

PHILIPS

Lifeline

Medical Alert
Service

Instructions for use



GoSafe 2 Mobile Medical Alert Service

Instructions for use

Important Notice to User

The GoSafe 2 Mobile Pendant is a radio frequency (RF) device that transmits all of its signals to the Lifeline Response Center over a cellular network. As such, it relies upon adequate cellular network availability and signal strength, at the time and location of alarm generation, to send your help signal to the Lifeline Response Center. Cellular signal strength and availability inside of your home is tested during the system setup process, but can vary from time to time depending on multiple factors, and is therefore not guaranteed to remain at that level over time. This variation is not due to the design of GoSafe 2, nor is it unique to a single cellular carrier. It is the general nature of cellular communication, and indicative of the limitations thereof. Please refer to this Instruction for Use, as well as the Terms and Conditions of Sale/Use provided with your System for a full listing of Limitations of cellular service.

Philips Lifeline also provides a GoSafe Mobile System that utilizes a Home Communicator to help provide increased communication capability for signals generated from within your home. If this statement or the Limitations defined herein are unclear to you, if you would like to learn more about the GoSafe Mobile System with Home Communicator, or if you did not receive a copy of the Terms and Conditions of Sale/Use, please contact Philips Lifeline or its representative.

Contents

About This Manual4

Training

Definitions and Terminology

Philips Lifeline Service 9

Welcome to Philips Lifeline

Setting up your Philips Lifeline Service

Responders and People to Notify

Calling for help

Signal Range

Battery information

Equipment service

Contact Philips Lifeline or your representative

GoSafe 2 Mobile Medical Alert System

General Information18

Cleaning and Care

General Cautions and Warnings

GoSafe 2 Mobile Pendant (7150 MHB)21

Charging the battery

Sleep mode

Recommended usage

GoSafe 2 Mobile Pendant Alarms

Alarm Descriptions/Summary Tables

Safety and Regulatory Compliance..... 46

IEC regulations	Compatibility
Device classification	Risks and Benefits
Radio specifications	Safety
FCC Notice to Users	Maintenance
Intended Use	Technical Specifications

About This Manual

Training

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

7150MHB: The model name for the GoSafe 2 Mobile 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 un-revoked fall is detected, the Pendant will initiate a help call to the Philips Lifeline Response Center. 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 that can be activated by the Response Center during Alarm State. It is designed to help responders find you more easily while searching for you. Refer to page 25.

AutoAlert: The Philips fall detection technology that is used by the GoSafe 2 Mobile Pendant.

Cellular Network: The AT&T cellular/wireless network.

Charger: The component of your GoSafe 2 Mobile System that is used to re-charge your Mobile Pendant. (See p. 22)

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 and connecting a help call. As a cellular communication device, the coverage area for GoSafe 2 Mobile Pendant is defined by the cellular network availability and signal in your location, at the time of the alarm. 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.

EMS: Emergency Medical Services. Police, Fire or Ambulance service depending on your area.

End Device: The device that initiated the alarm. In this case, the GoSafe 2 Mobile Pendant.

Fall Revocation: Many Users may experience mild, non-harmful falls from which they are able to self-recover without assistance. As a result, the AutoAlert fall detection technology incorporates a revocation feature. Upon detecting a fall, the system will wait approximately 30 seconds before alarming to the Response Center. If the User self-recovers from the fall

within that time period, the fall will not be reported. Users should always press the Help Button when they need help if they are able to do so.

Help Button: The Help Button is the depressed square area inside the grey field on the front of the pendant itself. When pressed, a prompt call to the Philips Lifeline Response Center is placed. To initiate a call to Philips Lifeline, press the Help Button. A voice prompt and red Indicator Light will confirm that you have activated the Pendant and that your call is in progress.

GoSafe 2: GoSafe 2 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 Center. Together, the Pendant, Network and Response Center comprise the service elements.

GoSafe 2 Mobile Medical Alert System: Your System is comprised by your GoSafe 2 Mobile Pendant and the Pendant Charger.

Help Alarm Signal: This is the type of signal that the Philips Lifeline Response 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 may illuminate 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 for Use. See Alarm description and summary table, page 37.

Initial Recharge 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 2 was designed for people to wear and help maintain their independence, knowing that if they need assistance at home or away,* they can access help.

Lifeline: The emergency response service associated with your GoSafe 2 Mobile Pendant.

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 and Philips Lifeline was engaged to facilitate response. Notices will not be advised of false alarms or test calls. See page 12.

Pendant: This is the device that you physically wear around your neck. Also, the 7150MHB.

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

Philips Lifeline: the name of the company that provides GoSafe 2 and the Lifeline medical alert service.

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

* GoSafe 2 coverage inside and outside the home is provided where AT&T wireless network coverage is available. Recharging of the GoSafe 2 Mobile Pendant is done by the user as needed, when connected to the Charger.

Responder(s): If you should need emergency assistance and activate your Pendant, 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. See page 11.

Response Center: The Philips Lifeline call center where calls from your Pendant are answered.

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.

Standby Mode: This is the normal operating 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 Philips Lifeline Medical alert service. Also, *User*.

Your Philips Lifeline Service

Welcome to Philips Lifeline

Thank you for choosing the Philips Lifeline Medical Alert Service.

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 Philips 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.

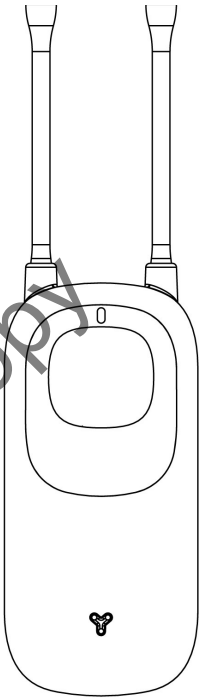
 **Warning** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

 **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 property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.

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

This manual covers the following:

GoSafe 2 Mobile Pendant (7150MHB)	
Works inside and outside* of your home	✓
Can only be worn around the neck as a pendant	✓
Can detect falls** inside your home	✓
Can detect falls** outside* your home	✓
Provides 2-way voice communication with Philips Lifeline	✓
Waterproof to 1 meter (40") for up to 30 minutes	✓



* GoSafe 2 coverage inside and outside the home is provided where AT&T wireless network coverage is available. Recharging of the GoSafe 2 Mobile Pendant is done by the user as needed, when connected to the Charger.

**The GoSafe 2 Mobile Pendant provides an extra layer of protection by placing a Help Call if a fall is detected and you can't push the Help Button. Not all falls can be detected. If you need help, always press the Help Button if you are able to do so.

Setting up your Lifeline Service

Before you can use your GoSafe 2 System, it must be properly set up. Please see the Quick Setup Guide for instructions on how to set up your system. If you have any questions, please contact Philips Lifeline or your representative.

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, and
- Is physically capable of assisting you.

Since the GoSafe 2 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 phone number or numbers that each responder is most likely to answer.

It is very important that you keep your Responder 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” or “Notifies”?

If you use your 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 Help Button press.

Calling for help inside your home

1. Press the Help Button on the GoSafe 2 Mobile Pendant.

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 Pendant will tell you that your call has been connected. This means that our system has compiled all of your information and that your case is being delivered to a Lifeline Personal Response Associate who will speak with you momentarily.

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. The Personal Response Associate will ask if you need help. If you do not need help, just tell them that no help is needed.

Note: If you cannot speak or be heard through the Pendant, the Response Associate may try calling you back on your home phone. 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 2 Pendant or your alternate contact numbers such as your home or cell phone, emergency services will be contacted to respond. Please contact Philips Lifeline if you wish 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 Lifeline has dispatched help, the Response Associate will contact you by calling your home phone or by calling-back your Pendant to confirm that you received the help that you needed.
6. Once Lifeline confirms that you have been assisted, a Response Associate will contact the “People to Notify” you’ve designated, letting them know that you needed and received help.

Note: If you accidentally press your Help Button, do not panic. 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 service that you are paying for and there is no extra charge for accidental calls.

Signal Coverage

Please see the Quick Setup Guide located in the box for instructions on how to set up your GoSafe 2 system. Your Pendant must be tested prior to use by initiating a call to the Response Center. The GoSafe 2 Mobile Pendant is a radio

frequency (RF) device that transmits a signal to the Lifeline call center over a Cellular network. It relies upon adequate cellular network availability to send your help signal to the Lifeline Response Center. Cellular signal strength and availability inside of your home is tested during the system setup process, but can vary from time to time depending on multiple factors. It is therefore 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 bedroom, bathroom and kitchen – to check that your GoSafe 2 pendant has sufficient cellular signal available to operate reliably from within your home. See the caution section on page 17.

⚠ Caution: Your GoSafe 2 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 press the Help Button while away from home, help will be sent to your location.* Please refer to page 25 for further information.

It is important to note that the ability of your GoSafe 2 Mobile Pendant to make a help call may be affected by environmental factors, including building materials, large masses covering the Pendant (i.e. a person laying on top of it) and submersion in liquid.

* Lifeline may not always be able to determine your location. During an alarm, always tell the Response Associate where you are if you are able to do so.

Battery information

Your GoSafe 2 Mobile Pendant contains a rechargeable battery that can only be replaced at the Philips factory. Your Pendant will automatically send a silent maintenance signal to Philips Lifeline when the battery needs to be replaced. Philips Lifeline or our representative will contact you directly to make arrangements for a replacement.

Equipment service

Every GoSafe 2 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 2 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.

Contact Philips Lifeline at the number below if:

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

- someone else in your home needs to use the Lifeline Service. More than one person living in the same household can have the service, but each individual user requires their own Pendant.

Safety information

The GoSafe 2 Mobile Pendant uses the AT&T wireless network to communicate with the Lifeline Response Center.

1. **⚠ Caution**, the strength of the wireless (cellular) signal may be stronger in some areas of your home than others. Be sure to test your Pendant by pressing the Help Button from places where you spend the majority of your time to help to check the Pendant's ability to connect to the cellular network from these areas. A successful test will result in a call to the Response Center. Once connected, tell the Response Associate that you are testing your system and that no help is needed and they will reset your Pendant.
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. If this happens, dial 911 for emergency assistance.**
3. Your Pendant contains a rechargeable battery. It must be sufficiently charged to send a signal to the Response Center.

GoSafe 2 Mobile Medical Alert System

General Information

The information in this section applies to the proper use and care of your GoSafe 2 Mobile Pendant.

Cleaning and Care

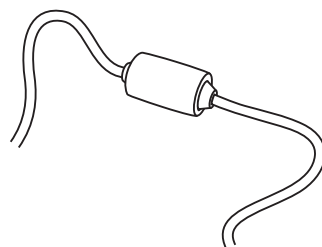
Your GoSafe 2 Mobile Pendant is water resistant to the IPX7 standard. This means that you can submerge it in up to 1 meter (about 40”) of water for up to 30 minutes without damaging it. As such, you can submerge it in warm water for easy cleaning and can also bathe/shower without removing it.

1. Wash the neck cord with a mild liquid detergent such as liquid dish detergent. Replacement neck cords are available from Philips Lifeline for a nominal fee and include a convenient tool that simplifies replacement.
2. Wash the Pendant 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. (See pages 22-23)
3. Blot excess moisture with a towel and allow the Pendant to finish air-drying while you're wearing it.

Note: If you accidentally press the 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

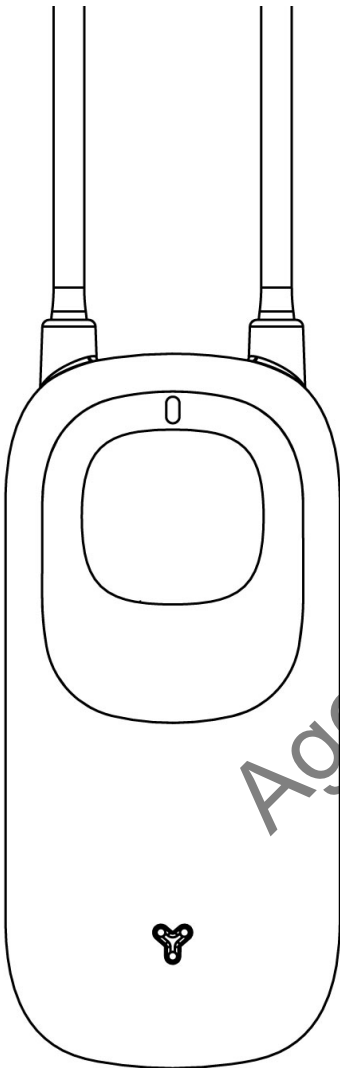
- Any cord worn around the neck can pose a strangulation risk, including the possibility of death and serious injuries. This may be of more concern to wearers in wheelchairs, using walkers, using beds with guard rails, or who might encounter other protruding objects upon which the cord can become tangled.
- The neck cord on your GoSafe 2 Mobile Pendant employs a special fuse (see image right). This fuse is designed to break away under certain conditions to reduce the 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 Pendant.



- 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 anesthetic mixtures with air or with oxygen or nitrous oxide. See page 50.
- 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 Pendant on the dashboard of your car, a window sill or on any other area that receives intense, direct sunlight. Likewise, do not wear your Pendant into a hot tub or sauna. Normal bathing and showering temperatures WILL NOT damage your Pendant. See page 52 for bathing temperature limits.

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GoSafe 2 Mobile Pendant (7150MHB)



The GoSafe 2 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 2 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.

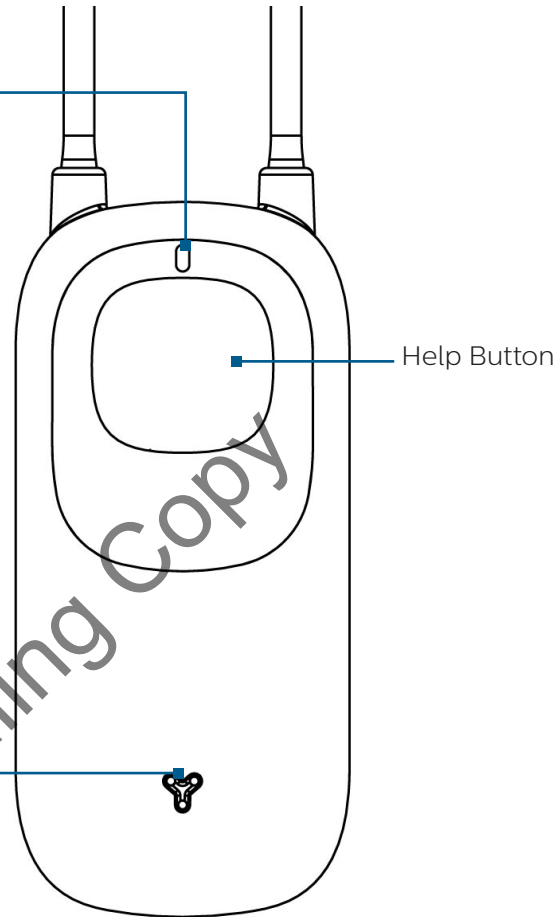
GoSafe 2 Mobile Pendant (7150MHB)

Front view

Indicator light – This light will indicate the status of the GoSafe 2 Mobile Pendant. (see: Alarm Descriptions / Summary Tables section.)

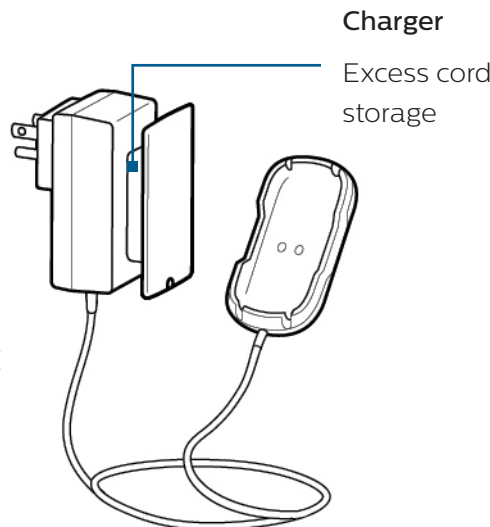
Microphone – The GoSafe 2 Mobile Pendant has a microphone that is used to talk to the Response Associate

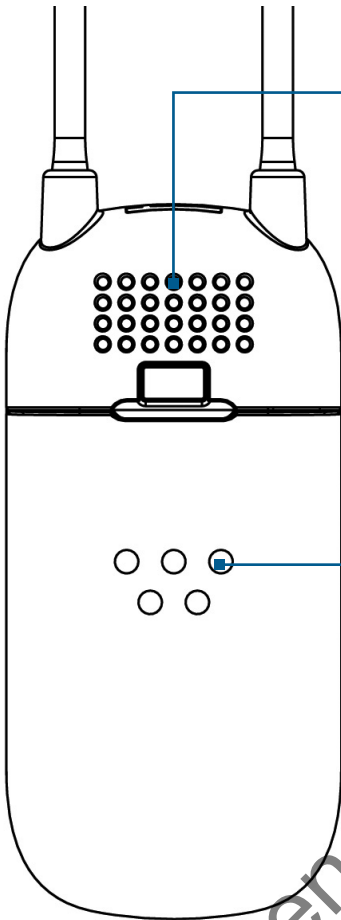
Help Button – The Help Button is the portion of your Pendant that can be pressed to send a Help call to Philips Lifeline.



Charger

The GoSafe 2 Mobile Pendant has a rechargeable battery. Use only the charger provided with your GoSafe 2 system to recharge the Pendant when the light & voice prompts indicate that the Pendant needs to be charged. See the Charging the battery section on page 29.



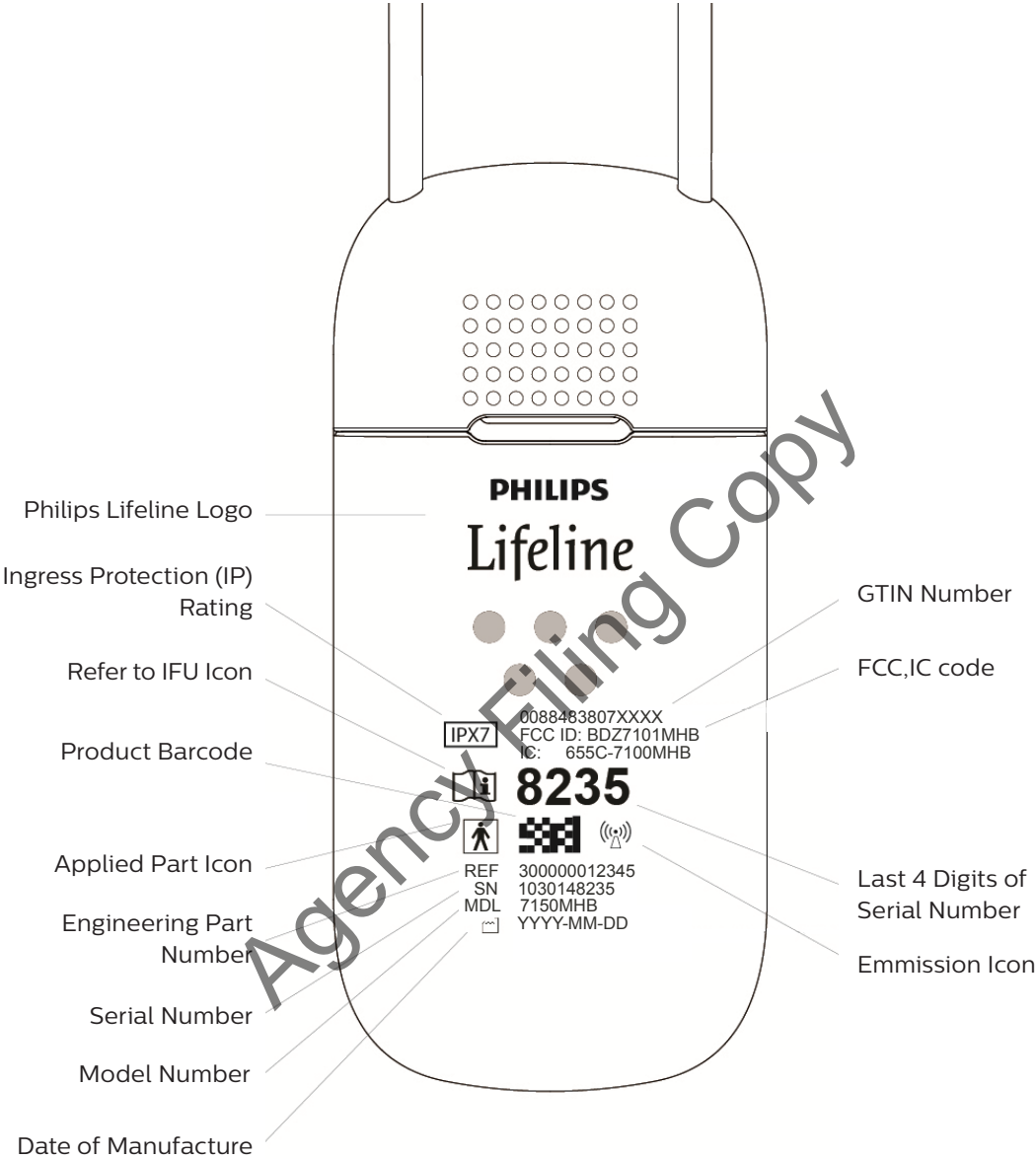


Back view

Speaker – The GoSafe 2 Mobile Pendant has a built-in 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.

Back view with labeling description



Determining your location

When in Alarm State, the GoSafe 2 Mobile Pendant is designed to help identify your 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.** 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.

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What to expect when the AutoAlert fall detection technology in your GoSafe 2 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 Pendant detects that you have self-recovered from the fall, within less than 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 do so.
- 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 promptly generates the Help Call. 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 promptly send the help call.

About Fall Detection

Warning

The AutoAlert fall detection technology may not detect every fall. In certain situations, the AutoAlert technology 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:

- A gradual slide such as from a seated position – such as from a wheelchair.
- Lowering oneself slowly to the ground
- Bracing the impact of a fall or interrupting the fall in-process, such as by holding-on to a piece of furniture during the fall.
- A fall from a height of less than 20 inches (0.5 meters)

Caution

Certain conditions can affect the ability of the AutoAlert Technology 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)

Any of these conditions can reduce the fall detection capability of the AutoAlert technology. However, the ability to send a help call by pressing the Help Button is not affected by such conditions.

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

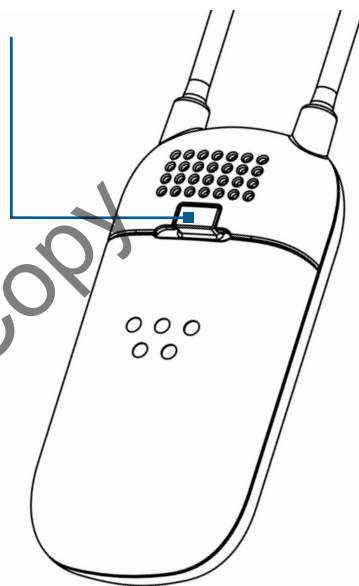
False “fall detected” alarms may occasionally occur

While the GoSafe 2 Mobile Pendant is designed to have very few false alarms, a fall detected alarm might occasionally occur when there was not a fall (i.e., a false alarm). This is considered normal operation. If this occurs, don't panic.

Allow the call to connect. A Philips 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. There are no additional charges for false alarms.

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

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 it. However, your Pendant should be worn at all times as it is waterproof for showering and bathing.



Back view vent area

⚠ Caution

Potential Interference

Do not use the GoSafe 2 Mobile Pendant if you have an implantable cardiac device, such as a defibrillator or pacemaker. The GoSafe 2 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, and hearing aids. It may also interfere with metal detectors.

Air Travel

Because it is a cellular communication device, the GoSafe 2 Mobile Pendant may interfere with aircraft communications

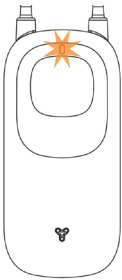
while in normal Stand-by mode. For this reason, the Pendant has a Sleep Mode. Be sure to place your Pendant in sleep mode during air travel. Please see instructions for putting your Pendant in Sleep Mode on page 32.

The GoSafe 2 Mobile Pendant can only place a Help Call when in Stand-by mode, and when the AT&T wireless network is available and when it has sufficient battery charge.

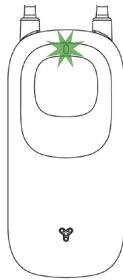
Charging the battery

Your GoSafe 2 Mobile Pendant is powered by a rechargeable battery. This means that it must be re-charged regularly, as indicated, for proper function. The Pendant will chime once and the Indicator Light will flash orange whenever the Pendant initially needs to be charged. Typically, it will take less than 45 minutes to charge your GoSafe 2 Mobile Pendant 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 now 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 this will not hurt the device.

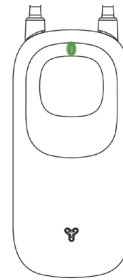
⚠ Warning: once the Critical Charge Warning is played and the Pendant shuts down, it cannot be used to make a help call of any type until it is re-charged.



Flashing orange Indicator Light = charging needed



Flashing green Indicator Light = charging in progress



When connected to the charger, a steady green Indicator Light = fully 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 Pendant 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.

3. Charge until the Indicator Light shines a steady green.
4. Remove from the charger. The green Indicator Light will turn off, and the Pendant 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 Pendant is powered on, hold it in your hand and shake it briefly, watching the Indicator Light while shaking.
 - A flashing green Indicator Light when shaken means that the Pendant has sufficient battery power for normal operation.
 - No flashing green Indicator Light means that the battery is dead and needs to be charged, or that the Pendant 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 Charger power cord while doing so.
- 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 Pendant.
- 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 2 Mobile Pendant provides audible and visual reminders of when to charge. You should charge it when it indicates charging is needed. Depending on environmental conditions and your level of mobility, you will have to charge your GoSafe 2 Pendant once every 2–3 days.

Sleep mode

The GoSafe 2 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) your Pendant must be placed in Sleep Mode. This is true regardless of whether you are “carrying-on” the pendant into the passenger cabin, or if you pack the Pendant in your checked luggage.
- 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

re-orient to its new location. To exit Sleep Mode, press the Help Button once and release it. Your Pendant will say: “Your Help Button is now ready to use. If you need help, please press your Help Button again”. This initial button press that wakes the Pendant out of sleep mode will not initiate a Help Call. If you need help in this instance, be sure to press the Help Button a second time.

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 2 Mobile Pendant to Philips Lifeline for service, replacement or recycling, you must contact Philips Lifeline at the number at the bottom of the page prior to returning it. Philips Lifeline will provide you with special packaging and instructions for return to help ensure that the Pendant does not send help signals 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 Pendant at ALL times, at and away from home. The GoSafe 2 Mobile Pendant can send a Help Call from any location where the AT&T wireless network is available.

- During an alarm, you can talk to Philips Lifeline using the microphone and speaker on your Pendant. For best results, hold the Pendant up and away from your chest when you are speaking to Lifeline. Maintain a minimum separation distance of 10mm/0.394 inches when operating the device in this manner. 10mm is less than the thickness of your finger.



- Your GoSafe 2 Mobile Pendant should be worn while showering or bathing. The Pendant has an IPX7 waterproof rating. This means that it can be submerged to a depth of 1 meter (40") 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 Pendant 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 provide proper function.
- Your Pendant can be used while driving. However, when entering and exiting your vehicle, take care to prevent the Pendant from hitting the steering wheel because it may accidentally send a Help Call.

GoSafe 2 Mobile Pendant – Alarms

Introduction

There are two types of alarms processed by the GoSafe 2 Mobile Pendant.

- High Priority – Require immediate response (by the Response 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 Pendant detects a *High priority alarm*: The Indicator Light on the Pendant flashes red, the device audible alarm sounds and a recorded voice message is played.

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

Silencing Alarms

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

During Medium Priority alarms, the Pendant will 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 Response Center after the alarm has been addressed. Additionally, the Pendant may periodically poll the Response Center to see if the alarm should be reset and does so accordingly. If the alarm is not reset by the Response Center, the Pendant will automatically reset the alarm after 30 minutes.

Note: Putting the GoSafe 2 Mobile Pendant into Sleep Mode during an active high priority alarm will reset the device, canceling the alarm. However, a prolonged (10 seconds) button press is required to put the Pendant into Sleep Mode and a Voice Message is played requiring the user to confirm this action by pressing the Help Button again to actually enter Sleep Mode. Since the alarm likely has already been reported to the Response Center, Philips Lifeline will likely attempt to contact the Subscriber via alternative means if this happens – such as by calling the home phone or cell phone of the user. If they are not able to contact the user, the Response Center will begin to facilitate response. If an alarm is accidentally initiated by the User, **they should not put the Pendant in Sleep Mode to try to cancel the alarm.** Instead, the User should wait for the Response Center

to establish voice communication and simply state that no help is needed.

The GoSafe 2 Mobile Pendant self-cancels certain Medium Priority alarms if the cause of the alarm is corrected, stopping the orange flashing Indicator Light from illuminating.

Alarm Descriptions / Summary Tables

Help Needed – 7150 MHB	
Alarm Event Description	Help Alarm initiated by the User pressing the Help Button on the End Device.
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 red.
Alarm Event Reported to Philips Lifeline?	Yes. A Help Alarm 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 Help Signal, the Response Center calls the End Device to establish contact with the Subscriber and to see what kind of help they need.

Help Needed – No Cell Signal Available	
Alarm Event Description	Help Alarm initiated by the User pressing the Help Button on the End Device or by the End Device detecting a fall; and the AT&T wireless network is unavailable: a verbal warning message is delivered by the End Device.
Priority	High
Device Action	The Help Alarm Signal will be buffered in the End Device. The End 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.
Alarm Event Reported/Displayed Locally?	Yes. Upon pressing the Help Button on the End Device or when the End Device 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 Response Center.

Help Needed – Fall Detected by Pendant

Alarm Event Description Help Alarm initiated by the End Device detecting a fall.

Priority High

Device Action Operates normally

Alarm Event Reported/Displayed Locally? Yes. When the End Device 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 End Device 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 End Device to establish contact with the Subscriber and to see what kind of help they need.

Agency Filing Copy

Device Error (Medium Priority) Alarms

The GoSafe 2 Mobile Pendant alarms described below are automatically generated alarms designed to periodically let the Response Center know that the Pendant is working properly. They are part of normal operation and are not the result of intentional action by the User.

Alarm Event Type

Low Battery Capacity – 7150 MHB	
Alarm Event Description	When the storage capacity of the battery in the End Device 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 End 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

Alarm Event Description	When the rechargeable battery in the End Device needs to be charged, a visual and audible warning Message is activated on the End 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 a single chime is played. This alarm will self cancel once the battery charge reaches an acceptable level.
Alarm Event Reported to Philips Lifeline?	No.

Depleted Battery – 7150 MHB

Alarm Event Description	When the charge level of the rechargeable battery in the End Device is critically low, a Warning Message is announced.
Priority	Medium
Device Action	End 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 Failure – 7150 MHB

Alarm Event Description	In the event that internal diagnostics indicate that the End Device has a Hardware Error, a Warning Message is displayed, if possible, based on the nature of the failure.
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Priority	Medium
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Device Action	May have limited operation, depending on the nature of the failure
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Alarm Event Reported/Displayed Locally?	No.
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Alarm Event Reported to Philips Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center if the nature of the failure does not impair the signal transmission function. 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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Agency Filing Copy

Software Failure-End Device 7150 MHB

Alarm Event Description	In the event that an End Device senses it has a software error, a warning message may be sent to the Response Center depending on the nature of the error.
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 if the nature of the error does not impair signal transmission function. Upon receiving the maintenance signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment. If the End Device is not capable of sending a signal due to the nature of the error, exception reporting at the Response Center that does not require a signal from the End Device will identify the device as requiring maintenance action.

Supervision and Check-in Alarms (Informational Messages)

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

Alarm Event Type

Auto Test Call 7150 MHB	
Alarm Event Description	Auto Test calls are automatically generated silent alarms sent by the End Device at regular intervals to the Response Center. They are designed to confirm proper End Device operation.
Priority	N/A
Device Action	Operates normally
Alarm Event Reported/Displayed Locally?	No visual or audible alarm is generated by the device.
Alarm Event Reported to Philips Lifeline?	Yes. A silent Maintenance Signal is sent to the Response Center by the End Device. Upon receiving the Maintenance Signal, the Response Center prioritizes the response and contacts the Subscriber to verify the status of their equipment. In certain cases, the absence of Auto Test Calls from the End Device may indicate the need for maintenance. In either case, the subscriber is contacted to verify the status of their equipment.

Delay in Determining Alarms

Reporting high priority help alarms from the GoSafe 2 Mobile Pendant to the Lifeline Response Center is done promptly when generated by a button press, depending on the status of the cellular network and signal strength available.

The GoSafe 2 Mobile Pendant provides an added layer of protection. It is designed to detect falls under certain conditions. It takes approximately 35-40 seconds to determine that an activity that resembles a fall has occurred, and that the User has not recovered from the fall on their own. If a fall is detected, the signal is sent directly to the Response Center via the AT&T wireless network, if available.

Logging Alarms

All alarm events reported to the Response Center are logged by the Response Center. There are no User accessible logs.

Safety and Regulatory Compliance

IEC regulations

The GoSafe 2 Mobile Pendant (7150MHB) 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 the GoSafe 2 Mobile Pendant (7150MHB) is not classified as a medical device. It falls under the Canada Consumer Product Safety Act.

Device classification

The GoSafe 2 Mobile Pendant (7150MHB) is registered as an FDA Class II device. **It is an internally powered device for continuous operation.**

Radio specifications

The GoSafe 2 Mobile Pendant (7150MHB) complies with the FCC Parts 15, 22 and 24 Subparts B, C and E. Its radio transmitters have the following characteristics:

- Cellular 3G (824–849MHz and 1850–1910MHz transmission bands).
- Bluetooth ISM band 2.4GHz; maximum EIRP 2 dBm, GFSK modulation
- WiFi (a, b, g) ISM bands 2.4GHz and 5GHz; maximum EIRP 15 dBm; OFDM modulation

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

The equipment complies with FCC RF radiation exposure limits set forth of an uncontrolled environment. For hand-held/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 may void the FCC authorization to operate this equipment. For assistance visit our website www.philips.com/support or call toll-free 1-800-635-6156.

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 2 Mobile Pendant (7150MHB) provides essential performance (EP) under normal operating conditions (includes EMC exposure) by sending Help Calls to the Lifeline Response Center. If the Pendant is unable to signal to the Response Center, exception reporting at the Response Center will identify the issue in the absence of a device signal.

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 these Instructions for Use for the purpose for which it was designed. The purpose for which the product is intended is given below.

The GoSafe 2 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 2 Mobile Pendant (7150MHB) is designed to directly connect to an emergency help service via the AT&T wireless network.

Uses of the GoSafe 2 Mobile 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

Caution

This device may be contraindicated for any person who is connected to, or has implanted in their body, an a implanted electronic medical device or instrument such as a pacemaker or defibrillator. This device may cause the electronic medical device to malfunction. Philips Lifeline makes no claims or warranties, implied or otherwise, regarding the suitability of this equipment for use with said implantable electronic medical devices, or any inter-compatibility for concurrent operation thereof. Users who have such devices implanted in their body and chose to use this equipment despite these stated Contraindications do so at their own risk and without the consent of Philips Lifeline. In no case may Philips Lifeline be held liable for events arising from use of this equipment concurrent with said implantables within their body.

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.

Warning

Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts will void the warranty. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

Risks and Benefits

The GoSafe 2 Mobile Pendant (7150MHB) 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 2 Mobile Pendant (7150MHB) depends on the user being capable of pressing the Help Button when they are in need of help and (re) charging the Pendant when necessary for proper operation.

Safety

Warnings

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

Warnings

- 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.

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 2 Mobile Pendant (7150MHB). Use caution when using such communication devices within the specified range of the GoSafe 2 Mobile Pendant (7150MHB). Refer to Table 6 in the EMC section (page 58) for the required separation distances between portable and mobile RF communications equipment and this device.

Maintenance

Expected Service Life

The Expected Service Life of the GoSafe 2 Mobile Pendant is as follows:

- GoSafe 2 Mobile Pendant (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, per ISO 10993-1, Part 1.

Passing the product on to another user

As a medical device, and due to the potential for bio-hazardous materials to contaminate the device, 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.

Technical Specifications

Standards Compliance

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

- IEC/ANSI/ AAMI60601-1:2005/R(12)2012, 3rd edition, Part 1- General 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’.

Open source software

The GoSafe 2 Mobile Pendant (7150MHB) utilizes the Wiced™ SDK and associated third party, open-source code and object files which are used under license from their respective providers within the SDK. Wiced is a trademark of Cypress Semiconductor Corporation.

Environmental Ratings

	Operating	Storage	Bathing*
Temperature	32° F to 104° F (0° C to 40° 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)	10 -90% (non-condensing)
Atmospheric Pressure	101 kPa to 80 kPa (approximately 0-6600 ft/0-2000 m)	N/A	101 kPa to 80 kPa (approximately 0-6600 ft/0- 2000 m)
Altitude	6,600 feet (2 km) Maximum	N/A	6,600 feet (2 km) Maximum

* Up to 30 minutes exposure.

Electrical Specifications

GoSafe 2 Mobile Pendant (7150MHB)	
AC Voltage Source ^[1] (VAC)	N/A – EUT battery operated. AC battery charger adapter 100–240Vac 50/60Hz, 0.5A
DC Power Source (VDC)	3.7 V, 920mAh ^[2] , Lithium Ion Rechargeable ^[3] Battery
Type of Protection Against Electric Shock	Class II (Power Supply Adapter)/GoSafe 2 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 Operation
Sound Pressure Level	116–123 dB at 1 kHz (measured 1 cm from the speaker)

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

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

[3] Recharging of the GoSafe 2 Mobile Pendant (7150MHB) battery is done by the user as needed, when connected to the charger.

Product Disposal – Environmental Requirements

Introduction

Philips Lifeline is committed to protecting the natural environment, and to helping to provide for the continued safe and effective use of this product, through proper support, maintenance and training. Therefore, Philips Lifeline 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” refers to the point at which 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 2 Mobile Pendant (7150MHB) and Charger, User may return the device to Philips Lifeline or its representative for proper disposal.

Philips supports Users in:

- Recovering reusable parts,
- Recycling of useful materials by competent disposal companies, and,
- The safe and effective disposal of this product.

Electromagnetic Comparability – EMC

Medical electrical equipment can either generate or receive electromagnetic interference. The GoSafe 2 Mobile Pendant (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 2 Mobile Pendant (7150MHB) 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 2 Mobile Pendant (7150MHB) 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.

1. 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 if 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. 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.

EMC Informational Tables

Table 1 – Guidance and Manufacturer’s Declaration – Emissions

The GoSafe 2 Mobile Pendant (7150MHB) is intended for use in the electromagnetic environment specified below. The GoSafe 2 Mobile Pendant (7150MHB) is provided with battery power adapter charger. The customer or User of the GoSafe 2 Mobile Pendant (7150MHB) should ensure that it is used in such an environment.

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

Table 2 – Guidance and Manufacturer’s Declaration – Immunity

The GoSafe 2 Mobile Pendant (7150MHB) is intended for use in the electromagnetic environment specified below. The User of the GoSafe 2 Mobile Pendant (7150MHB) should ensure that it is used in such an environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic 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%
Electrical fast transient/burst EN/IEC 61000-4-4 (only for battery charger power supply)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Electrical power quality should be that of a typical commercial or hospital environment.
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	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_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.	<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.	Electrical power quality should be that of a typical commercial or hospital environment. During charging, if the the User of the GoSafe 2 Mobile Pendant (7150MHB) requires continued operation during power mains interruptions, it is recommended that the device power adapter is powered from an uninterrupted power supply or a battery.

NOTE: U_T is the ac mains voltage prior to application of the test level.

Table 4 – Guidance and Manufacturer’s Declaration – Immunity

The GoSafe 2 Mobile Pendant (7150MHB) is intended for use in the electromagnetic environment specified below. The customer or user of the GoSafe 2 Mobile Pendant (7150MHB) should ensure that it is used in such an environment.

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*	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 80 MHz to 2.5 GHz	10V/m	Portable and mobile communications equipment should be separated from the GoSafe 2 Mobile Pendant (7150MHB) by no less than the distances calculated/listed below*: D=(3.5/V1)(√P) D=(3.5/E1)(√P) 80 to 800 MHz D=(7/Eq)(√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: 

NOTE: Conducted RF Immunity does not apply to an internal battery operated

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 2 Mobile Pendant (7150MHB) is used exceeds the applicable RF compliance level above, the GoSafe 2 Mobile Pendant (7150MHB) 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 2 Mobile Pendant (7150MHB).

(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 the GoSafe 2 Mobile Pendant (7150MHB)

The GoSafe 2 Mobile Pendant (7150MHB) is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communication Equipment and the GoSafe 2 Mobile Pendant (7150MHB) as recommended below, according to the maximum output power of the communications equipment.

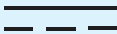
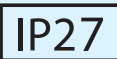
Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $d = 1.17/\sqrt{P^*}$	Separation (m) 80 to 800MHz $d = 0.35/\sqrt{P}$	Separation (m) 800MHz to 2.5GHz $d = 0.70/\sqrt{P}$
0.01	0.117	.035	.07
0.1	0.37	.11068	.22136
1	1.17	.35	.7
10	3.7	1.1068	2.2136
100	11.7	3.5	7

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. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Symbols

Symbol	Description
	Symbol for dc (direct current) power.
	Polarity symbol. Indicates that the center (tip) of the output plug is Positive (+) and the barrel of the output plug is Negative (-).
	The power supply efficiency performance is Level 5, indicating a high standard in use efficiencies and no-load power consumption.
	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).
	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 equipment to Philips Lifeline or its representative for proper disposal.
	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.
	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.
	Type BF Applied Part

Symbol	Description
	Consult accompanying instructions for use.
	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.
	Use by Date.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the manufacturer's catalog number so that the device can be identified.
	Indicates the manufacturer's serial number so that a specific device can be identified.
	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.
	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Refer to instruction manual/booklet

SECURITY and PRIVACY-related controls that are supported by this product:

- The GoSafe 2 Mobile Pendant (7150MHB), the “Device”, is sealed. The user has no access to any of the internal components of the Device without violating/destroying the device enclosure.
- Specialized, precision manufacturing equipment is required to access the physical components that store data within the Device.
- Data access interactions with the Device can only be facilitated using proprietary equipment not distributed outside of Philips.
- Wireless/network transmissions made by the Device are made using secure protocols and connections.

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Signal range may vary due to environmental factors.
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