. Remove the old batteries and properly dispose of them.

Note Check with your local authorities on the proper way to dispose of batteries.

Step 5. Place the new batteries in the Battery Compartment so that the positive (+) and negative (-) terminals match the diagram in the compartment.



Notes To keep the batteries from popping out, insert the bottom row first.

Make sure that the battery terminals are touching the compartment terminals.

Step 6. Replace the cover by inserting its tabs into the slots and gently pressing the cover into place.

The **Stand Still** and **Step Off** lights will turn on for about 6 seconds, then turn off. If the device is face down, you may not see these lights.

The display will then show 8.8.8.8 briefly, and the **Step Off** light will flash slowly.

Step 7. Replace the display as follows:

- Place the connection cord through the display cutout.
- Hold the scale display above the top of the column with the display facing you.
- Plug the cord into the adapter inside the top of the column.
- Center the display over the top of the column so that the plastic fastener strips on the display and the column match.
- Press down on the display. The back of the display should rest against the rim on the top of the column.

When the display is properly connected to the Scale:

- the **Step Off** light stops flashing.
- the Scale will say *"zero pounds"*, display **0.0**, and then turn off.

Note

Important: Do not step on the Scale while doing this step.

If the **Step Off** light does not stop flashing, check the cord connections by unplugging the cord and replugging it in until it snaps into place. Also check that the batteries are inserted the right way.

Step 8. Return the Scale to its original spot.

Caution

Do not lift the Steady Scale.
If the Steady Scale must be moved, ask for assistance or call your healthcare provider for help.

Step 9. Perform the **Radio Test** described in the **Troubleshooting** section.

Step 10. Step on the Scale and verify that it is working properly.

Note

If the Scale does not seem to be operating properly or the **Radio Test** fails, contact your healthcare provider.

Blood Pressure Monitor

- Replace the batteries in the Blood Pressure Monitor every 3 months or sooner if required. The expected battery life for the BP Monitor is approximately 3 months with 1 daily reading.
- Replace the batteries in the BP Monitor when you see the **Low Battery** symbol on the BP Monitor display.
- The Blood Pressure Monitor uses 4 AA alkaline batteries.

Procedure

To replace the batteries in the BP Monitor:

Step 1. Turn the display over.

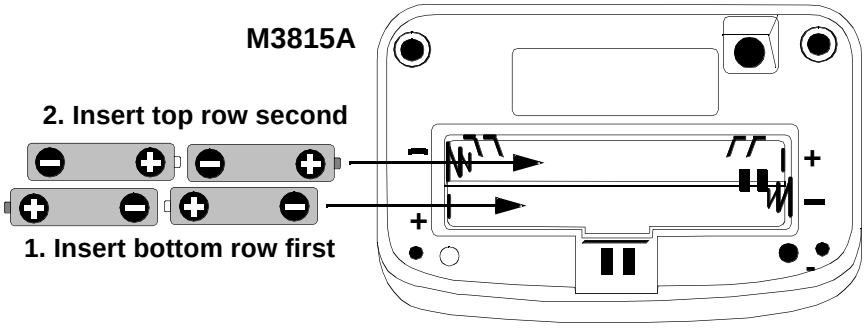
Step 2. Gently push the Battery Compartment cover in the direction of the arrow symbol and lift it off.

Step 3. Remove the old batteries and throw them away.

Note Check with your local authorities on the best way to recycle or throw away batteries.

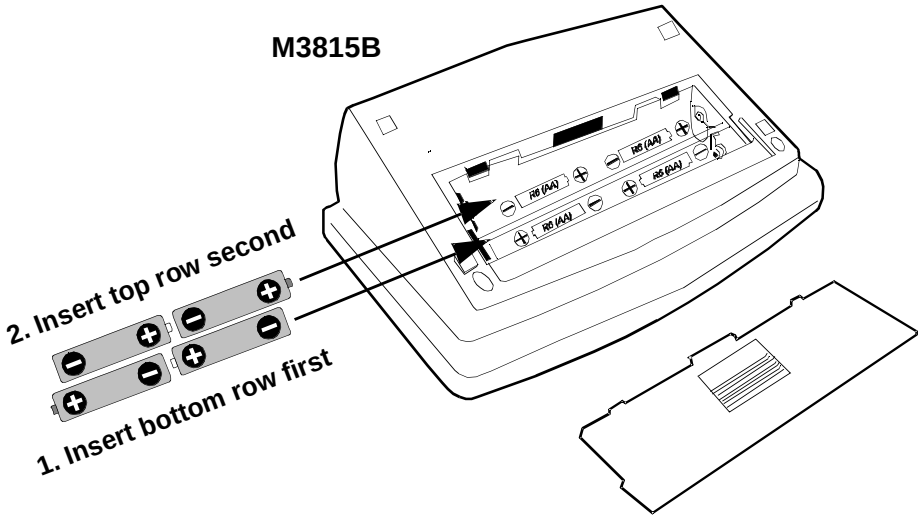
Step 4. Place the new batteries in the Battery Compartment so that the positive (+) and negative (-) terminals match the diagram in the compartment. Diagrams for both the **M3815A** and **M3815B** units are shown following.

M3815A



Notes To keep the batteries from popping out, insert the bottom row first.

Make sure that the battery terminals are touching the compartment terminals.



Step 5. Replace the cover by inserting its tabs into the slots and gently pressing the cover into place.

Step 6. Perform the **Radio Test** described in **Troubleshooting**.

Step 7. Take your Blood Pressure and verify that it is working properly.

Note If the Blood Pressure Monitor does not seem to be operating properly or the **Radio Test** fails, contact your healthcare provider.

Rhythm Strip Recorder

- Replace the batteries in the Rhythm Strip Recorder every 6 months or sooner if required.
- If the Rhythm Strip Recorder beeps twice quickly before beginning normal on and off beeping, the batteries are low and should be replaced within a week.
- The Rhythm Strip Recorder uses 4 AA alkaline batteries.

Procedure

To replace the batteries in the Rhythm Strip Recorder, follow the procedure for the Blood Pressure Monitor on page **3-9**, except for Step 7.

The Recorder will make a series of beeps.

If the series ends with a rising tone, the batteries have been inserted correctly.

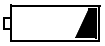
If the series ends with a falling tone or no tone, the batteries have been inserted the wrong way. Repeat the battery insertion steps.

After Step 6:

Step 7. Measure your heart rhythm with the Rhythm Strip Recorder to verify that it is working properly.

Note If the Rhythm Strip Recorder does not seem to be operating properly or the **Radio Test** fails, contact your healthcare provider.

Pulse Oximeter

- Replace the batteries in the Pulse Oximeter every 6 months or sooner if required.
- Batteries should be replaced when the Low Battery indicator displays:
  - on the **M3814A**, bAtt flashes on the Pulse Oximeter display
  - on the **M3814B**,  flashes on the Pulse Oximeter's **Pulse /min** display.
- The Pulse Oximeter uses 4 AA alkaline batteries.

Procedure

To replace the batteries in the Pulse Oximeter, follow **Step 1** through **Step 5** of the procedure for the Blood Pressure Monitor on page **3-9**.

After battery replacement:

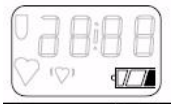
- **M3814A** displays the message Good .

  If the message bAd appears, replace the batteries with known good batteries and try again.

- **M3814B** self tests for 6 seconds, after which the full battery symbol appears on the lower display for 5 seconds.

  If the depleted battery symbol flashes, replace the batteries with known good batteries and try again.

After **Step 5**:

Step 6. Take your Pulse Oximeter measurement and verify that it is working properly.

Note If the Pulse Oximeter does not seem to be operating properly, contact your healthcare provider.

4
Troubleshooting

Overview

Chapter 4 describes procedure to follow if you have problems with any of the Philips Telemonitoring Set. The tables on the following pages can serve as a guide to help resolve problems that may occur.

Caution

Do not try to repair any device yourself.

If a problem cannot be resolved using the procedures given in this chapter, contact your healthcare provider.

Each device provides an error message when some part of the system is not working properly. If you see an error message on a device, the first thing to do is to check the device and try the measurement again. Be sure to follow the voice and light prompts provided by the device to assure that the measurement is being made properly.

This chapter includes the following sections:

Radio Test

If the **data/holding results** light does not come on after you take a measurement, another step that can be taken is to perform a Radio Test.

The **Radio Test** makes sure that your measurements are being properly sent from the measurement device to the Home Hub/TeleStation. The **RADIO TEST** button, {  or  }, is on the front of the device.

To perform the Radio Test, follow these steps:

Step 1. 1. Press and hold down the **RADIO TEST** button on the measurement device for **3 to 5 seconds** or until the Home Hub/ TeleStation starts beeping.

Note

If the **using phone** light on the Home Hub/TeleStation lights, stop and wait until it turns off before performing the Radio Test.

The following messages will appear on the indicated device.

The **Scale** and **Pulse Oximeter** will display **rF**.

The **Rhythm Strip Recorder's RELAX** light will flash once per second.

The **Home Hub/TeleStation** should beep:

If the Home Hub/TeleStation does not beep, do the following:

- Make sure the measurement device has fresh batteries
- see if there are any large objects between the measurement device and the Home Hub/TeleStation.
  If there are large objects, move the measurement device to a different location.
  If there are no large objects, move the measurement device closer to the Home Hub/TeleStation.
- Make sure there are no cordless or cellular telephones or computers in use near the Home Hub/TeleStation.
- Repeat the Radio Test

If the Radio Test is still not successful, refer to the following Troubleshooting tables to try to further resolve the problem

Troubleshooting Tables

The following tables gives possible **Problems** that can occur, **Reasons** why they may have occurred, and **Possible Solutions** that should be tried to resolve the problem.

Find the Problem entry that seems to describe what you observe, and then try the various Possible Solutions. If none of the solutions seem to be successful, contact your healthcare provider for additional suggestions.

Caution

Do not try to repair any device yourself.

If a problem cannot be resolved using the procedures given in this section, contact your healthcare provider.

Home Hub/ Telestation

The following table describes problems that may occur with the Home Hub or TeleStation.

Problem	Reason	Possible Solutions
The screen is unreadable	The Home Hub/TeleStation may be hot from sitting in sunlight or storage at a high temperature	Let the Home Hub/TeleStation cool to room temperature and the screen display may be restored.
When taking a measurement, the **data/holding results** light does not turn on	There may be interference from electronic devices, such as cordless or cell phones or computers.	Move any electronic devices away from the Home Hub/TeleStation
	The measurement device may be too far from the Home Hub/TeleStation	Move the measurement device closer to the Home Hub/TeleStation. Perform the Radio Test to determine if the device signals are being received by the Home Hub/TeleStation

Problem	Reason	Possible Solutions
When you take a measurement, the data/holding results light remains on	There may be a problem with your telephone service or your healthcare provider's connection	Perform the **CALL** button test as follows: - Find the **CALL** button on the far right of the back panel of the Home Hub/ TeleStation - Press the **CALL** button for less than 2 seconds. The Home Hub/TeleStation should beep once. (For some Home Hubs, you may need to use a pen or other pointed object to depress the **CALL** button) - Release the **CALL** button. - In 10 seconds, the **using phone** light should turn on and the Home Hub/ TeleStation will dial your healthcare provider. - After a few minutes, the **using phone** light and the **data/holding results** light should turn off. - If the **data/holding results** light turns off, the Home Hub/TeleStation is operating correctly. (It may take a few minutes for it to turn off.) - If the results above do not occur, contact your healthcare provider.

Problem	Reason	Possible Solutions
When you take a measurement, the **data/holding results** light remains on **and** you have a special phone service such as voice mail	There may be a conflict between your special phone service and the Home Hub/ TeleStation connection, **or** a problem with your telephone line or your healthcare provider's connection.	- Have someone call and leave a message on your special telephone service Perform the CALL button test as follows: **Note:** Keep your phone on the hook for the following steps unless told otherwise. - Find the **CALL** button on the far right of the back panel of the Home Hub/ TeleStation - Press the **CALL** button for less than 2 seconds. The Home Hub/TeleStation should beep. (For some Home Hubs, you may need to use a pen or other pointed object to depress the **CALL** button) - Release the **CALL** button. - In 10 seconds, the **using phone** light should turn on and the Home Hub/ TeleStation will dial your healthcare provider. - After a few minutes, the **using phone** light and the **data/holding results** light should turn off. - If the **data/holding results** light is still on, listen to the saved message and then delete it. - Press the **CALL** button for less than 2 seconds. The Home Hub/TeleStation should beep once. - Release the **CALL** button. - In 10 seconds, the **using phone** light should turn on and the Home Hub/ TeleStation will dial your healthcare provider.

Problem	Reason	Possible Solutions
Continued from previous page		- After a few minutes, the **using phone** light and the **data/holding results** light should turn off. - If the **data/holding results** light **turns off**, the Home Hub/TeleStation is operating correctly. (It may take a few minutes for it to turn off.) However, your special phone service may be interfering with the Home Hub/ TeleStation - If the **data/holding results** light **stays on**, there is probably not a conflict with your special phone service. However, there may be a problem with your phone line or your healthcare provider's connection. - If the results above suggest a problem, contact your healthcare provider.

Problem	Reason	Possible Solutions
Liquid spilled onto the Home Hub/ TeleStation (for example, where the wires connect to the back)	The Home Hub/TeleStation should be placed far from liquids (especially a sink or anywhere liquids might spill onto the unit.)	For liquid spills, do the following: - Unplug the Home Hub/TeleStation power adapter from the wall or power strip. - Unplug the phone connection cord from the wall jack. - Use a towel to dry off the Home Hub/ TeleStation, paying special attention to connection points. - Wait 3 hours for the unit to completely dry. - Plug the connection cords back into the Home Hub/TeleStation and the electrical and phone lines. Make sure they snap into place. - Pick up your telephone receiver and listen for a dial tone. - If you do not hear a dial tone, hang up and try again. - If you still do not hear a dial tone, unplug the Home Hub/TeleSTation. - Connect your telephone directly to the phone jack. - Contact your healthcare provider.

Scale

The following table describes problems that may occur with the each of the two types of Scale -- Standard Scale and Steady Scale. Use the table for your type of Scale.

Standard Scale

The following troubleshooting table applies to the **Standard Scale**.

Problem	Reason	Possible Solutions
Err.1 appears on the display and it says *"Please try again."*	You may have stepped off the Scale too soon.	Take your weight again and wait for the voice prompt before stepping off the Scale.
Err.2 appears on the display and it says *"Please try again."*	You may have moved during the measurement	Take your weight again and do not move while the scale measures your weight
Err.3 appears on the display and it says *"Please try again."*	You may have stayed on the scale too long.	Take your weight again and step off the scale as soon as you hear the voice prompt.
Err.4 appears on the display and it says *"The maximum weight was exceeded."*	Your may have exceeded the maximums weight of 440 lbs (200 kgs)	Use a regular scale to see if your weight exceeded 440 lbs (200 Kg).
No voice prompt when you stand on the Scale and it is not set to 0	The Scale's batteries are low.	Replace all 4 batteries in the Scale as described in Chapter 3
The display alternately flashes **Lo** and **batt**		
The Scale announces *"Please replace the scale batteries"*		
Scale does not turn on.	The Scale is not properly installed or the batteries are low.	- Replace all 4 Scale batteries following the procedure in Chapter 3. - Move the Scale to a hard, flat surface. - If it still des not turn on, contact your healthcare provider.
The final weight reading keeps changing or is incorrect.	The Scale is on a carpeted or irregular surface, or the Scale is broken.	- Move the Scale to a hard, flat surface and take your weight again. - If this does not resolve the problem, contact your healthcare provider.

Steady Scale The following troubleshooting table applies to the **Steady Scale**.

Problem	Reason	Possible Solutions
Err. appears on the display	You stepped off the Scale too soon.	Take your weight again and wait for the **Step Off** light and voice prompts before stepping off the Scale.
Err.1 or **Err.2** or **Err.6** appears on the display	The Scale display is not connected to the Scale or there is a problem with the Scale	Check the connection of the display to the Scale. If this does not resolve the problem, contact your healthcare provider.
Err.3 appears on the display	You moved the scale immediately after stepping off.	Take your weight again and wait for the **Step Off** light and voice prompt before stepping off the Scale and do not touch the Scale.
Err.4 appears on the display	You moved during the weight measurement.	Take your weight again and remain still during the measurement.
Err.5 appears on the display	The Scale was unable to read the measurement.	Use a regular scale to see if your weight exceeded 365 lbs (166 Kg)
Err.6 appears on the display	You did not step off the Scale when prompted.	Take your weight again and when the **Step Off** light and voice prompt occur, step off the Scale.
Stand Still light blinks when you stand on the Scale.	The Scale's batteries are low.	Replace all 4 batteries in the Scale as described in Chapter.3
Stand Still light blinks and there is no voice prompt when you stand on the Scale and it is not set to 0.	The Scale's batteries are low.	Replace all 4 batteries in the Scale as described in Chapter.3
Step Off light flashes slowly	The Scale display is not connected to the Scale.	- Check the cord connection between the platform and the display - Unplug and replug the cord until it snaps into place

Problem	Reason	Possible Solutions
Scale does not turn on.	The Scale is not properly installed or the batteries are low.	- Check the cord connection between the platform and the display. - Replace all 4 Scale batteries following the procedure in Chapter 3. - Move the Scale to a hard, flat surface. - If it still des not turn on, contact your healthcare provider.
The final weight reading keeps changing or is incorrect.	The Scale is on a carpeted or irregular surface, or the Scale is broken.	- Move the Scale to a hard, flat surface and take your weight again. - If this does not resolve the problem, contact your healthcare provider.

Rhythm Strip Recorder

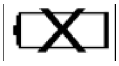
The following table describes problems that may occur with the **Rhythm Strip Recorder**.

Problem	Reason	Possible Solutions
Poor heart rhythm measurement, **or** the Home Hub/ TeleStation is not receiving the heart rhythm measurement.	The wrist bands are too loose or not properly positioned.	Push the wristbands up you arms until there is a smooth, snug fit against the skin or you inner wrists or arms.
	The measurement device may be too far from the Home Hub/TeleStation	- Move the measurement device closer to the Home Hub/TeleStation. - Perform the Radio Test to determine if the device signals are being received by the Home Hub/TeleStation. - If the Recorder is still not operating properly, contact your healthcare provider.

Blood Pressure Monitor

The following tables describes problems that may occur with the **Blood Pressure Monitor** The first table is for the **M3815A** and the second table is for the **M3815B**.

M3815A

Problem	Reason	Possible Solutions
Inaccurate blood pressure readings.	Improper blood measurement procedure.	Review the blood pressure tips in Chapter 2 and repeat the measurement.
Err 1 appears on the display	The systolic and diastolic measurements are within 10 mm Hg of each other. There may be air leakage in the air hose connections.	- Check that the air hose is properly connected to the BP Monitor and cuff by unplugging it and then plug it back in, pushing and twisting until it snaps into place.
Err 2 appears on the display	You moved during the reading.	- Take your blood pressure again, remaining very still during the reading.
Err 3 appears on the display	The pressure measurement did not increase during cuff inflation or the cuff is not securely fastened.	- Check that the air hose is properly connected to the BP Monitor and cuff by unplugging it and then plug it back in, pushing and twisting until it snaps into place. - Make sure the cuff is securely fastened
 appears on the display	The BP Monitor batteries are low.	- Replace all 4 batteries in the BP Monitor following the procedure in Chapter 3. **Note:** If the batteries need frequent replacement, check the initial snugness of the cuff. A loose cuff requires longer pumping times and will shorten battery life.

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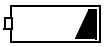
M3815B

Display Symbol	Reason	Possible Solutions
	Battery power full indicator	No action required.
	Battery power low indicator	When battery power indicator blinks, replace all batteries with new ones.
Err.	Unstable blood pressure due to excessive body movement.	Repeat the measurement and remain very still during the measurement.
	Pulse is not detected correctly.	Repeat the measurement and remain very still during the measurement.
	Systolic and diastolic values are within 10 mmHG of each other.	Refasten the cuff and repeat the measurement remaining very still during the measurement.
	Pressure value did not increase during inflation.	Check for air leaks along the tube and around the air socket.
Err CUF	Cuff is not fastened correctly.	Refasten the cuff and repeat the measurement.

Pulse Oximeter

The following tables describes problems that may occur with the **Pulse Oximeter**. The first table is for the **M3814A** and the second table is for the **M3814B**.

M3814A

Problem	Reason	Possible Solutions
Err. appears on the display	A hardware malfunction is detected.	If condition persists, contact your healthcare provider.
rEdo appears on the display	A reading was not obtained.	- Reduce the light. - Warm your finger. - Keep your hand still. - Repeat the measurement. - If the condition persists, contact your healthcare provider.
bAtt appears on the display and flashes.	Batteries are too low for the Pulse Oximeter to work properly.	- Replace all 4 batteries following the procedure in Chapter 3. - Perform a Radio Test.
Good appears on the display along with a rising audio tone after battery replacement	Indicates that the batteries are good.	No action required. Proceed with Pulse Oximeter measurement.
bAd appears on the display along with a low audio tone after battery replacement.	There is a hardware malfunction.	- Replace all 4 batteries following the procedure in Chapter 3. - Perform a Radio Test. - If condition persists, contact your healthcare provider.

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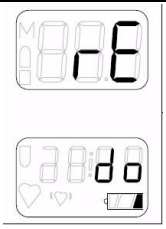
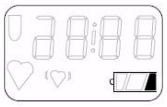
M3814B

Problem	Reason	Possible Solutions
 appears on the display	A hardware malfunction is detected.	If condition persists, contact your healthcare provider.
 appears on the display	A reading was not obtained.	- Reduce the light. - Warm your finger. - Keep your hand still. - Repeat the measurement. - If the condition persists, contact your healthcare provider.
 appears on the display and flashes	Batteries are too low for the Pulse Oximeter to work properly.	- Replace all 4 batteries following the procedure in Chapter 3. - Perform a Radio Test.
 appears on the display during start up and after battery replacement	Indicates that the batteries are good.	No action required. Proceed with Pulse Oximeter measurement.
No Pulse rate appears on the display after a measurement.	The Pulse rate function is normally turned off.	Your healthcare provider can turn the Pulse rate function on if necessary or applicable.

5 Specifications and Regulatory

Overview

Chapter 5 provides information about the Philips Telemonitoring Set of devices that is required by law to completely describe their characteristics, performance and compliance with regulatory requirements. It includes the following sections.

Intended Use/Indications for Use

The Model 3810A is intended to be used upon prescription of a licensed physician or authorized healthcare provider by patients as a means to automatically collect and transmit medical information, such as weight, blood pressure, and non-diagnostic ECG, over normal residential telephone lines, between a patient, typically at home, and a healthcare professional at the authorized provider.

Indications for Use

The M3810A is indicated for patients at home, who are capable and willing to self-administrate this device, upon prescription of their healthcare provider, to collect and transmit medical information, such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone time to the healthcare provider. The device does not send any real-time alarms. Clinical judgement and experiences are required to check and interpret the information delivered.

Contra-indications

The device is not intended as a substitute for medical care. The device is contra indicated for patients with uncompensated heart failure, patients at high risk of life threatening arrhythmias, patients with recent myocardial infarctions, or patients requiring direct medical supervision or emergency interventions.

Specifications

This section gives technical descriptions and specifications of the Philips Telemonitoring Set devices, including physical, electrical, and environmental.

Description

Home Hub

Model	M3812A
Type	Class II equipment, continuous operation
Display	LED panel
Ports	Serial Modem

TeleStation

Model	M3812B
Type	Class II equipment, continuous operation
Display	LCD panel
Ports	Serial Modem

Standard Scale

Model	M3813B
Type	- Type B applied part  - IPXO ordinary equipment - Internally powered continuous operation
Display	- Digital, 2.0 in (51 mm) character height - Weights displayed and announced simultaneously
Language	English or Spanish
Audio Volume	Voice readout of weight, prompts, and 4 settings
Measurement Range	66 to 440lbs (30 to 200 kg)
Accuracy[a]	$\pm$ 0.5% of loading at maximum patient weight $\pm$ 2.2 lbs (1.0 kg)
Display Units	pounds (lbs) or kilograms (kg), user selectable
Maximum Allowed Weight	440 lbs (200 kg)
Grab Bar and Post	check for availability

a. Scale accuracy testing was performed on polyester carpet with a weight of 80 oz., twist of 4.8 x 3.3, and density of 4,000. A standard 8 lb. pad was used as underlayment.

Steady Scale

Model	M3813A
Type	- Type B applied part  - IPXO ordinary equipment - Internally powered continuous operation
Display	- Digital, 0.71 in (18 mm) character height - Weights displayed and announced simultaneously
Language	English only
Audio Volume	Voice readout of weight, prompts, and 4 settings
Measurement Range	66 to 365lbs (30 to 166 kg)
Accuracy	$\pm$ 1% of loading $\pm$ 1.1 lbs (0.5 kg) at maximum patient weight $\pm$ 4.8 lbs (2.2 kg)
Display Units	pounds (lbs) or kilograms (kg), user selectable
Maximum Allowed Weight	365 lbs (166 kg)
Grab Bar and Post	Removable attachment

Blood Pressure Monitor

M3815A

Model	M3815A
Type	- Type B applied part  oscillometric - IPXO ordinary equipment - Internally powered continuous operation
Display	- Digital, 0.63 in (16 mm) character height - Pressure and pulse displayed simultaneously
Measurement Range	- Pressure: 20 to 280 mm Hg - Pulse: 40 to 200 pulses per minute
Accuracy	Pressure transducer: ± 2% or ± 3 mm Hg
Pressurization	Automatic, using micropump
Depressurization	Constant-air release-valve system
Deflation	Automatic exhaust

M3815B

Model	M3815B
Type	- Type B applied part  oscillometric - Internally powered continuous operation
Display	- Digital, 0.79 in (20 mm) character height - Pressure and pulse displayed simultaneously
Measurement Range	- Pressure: 20 to 280 mm Hg - Pulse: 40 to 200 pulses per minute
Accuracy	Pressure transducer: ± 2% or ± 3 mm Hg
Pressurization	Automatic, using micropump
Depressurization	Constant-air release-valve system
Deflation	Active exhaust valve

Rhythm Strip Recorder

Model	M3816A
Type	- 1-channel lead - Oscillometric, Type B applied part  - IPXO ordinary equipment - Internally powered continuous operation
Display	LED light

Pulse Oximeter

M3814A

Model	M3814A
Type	- Type B applied part  - IPXO ordinary equipment - internally powered continuous operation (does not imply continuous monitoring
Display	- Digital 0.7 in. (1.8 cm) character height - %SpO_2 - Pulse displayed alternately - %SpO_2 display range: 0 - 100%
Measurement Range	- %SpO_2: 70 - 100% (functional hemoglobin) - Pulse rate: 18 to 300 beats per minute
Measurement Accuracy	- %SpO_2: 70 - 100%, $\pm$ 2 digits ($\pm$ 1 Standard Deviation a statistical measure) - %(SpO_2 calibration range: 70 - 100% determined by arterial blood measurement on a Co-oximeter Test methods available upon request.) - Pulse rate: $\pm$ 3%, $\pm$ 1 digit
Measurement Wavelengths	- 660 nanometers, 3 milliwatts (nominal) - 910 nanometers, 3 milliwatts (nominal)
Biocompatibility	Suitable for surface device, skin contact, limited contact duration (up to 24 hours)

M3814B

Model	M3814B
Type	- Type BF applied part  - IPX1 ordinary equipment - internally powered continuous operation (does not imply continuous monitoring)
Display	- %SpO_2 displayed in top window 0.75 inches character height - Pulse rate displayed in bottom window 0.5 inches character height
Measurement Range	- %SpO_2: 70% to 100% (functional oxygen saturation of arterial hemoglobin) - Pulse: 30 to 250 beats per minute
Measurement Accuracy	- %SpO_2: 70% to 100%, $\pm$ 3% - Note: the %SpO_2 calibration range of 70% to 100% was determined by arterial blood measurement on a Co-oximeter. Test methods available upon request.) - Pulse rate: $\pm$ 5 bpm
Measurement Wavelengths	- 660 nanometers, 15 milliwatts (maximum) - 910 nanometers, 15 milliwatts (maximum)
Biocompatibility	Suitable for surface device, skin contact, limited contact duration (up to 24 hours)

Note Because pulse oximeter equipment measurements are statistically distributed, only approximately 2/3 of pulse oximeter equipment measurements can be expected to fall within the $\pm$ Arms value measured by a CO-oximeter. Functional testers, such as an SpO2 simulator, cannot be used to assess the accuracy of pulse oximeter sensors.

Technical Specifications

Physical

Philips Device	Product Part #	Height cm (in.)	Width cm (in.)	Depth cm (in.)	Weight kg. (lbs.)
Home Hub	M3812A	3.8 (1.5)	20.0 (7.9)	27.9 (11.0)	0.93 (2.05)[a]
TeleStation	M3812B	12.7 (5.0)	21.8 (8.6)	15.9 (6.3)	0.77 (1.70)[a]
Standard Scale	M3813B	5.7 (2.3)	38.1 (15.0)	38.1 (15.0)	3.8 (8.4)[b]
Steady Scale	M3813A	5.1 (2.0)	48.8 (19.2)	48.8 (19.2)	6.8 (15)[b]
Blood Pressure Monitor	M3815A	6.9 (2.7)	16.5 (6.5)	11.2 (4.4)	0.57 (1.25)[b]
	M3185B	6.2 (2.4)	16.3 (6.4)	11.2 (4.4)	0.35 (0.77)
Rhythm Strip Recorder	M3816A	6.9 (2.7)	16.5 (6.5)	11.2 (4.4)	0.34 (0.75)[b]
Pulse Oximeter	M3814A	6.9 (2.7)	16.5 (6.5)	11.2 (4.4)	037 (0.81)[b]
	M3814B	6.2 (2.4)	16.3 (6.4)	11.2 (4.4)	0.35 (0.77)

a. Net weight, without power module
b. Net weight, with batteries

Electrical

Philips Device	Product Part #	Power Source	Battery Life
Home Hub	M3812A	9.0VAC/ 500mA (Use Philips-supplied power adapter only)	n/a
TeleStation	M3812B		
Standard Scale	M3813B	4 AA (1.5V) alkaline batteries connected in series for a total of 6 V	~ 12 months with 1 daily measurement
Steady Scale	M3813A		~ 6 months with 1 daily measurement
Blood Pressure Monitor	M3815A M3815B		~ 3 months with 1 daily measurement
Rhythm Strip Recorder	M3816A		~ 12 months with 1 daily measurement
Pulse Oximeter	M3814A M3814B		~ 6 months with 1 daily measurement

Environmental

Philips Device	Product Part #	Temperature		Atmospheric Pressure	Altitude	Relative Humidity
		Operating	Storage	Operating and Storage (hPa)	Operating and Storage (hPa)	(Non-condensing)
Home Hub	M3812A	10 - 40°C (50 - 104°F)	-9 - 54°C (15 - 130°F)	572-1013	0-4600m (0-15,000ft)	less than 85%
TeleStation	M3812B					
Standard Scale	M3813B					
Steady Scale	M3813A					
Blood Pressure Monitor	M3815A					
	M3815B					
Rhythm Strip Recorder	M3816A					
Pulse Oximeter	M3814A					
	M3814B					

Warning **These devices are not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. Oxygen concentrations must be <25% and partial pressure <27.5 kPa when no other oxidants are present.**

Electromagnetic Compatibility (except M3813B and M3815B)

Note

The section applies to all Telemonitoring Set devices ***except*** the M3813B Scale and M3815B Blood Pressure Monitor. See the following section for Electromagnetic Compatibility information for these devices.

When using the Philips Telemonitoring System, electromagnetic compatibility with surrounding devices should be assessed.

A medical device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed according to international medical device standards EN 60601-1-2.

These EMC standards describe tests for both emitted and received interference. Emission tests deal with interference generated by the device itself, whereas Immunity tests deal with determining electromagnetic compatibility of the device while used in the presence of surrounding electronic equipment or other external sources that may generate interference.

Warning

Radio frequency (RF) interference from nearby transmitting devices may degrade performance of Philips Telemonitoring Set devices. Electromagnetic compatibility with surrounding devices should be assessed prior to using this equipment.

Philips Telemonitoring Set devices should not be used next to or stacked with other equipment. If you must stack the device, check that normal operation is possible.

Emissions and Immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their devices when there is reduced performance.

During the EN 61000-4-3 Radiated Immunity test, some reduced performance was observed.

EN 61000-4-3 specifies that devices be subjected to a field of 3 Volts/meter over a frequency range of 26 to 1000 MHz with no degradation of performance or loss of function below the performance level specified when equipment is operated as intended. Radio communication from the Philips Telemonitoring Set devices may occasionally be interrupted when subjected to frequencies in the 800 MHz - 942 MHz range at field strength levels as low as 0.05 V/m. The phenomena discussed above are not unique to this unit but are characteristic of radio instrumentation in use today. The M3812A Home Hub and M3812B TeleStation are radio receivers and their reception of Philips Telemonitoring Set device signals can be degraded by electromagnetic interference.

Avoiding Electro-magnetic Interference

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.

The M3812A Home Hub and M3812B TeleStation contain a sensitive radio receiver that is intended to receive radio signals from the measurement devices and can be degraded by electromagnetic energy in the frequency range of 870 MHz to 960 MHz. Avoid the use of any radio frequency device operating in this frequency range when using the Philips Telemonitoring System. Possible sources of interfering radio frequency radiation are cellular telephones, cordless telephones, and other products that contain radio transmitters. The following table gives safe distances to keep radio frequency transmitters away from your Philips Telemonitoring Set devices.

Recommended separation distances between portable and mobile RF communications equipment and Philips Telemonitoring Set devices except M3813B and M3815B				
Rated maximum output power of transmitter (Watts)	Recommended separation distance for various transmitter frequencies			
	26 to 800 MHz		800 MHz to 2.5 GHz	
	feet.	meters	feet	meters
0.01	11.5	3.5	23	7
0.1	36	11	72	22
1	115	35	230	70
10	361	110	720	220
100	1150	350	2300	700

Note These guidelines may not always apply. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Philips Telemonitoring Set devices have a Radio Test button that sends a reduced strength test radio signal to the Home Hub or TeleStation, which 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 strength and reduce interference. In addition, Philips Telemonitoring Set devices and Home Hub or TeleStation can be placed closer to each other so that the radio transmission from the Philips Telemonitoring Set devices to the Home Hub or TeleStation has less distance to travel and interfering radio signals have less effect. The radio transmission from the Philips Telemonitoring Set devices is repeated periodically so that an intermittent source of interference should only delay reception.

Avoiding Static Electrical Discharges

Static discharges to Philips Telemonitoring Set devices may cause temporary, unusual behavior. If a static discharge causes a temporary malfunction, simply restart the measurement.

Electromagnetic Compatibility (M3813B and M3815B)

The electromagnetic compatibility (EMC) validation of the **M3813B Scale** and **M3815B Blood Pressure Monitor** included testing performed according to the international standard for EMC for medical devices. See the Manufacturer's Declaration for details.

Electronic devices can either generate or receive electromagnetic interference. The M3813B and M3815B have been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2001, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2001.

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the electronic equipment. Electromagnetic compatibility with surrounding devices should be assessed prior to using the equipment.

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electronic equipment. See your Service Provider for assistance with the minimum recommended separation distance between RF communications equipment and these devices.

Warning

The use of accessories, transducers and cables other than those specified in the Philips Telemonitoring system service and user documentation can result in increased emissions or decreased immunity of the system.

The products should not be used next to or stacked with other equipment. If you must stack the product, you must check that normal operation is possible in the necessary configuration before the product is used.

Emissions and Immunity

The M3813B and M3815B may be susceptible to interference from other RF energy sources. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmission. If interference is encountered, as demonstrated by anomalous product behavior, attempt to locate the source. Assess the following:

- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain equipment?

Reducing Electro-magnetic Interference

Once the source is located, attempt to attenuate the interference by distancing the product from the source as much as possible. If assistance is needed, contact your local Service Provider.

Electromagnetic Emissions (M3813B and M3815B)

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The M3813B and M3815B use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The M3813B and M3815B are suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Note The M3813B and M3815B are intended for use in the electromagnetic environment specified above. The customer or the user of these devices should assure that it is used in such an environment.

Electromagnetic Immunity (M3813B and M3815B) - General

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec.	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	Note: U_T is the AC mains voltage prior to application of the test level.		

Electromagnetic Immunity (M3813B and M3815B)

Immunity Test	IEC 60601Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the M3813B Scale and M3815B Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's specified output power and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol : 

Electromagnetic Immunity (M3813B and M3815B)

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location in which the M3813B Scale or M3815B Blood Pressure Monitor are used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The M3813B Scale and M3815 Blood Pressure Monitor are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of these devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and these devices as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the M3813B Scale and M3815 Blood Pressure Monitor

Rated maximum output power of transmitter (Watts)	Recommended separation distance for various transmitter frequencies			
	150 to 800 MHz		800 MHz to 2.5 GHz	
	feet.	meters	feet	meters
0.01	0.32	0.1	0.66	0.2
0.1	1.3	0.4	2.3	0.7
1	3.9	1.2	7.5	2.3
10	13	4	23	7.0
100	39	12.0	75	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer.

Note

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Regulatory Information

FCC Regulations

This equipment 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. Philips Telemonitoring Set devices generate, use, 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 this equipment 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 Philips Telemonitoring Set devices or the Home Hub or TeleStation and the device being interfered with, for example, a TV,
- consulting your healthcare provider.

Notes

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

The possibility of hazards arising from errors in the software and hardware design are minimized by Philips' use of a risk analysis and risk management process as defined in Philips' document CMS RISK ANALYSIS PROCESS, document number A-Q2920-00126.

Telephone Regulatory Notice

Your Philips Home Hub is registered with the Federal Communications Commission (FCC) and is in compliance with part 68 of the FCC Rules and Regulations. The FCC requires Philips to provide you with the following information. The Home Hub contains a 14.4 Kbps modem. You must, upon request, provide the following information to your local telephone company (this information is also printed on the bottom of the device): FCC Part 68 ID Number: 2M6USA-33569-DT-E and Ringer Equivalence Number (REN): 0.3A.

Your Philips TeleStation complies with Part 68 of the FCC rules and the requirements adopted by the Administrative Council for Terminal Attachments (ACTA). ACTA requires Philips to provide you with the following information. The TeleStation contains a 14.4 Kbps modem. You must, upon request, provide this information to your local telephone company.

On the bottom of the device is a label that contains, among other information, a product identifier in the format

US: AAAEQ##TXXXXX.

For products approved after July 23, 2001, the digits in the product identifier represented by ## are the REN without a decimal point (for example, 03 is a REN of 0.3). If requested, this number must be provided to the telephone company.

The REN is useful to determine the number of devices you can connect to your telephone line and still have all of these devices ring when your telephone number is called. In most (but not all) areas, the sum of the RENs of all devices connected to one line should not exceed 5. To be certain of the number of devices connected to your line as determined by the REN, contact your local telephone company.

Note: (a) The Home Hub or TeleStation may not be used on coin service phones provided by the telephone company. (b) Party lines are subject to state tariffs and, therefore, you may not be able to use your own telephone equipment if you are on a party line. Check with your local telephone company. (c) Notice must be given to the telephone company upon permanent disconnection of your telephone from your line.

Rights of the Telephone Company: Should your Home Hub or TeleStation cause trouble on your line that may harm the telephone network, the telephone company shall, if possible, notify you that temporary discontinuation of service may be required. If advance notice is not practical, the telephone company may discontinue service immediately, but temporarily. In such case of discontinuance, the telephone company must (1) promptly notify you of such temporary discontinuance, (2) afford you the opportunity to correct the situation, and (3) inform you of your right to bring a complaint to the FCC pursuant to the procedures in Subpart E of Part 68, FCC Rules and Regulations.

The telephone company may make changes in its communications facilities, equipment, operations, or procedures where such action is required in the operation of its business and not consistent with FCC Rules and Regulations. If these changes are expected to affect the use or performance of your Home Hub or TeleStation, the telephone company must give you adequate notice, in writing, to allow you to maintain uninterrupted service.

A plug and jack used to connect the TeleStation must comply with applicable FCC Part 68 rules and requirements adopted by the ACTA. A compliant telephone cord with a modular plug is provided with the TeleStation. It is designed to be connected to a compatible modular jack that is also compliant. See installation instructions for details.

Consult your telephone company or qualified installer if you are using a TeleStation and have specially wired alarm equipment connected to your telephone line.

Contact Philips Medical Systems at **(866) 246-7316** for repair or warranty information.

Part Number M3810-90096, Issue 5
Printed in the U.S.A.
October 2008

M3810-90096

PHILIPS