



Patient Instruction Booklet

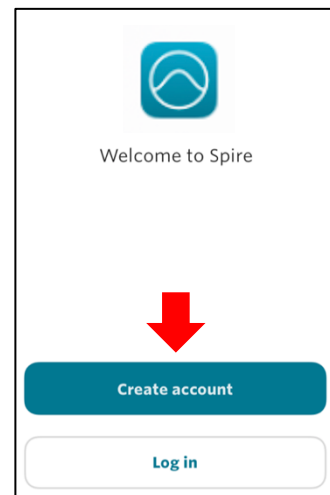
Welcome to Spire Health!

Medical Health Tags help your doctor understand changes in your health and wellness while you're at home. Medical Health Tags also promote healthier habits like increased activity and sleep which can contribute to improvements in your condition. With Medical Health Tags all you need to do is get dressed and go!



Setting Up the Spire Health App

1. Download the Spire Health App by going to www.spirehealthapp.com on your iPhone or Android device.
2. Next open your App and tap on “Create Account”.
3. Follow the instructions in the App to create your account and start using your Medical Health Tags.



Important Notes for App Setup:

- You'll need your Medical Health Tags and undergarments you wear most frequently ready for this step.
- You only need to pair (connect) one Medical Health Tag with the App. The rest of your Medical Health Tags in your pack will pair automatically.
- **You must enable Bluetooth, Notifications, and Location Services during setup to ensure you're monitored effectively.**

Attaching Medical Health Tags

Instructions for attaching your Medical Health Tags are included in the Spire Health App. They are also included below for your reference:

1. For each piece of clothing, remove the adhesive strip from the back of the Medical Health Tag and position it on clothing as shown below.



Underwear: place 1-2 inches from center on the **front** waistband



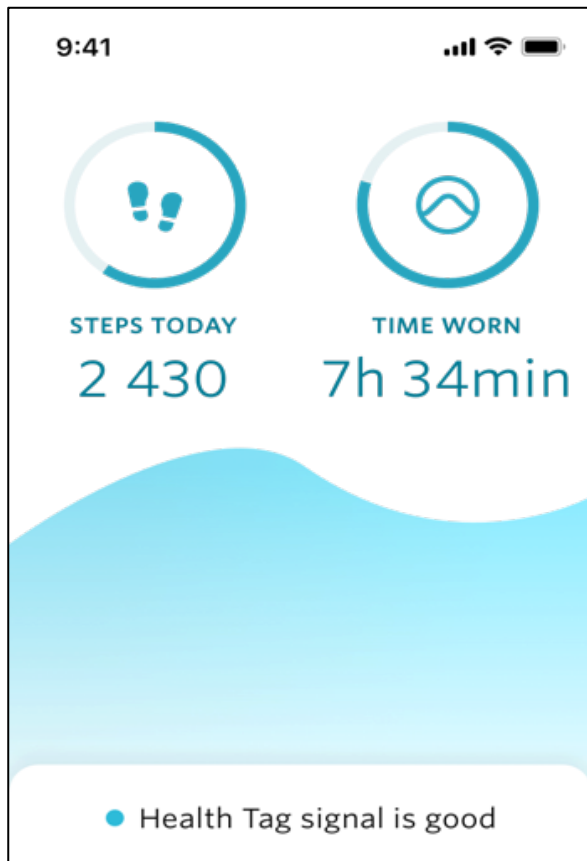
Bras: place ½ inch from bra cup on the inside wing of your bra

2. Press Medical Health Tag firmly into clothing, massaging for a few seconds to ensure placement. Medical Health Tags should be placed on your first layer of clothing (e.g. underwear, bra, or pajamas), such that the side with the “Spire Health” logo is snug against your skin.
3. Once your Medical Health Tags are attached, wait at least 24 hours before wearing them or putting them through the wash.

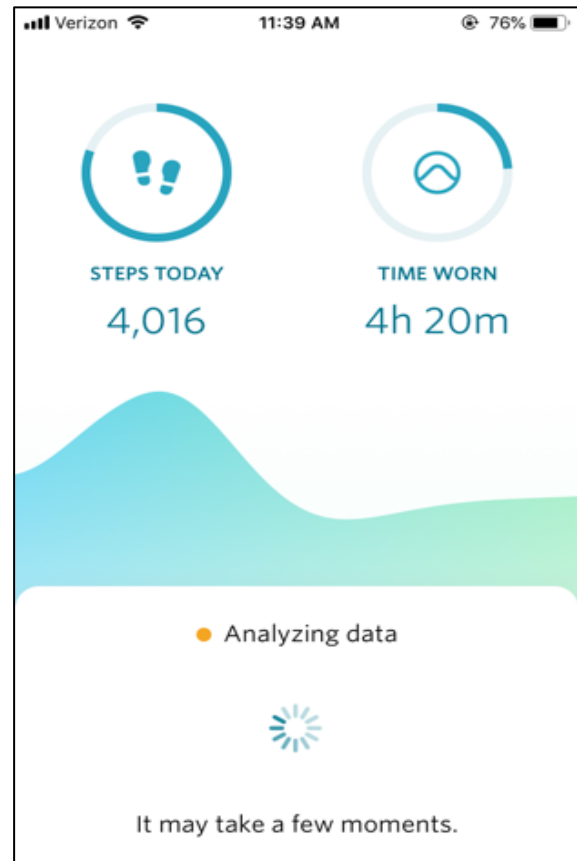
Understanding the App

It is important that you wear a Medical Health Tag as often as possible. Use your app to confirm that your device is being worn correctly.

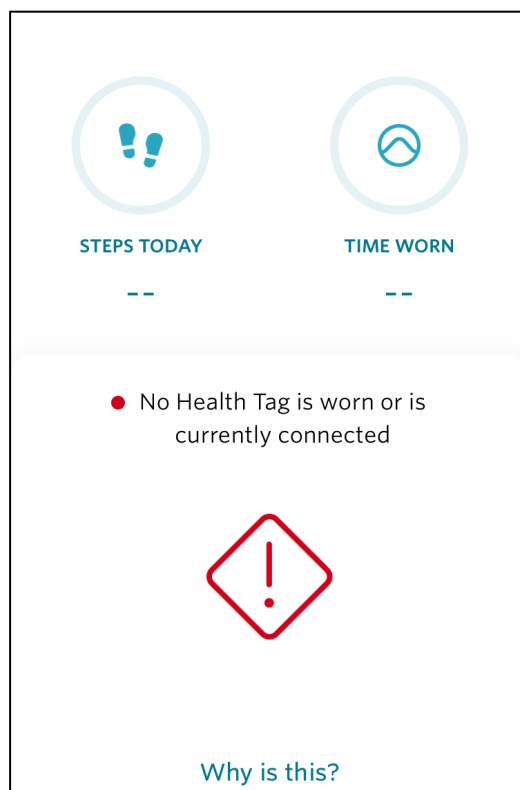
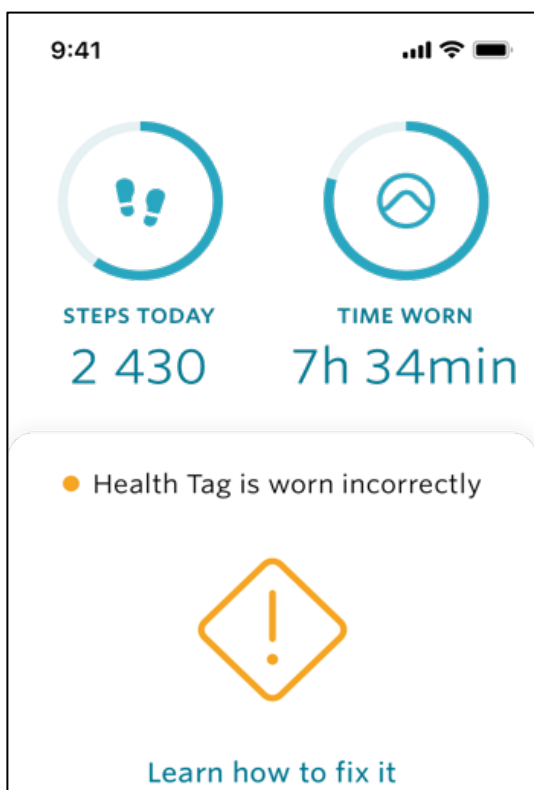
The different screens you may see are shown below:



This screen indicates that your Medical Health Tag is working correctly.



This screen means your Medical Health Tag is still processing. This is normal and may take up to 15 minutes.



The error message “Medical Health Tag is worn incorrectly” means you need to adjust how your Medical Health Tag is being worn.

Make sure the soft side of the Medical Health Tag is in contact with your skin.

The error message “No Medical Health Tag is worn or currently connected” means there is no Tag currently connected to your mobile device.

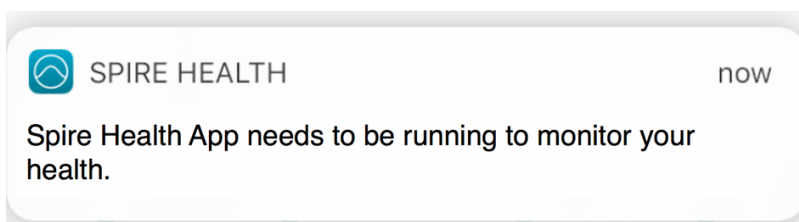
Make sure you are wearing a Medical Health Tag.

If you cannot resolve these errors, contact Spire Health customer support at (415) 980-3858

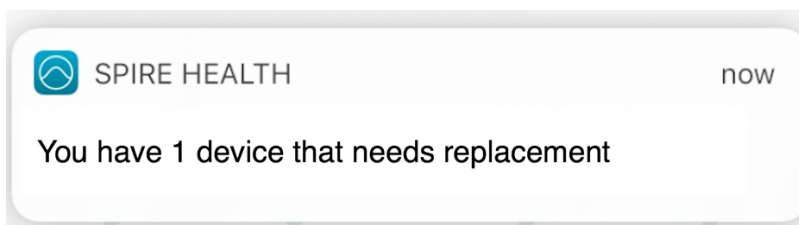
App Notifications

The App may send you notifications to make sure your Medical Health Tags and App are working correctly. The different notifications you may see and how to resolve them is shown below:

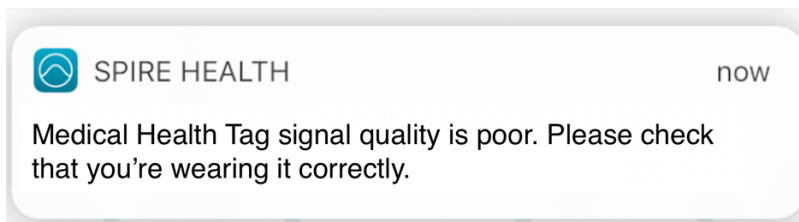
Re-open your app by tapping the blue Spire Health icon on your mobile device



Navigate to "Settings" in your App to replace your device(s)



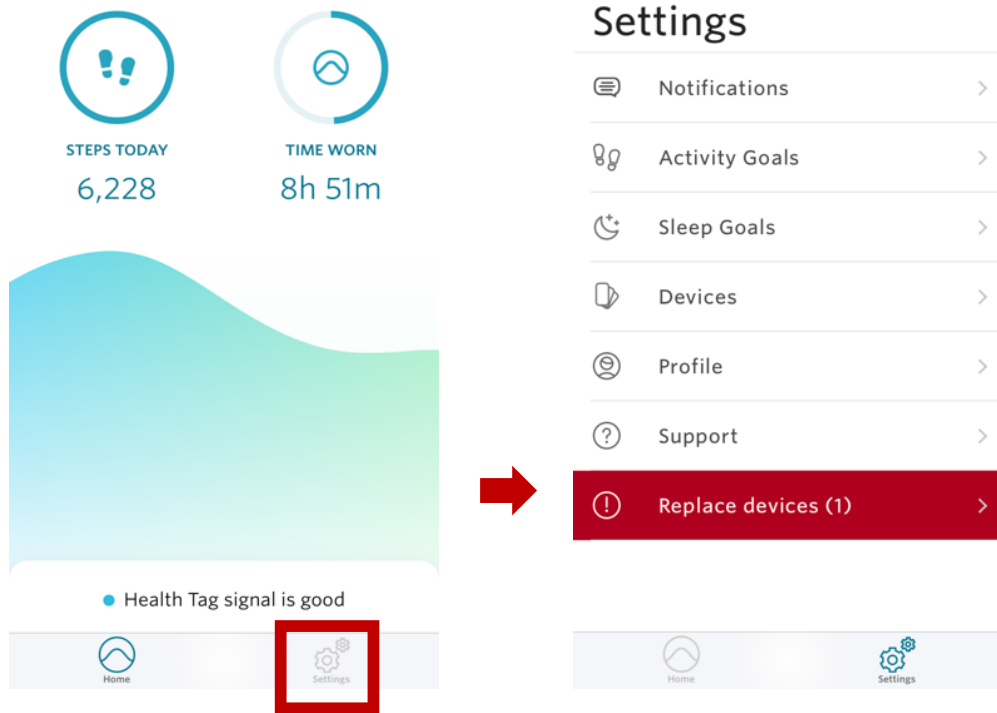
Make sure your Medical Health Tag is worn so that the soft side is in contact with your skin



Replacing Medical Health Tags

Your Medical Health Tags have a long battery life that does not require charging. When a Medical Health Tag has reached the end of its battery life, you will need to remove it and replace it with a new device.

To replace the device, go to your app and tap on Settings. The Settings tab shows the device(s) that need to be replaced. Follow the instructions on the screen to replace your device.



For help with device replacement, contact Spire Health customer support at (415) 980-3858.

Replacement Adhesive

If for any reason, your Medical Health Tag comes off of your garment before it is ready to be replaced, you can re-attach it using the Medical Health Tag adhesives included in your kit.

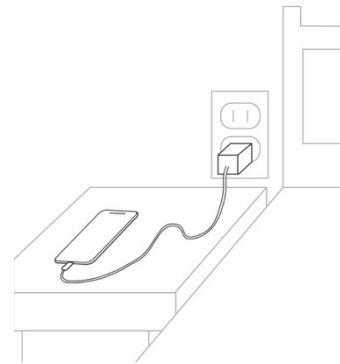
The Medical Health Tag adhesives are a special type of double-sided tape.

To use a replacement adhesive:

1. First, take a replacement adhesive strip and remove one side of the backing. Both sides are identical, so either side is OK.
2. Attach the replacement adhesive to the back of the Medical Health Tag (over the old adhesive is OK) and apply pressure on it for 5 seconds with your thumbs.
3. Remove the second backing to expose the other side of the adhesive. Then attach the Medical Health Tag to your clothing as usual.
4. In order for the adhesive to work properly, do not wear the garment for the next 24 hours.

Important Notes

1. For best care of your Medical Health Tags, wash clothing in warm water and dry with low heat. Do not wash or dry on high heat. Do not use bleach or fabric softeners.
2. Once your Medical Health Tags are ready to wear, be sure to only wear one Tag at a time.
3. To be monitored most effectively, be sure to keep your mobile device charged and in close proximity to you.



4. **Important: Medical Health Tags are designed to be attached to clothes. Do not adhere to skin.**



Stick on clothing



DO NOT stick on skin

If you would like to re-watch the video on how to install Health Tags, or to learn more about attaching your Health Tags, visit

support.spirehealth.com

Frequently Asked Questions

How do Medical Health Tags work?

Medical Health Tags monitor your breathing, pulse rate, steps and sleep throughout the day and night. Health Tags are able to share this data with your care team through your app.

Do I need to turn on my Medical Health Tags?

No, the Medical Health Tags turn on automatically when you wear them. The green light may flash on and off; this is normal.

Do I need to charge my Medical Health Tags?

No, your Medical Health Tags have a long-lasting battery and do not require charging. Battery life will vary based on usage.

What happens if my Medical Health Tag stops working?

If your Medical Health Tag is not working correctly, you will see an error notification on your app screen. Make sure the soft side of your Medical Health Tag is in contact with your skin. If you continue to see an error, contact Spire Health customer service at (415) 980-3858.

What happens if my Medical Health Tag falls off my clothing? Your Medical Health Tag kit comes with replacement adhesives. Use one of the replacement adhesives you received in your kit to reattach your Medical Health Tag – see **Replacement Adhesive** section for help on how to do this.



WARNINGS

- For any medical concerns or a medical emergency contact your doctor or call 911.
- Stop wearing garments with Medical Health Tags immediately if you experience any discomfort.
- Do not use Medical Health Tags on broken or wounded skin.
- Do not adhere the adhesive of the Medical Health Tag directly on skin.
- Do not use Medical Health Tags if you have a known allergy to suede or adhesives.
- Do not share Medical Health Tags with anyone else; it is a single patient use device.
- Do not launder Medical Health Tags on hot settings (>140°F) or with bleach or fabric softener or device may become damaged.
- Do not wear or use a Medical Health Tag that has been damaged.
- The Medical Health Tags are magnetic resonance (MR) unsafe! Do not expose Medical Health Tags to a MR environment.

PRECAUTIONS

- Safety and effectiveness of Medical Health Tags on pediatric patients (younger than 18 years old) has not been established.
- The Medical Health Tag includes temperature and humidity limitations when stored/transported. If exposed during storage/transport, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The Medical Health Tags should be adhered to clean clothing and let sit for 24 hours before wearing. Otherwise, patients may experience

degradation of adhesive performance causing the Medical Health Tag to slip or fall off during the patient wear duration.

- The Medical Health Tag has a shelf-life date. Use of expired device may cause a degradation of signal quality and/or low battery condition.
- Expired or faulty Medical Health Tag devices should be properly disposed with a certified electronics recycler or returned back to the manufacturer.
- Do not use the Medical Health Tag if package is damaged. Device may not perform as intended.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Medical Health Tags contain button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.
- Registration errors may result in limited functionality or erroneous data reporting. Utmost caution should be applied to ensure that patient registration is accurate and complete.
- Using Medical Health Tags in areas with limited or no cellular reception may result in limited or no functionality.
- The MHT may reach temperatures up to 43.0°C during abnormal operating conditions that cause a battery short.

Need help?

Contact us at **(415) 980-3858** for support.

DETAILED DEVICE DESCRIPTION

Spire's Remote Patient Monitor (RPM) is designed to capture, process, and longitudinally track clinically relevant patient health data and share this data with healthcare providers with a view to improving patient health and outcomes. The RPM is intended for longitudinal monitoring of pulse rate, respiratory rate, sleep/wake behavior, and activity associated with movement.

The RPM solution is comprised of four components - a Medical Health Tag (MHT), a Spire Mobile Application (App), a Cloud Platform (Platform), and a Healthcare Professional Dashboard (HPD). The patient facing components of the system (the MHT and Mobile App) are intended for daily use in the home, the workplace, and alternate care settings. The MHT is a component designed to be affixed semi-permanently via an adhesive to the patient's first layer of clothing (e.g. underwear, bras, or pajamas), passing through laundry cycles without detaching. It does not require charging by the user.

The App is installed on a patient's iPhone or Android mobile device and connects via Bluetooth to the MHT. The App has a dual purpose of relaying information captured on a user's MHT to the cloud-based application (CBA) and to present the information captured on the MHT back to the user in an easy to understand format.

The HPD is a web-based software application accessed through an internet browser by a nurse, doctor, researcher, or other clinical professional. Data captured by MHTs for a population of users can be viewed by an associated professional in the HPD.

INDICATIONS FOR USE

The Spire Health Remote Patient Monitoring System is intended for reusable bedside and mobile multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Spire Health Remote Patient Monitoring System is intended for longitudinal monitoring of the following parameters in adults:

- Pulse Rate
- Respiratory Rate
- Sleep/Wake Behavior
- Activity associated with Movement

The Spire Health Remote Patient Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Spire Health Remote Patient Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG.

The Spire Health Remote Patient Monitoring System is not a substitute for an ECG monitor










CONTRAINDICATIONS

There are no known contraindications for the Spire Remote Patient Monitor



Spire Health
 2030 Harrison Street
 San Francisco, CA 94110
 Tel: +1-800-501-2256 (USA Only)

SYMBOLS

	Manufacturer		Date of Manufacture		Use-by-date
	Type BF Applied Part	Rx ONLY	Prescription Use Only	QTY:	Net Quantity of Contents
LOT	Batch Code	REF	Catalog Number	SN	Serial Number
	Consult Instructions for Use		Do not re-use		Separate Collection
	Temperature Limit		Caution	IP27	Water Resistance Rating IP27

MHT DEVICE SPECIFICATIONS – Model MHT900100

PERFORMANCE CHARACTERISTICS

Memory Capacity	48 hours
Useful Life	3 months
Shelf Life	14 months
Respiration Rate Range	8-35 breaths per minute
Pulse Rate Range	40-190 beats per minute

ELECTRICAL CHARACTERISTICS

Sensor Sampling Rate	25 Hz
Nominal Battery Voltage	3V
Bluetooth Version	4.0
Bluetooth Frequency Band/Bandwidth	2.4-2.5 GHz ISM Band/ 1MHz
Frequency Modulation Method	FSK
CPU Clock Rate	48 MHz
Maximum Radiated Power	-4.82 dBm, at 2402-2480 MHz frequency

POWER SPECIFICATIONS

Battery Type	1 Lithium Manganese Coin Cell
Battery Life	Minimum of 500 hours of use

PHYSICAL CHARACTERISTICS

Dimensions	55mm x 34mm x 9mm
Weight	25g

ENVIRONMENTAL CHARACTERISTICS

Allowable Transit Temperature	-29° C to 60° C
Recommended Storage Temperature	-29° C to 60° C
Operating Temperature	5°C to 40°C
Storage Humidity	15-85%
Operating Humidity	15% to 90%
Operating Atmospheric Pressure	700 hPa to 1060 hPa

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The MHT device needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The MHT device should not be used adjacent to or stacked with other equipment.

Table 1: Guidance and manufacturer's declaration— electromagnetic emissions		
The Medical Health Tag device is intended for use in the electromagnetic environment specified below. The customer or the user of the Medical Health Tag device should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The Medical Health Tag device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Medical Health Tag device is suitable for use in home, workplace, and alternate care settings

Table 2: Guidance and manufacturer's declaration— electromagnetic immunity			
The Medical Health Tag device is intended for use in the electromagnetic environment specified below. The customer or the user of the Medical Health Tag device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000- 4-2	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000- 4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment
Conducted RF IEC 61000- 4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Medical Health Tag, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000- 4-3	10 V/m 80 MHz to 2 .7 GHz	10 V/m	<p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be</p>


			<p>less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<ul style="list-style-type: none"> 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 Medical Health Tag is used exceeds the applicable RF compliance level above, the Medical Health Tag should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Medical Health Tag. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 			

Table 3: Recommended separation distances between portable and mobile RF communications equipment and the Medical Health Tag

The Medical Health Tag is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical Health Tag can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Medical Health Tag as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	80 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

REGULATORY

Spire Medical Health Tag

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

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 and 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 to 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.

Important: Changes or modifications to this product not authorized by Spire could void the electromagnetic compatibility (EMC) and wireless compliance and negate your authority to operate the product. This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices and shielded cables between system components. It is important that you use compliant peripheral devices and shielded cables between system components to reduce the possibility of causing interference to radios, televisions, and other electronics devices.

Trademarks

Spire®, the Spire wave, and the Spire Medical Health Tag are registered trademarks of Spire, Inc. The Bluetooth® wordmark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Spire, Inc. is under license. Other trademarks and trade names belong to their owners.



Copyright

Copyright © 2014-2019 Spire, Inc. All rights reserved.

© 2019 Spire, Inc. Spire® Medical Health Tags™ are trademarks owned by Spire, Inc.

All other trademarks are property of their respective owners.

Patent Pending. Made in China. Designed in California.