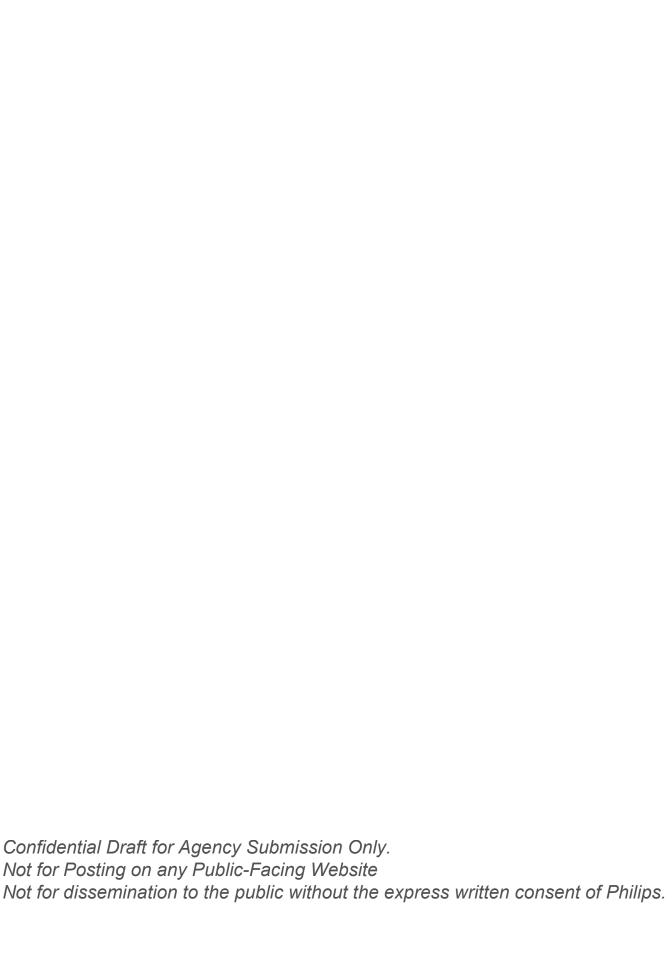


GoSafe Lite 2 Mobile Personal Emergency Response System and Service

# Instructions for use

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# **About This Manual**

#### **Training**

Reading and understanding these Instructions for Use and the Quick Setup Guide serves as adequate training for the safe installation, use and disposal of the equipment. Users of this product must review and understand the instructions for use document to ensure safe and effective use.

If you require further information about training in the use of this product, please contact Philips Lifeline or your Philips Lifeline representative.

# **Definitions & Clarifying Terminology**

**7150 MHB**: The technical /Mc name for the GoSafe Lite Pendant for FDA registration purposes. This name is used in the "Alarms" and "Safety and Regulatory Compliance sections

**Alarm State**: When you press the Help Button or when an unrecovered fall is detected, the Pendant will initiate a help call to Philips Lifeline. During this time, until the Pendant is reset, the Pendant is in alarm state. Certain behaviors described herein only take place during Alarm State.

**Audio Beacon**: A very loud, siren-like noise generated by the Pendant. It is designed to help responders find you more easily while searching for you.

**AutoAlert**: The Philips fall detection technology that is used by the GoSafe Lite Mobile Pendant.

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**Charger Pins**: The gold pins on the charger itself that engage with the charging interface contacts.

**Charging Interface Contacts**: The gold circles on the back side of the pendant.

**Coverage Area**: The area from which your pendant is capable of sending & connecting a help call. As a cellular communication device, the coverage area for GoSafe Lite is defined by the cellular network availability and signal in your location, at the time of activating the pendant. Refer to the "Terms and Conditions of Use" document you received with your system for details on the limitations of cellular service.

**Critical Charge Indication**: The point at which the Pendant no longer has sufficient battery power left to operate normally. It will play a voice prompt and turn off at this point.

**End Device**: The device that initiated the alarm. In this case, the GoSafe Lite, Pendant.

GoSafe Help Button or Help Button: The button is the depressed square area inside the grey field on the front of the pendant itself. When pressed, an immediate call to the Philips Lifeline Call Center is placed. To initiate a call to Philips Lifeline, press the Help Button. A voice prompt and Red light will confirm that you have activated the pendant and that your call is in progress.

**GoSafe Lite**: GoSafe Lite is a product-enabled service. The mobile pendant that you wear works in conjunction with the mobile network to connect to the Philips Lifeline response

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GoSafe Lite\_Mobile Pendant, or Pendant: This is the pendant that you physically wear around your neck. Also, known as the 7150 MHB.

**Help Alarm Signal**: This is the type of signal that the Philips Lifeline call center receives from the Pendant when the Help Button is pressed.

**Indicator Light**: A small light just above the Help Button, inside the grey area on the front of the Pendant. It will illuminate in either green, orange or red, and either blink or shine consistently depending on what it is indicating. A complete guide to the different colors and whether they are blinking or not is included at the back of this Instruction.

**Initial Charge Indication**: The Pendant chimes and the orange Indicator Light starts to blink. This is the point at which you should re-charge your Pendant.

**Intended Use**: The purpose for which the system was specifically designed. GoSafe Lite was designed for people to wear to help maintain their independence, knowing that if they need assistance at home or away, they can call for help.

**Lifeline**: The emergency response service provided by Philips Lifeline

**Notify**: An individual who will be advised, after the fact, of any alarm whereby assistance was required. A person or persons who you want to be told if you experienced an emergency whereby Philips Lifeline was engaged to facilitate response. Notifies will not be advised of false alarms or test calls.

**Philips Lifeline**: the name of the company that provides GoSafe Lite and the Lifeline emergency response service.

**Recommended Usage**: How you should use and interact with the Pendant can Call Center for normal use.

**Responder(s)**: If you should need emergency assistance and activate your Lifeline system, a responder is someone you want Philips Lifeline to contact to physically go to you and help you. You can have more than one responder. In an emergency, Philips Lifeline will contact them in prioritized order until we are able to connect with someone that can get to you and help you.

**Response Associate**: A Lifeline operator. Response Associates are trained to take emergency calls and facilitate assistance for Lifeline subscribers.

**Sleep Mode**: The Pendant is essentially turned off. When in Sleep Mode, the Pendant will not detect falls, will not automatically update its location information, and will not make a help call with a single button press.

**Stand-by mode**: This is the mode that the Pendant is most often in while you are wearing it. The pendant is powered-on, with all systems functioning, but is not in Alarm State.

**Subscriber**: A user of the Lifeline Personal Emergency Response Service. Also, *User*.

# Your Philips Lifeline Service

## Welcome to Philips Lifeline

Thank you for choosing the Lifeline Medical Alert Service from Philips.

Please refer to the Quick Setup Guide provided for instructions on setting up your equipment. These Instructions for Use will provide you with information about your equipment and the Philips Lifeline Medical Alert Service. Please read this manual and the Quick Setup Guide carefully, and note the Warnings and Cautions. If you have questions, call Lifeline at any time using the number listed at the bottom of the page. Please save this manual. It includes important information you may need to refer to later.



# Warnings and Cautions

Please pay special attention to all the instructions provided in the **Warning** and **Caution** sections.

A **Warning** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.



A Caution alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other

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on to the public without the express written consent of Philips.

These Instructions for Use and the Quick Setup Guide describe the most extensive configuration of the product.

# This manual covers the following:

GoSafe Lite Mobile Pen	dant (7150MHB)	A
Works inside and outside of your home*	✓	
Can only be worn around neck as a pendant	$\checkmark$	
Can detect falls** in your home	$\checkmark$	
Can detect falls** outside* your home	✓	
2-way voice communication with Philips Lifeline	$\checkmark$	
Waterproof to 1 meter (3.3') for up to 30 minutes	$\checkmark$	

<sup>\*</sup> When access to the AT&T wireless network is available.

## Setting up your Lifeline Service

Before you can use your GoSafe Lite system, the coverage range of your Help Button must be determined. Please see the Quick Setup Guide for instructions on how to set up your system and test the coverage range of your Help Button. If you have any questions, please contact Philips Lifeline or your representative.

<sup>\*\*</sup>The GoSafe Lite, Mobile Button provides an extra layer of protection by placing a Help Call if a fall is detected and you can't push the Button. Not all falls can be detected. If you need help, always press your Help Button if you are able to do so.

## Responders and People to Notify

#### What is a "Responder"?

As a Philips Lifeline subscriber, you should have designated people who have agreed to be "Responders." These are people whom Lifeline should call in an emergency, when appropriate. Examples include: neighbors, friends, relatives, your current nursing aide, etc.

#### **Choosing a Responder**

It is best to choose a Responder who:

- Has a key to your home or knows where one is located (perhaps in a key lockbox)
- · Could come to help you at different times of the day or night
- · Lives or works within 10 minutes of where you live
- · Has a phone, preferably a cell phone
- Ideally has a driver's license and access to a vehicle
   Since the GoSafe Lite System allows you to call for help both at and away from home, it is best to choose a Responder who can also:
- Drive to your location, whether you are at home or away from home, and provide help if needed.

#### Information Philips Lifeline needs about Responders

Please ensure that Philips Lifeline has the following information about each person acting as a Responder:

- Name
- Phone numbers home, work and cell phone
- Confidential Draft for Agency Submission Only.
  Whether or not the Responder has a key to your home Not for Posting on any Public-Facing Website
- Not for dissemination to the public without the express written consent of Philips.

It's very important that you keep your Responders and their contact information up to date. Remember to contact Philips Lifeline if one of your Responders is no longer able to assist you or if they get a new telephone number.

Please contact Philips Lifeline for any questions about selecting or being a Responder. Most importantly, if you list someone as a Responder, make sure you tell that person that you have done so, and that they agree to act as a Responder.

#### Who are "People to Notify"?

If you use your Lifeline system to call for help, after response has been facilitated, Philips Lifeline will contact the "People to Notify" identified in your subscription profile to let them know that you received assistance. "People to Notify" will not be contacted to help you, unless they are also on your list of "Responders." Neither responders nor notifies will be contacted in the event of a test signal or when you activate your system but do not need help — such as during an accidental button press.

# Calling for help inside your home

1. Press the button area on the GoSafe Lite, pendant Help Button that you wear. The pendant will tell you that your call is in progress, and to please wait. Once the call has registered with the Lifeline response center, your button will tell you that your call has been connected. This means that our system has compiled all of your information and is being delivered to a Lifeline response associate who will

call you momentarily.

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**Note**: The Response Center is available 24 hours a day, 365 days a year. Your Lifeline subscription provides for unlimited calls to the response center without penalty. A trained Personal Response Associate is always available to assist you.



- 2. Your Pendant calls the Lifeline Response Center. When it dials the Response Center, your pendant will repeatedly say: "Your Help Call is in progress; please wait." Once it connects with the Response Center, it will say: "Your call has been connected; Lifeline will be right with you." It is normal to experience a slight delay prior to speaking with a response associate.
- 3. The Response Center will answer the call. A Lifeline Response Associate will speak to you through the pendant's built-in speaker and hear you through the highly sensitive microphone. He/she will ask if you need help. If you do not need help, just tell the Response Associate that no help is needed.

**Note**: If you cannot speak or be heard, the Response Associate will try calling you back. If you cannot answer or if the Response Associate cannot hear you, Lifeline will contact your Responder(s) or emergency services.\*

\*In the case of a fall detected, if the response associate cannot hear you and/or is unable to contact you through your GoSafe Lite, pendant or your alternate contact numbers such as your home or cell phone, EMS will be contacted to respond. Please contact Philips Lifeline to opt out of this escalation protocol.

- 4. The Response Center will assess the situation. If help is needed, the Response Associate will begin contacting your list of Responders (or emergency services) in accordance with your request, until they are able to reach someone who accepts the action of going to help you.
- 5. Once your Responder or the emergency service arrives, they should press your Help Button to let Lifeline know that help has arrived. The Response Associate will contact the household to confirm that you received the help that you needed. [Need to check this behavior]
- 6. Once Lifeline confirms that you have been assisted, a Response Associate will contact the "People to Notify" you've designated, letting them know you needed and received help.

**Note**: If you accidentally press your Help Button <u>don't panic</u>. Allow the call to connect. A Response Associate will answer your call and ask if you need help. Simply tell them that "No help is needed", and confirm to them that you are OK. Don't be concerned that you are bothering Lifeline; we just want to be sure that you are alright. This is part of the serivce that you are paying for and there is no extra charge for accidental calls.

## Signal Range

Please see the Quick Setup Guide located in the box for instructions on how to set up your GoSafe Lite system. and test the range of your Help Button. The coverage area of the your Help Button must be tested prior to use. The GoSafe Lite pendant is a radio frequency (RF) device that transmits a signal to the Lifeline call center over the Cellular network. It depends upon cellular network availability to send your help signal to the Lifeline call center. Signal availability inside of your home is defined during the system setup process, but can vary from time to time depending on multiple factors.

It is recommended that, once your welcome/setup call is complete, you go to areas of your home where you commonly spend time, as well as areas where you are most likely to have an accident – such as the bathroom and kitchen – to help ensure that your GoSafe Lite pendant has sufficient signal to operate reliably.

**Caution** 

add note about cellular limitations indoors here, for example: The strength of the wireless (cellular) signal, etc.... same as in page 16.

**Note**: Your GoSafe Lite pendant is designed to work inside and outside of your home from anywhere sufficient connectivity to the AT&T cellular network is available. When you activate your pendant away from home, Help will be sent to your location. Please refer to page 24 for further information.

It is important to note that the ability of your GoSafe Lite Pendant to make a help call may be affected by environmental factors, including building materials, large masses covering the Help Button (i.e. a person laying on top of it) and submersion in

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#### Signal Range Test

# **Battery information**

Your GoSafe Lite mobile pendant contains a battery that can only be replaced at the Philips factory. Your pendant will automatically send a signal to Philips Lifeline when the battery needs to be replaced. We will contact you directly to make arrangements for a replacement.

## **Equipment service**

Every GoSafe Lite mobile pendant is manufactured to high quality standards, and can only be factory-serviced by Philips Lifeline, with the exception of the neck cord, which can be replaced by the user. You can only replace the neck cord with a Philips replacement neck cord designed specifically for your pendant. Your GoSafe Lite pendant performs periodic diagnostic self-tests to verify proper functionality. If you ever experience issues with your equipment, or if it becomes damaged, please contact Philips Lifeline or your representative to arrange service or a replacement..

## Contacting Philips Lifeline or your representative

- If you would like to transfer your service to a new or second home.
- If your Responder or People to Notify list needs to be updated. It is important that your list is up to date with the correct people and contact information.

can have the service, but each individual user requires their own pendant.

## Safety information



The GoSafe Pendant uses the AT&T wireless network to communicate with the Lifeline Response Center.

- 1. The strength of the wireless (cellular) signal may be stronger in some areas of your home than others. Be sure to test your GoSafe pendant from the locations in your home where you spend the majority of your time to help to ensure that the pendant is capable of connecting to the cellular network from these areas.
- 2. If the AT&T wireless network experiences an outage or your pendant loses its signal, it will not be able to send a Help Call to Lifeline.

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# GoSafe Lite Mobile Personal Emergency Response System

# **General Information**

The information in this section applies to your GoSafe Lite Pendant.

## Cleaning and Care

Your GoSafe Lite pendant is water resistant to the IPX7 standard. This means that you can submerge it in up to 1 meter (about 40") of water for up to 30 minutes without damaging the pendant. As such, you can submerge it in warm water for easy cleaning and can also bathe/shower without removing it.

- Wash the neck cord with a mild liquid dishwashing detergent. Replacement neck cords are available from Philips Lifeline for a nominal fee and include a convenient tool that simplifies replacement.
- 2. Wash the Help Button under warm running water. You may also gently wipe it with an isopropyl (rubbing) alcohol wipe or a cotton pad moistened with alcohol. However, **do not soak** it in alcohol or pour alcohol into the microphone or speaker area of the pendant.
- 3. Blot excess moisture with a towel and allow the Help Button to finish air-drying while you're wearing it. Confidential Draft for Agency Submission Only.

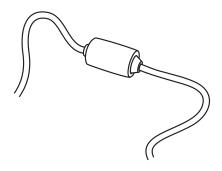
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**Note**: If you accidentally push your Help Button during cleaning, don't panic. Allow the call to connect. A Personal Response Associate will answer the call when it connects. Simply tell them that "No help is needed", and confirm to them that you are OK.



#### Warnings

- Any cord worn around the neck can pose a strangulation risk, including the possibility of death and serious injuries. This may be of more concern to wearers in wheelchairs, using walkers, using beds with guard rails, or who might encounter other protruding objects upon which the cord can become tangled.
- The neck cord on your GoSafe Lite pendant employs a special fuse (see image below). This fuse is designed to break away under certain conditions to reduce the remote risk of strangulation. If this fuse breaks apart, contact Philips Lifeline or your authorized representative for a replacement, as the fuse cannot be repaired or re-used.

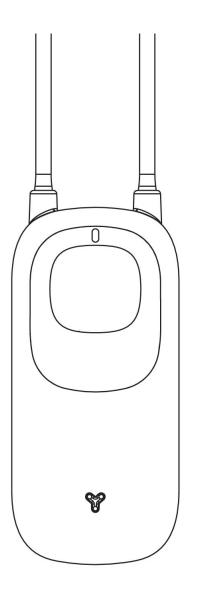


- Do not use any neck cord other than the one provided by Philips Lifeline or your representative. Other neck cords may not provide the feature to break apart therefore increasing the risk of strangulation.
- Do not tie a knot in your neck cord since this may prevent the break away feature from working properly.
- There are no user-serviceable parts inside the pendant.
   Do not attempt to open or modify the device.
- The pendant contains a lithium battery that must be disposed of properly. Do not discard the pendant in the trash or expose it to flames or intense heat.
- The pendant is not suitable for use in the presence of flammable mixtures.
- Do not put your pendant through the dishwasher, clothes washer or dryer. Please be sure to remove your pendant from articles of clothing that are being dry-cleaned.
- Excessive heat may damage your pendant. Do not leave your Help Button on the dashboard of your car, a window sill or on any other area that receives intense, direct sunlight. Likewise, do not wear your Help Button into a hot tub or sauna. Normal bathing and showering temperatures WILL NOT damage your Help Button.

# **A** Caution

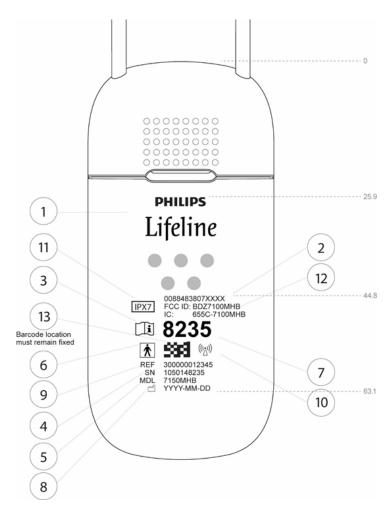
 Your Help Button may interfere with certain medical equipment, such as magnetic resonance imaging (MRI), X-Ray machines, as well as metal detectors.

# GoSafe Lite Mobile Pendant (7150MHB)



The GoSafe Lite Mobile Pendant allows you to connect to the Lifeline Response Center 24 hours a day, 7 days a week. It can be used at home, or from any other location in the United States where the AT&T wireless network is available.

The GoSafe Lite Mobile Pendant includes Philips AutoAlert fall detection technology, which provides an added layer of protection for the user by automatically calling for help when a fall is detected. AutoAlert technology is highly accurate, but does not detect 100% of falls. If you are able, you should always press your Button when you need help.



Item	Description	Notes
1	Philips Lifeline Logo	min width 12.5 mm
2	GTIN Number	variable
3	Refer to IFU Icon	ISO 7000-1641
4	Serial Number	variable
5	Model Number	7150MHB
6	Applied Part Icon	IEC 60417-5333
7	Last 4 Digits of Serial Number	variable
8	Date of Manufacture	variable, YYYYMMDD
9	Engineering Part Number	variable (no L, R, U, etc.)
10	Emmission Icon	IEC 60417-5140
11	Ingress Protection (IP) Rating	IPX7
		USA and Canada Regulatory ID
12	FCC,IC code	FCC: BDZ7100MHB
		IC: 655C-7100MHB
13	Product Barcode	variable

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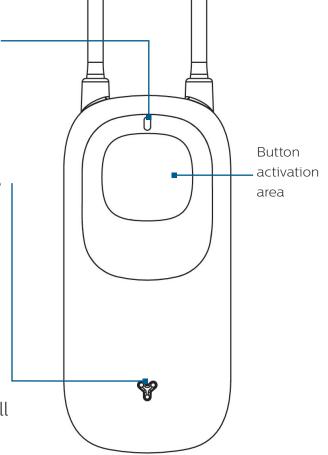
## GoSafe 2 Pendant (7150MHB)

#### Front view

Indicator light — This light will indicate the status of the GoSafe Lite Pendant. (see: Alarm Descriptions / Summary Tables section.)

Microphone – The GoSafe Lite Mobile Pendant has a microphone that is used to talk to the Response Associate

Help Button – The Help Button is the portion of your Pendant that can be pressed to send a Help Call to Lifeline.



#### Charger

The GoSafe Lite Mobile Pendant has a rechargeable battery. Use only the charger provided with your GoSafe system to recharge the Pendant when the light & voice prompts indicate indicates that the Pendant needs to be

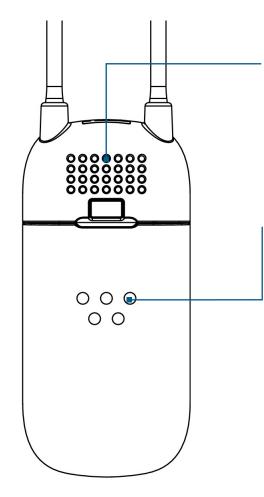
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Excess cord storage

Only.

Charger



#### **Back view**

Speaker – The GoSafe Lite Mobile Pendant has a builtin speaker that allows you to hear the Personal Response Associate, voice prompts and alert sounds.

Charging Contacts – The gold circles on the back of the Pendant are the charging interface contacts. When you place your Pendant in the Charger, the charger Pins engage with these contact points.

Important: This area is part of the fall detection sensor system and needs to remain clear of obstructions (e.g., lint or food products).

#### **Determining your location**

In Alarm State, the GoSafe Lite Mobile Pendant is designed to help identify your general location, at or away from home. However, you should always tell the Personal Response Associate your exact location if you are able to do so. Even if you are unable to speak or describe your exact location, Lifeline will contact help to find and assist you where you are. Lifeline cannot guarantee that your location can be determined at all times.

If your Responder or emergency services is having trouble locating you, Lifeline may activate the audio beacon feature on the pendant. This is a very loud, siren-like noise that will come from the Pendant speaker and will help responders to find you more easily. Each time the audio beacon is activated, it will sound for 5 minutes. Pressing the Help Button will silence the audio beacon and will not initiate another Help Call.

# What to expect when the AutoAlert fall detection technology in your GoSafe Lite Mobile Pendant detects a fall

- A Help Call is automatically generated after approximately 30 seconds of a fall being detected While the fall may be detected in only a few seconds, the 30 second period is provided for users to "self-recover" from a fall if able.
- If the Button detects that you have self-recovered from the fall, within approximately 30 seconds of a fall being detected, a Help Call will not be generated.
- · Do not attempt to stand if you feel unable to.
- Regardless of whether you have fallen or not, if you think you need assistance, always push the Help Button immediately to initiate the Help Call if you are able to do so. Pushing the Help Button generates the Help Call immediately. If your Pendant has detected a fall but 30 seconds have not yet passed, pressing the Help Button WILL NOT cancel the help call. It will send the help call immediately.

#### **Limitations on Fall Detection**

The AutoAlert fall detection technology may not detect every fall. In certain situations, the AutoAlert Help Button may not detect a fall. Some movements may not register as a fall and would not be detected. Examples include, but are not limited to:

- Lowering oneself slowly to the ground (to brace the impact of a fall)
- A fall from a height of less than 20 inches (0.5 meters)



Certain conditions can affect the ability of the AutoAlert Help Button to detect a fall:

- If you live at an altitude above 6,600 feet (2000 meters)
- If you are less than 4 feet 6 inches in height (1.4 meters)
- If you weigh less than 88 pounds (40 kilograms)

  However, the ability to send a help call by pressing the button is not affected by such conditions.

#### False "fall detected" alarms may occasionally occur

While the GoSafe Lite Mobile Pendant is designed to have very few false alarms, a fall detected alarm it might occasionally occur when there was not a fall (i.e., a false alarm). This is considered normal operation. If this occurs, please simply don't panic. Allow the call to connect. A Philips Response Associate answer the call when it connects. Simply tell them that "No help is needed", and confirm to them that you are OK. There are no additional charges for false alarms.

**Note**: Occasional false alarms do not indicate that the GoSafe Lite Pendant is malfunctioning.



# Warning

#### About fall detection

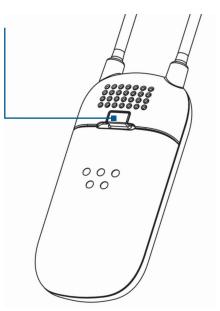
In certain situations, the Pendant may not detect a fall.

A gradual slide from a seated position — such as from a Confidential Draft for Agency Submission Only.

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Button if you are able to. Note that if your Pendant did detect the fall and is already in-process of calling Lifeline, pressing the button WILL NOT cancel or interrupt the call already in-progress, and will not interfere with system operation in any way.

The vent area located on the back of the Pendant is part of the AutoAlert fall detection sensor system and needs to remain clear of obstructions (e.g., lint or food products). A continuous flow of water (e.g., a shower) hitting the vent directly may also temporarily obstruct the vent. However, your Pendant should be worn at all times as it is waterproof for showering and bathing.



**Back view** 



#### CAUTION

#### **Potential Interference**

Do not use the GoSafe Lite Mobile Pendant if you have an implantable cardiac device, such as a defibrillator or pacemaker. The GoSafe Lite Mobile Pendant *may* interfere with certain medical equipment, such as magnetic resonance imaging (MRI), X-ray machines, Automatic External Defibrillators, cardiac monitors, pacemakers, insulin pumps, hearing aids, as well as metal detectors.

#### **Air Travel**

Because it is a cellular communication device, the GoSafe

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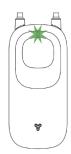
Sleep Mode. Be sure to place your Pendant in sleep mode when on an airplane. Please see instructions for putting your GoSafe Mobile Button in Sleep Mode on page 31.

The GoSafe Mobile Button can only place a Help Call when in Stand-by mode, and when the AT&T wireless network is available.

# Charging the battery



Flashing orange light = charging needed



Flashing green light = charging in progress



When connected to the charger, a steady green light = fully charged





Your GoSafe Lite Mobile Pendant is powered by a rechargeable Confidential Drath for Agency at a transfer of the Political Property of Philips. Not for dissemination to the public without the express written consent of Philips.

the Indicator Light will flash orange whenever it initially needs to be charged. Typically, it will take less than 45 minutes to charge your GoSafe Mobile Button if you put it in the charger at this initial charge indication point. It will take longer than this if you wait additional time after this indication point to put the Pendant in the charger. Your Pendant is fully charged when it chimes and the Indicator Light turns to a steady green. If you do not charge the Pendant at the time of Initial Charge Indication, the battery charge will continue to deplete and the orange light will continue to blink. Once it reaches a critical power state, the Pendant will reach the Critical Charge Indication. When this happens, the Pendant will play a voice prompt: "Your Help Button is not out of power and will shut down. Please charge your device as soon as possible". It may take more than one hour to charge your Pendant if it reaches this point, but will not hurt the device.

**Warning**: once the Critical Charge Warning is played and the Pendant shuts down, it cannot be used to make a help call of any type until it is re-charged. When charging:

- 1. Make sure the charger is plugged into a power outlet (wall plug) that is receiving power. For this reason, we do not recommend plugging the charger into outlets controlled by a wall switch, or power strips unless you can confirm that they are powered on.
- 2. Attach your GoSafe Mobile Button to the charger. You will hear a chime and a voice prompt that says "I am now charging. My light will turn solid green when I am ready to use." to acknowledge that you are charging. The Indicator

Light will begin flashing Green.

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- 3. Charge until the light turns to a steady green. To provide the user with the longest possible battery life between charges, there is no constantly illuminated power indicator. Instead, the Pendant includes a "shake to indicate" feature.
- 4. Remove from the charger. The green light will turn off, and the Button is ready to use.
- 5. To provide the user with the longest possible battery life between charges, there is no constantly illuminated power indicator. Instead, the Pendant includes a "shake to indicate" feature. To determine if your GoSafe Mobile Button is powered on, hold it in your hand and shake it briefly, watching the Indicator Light while shaking.
  - A flashing green light means that the Button has battery power.
  - No flashing green light means that the battery is dead and needs to be charged or, it is in sleep mode.

#### Important reminders

- You should continue wearing your Pendant while it is being charged. Please be cautious not to trip on the cord.
- When you are charging your Pendant while wearing it, be sure to remove it from the charger prior to standing up. Failure to do so may compromise the fall detection capability of your GoSafe system.
- Do not charge your Pendant while sleeping or bathing.
- Battery life varies based on activity level, Cellular signal strength in your area, battery age, and actual emergency use Your GoSafe Lite Pendant provides audible and visual Confidential Draft for Agency Submission Only.

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indicates charging is needed. In general, you will have to charge your GoSafe Lite Pendant once every 2 days.

# Sleep mode

The GoSafe Lite Mobile Pendant utilizes cellular communication technology. As such, you must turn it off in the following circumstances:

- During Air Travel (when flying on an airplane) regardless of whether you are "carrying-on" the pendant into the passenger cabin, or if you pack the Pendant in your checked luggage. Either way, it must be placed in Sleep mode.
- · If you are returning the Pendant to Lifeline

The Pendant has a "sleep mode" for these situations. To put the Pendant into sleep mode, press and hold down the Help Button for 10 seconds. Your Pendant will say: "If you would like to turn off your Help Button, please press it again." Release the Help Button and then press and release it again without holding it down. The Pendant will confirm it is entering sleep mode by saying: "Your Help Button is now turning off."

You should take the Pendant out of Sleep Mode as soon as conveniently possible upon exiting the plane to allow it to reorient to its new Geolocation. To exit sleep mode, press the Help Button. Your Button will say: "Your Help Button is now ready to use. If you need help, please press your Help Button again". This button press that wakes the Pendant out of sleep mode will not initiate a Help Call. If you need help in this

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# **^** Caution

You will not be able to send a Help Call when the Pendant is in sleep mode. Be sure to remember to exit sleep mode as soon as wireless/electronic device use is allowed, e.g., after the airplane has landed.

**Note**: If you are returning a GoSafe Lite Mobile Pendant to Philips Lifeline for service, replacement or recycling, you must contact Lifeline at the number at the bottom of the page before returning it. Philips Lifeline will provide you with special packaging and instructions for return to help ensure that the button does not send signals to Lifeline while in-transit. Do not ship the Pendant without notifying Philips Lifeline that you are doing so.

## Recommended usage

- Press the Help Button on your Pendant any time you need help, or in situations/locations outside the home where you want to determine if the AT&T wireless network is available.
- Wear your GoSafe Mobile Button at ALL times, even when you are away from home. The GoSafe Mobile Button can send a Help Call from any location where the AT&T wireless network is available.

 During an alarm, you can talk to Lifeline using GoSafe's microphone and speaker. For best results, hold the pendant up and away from your chest when you are speaking to Lifeline.
 Maintain a minimum separation distance of 10 mm/ 0.394 inches when operating the device in this manner.



- Your GoSafe Lite pendant should be worn while showering or bathing. The GoSafe Pendant carries an IPX7 waterproof rating. This means that it can be submerged to a depth of 1 meter in water for up to 30 minutes. It is not designed for submersion deeper than 1 meter for any period of time, and should not be left submerged under water at any depth up to and including one meter for longer than 30 minutes.
- Do not throw or toss the GoSafe Mobile Button onto a bed, table, or other surface because it may interpret this as a fall and accidentally send a Help Call.
- Your Pendant may be worn outside of or underneath your clothing depending on your preference. Regardless, it must always be worn as a pendant to help ensure proper function.
- GoSafe is safe to use while driving. However, when entering and exiting your vehicle, take care to prevent the GoSafe Mobile Button from hitting the steering wheel because it may accidentally send a Help Call.

#### GoSafe Lite Pendant - Alarms

#### Introduction

There are two types of alarms processed by the GoSafe Lite Pendant.

- High Priority Require immediate response (by the Call Center)
- Medium Priority Require prompt response (by the operator/user)

Additionally, the Pendant also plays verbal informational messages and confirmation alerts that notify you of conditions that need attention but do not qualify as alarm conditions (e.g. installation prompts).

**Note**: If multiple alarms occur at the same time, all alarms are processed and displayed, but the alarms are ordered first by priority and then by occurrence, with the newest, highest priority alarms at the top of the list. The alarm precedence is in the following order: high priority, medium priority, and informational messages.

**Note**: Not all alarms are available in every mode (e.g. during installation); some alarms are mode-dependent.

#### **Audible and Visual Alarm Indicators**

When the device detects a *High priority alarm*: The light on the Mobile Help Button flashes red, the device audible alarm sounds and a recorded voice message is played.

When the device detects a *Medium priority alarm*: The light on the Mobile Help Button flashes orange, the device may play a chime and/or a voice prompt.

#### Silencing Alarms

Once a High Priority alarm is detected, it cannot be silenced.

Medium Priority alarms play a sound and possibly a voice prompt once upon detection of the alarm, but the red Indicator Light flashes until the alarm condition is corrected.

#### Resetting an Alarm - what does reset mean?

High Priority alarms are normally reset (cancelled once addressed) by the Call Center after the alarm has been responded to. Additionally, the Mobile Help Button may periodically poll the Call Center to see if the alarm should be reset and does so accordingly. If the alarm is not reset by the Call Center, the Mobile Help Button will automatically reset the alarm after 30 minutes.

Confidential中DitattifelMentageneryoSubstationngQndytive high priority alarm will reset the Not for Proisting on priority alarm will reset the Not for dissemination to the public without the express written consent of Philips.

alarm has already been reported to the Call Center, they will likely attempt to contact the Subscriber. If an alarm is accidentally initiated by the User, **they should not put the Pendant to sleep**. Instead, they should wait for the Call Center to establish voice communication and simply state that no help is needed.

The Pendant self-cancels certain Medium Priority alarms if the cause of the alarm is corrected, stopping the orange flashing Indicator Light.

# Alarm Descriptions / Summary Tables

Help Needed – 7150 MHB	
Alarm Event Description	Help Alarm initiated by the User pressing the Help Button
Priority	High
Device Action	Operates normally
Alarm Event Reported/ Displayed Locally?	Yes. Upon pressing the Help Button on the End Device, a Voice Message plays and the Indicator Light LED flashes <b>red</b> .
Alarm Event Reported to Philips Lifeline?	Yes. A Help Alarm Signal is sent to the Call Center by the End Device from anywhere wireless signal is available on the AT&T wireless network. Upon receiving the Help Signal, the Call Center calls the End Device to establish contact with the Subscriber and to see what kind of help they need.

Help Needed – No C	ell Signal Available
Alarm Event Description	Help Alarm initiated by the User pressing the button on the Pendant or by the Pendant detecting a fall; and the AT&T wireless network is unavailble. Then a verbal Warning Message is delivered by the pendant.
Priority	High
Device Action	The Help Alarm Signal will be buffered in the device. The device will continue to try to connect to the network and deliver the alarm. It will re-announce the voice prompt every 5 minutes until: the condition is corrected and the alarm signal is delivered, or, 30 minutes has elapsed, or, the battery is exhausted. button re-tries constantly, annunciates every 5 minutes, resets after 30 minutes.
Alarm Event Reported/ Displayed Locally?	Yes. Upon pressing the Help Button on the Pendant or when the Pendant has detected a fall, a Voice Message plays: "Your call cannot be connected. There is no signal strength. Please move to another area." The Indicator Light flashes red. This is an alarm that will self-cancel once connection to the AT&T wireless network is re-established.
Alarm Event Reported to Philips Lifeline?	No. If the AT&T wireless network is unavailable a Help Alarm Signal cannot be sent to the Call Center.
Help Needed – Fall I	Detected by Pendant
Alarm Event Description	Help Alarm initiated by the Pendant detecting a fall.
Priority	High
Device Action	Operates normally
Alarm Event Reported/ Displayed Locally?	Yes. When the Pendant has detected a fall, it plays a Voice Message and the Indicator Light flashes red. Voice Message: Your help call is in progress. Please wait. For proper use, hold your help button up in front of you.
Alarm Event Reported to Philips Lifeline?	Yes. The Pendant sends a "fall detected" Help Alarm Signal to the Response Center from anywhere wireless signal is available on the AT&T wireless network. Upon receiving the "fall detected" Help Signal, the Response Center calls the Mobile Button to establish contact with the Subscriber and to see what kind of help they need.

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#### **Device Error (Medium Priority) Alarms**

The GoSafe Lite Pendant alarms described below are automatically generated alarms designed to periodically let the Call Center know that the Pendant is working properly They are part of normal operation and are the result of no intensional action by the user.

#### **Alarm Event Type**

Low Battery Capacity	y – 7150 MHB	
Alarm Event Description	When the capacity / life of the battery in the Pendant has diminished materially and should be replaced, a Warning Message is displayed	
Priority	Medium	
Device Action	Charge cycle frequency increases, otherwise. Operates normally until battery is depleted.	
Alarm Event Reported/Displayed Locally?	No.	
Alarm Event Reported to Philips Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center by the device. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment.	
Battery Requires Charging – 7150MHB		

Battery Requires Cha	arging – 7150MHB
Alarm Event Description	When the rechargeable battery in the Pendant needs to be charged, a visual and audible warning Message is activated on the device.
Priority	Medium
Device Action	Operates normally until the battery is critically low.
Alarm Event Reported/ Displayed Locally?	Yes. The Indicator Light flashes orange and plays a single chime. This alarm will self cancel once the battery charge reaches an acceptable level.
Alarm Event Reported to Philips Lifeline?	No.

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Depleted Battery – 7	150 MHB		
Alarm Event Description	When the charge level of the rechargeable battery is critically low, a Warning Message is announced.		
Priority	Medium		
Device Action	Device shuts down after the message is announced.		
Alarm Event Reported/ Displayed Locally?	Yes. Indicator Light flashes orange, Voice Prompt plays: "Your help button is now out of power and will shut down. Please charge your device as soon as possible". This alarm will self cancel once the battery charge reaches an acceptable level.		
Alarm Event Reported to Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center by the End Device from anywhere wireless signal is available on the AT&T wireless network. Upon receiving the Maintenance Signal, the Response Center stores the status information but no direct action is taken.		
Device Hardware Fail	ure – 7150 MHB		
Alarm Event Description	In the event that internal diagnostics indicate that the Pendant it has a Hardware Error, a Warning Message is displayed if possible based on the nature of the failure.		
Priority	Medium		
Device Action	May have limited operation, depending on the failure		
Alarm Event Reported/Displayed Locally?	No.		
Alarm Event Reported to Philips Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment.		

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Software Failure-End	Device 7150 MHB
Alarm Event Description	In the event that a device senses it has a Software Error, a Warning Message is displayed
Priority	Medium
Device Action	May have limited operation, depending on the failure
Alarm Event Reported/Displayed Locally?	No
Alarm Event Reported to Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment.  [No communicator, What happens here?]

## Supervision and Check-in Alarms (Informational Messages)

The alarms described below are automatically generated alarms designed to periodically let the Lifeline Call Center know that the Pendant is working properly. These alarms are silent and require no immediate action from the User/Subscriber.

#### **Alarm Event Type**

Auto Test Call 7150 M	Auto Test Call 7150 MHB		
Alarm Event Description	Auto Test calls are automatically generated silent alarms designed to periodically let the Response Center know that the Pendant is working properly.		
Priority	N/A		
Device Action	Operates normally		
Alarm Event Reported/Displayed Locally?	No visual or audible alarm is generated by the devices.		
Alarm Event Reported to Philips Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center by the Pendant. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment.		

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Supervision Failure –	7150 MHB
Alarm Event Description	End Devices periodically check-in to the <del>Communicator</del> . If the <del>Communicator</del> has not received a check-in from the End Devices for a week, then a silent alarm is sent to the Response Center [What happens here?]
Priority	N/A
Device Action	Operates normally
Alarm Event Reported/Displayed Locally?	No visual or audible alarm is generated by the devices.
Alarm Event Reported to Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center by the Home Communicator. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment. [What happens here?]

#### **Priority of Device Error Alarms**

Fault Condition	Audio Message

# **Delay in Determining Alarms**

Reporting high priority help alarms from the GoSafe Lite Pendant to the Lifeline Response Center is typically done in less than a minute when generated by a button press, depending on the status of the cellular network and signal strength available clarify time to voice on line.

The GoSafe Lite Mobile Pendant provides an added layer of protection by being able to detect falls under certain conditions. This takes approximately 30 seconds to determine that an activity that resembles a fall has occurred, and that the user has not Confidential Dratingue Bubmissians Only ted by the 7150MHB, the signal is Not for Postingue and have particles parting after the Difference of the province of th



All alarm events reported to the Response Center are logged by the Response Center.

**Logging Alarms** 

There are no user accessible logs.

# Safety and Regulatory Compliance

# **IEC Regulations**

The GoSafe Lite Pendant complies with the relevant National and International standards listed in the Technical Section. It is classified as medical electrical (ME) equipment in the USA according to the FDA product classification. According to Health Canada GoSafe Lite Pendant is not classified as a medical device. It falls under the Canada Consumer Product Safety Act.

Medical electrical equipment can either generate or receive electromagnetic interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601–1–2:2007, the international standard for EMC for medical electrical equipment. Refer to EMC section on page xx for details.

The GoSafe Pendant must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

#### Device classification

The GoSafe Lite pendant is a FDA Class II device. It is an internally powered device for continuous operation.

# Radio specifications

The GoSafe Lite 7150MHB pendant complies with the FCC Parts 15, 22 and 24 Subparts B, C and E. Its radio transmitter have the following characteristics:

Cellular 3G (824-849MHz and 1850-1910MHz transmission bands).

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Bluetooth ISM band 2.4MHz; maximum EIRP 2 dBm, GFSK modulation

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#### **FCC Notice to Users**



This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) Device may not cause harmful interference
- 2) Device must accept any interference received, including interference that may cause undesired operation.

Pursuant to Part 15.21 of the FCC Rules, any changes or modifications not expressly approved by Philips Healthcare, Home Monitoring, Lifeline Systems Inc. could void the user's authority to operate the equipment. The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

**Note:** 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 are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful 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 the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

# Radio interference

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. For ZS` VZZVW/body-worn operation, this equipment has been tested and meets the FCC RF exposure guidelines. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. Use of other accessories may not ensure compliance with FCC RF guidelines.

Do not attempt to repair or modify this equipment. Any repairs or alterations made by the user to the equipment may void the warranty and compliance of the equipment. Changes or modifications made to this equipment not expressly approved by Philips

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# Industry Canada Notice to Users

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

- 1) Device may not cause interference
- 2) Device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

- · l'appareil ne doit pas produire de brouillage
- l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

# Class B digital device notice

This Class B digital apparatus complies with Canadian ICES-003, RSS-Gen and RSS-210.

Cet appareil numérique de la classe B est conforme à la norme NMB-003, CNR-Gen et CNR-210 du Canada.

# Essential performance

The GoSafe Lite Help Button provides essential performance (EP) under normal operating conditions (includes EMC exposure) by sending Help Calls to the Lifeline Response Center. If the GoSafe Lite is incapable of sending Help Calls, it will periodically send a status alarm to the Lifeline Response Center, need to either remove or edit for accuracy.

## Intended Use

This Philips product is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions provided in, the Quick Setup Guide and the Instructions for Use for the purpose for which it was designed. The purpose for which the product is intended is given below.

The GoSafe Mobile Pendant (7150MHB) is intended to be worn as a pendant and is capable of detecting certain types of falls or being activated manually. The GoSafe Mobile Pendant (7150MHB) is designed to directly connect to an emergency help service via the AT&T wireless network.

Uses of the GoSafe System for purposes other than those intended and expressly stated by Philips Lifeline, as well as incorrect use or operation, may relieve Philips Lifeline (or its agent) from all or some responsibility for resultant non-compliance, damage or injury.

# Contraindications

This device may contraindicated for any person who is connected to a implanted electronic medical device or instrument such as a pacemaker or defibrillator. This device may cause the electronic medical device to malfunction.

# Compatibility

The products described in this manual are compatible only with the components described herein and should not be used in combination with any other products or components unless such other products or components are expressly recognized as compatible by Philips Lifeline.

Changes and/or additions to the product should only be carried out by Philips Lifeline or by third parties expressly authorized by Philips Lifeline to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.



Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may void the warranty.

Confidential Drath Recognition of the warranty of the basis of the serious risks of damage to the Not for Public Public Without the express written consent of Philips.

#### Risks and Benefits

The GoSafe Lite Pendant depends on connecting to the AT&T wireless network in order to communicate with the Philips Lifeline Call Center. As with all wireless devices, the availability of the network cannot always be guaranteed.

The GoSafe System Pendant depends on the user being capable of pressing the Help Button when they are in need of help.

# Safety



Maintenance & faults: If any part of the product is known (or suspected) to be defective or wrongly adjusted, DO NOT USE the product until a repair has been made. Operation of the product with defective or wrongly adjusted components could expose the user or the patient to safety hazards.

**Safety awareness**: Do not use this product for any application until you read and understand the safety information, safety procedures and emergency procedures contained in this SAFETY section. Operation of the product without a proper awareness of how to use it safely could lead to fatal or other serious personal injury.

**Safety devices**: Never attempt to remove, modify, or otherwise defeat any safety device on the product. Interfering with safety devices could lead to fatal or other serious personal injury.

**Intended use and compatibility**: Do not use this product for any purpose other than those for which it is intended. Do not use the product with any product other than that which Philips Lifeline recognizes as compatible. Operation of the product for unintended purposes, or with incompatible product, could lead to fatal or other serious injury.

## **Electrical safety**



- Do not remove covers or cables from the provided power supply adapter.
   Dangerous electrical voltages are present within this product. Removing covers or cables could lead to serious or fatal personal injury.
- Covers or cables should only be removed by qualified and authorized service personnel.

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## **Explosion safety**



# !\ Warnings

- · Do not use this product in the presence of explosive gases or vapors, such as certain anesthetic gases.
- · Do not use flammable or potentially explosive disinfecting sprays in the presence of this product.
- · Use of this product in an environment for which it was not designed can lead to fire or explosion.



## Caution

Portable and Mobile Phones: Portable and mobile RF communications can affect the GoSafe Lite device. Use caution when using such communication devices within the specified range of the GoSafe Lite Pendant. Refer to Table 6 in the EMC section for the for separation distances between portable and mobile RF communications equipment and GoSafe Lite device.

ss communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie talkies can Confidential Draft for Agency Sulbmission Only, a distance 3.3 meters or 11 feet Not for Prosting Go Safayd Printing ad in a Weigs itell phone with a maximum output Not for dissemination to the public without the express written consent of Philips. [Bill to Clarify where does this come from, and does this mean that a person cannot carry a cell phone with them if they are using GoSafe? Also, with GoSafe being a medical device, shouldn't the other devices accept interference from it?]

#### Maintenance

## **Expected Service Life**

The Expected Service Life of the GoSafe Pendant is as follows:

GoSafe Lite Mobile Help Button (7150MHB) – 2-3 years\*

\*The Service Life indicated above is primarily based on the expected life of the device's internal battery. Actual performance may vary depending upon conditions such as battery charge cycling, temperature, cell signal strength in your area and other factors.

#### Power Supplies, Extension Cords and Power strips

Do not use extension cords or power strips with this device.

#### Biocompatible materials, Latex-Free

This product does not contain natural latex rubber or dry natural rubber in user or operator accessible areas. All materials of construction of this product that come into contact with the skin of the user during normal use are certified biocompatible.

#### Passing the product on to another user

This product cannot be passed to another user by an existing user or re-sold to another user. Please see the Terms and Conditions of Use for more information. In the event the original user wishes to end their service, they must call Philips Lifeline to cancel their service.

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# **Technical Specifications**

#### **Standards Compliance**

This device is designed to conform to the following Standards and Regulations:

- IEC/ANSI/ AAMI60601-1:2005/R(12)2012, % W W[f[a` l BSd #ŽGeneral requirements for basic safety and essential performance.'
- CSA C22.2 # 60601-1:2014 Ed.3 Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2, 3rd Edition (2007-03), General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests
- IEC 62366, 1st Edition (2015), 'Medical devices Application of usability engineering to medical devices'
- IEC 60601-1-6, 3rd Edition (2013), 'Collateral standard: Usability'
- IEC 60601-1-8, 2nd Edition (2006), 'Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems'
- IEC 60601-1-11, 2nd Edition (2015) 'Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment'
- ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing (Biocompatibility)
- ISO 14971, 2nd Edition (2007), 'Medical devices Application of risk management to medical devices'.
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## **Environmental Ratings**

	Operating	Storage	Bathing*
Temperature	41° F to 95° F (5° C to 35° C)	-4° F to 140° F (-20° C to 60° C)	Up to 122° F (50° C)*
Relative Humidity	10 to 90% (non-condensing)	10 to 90% (non-condensing)	
Atmospheric Pressure	101 kPa to 77 kPa (approximately 0-7500 ft/0- 2286 m)	N/A	
Altitude	6,600 feet (2 km) Maximum	N/A	

<sup>\*</sup> Up to 30 minutes exposure.

#### **Electrical Specifciations**

GoSafe Lite Mobile Pendant (7150MHB)		
AC Voltage Source <sup>[1]</sup> (VAC)	N/A-EUTbattery operated. AC battery charger a dapter 100-240Vac 50/60Hz	z, o.5A
DC Power Source (VDC)	3.7 V, 920mAh <sup>[2]</sup> , Lithium Ion Rechargeable <sup>[3]</sup> Battery	
Type of Protection Against Electric Shock	Class II (Power Supply Adapter) / GoSafe Lite is Battery operated	
Degree of Protection Against Electric Shock	Type BF Applied Part	
Degree of Protection Against Ingress of Water	Water Resistant (1 meter, for 30 Minutes), IPX7	
Mode of Operation	Continuous O <mark>peration</mark>	
Sound Pressure Level	116-123 dB at 1 kHz (measured 1 cm from the speaker)	

<sup>[1]</sup> The means of isolating the device from the supply mains is by disconnecting the device from the wall outlet.

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<sup>[2]</sup> The capacity restored by the cell varies according to current drain, temperature and cut-off.

<sup>[3]</sup> Recharging of the GoSafe Mobile Button battery is done by the user as needed, when connected to the charger.

## **Product Disposal**

#### **Environmental Requirements**

#### Introduction

Philips Lifeline is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance and training. Therefore Philips products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain materials, which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential to performing the functions of the product, and to meeting statutory and other requirements.

#### Final disposal of the product

Final disposal is when the user disposes of the product in such a way that it can no longer be used for its intended purpose. In the event a user wishes to end their service or no longer needs the GoSafe Lite device, it must return the device to Philips Lifeline or their representative for proper disposal.

#### Philips supports users in:

- Recovering reusable parts.
- Recycling of useful materials by competent disposal companies.
- Safe and effective disposal of product

# **Electromagnetic Comparability - EMC**

Medical electrical equipment can either generate or receive electromagnetic interference. The GoSafe Lite (7150MHB) has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 6060-1 collateral standard IEC 60601-1-2:2007, the international standard for EMC for medical electrical equipment.

The GoSafe Lite pendant complies with relevant laws and standards on electro-magnetic compatibility (EMC) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from this product and its required immunity to electromagnetic interference from external sources.

The GoSafe Pendant must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.
- 2. Other equipment such as Portable and Mobile RF Communications Equipment may interfere with the medical device even of the other equipment complies with CISPR emission requirements.
- 3. The use of accessories and cables other than those specified, with the exception of those sold by the manufacturer may result in increased emissions or decreased immunity of the equipment or system.
- 4. The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

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#### **EMC Informational Tables**

Table 1 - Guidance and Manufacturer's Declaration – Emissions The EUT "GoSafe Lite" model 7150MHB is intended for use in the electromagnetic environment specified below. The EUT is provided with battery power adapter charger. The customer or user of the GoSafe Lite should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 2	The GoSafe Lite 7150MHB must emit Electromagnetic energy in order to perform its
RF Emissions CISPR 11	Class B	intended function. Nearby electronic equipment may be affected.
Harmonics IEC 61000-3-2	N/A for EUT Class A for charge	The EUT is Battery Powered.  The GoSafe Lite 7150MHB power charger is
Flicker IEC 61000-3-3	Complies	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.

Table 2 - Guidance and Manufacturer's declaration - Immunity

The GoSafe Lite 7150MHB is intended for use in the electromagnetic environment specified below. The customer or user of the GoSafe Lite should ensure that it is used in such an environment.

	Immunity Test EN/IEC 60601 Test Level		Compliance	Electromagnetic
		Level	Environment – Guidance	
	Electrostatic Discharge (ESD) EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic the relative humidity should be at least 30%
onfia	Electrical fast transient/burst EN/IEC 61000-4-4 (only for battery charger COLUMN FATTER COLUMN FOR TOP	input/output Agency Subi	mission Only	Electrical power quality should be that of a typical commercial or hospital environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance	
Surge EN/IEC 61000-4-5 (only for battery charger power supply)	±1 kV line(s) to line(s)±2 kV line(s) to earth	±1 kV line(s) to line(s)±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.	
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	•	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines EN/IEC 61000-4-11 (only for battery charger power supply)	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle. 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles.  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec.	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle. 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles.  70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec.	GoSafe Lite device power adapter is powered from an uninterrupted power supply	
NOTE : $U_T$ is the a.c. mains voltage prior to application of the test level.				

Table 4 - Guidance and Manufacturer's declaration - Immunity

The GoSafe Lite 7150MHB is intended for use in the electromagnetic environment specified below. The customer or user of the GoSafe Lite should ensure that it is used in such an environment.

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	Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance		
	Conducted RF EN/IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms <sup>⋆</sup>	D=1.17√P D=0.35√P 80 to 800 MHz		
				D=0.70√P 800 MHz to 2.5 GHz		
	Radiated RF EN/IEC 61000-4-3	10 V/m 10V/m 80 MHz to 2.5 GHz		Portable and mobile communications equipment should be separated from the GoSafe Lite 7150MHB by no less than the distances calculated/ listed below*:		
				$D=(3.5/V1)(\sqrt{P})$		
				$D=(3.5/E1)(\sqrt{P})$		
				80 to 800 MHz		
				$D=(7/Eq)(\sqrt{P})$		
				800 MHz to 2.5 GHz		
				where P is the maximum power in watts (W) 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:		
				$((\overset{\bullet}{\bullet}))$		

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**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 in the location in which the GoSafe Lite is used exceeds the applicable RF compliance level above, the GoSafe Lite should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GoSafe Lite.
- (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Table 6 - Recommended Separations Distances between Portable and Mobile RF Communications equipment and GoSafe Lite

The GoSafe Lite 7150MHB is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the GoSafe Lite 7150MHB can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communication Equipment and GoSafe Lite 7150MHB as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz d = 1.17√P*	Separation (m) 80 to 800MHz d = 0.35√P	Separation (m) 800MHz to 2.5GHz d = 0.70√P
0.01	0.117	.035	.07
0.1	0.37	.11068	.22136
1	1.17	.35	.7
10	3.7	1.1068	2.2136
100	11.7	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 manufacturer.

**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations.

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# **Symbols**

Symbol	Description
===	Symbol for DC (Direct Current) Power.
$\ominus$ $\oplus$	Polarity symbol. Indicates that the center (tip) of the output plug is Positive (+) and the barrel of the output plug is Negative (-).
$\bigcirc$	The power supply efficiency performance is Level 5, indicating a high standard in use efficiencies and no-load power consumption.
CE	The CE Mark is a conformity symbol for European countries. The symbol stands for Conformité Européenne.
	A Class II or double insulated electrical device. This is one which has been designed in such a way that it does not require a safety connection to electrical earth (ground).
TÜVIDal-band c us	The TÜV logo is a certification mark of TÜV Rheinland, a Nationally Recognized Testing Laboratory (NRTL). The "C" on the left of the mark denotes compliance in Canada and the "US" on the right indicating compliance for the US.
	The symbol for WEEE — Waste Electrical and Electronic Equipment. This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Note: Please return the HomeSafe/GoSafe devices to Philips Lifeline or your Philips Lifeline representative for proper disposal.
c us Intertek	The ETL Listed Mark – demonstrates compliance to the requirements of widely accepted product safety standards, as determined through independent testing and periodic follow-up inspections by a Nationally Recognized Testing Laboratory (NRTL). The "C" on the left of the mark denotes compliance in Canada and the "US" on the right indicating compliance for the US.
IP27	Per EN 60529. The IP27 rating indicates (2)protection against fingers or other object not greater than 12mm in diameter and (7) Ingress of water in harmful quantity shall not be possible when the enclosure is immersed in water up to 1 meter of submersion for up to 30 minutes.
木	Type BF Applied Part

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[]i	Consult accompanying instructions for use.
$((\bullet))$	Symbol for non-ionizing radiation. Indicates that the device(s) include(s) RF transmitters.
	Indicates the device manufacturer.
	Indicates the date when the device was manufactured.
$\subseteq$	Use by Date.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Indicates the manufacturer's catalog number so that the device can be identified.
SN	Indicates the manufactu
1	To identify the temperature limits, for example on transport packaging to indicate limits within which the package has to be kept and handled. The temperature values may be shown adjacent to the symbol.
<u></u>	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Refer to instruction manual/booklet

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#### **Philips Lifeline**

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