

Perin Health Patch Instructions for Use

Document Version 3.2

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Device Description

The Perin Health Patch is a battery powered, physiological monitoring device with an adhesive patch and sensor module. The Health Patch houses numerous sensor technologies, including an acoustic sensor, accelerometer, temperature sensors, bioimpedance sensor, electrocardiography sensor, and multiple LEDS and photodetectors across several spectral bands. The sensors derive physiological data including skin temperature, auscultation sound data, heart rate, oxygen saturation, blood pressure, and respiratory rate. The data is transmitted by the mobile device application to the Perin Health Cloud System where it is analyzed and made available to a healthcare provider.

Go to www.perinhealth.com/support for additional tips and tutorials, a full list of supported devices, warranty, troubleshooting, and customer support.



Scan for access
to support page.

Note: The Health Patch is only to be used with compatible devices or applications. Verify compatibility before use to ensure the sensor functions properly.

⚠ IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY. Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

! Do not throw the outer box away. You will need to use it to return the Health Patch Sensor Module after completing your monitoring period.

Indications for Use

The Perin Health Platform is a wireless remote monitoring system intended for use by patients and healthcare professionals for continuous collection of physiological data in clinical and non-clinical settings for long-term monitoring. This can include auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation, heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the Sensor Patch to a mobile application, or web-based portal for storage, analysis, and review. The Perin Health Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.

Contraindications

- The device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.
- The device is not intended for people who exhibit allergic reactions to adhesive tape.

- The device is not intended for neonatal or pediatric patients.
- The device is not intended for patients with implanted pacemakers.
- The device is not intended to be used during physical activity.

⚠ Warnings

A warning indicates precaution to avoid the possibility of personal injury or death.

- The Perin Health Patch is a secondary, adjunct monitor and is not intended to replace existing standard-of-care monitoring practices. Do not self-diagnose or self-medicate on the based on the measurements. Always consult your doctor.
- Histories of skin irritations should be considered before placing on the skin.
- The adhesive may cause adverse skin reactions. Discontinue use if severe discomfort or irritation occurs. Seek medical attention if either of the following occurs: (1) a severe adverse event or (2) an allergic reaction persisting beyond two to three days.
- Only place the Health Patch on intact skin. Do not place on broken skin including wounds, sores, or abrasions.
- Inaccurate heart rate, respiration rate, or oxygen saturation measurements may be caused by motion.
- Only use Perin Health approved accessories and devices with the Perin Health Patch to prevent damage to the device and inaccurate readings. Approved accessories will be recorded in the instructions for use.

Precautions

A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment

Data Transmission

- Temporary interruptions to data transmission are possible when wireless connectivity is poor or unavailable. During these interruptions, continuous or real-time monitoring may be interrupted, however, data will be stored on the Perin Health Patch and transferred once wireless connectivity is reestablished.
- For data transmission to a healthcare professional for review:
 - The Health Patch must be properly adhered to the body.
 - The Health Patch must remain within range of the relay device (phone with mobile application).
 - The Health Patch must have adequate power for data transmission. Notification of the device battery level via the mobile application will indicate when the battery power is low.
 - The relay device (phone with mobile application) must remain charged and functional for data transmission. Wireless connectivity must be active for transmission of data from the relay device to the server.
- Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.

General Use

- Medical electrical equipment or electrical stimulators attached to the patient's body may degrade signal quality or produce erroneous results from the Perin Health Patch. The potential interaction must be evaluated and authorized by your provider.
- If discomfort or irritation occurs, the Perin Health Patch should be removed. If mild soreness or redness is experienced after removing the Perin Health Patch, do not apply a new Perin Health Patch in the same location. Choose another recommended location. Refer to section 'Applying the patch.'
- Incorrect handling, excessive force, or dropping the Perin Health Patch may cause malfunction or permanent damage.
- If the Perin Health Patch fails to operate, contact your healthcare provider immediately.
- Keep the Perin Health Patch away from electrical equipment that emits radio frequencies to minimize radio interference. Radio interference may result in no or inaccurate readings.
- Periodically check the Perin Health Patch site for proper adhesion to minimize the risk of incorrect or no readings.
- The Perin Health Patch is not intended for use as an apnea monitor.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the Health Patch. Otherwise, degradation of the performance of this equipment could result.

Validation

- Clinical validation has not been established for individuals with implantable devices, such as defibrillators and pacemakers.
- Clinical performance has not been assessed in a patient population experiencing cardiac arrhythmias. For patients experience an arrhythmia, resting heart rates reported by the Health Patch may be inconsistent relative to other heart rate monitoring devices.
- Use of the Perin Health Patch for pregnant or breastfeeding individuals has not been assessed and performance characteristics are not known.

Do not

- **Do not** use the Perin Health Patch if the package has been opened or appears used, damaged, or expired.
- **Do not** modify or alter the Perin Health Patch in any way. Alteration or modification may affect performance and/or accuracy.
- **Do not** soak or immerse the Perin Health Patch in any liquid solution.
- **Do not** attempt to sterilize by irradiation, steam, autoclave, or ethylene oxide.
- **Do not** attempt to perform maintenance on the Perin Health Patch while adhered to the body.
- **Do not** wear or use the Perin Health Patch during a magnetic resonance imaging (MRI) procedure or in a location where exposure to strong electromagnetic forces is possible.
- **Do not** exert excessive force, drop, modify, or attempt to disassemble the Perin Health Patch.
- **Do not** use accessories, detachable parts, and/or materials not described in the Instructions for Use.
- **Do not** apply directly over a pacemaker to avoid any potential interference from the Bluetooth communication.
- **Do not** wear the Perin Health Patch over thick body hair.
- **Do not** attempt to reuse on multiple people. Reprocessing, reconditioning, or recycling may damage the sensor.
- **Do not** reuse the battery. These parts are single use only and should be disposed of after use.

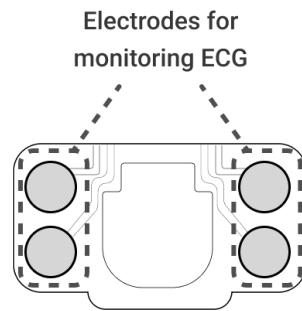
Accuracy

- Certain types of motions or vibrations may cause inaccurate heart rate or respiratory rate measurements.
- Heart rate and respiratory rate data are only reported when the wearer is at rest and not reported during periods of significant motion or activity.
- Rapid or large changes in ambient temperature may prevent or cause incorrect skin temperature readings.
- Avoid direct heating or cooling of the Perin Health Patch. Localized temperature exposure of the sensor prevent readings or result in incorrect readings.
- Incorrect readings may be caused by sensors that are not placed on an appropriate application site. Refer to 'Applying the patch' for appropriate application sites.
- The Perin Health Patch may not reflect the actual body temperature when used on people undergoing treatments that may alter their normal temperature regulation (e.g. therapeutic hypothermia, antipyretics).
- The Perin Health Patch is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin using a pulse oximeter. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
 - Perin Health Patch not applied correctly
 - Excessive motion
 - Methemoglobin
 - Intravascular dyes
- Avoid using the Perin Health Patch under bright light sources and direct sunlight to minimize interference that may prevent or result in inaccurate readings.

Safety

- Keep the Perin Health Patch away from children and pets. The Perin Health Patch may be a choking hazard, and may be harmful if swallowed.

- Remove the Perin Health Patch prior to using a defibrillator.
- The Perin Health Patch contains electrodes for monitoring ECG. Do not allow conductive parts of the electrodes to come in contact with other metal parts from external electrical equipment (including earth).



Cybersecurity

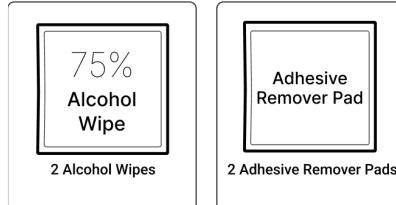
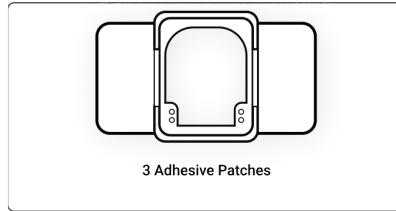
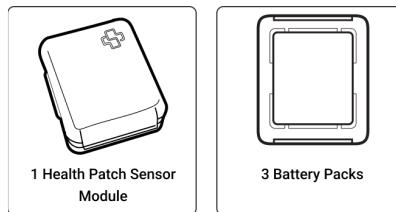
- Do not leave your phone unattended and open while using the mobile application.
- Use security measure to lock phone when not in use. You will be prompted to create a login pin for your Perin Health mobile application when signing up.
- Do not install apps on your mobile phone that may contain malware.

Use Instructions

These instructions describe how to handle the Health Patch, prepare the skin for Health Patch application, position the Health Patch, and apply the Health Patch to the skin.

Device and components overview

- Health Patch Sensor Module
- Adhesive patches (x 3)
- Battery packs (x 3)
- Alcohol wipe (x 2)
- Adhesive remover (x 2)



Getting started

1. Download the Perin Health mobile app on your phone.

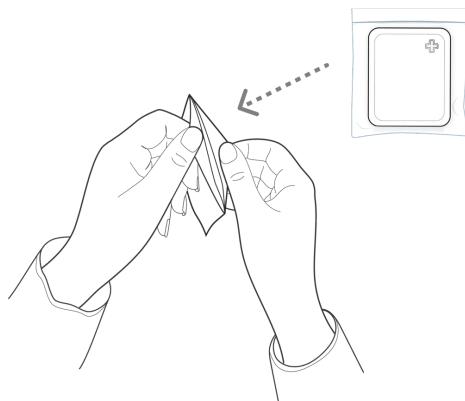


Scan to access
mobile
application for
iOS devices.



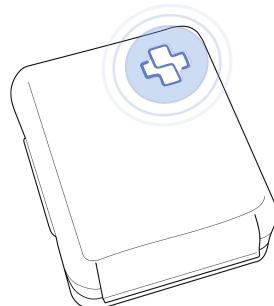
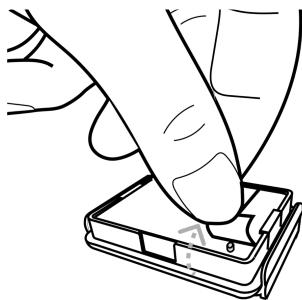
Scan to access
mobile
application for
Android devices.

2. Once downloaded, log in to the mobile application using the account information provided by your doctor.
3. Open the plastic pouch with the Health Patch Sensor Module and remove.

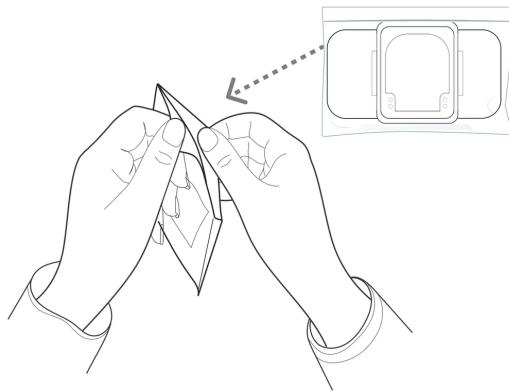


2. When ready to pair to your phone, pull and remove the tab from the sensor module to activate the battery. Once removed and the battery is inserted into the Sensor module, you should see a blue light blinking on the Perin Health Patch indicating that it is ready to be paired.

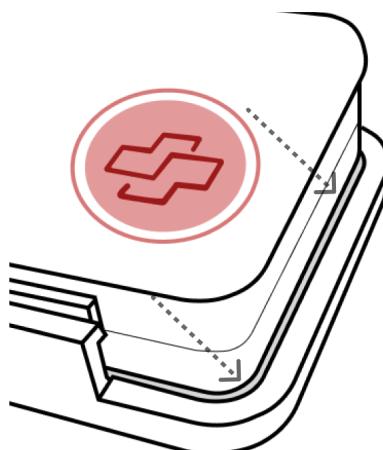
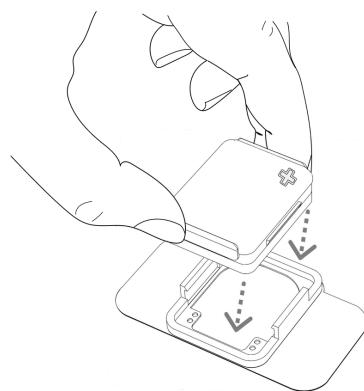
- ⓘ You will only have 5 minutes to pair the Perin Health Patch to your mobile application before the device goes to sleep. Please be sure to pull the battery tab only when ready to pair.



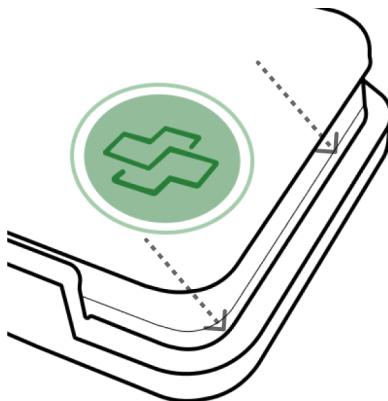
3. Open a single plastic pouch with an adhesive patch and remove the patch.



4. On a flat, hard surface, insert the Sensor Module into the clip with the adhesive patch. There should be no visible gaps between the clip and sensor module.



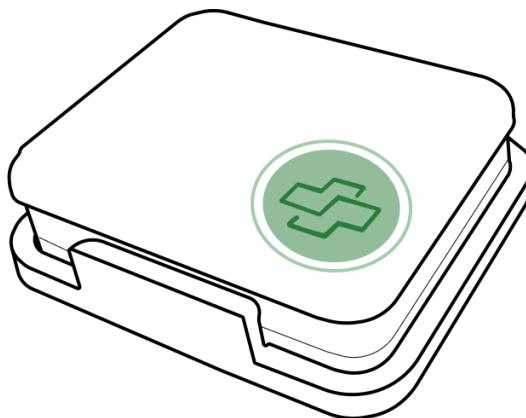
Gap between clip and sensor module
causing red light



No Gap between clip and sensor module

5. Pair and activate your Perin Health Patch by holding the device to your mobile phone with the application open. The Patch will blink **green** three times once pairing is successful.

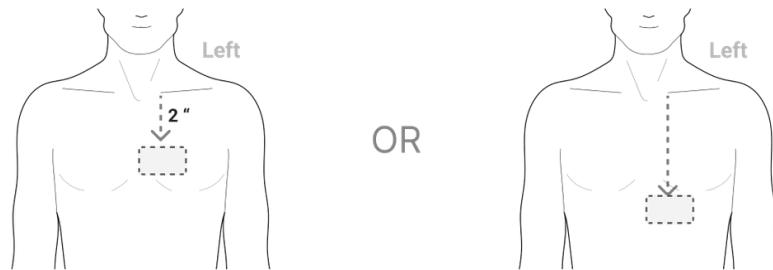
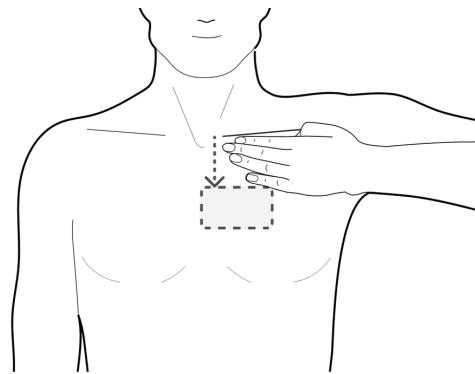
- i** Follow the detailed steps in the mobile application onboarding process to pair if the Tap-to-Pair feature is unsuccessful.
- The Perin Health Patch may need to perform a software update after pairing before it is ready to use. If so, the light will be a solid blue until the software update is complete.



Applying the patch

⚠ Proper skin preparation is required to achieve the full length of prescribed monitoring duration.

1. Locate the primary application site on the upper left chest, two inches below collar bone, and close to the sternum (breastbone). Be sure to choose a location with intact skin. The Perin Health Patch should not be applied to compromised skin. If the Perin Health Patch cannot be placed on the primary application site, use the secondary application site instead. The secondary application site is located just left of the centerline, below the chest on the rib cage.



LEFT- Primary application site. **RIGHT**- Secondary application site.

⚠ Only place the Perin Health Patch on intact skin. Do not place on broken skin including wounds, sores, or abrasions.

2. Prior to application, remove any body hair using an electric trimmer. The electric trimmer minimizes skin irritation. Remove all hair over sternal area by shaving close to the skin. Do not merely clip hair. The prepared area should extend 2 inches past where the Health Patch will be placed.

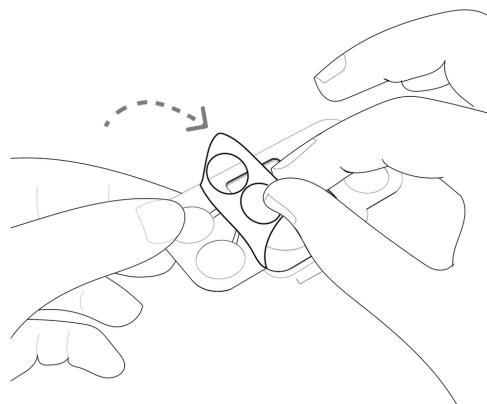


3. Cleanse the area with a warm, damp cloth. After drying, clean the area again with an alcohol wipe until the skin appears clean. Let the skin dry for additional 20 - 30 seconds. The skin should be free of oily residues, soaps, lotions, other products, and sweat.



4. Gently peel the liner from the adhesive patch.

⚠️ Avoid any unnecessary contact with the adhesive when removing the liner.



5. Adhere the Perin Health Patch to the upper left chest placement area near the sternum. Apply pressure for 15 seconds. Be sure to apply pressure around all adhesive areas.



Once adhered to the chest and connected with the mobile application, the Perin Health Patch will begin transferring data.

⚠️ The adhesive may cause adverse skin reactions. Remove the Health Patch immediately if severe discomfort or irritation occurs.

Seek medical attention if either of the following occurs: (1) a severe adverse event or (2) an allergic reaction persisting beyond 2 - 3 days.

⚠ Do not throw the outer box away. You will need to use it to return the equipment and supplies.

Calibration Measurements

Some of the measurement outputs of the Patch require calibration before they can be properly used.

⚠ Failure to properly calibrate the Patch may result in incorrect or inaccurate data.

Posture Calibration

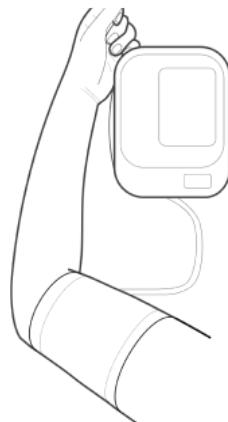
In order to calibrate for posture, you will be asked to sit upright for 30 seconds. Follow the instructions as provided in the mobile application. Your clinical team may help you with this at the time of enrollment.

- When ready, select 'Begin Calibration' on the mobile application. You will be asked to remain still and upright for 30 seconds.
- The mobile application will provide a visual and auditory notification when the 30 seconds has been completed.
- If significant motion was detected during the recording, you may be prompted to re-do the recording.

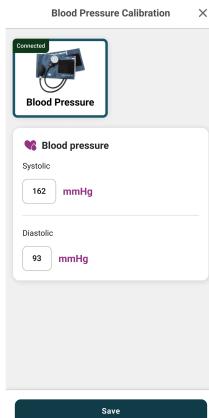
Blood Pressure Calibration

In order to calibrate for blood pressure, you will be asked to take a blood pressure reading with a standard blood pressure cuff. Follow the instructions as provided in the mobile application. Your clinical team may help you with this at the time of enrollment.

- Select your method of entry: manual blood pressure entry with a standard blood pressure cuff, or wireless entry using a Bluetooth enabled blood pressure cuff.
 - If wireless entry was selected, be sure that your device is paired with the mobile application. Select the device from the list of devices in the application and connect.
- Place the cuff on your upper arm and secure the cuff above your elbow, as shown below.



- Begin the measurement. The cuff will inflate and deflate.
- If manual entry was selected, input the values into the fields in the mobile application. If wireless entry was selected, the fields in the mobile application should automatically populate.



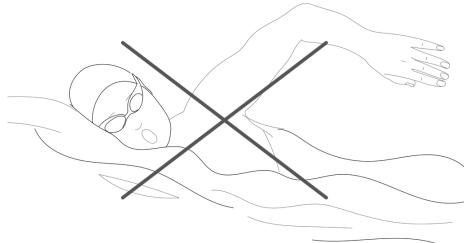
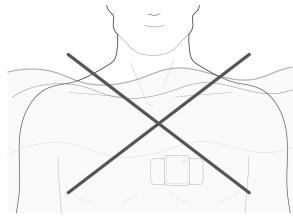
Temperature Response

The temperature sensor needs 30 minutes in order to stabilize to your skin temperature. Nothing is needed from you during this time. Measurements for temperature will not be shown until stabilization is reached.

During monitoring period

- Gently double tap the Perin Health Patch if you feel symptoms and would like to trigger a recording to send to your provider. Using the Perin Health mobile app, describe in a few words how you were feeling when you triggered the recording.
- If the Perin Health Patch becomes dirty, you may gently wipe exterior of device using a clean, dry cloth.
- Go about all daily activities while wearing the Health Patch.

 Avoid submerging the Perin Health Patch in a bathtub or swimming pool.



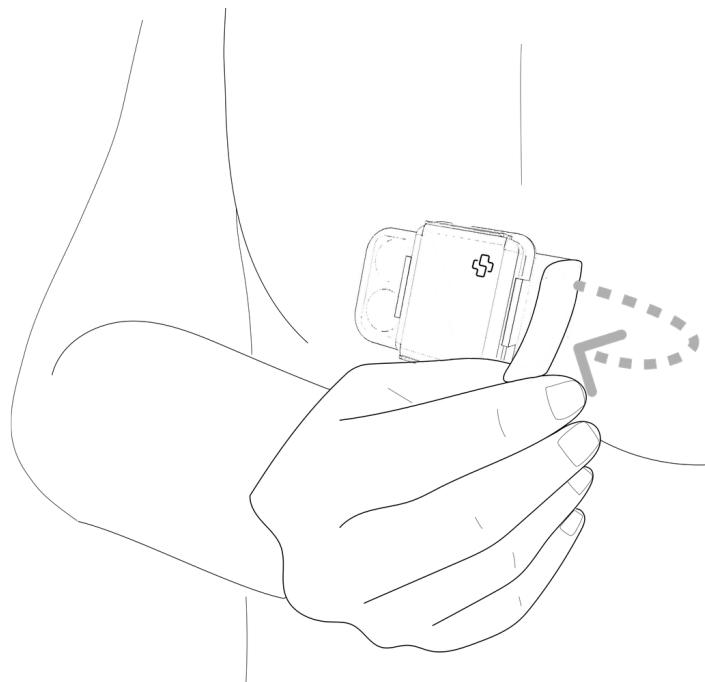
- Replace your adhesive when it is no longer sticky or if you experience redness or irritation the placement area. Each adhesive patch is intended to support up to 21 days of wear.
- Replace your battery when you receive a notification from the mobile application that the battery is low.

Changing the patch

Change the adhesive patch if it begins to loosen. Patches should last approximately 14 days. 3 adhesive patches are included.

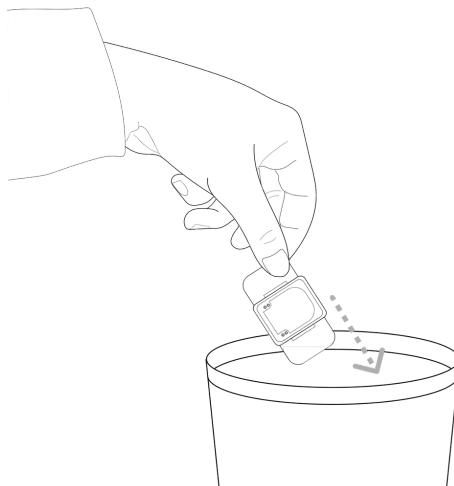
To change and apply a new patch:

- Remove the electronic modules from the clip and set aside.
- Remove the patch by pulling the adhesive layer away from your body.
- If the patch is difficult to remove, use the provided adhesive remover. Apply adhesive remover around the edges of the patch and slowly pull one end of the patch away from your body. Continue to apply adhesive remover until the entire adhesive is removed.

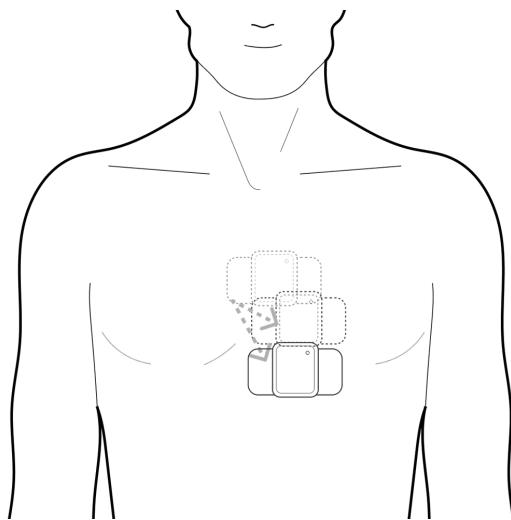


- Discard the used patch.

⚠ Do not discard the Sensor Module.



- Cleanse the skin. Ensure all adhesive residue is removed from skin by using the provided adhesive remover.
- Cleanse the sensor module with an alcohol wipe or warm, damp cloth to remove any visible dirt.
- Reapply the Health Patch following the steps above. If the skin is broken or irritated, you should apply the Perin Health Patch to a slightly different location within the placement area. Refer to section 'Applying the patch.'

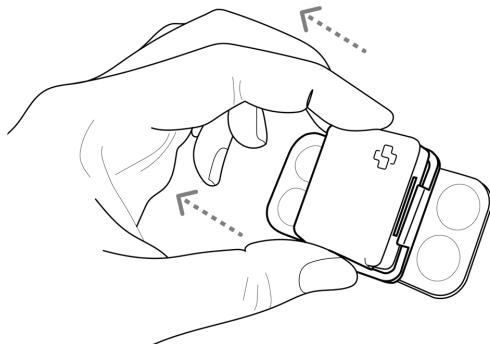


Replacing the battery

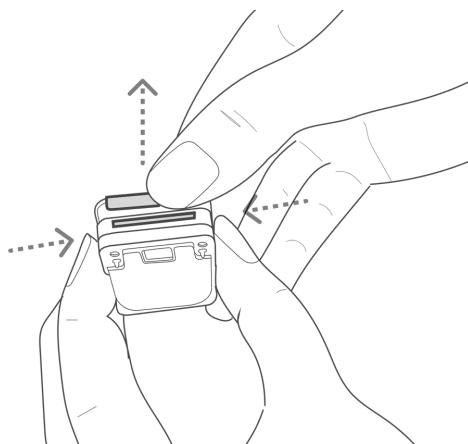
The Perin Health Patch will blink red during recordings to indicate low battery.

When the Perin Health Patch battery is low, the mobile application will provide a notification. Replace the battery by the time indicated on the notification to minimize data loss.

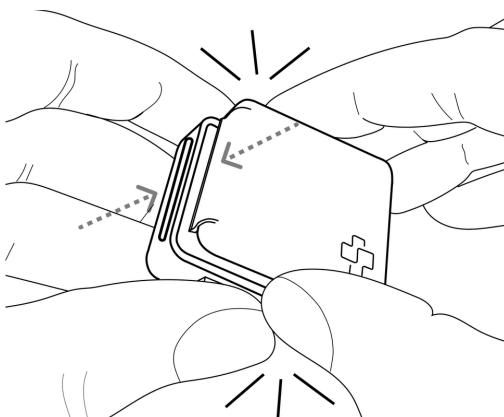
To replace the battery, remove the old battery pack by lifting the tab on the bottom of the device. Insert the new battery pack until you hear a click.



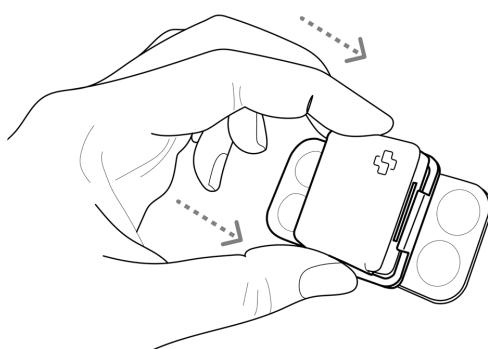
Remove the sensor module



Remove the battery



Insert new battery



Attach to the patch

- ⓘ If you are having trouble placing the battery, try turning the battery 180 degrees. There is only a single orientation that the battery can snap into the housing.

Batteries for household use in small quantities can be disposed of with normal household waste after their use, in accordance with any local regulations that may apply. Larger quantities of batteries for commercial use should be in a discharged condition prior to their disposal and

should be shipped to a hazardous waste facility for incineration.

End of monitoring

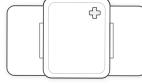
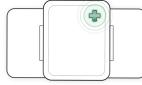
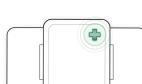
After your monitoring period is complete, remove the Sensor Module from the adhesive clip and set aside. Peel the adhesive patch from your skin as directed above and discard. Refer to the 'Returning Equipment' section for instructions on how to return the Sensor Module. Other than returning the Perin Health Patch, no other actions are required.

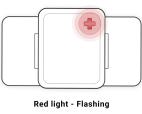
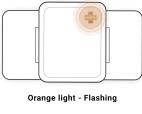
Returning the equipment

The Sensor Module should be returned upon completion of service. You will need to use it to return the equipment and supplies. There is no cost to you to mail back the equipment.

When you are ready to return the Health Patch, separate the battery from the sensor module. Pack sensor module and place into the kit. Seal the kit shut and follow the return instructions for shipping the kit to Perin Health Devices.

Troubleshooting

Light Indicator Guide			
Color	Behavior	Description	Next Steps
 No light	--	Sleep mode.	To confirm patch has battery and is operating correctly, check the mobile application. Alternatively, gently double tap on the device to turn the device on and initiate a recording.
 Blue light - Flashing	Flashing every 2 seconds.	Sensor is on and waiting to pair with a mobile phone.	Follow instructions to pair with your phone.
 Blue light - Solid	Solid.	Sensor is undergoing pairing process and, if needed, the software update process. The process should only take a few minutes.	The Patch can be applied to the body during this time.
 Green light - Flashing	Flashes 3 times.	Successful pairing of sensor and mobile phone.	Follow the remaining setup instructions in the mobile app.
 Green light - Solid	Flashes 3 times after a double tap.	A measurement was successful triggered manually and is being recorded.	A notification will be provided on the user's mobile phone when the measurement is complete. Add a brief description in the app explaining why the measurement was

			triggered for provider review.
 Red light - Flashing	Flashing every 3 seconds during a recording.	Low battery.*	Replace the battery pack. Refer to 'Replacing the battery' section.
 Orange light - Flashing	Flashing every 3 seconds during a recording.	Failure with the Health Patch identified.	Refer to the mobile application for troubleshooting. If the problem persists, contact technical support within the Settings page of the application.

* More frequency battery status notifications are provided by the mobile application.

FAQs

Can I shower or exercise with the Perin Health Patch? Yes, the Perin Health Patch is water resistant and can be worn during showers and exercise. Do not apply any deodorant or lotion to the placement areas as it will reduce adhesion of the Perin Health Patch to the skin.

Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry the Perin Health Patch after showering. Do not submerge the Perin Health Patch or use while in a sauna.

Can I swim or bathe with the Perin Health Patch? No, do not swim or bathe with the Perin Health Patch. The Perin Health Patch is water resistant, not waterproof. If planning to be submerged in water, it is recommended that the sensor module is removed from the clip while the adhesive patch remains adhered to the skin. After submersion is complete, dry the patch and re-install the sensor module.

I'm experiencing some skin irritation, what should I do? Minor skin irritation and itching may occur while wearing the Perin Health Patch. If a severe reaction develops (i.e. hives or blisters), discontinue wearing and contact your physician.

How long should I wear my Health Patch? The Perin Health Patch should be worn for the entire monitoring period prescribed by a health care provider.

How do I know my Perin Health Patch is working? Refer to the mobile application to access the most recent reading time and battery level, and any Perin Health Patch notifications. If additional confirmation is required, gently double tap the Health Patch to initiate a measurement. The indicator light will blink **green** 3 times at the start of the recording. If a different color is blinking, refer to the Indicator Light Guide table above.

I've tried powering on the Perin Health Patch several times and the light won't blink blue. What should I do? The Perin Health Patch may have gone to sleep after 5 minutes of inactivity after first turning on the device. Gently double tap the top of the Perin Health Patch to turn on and initiate pairing. If the problem persists, contact Customer & Technical Support in the Settings page of the mobile application.

Travel Information

Please retain the travel card in this document when traveling. The travel card provides TSA authorities with information about the Perin Health Patch to avoid patch removal during airport security checks.

1. The individual in possession of this travel card is using the Perin Health Patch, a prescription-only, continuously recording and non-transmitting medical device that contains a lithium-ion battery.
2. If you travel by aircraft while wearing the Patch, please show TSA authorities this card at the security checkpoint and let them know this cardiac monitoring device:
 - Is attached to your skin and cannot be removed or else it will prematurely end your service.

- Does not transmit data wirelessly in a manner that would impact travel safety.
- Contains a lithium manganese dioxide battery that can be carried on to the plane per FAA regulations regarding lithium batteries.*

If you are traveling outside the U.S. anytime during your monitoring period, contact Patient Services for assistance, Mondays–Fridays from 8am–8:30pm ET and Saturdays from 8am–4:30pm ET.

If you need assistance during your monitoring period, contact Patient Services for assistance, Monday–Friday: 8am–8:30pm ET and Saturday–Sunday: 8am–4:30pm ET.

* For more information, visit [Federal Aviation Administration](#)

Symbol Library

Perin Health Devices products display one or more of these symbols and warning labels.

Symbol	Title
IP44	Protected from objects > 1 mm and from water splashing against the enclosure from any direction
	Follow instructions for use
	MR Unsafe
	Do not use if package is damaged
	Single use only
	Type BF applied part
	Caution, consult documents
	Non-sterile
	Non-ionizing radiation
	MR Unsafe

Rx ONLY	Prescription use only
	Separate collection for electrical and electronic equipment (WEEE).
	Temperature limits (storage)
	Humidity limits (storage)
	Serial number
	Catalogue number (model number)
	Batch code
	Use by YYYY-MM-DD
	Consult instructions for use. Instructions/Directions for Use are available in electronic format at help.perinhealth.com
	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Atmospheric pressure limitation
	Not made with natural rubber latex

	Medical device
FCC ID:	Identifies unit has been certified as a radio device
	Bluetooth
	Unique device identifier
	Body weight
	Keep dry
	Indicator for signal inadequacy when measurements are taken. The values from measurements with these indicators should be interpreted with caution.
	Indicator for when data update period for pulse oximetry exceeds 30 seconds

Technical Specifications

Product Name	Perin Health Patch
Model Number	PHD80060
Device classification (EN 60601-1)	Internally Powered, Type BF applied parts, not protected against defibrillator, no functional earth terminal
Enclosure protection degree	IP44 (when the sensor is firmly connected to a compatible adhesive patch)
Battery	<p>Lithium Manganese Dioxide (LiMnO₂)</p> <p>Certified by UN 38.3, UL 1642, IEC 60086-4:2014.</p> <p>Nominal capacity: 600 mAh</p> <p>Nominal voltage: 3 V</p> <p>Capacity: 10 days of continuous use, 90 days of intermittent use for measurements every 30 minutes.</p>

	See "Replacing the Battery" for more details on mode of insertion.
Primary application site	Upper chest, below the left collarbone
Secondary application site	Left anterior axillary line, below the breast or pectoral muscle
Biocompatibility	Compliant to ISO 10993-1, 10993-5, 10993-10, 10993-23.
Service Life	24 months from manufacturing date
Shelf life	24 months from manufacturing date
Data storage	30 days onboard while disconnected
Recording capacity	Up to 48 hours of continuous data
Recording format	Continuous or semi-continuous based on physician settings

Physical characteristics

Approximate dimensions	Combined unit: 45 (L) x 80 (W) x 12 (H) mm Electronics module: 40 (L) x 30 (W) x 12 (H) mm.
Weight	19g
Enclosure material	Polycarbonate Color: White Texture: Semi-gloss Thermoplastic Elastomer Color: Grey Durometer: 60A Texture: Semi-gloss.
Adhesive	Duration: up to 21 days Thickness: 0.2 mm Biocompatibility: ISO10993 certified

Temperature performance characteristics

The Perin Health Patch measures skin temperature at the point of the patch placement (direct mode).

Skin Temperature Range	15 - 50°C
Skin Temperature Accuracy	±0.3°C
Resolution	0.008°C
Transient response	30 minutes

Compliance	ISO 80601-2-56
Measurement Mode	Direct

ECG Performance characteristics

ECG channels	1 channel
Sampling rate	512 Hz
Resolution	18 bits
Frequency response	0.4 - 150 Hz
Input impedance	XXX
Heart Rate Range	30 - 200 bpm with Root Mean Square Deviation (RMSD) \leq 5
Dynamic range	-10 mV to +10 mV
Compliance	ISO 80601-2-25, ISO 80601-2-47

Angular Position/Vibration

Bandwidth	100 Hz
Range	± 2 g
Fall detection	Fall or no fall (> 90% sensitivity and > 98% specificity)
Step count	< 5% Absolute Error Compared to Manual Count
Posture detection	Lying down, upright, walking, running, or leaning (> 70% accuracy compared to visual)

Optical (photoplethysmography) performance characteristics

The Perin Health Patch is indicated for the noninvasive spot checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) for adult patients during no motion conditions.

The Perin Health Patch has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70% to 100% SpO₂ against a laboratory co-oximeter. A functional tester cannot be used to assess accuracy.

The Perin Health Patch has been validated for pulse rate accuracy for the range of 25 bpm to 240 bpm in bench top testing against a simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%.

The emitted wavelengths range from 600 nm to 940 nm and the peak optical power is less than 10 mW. Information about the wavelength range can be especially useful to clinicians.

4 output channels:

- 1 IR (940 nm)
- 1 Red (650 nm)
- 1 Green (530 nm)
- 1 Blue (470 nm)

1 input channel:

1 broad spectrum photodiode

22-bit resolution and auto gain adjustment

Display Ranges

Parameter	Display ranges
SpO₂	70% - 100%
Arterial oxygen saturation	$\pm 3\%$
70% to 80%	
80% to 90%	
90% to 100%	
Pulse rate	30 - 200 bpm
Pulse rate accuracy	± 3 bpm
Compliance	ISO 80601-2-61

SpO₂ Accuracy

Condition	Range	Population	A _{RMS}
No motion	70% to 100%	Adults	3.3%

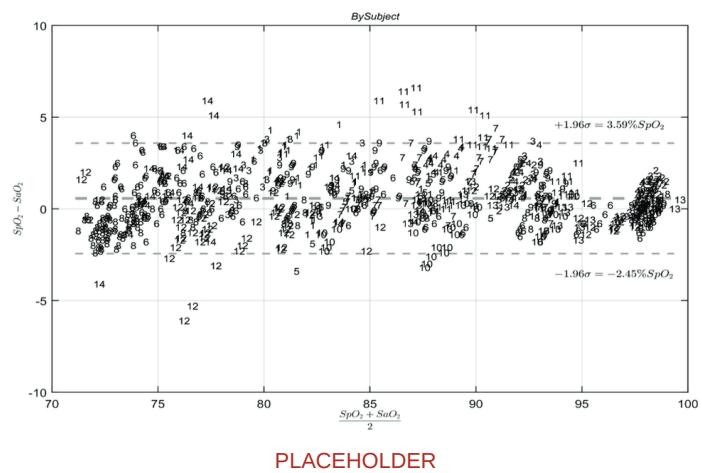
- A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- A_{RMS} of the reference measurements in a controlled study.

Pulse Rate

Condition	Range	Population	A _{RMS}
No motion	30 to 200 bpm	Adults	3 bpm

Respiration Rate

The below Bland-Altman plot represents the correlation of $(SpO_2 - SaO_2)$ versus $(SpO_2 + SaO_2)/2$ under no motion with an upper 95% and lower 95% limits of agreement.



SPO2 Performance Specifications

The ARMS (accuracy root mean square) values measured using the Perin Health Patch in a clinical study under no motion conditions.

	Range	A_{RMS}
Measured A_{RMS} value	90% - 100%	1.08%
	80% - 90%	1.95%
	70% - 80%	1.79%
Overall claimed accuracy value	70% - 100%	2%

Acoustic performance characteristics

Total harmonic distortion	< 0.25%
Signal-to-noise	65 dBA
Frequency range	55 - 2000 Hz
Sample rate	4 kHz
Resolution	16 bit
Auto-gain control	2.5 - 40x

Bioimpedance Characteristics

Respiratory Rate Range	10-30 Breaths per Minute with a mean absolute error of less than 1.5 Breaths per Minute, validated by clinical studies
	4-60 Breaths per Minute with a mean absolute error of less than 1.5 Breaths per Minute, validated by simulation studies

Blood pressure characteristics

Systolic	60 to 250 mmHg ± 5
Diastolic	40 to 150 mmHg ± 5

Electrode Characteristics

Number of electrodes	2
Type	Dry
Supplied as	Disposable, non-sterile
Materials	Ag/AgCl electrodes, Ag wire connections

Long term storage

Temperature Range	-20°C to 50°C
Humidity Range	10 to 75% RH
Atmospheric Pressure	70 - 102 kPa

Safe exposure for short term storage (< 6 hours)

Temperature Range	-40°C to 60°C
Humidity Range	10 to 95% RH

Operating conditions

Temperature Range	0°C to 40°C
Humidity Range	10 to 75% RH
Atmospheric Pressure	70 - 102 kPa
Dustproof and Waterproof Rating	IP24

Communications

Communication Technology	Bluetooth (BT5.4)
Distance ¹	Max. 10 meters (30 feet) line of sight
Radio Modulation	GFSK (Gaussian Frequency Shift Keying)
Radio Frequency	2.4 - 2.5 GHz
Transmit Power	0 dBm
Security	AES-CTR 128 bit encryption (Advanced encryption standard counter mode)
Data transmission rate	Minimum packet rate of 0.0167 Hz (1/60 Hz)
Max output power	-4.387 dBm (Peak)
EIRP	-3.89 dBm
Antenna peak gain	0.5 dBi typical
Antenna average gain	-0.5 dBi typical
Antenna return loss	0 dB minimum
¹ CAUTION: In order to maintain Bluetooth connectivity with the host device ensure that Perin Health Patch is within specified distance and line of sight of the host device.	

FCC ID: 2BKSW-PHP-0124

Note:

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.
- Consult the dealer or an experienced radio/TV technician for help.

Note: When using the Health Patch consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

Note: Change or modifications that are not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Note: The frequency bands of this device (2.4 GHz) are only for indoor use, in accordance with international telecommunication requirements.

Safety and Regulatory Information

Electromagnetic Emission Declaration

The Health Patch is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The ME Equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Health Patch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

FCC Compliance (FCC ID: 2BKSW-PHP-0124)

The Health Patch 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 (FCC Title 47, Subpart A, Part 15.19(3)).

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21).

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF Exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Recommended separation distances

Recommended separation distance between portable and mobile RF communication equipment and the ME equipment

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d = 1.17 * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 * \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.7	7.37
100	11.7	23.3

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 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.

Guidance and manufacturer's declaration - electromagnetic immunity

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment 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 +/- 15 kV air	+/- 8 kV contact +/- 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 typical location in a typical hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			

Immunity test	IEC 60601 Test Level	Compliance Level	Recommended separation distance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer 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



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 ME Equipment

is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Test specifications for enclosure port immunity to RF wireless communication equipment

2450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation (b) 217 Hz	2	0,3	28					
5240	5 100-5 800	WLAN 802.11 a/n	Pulse modulation (b) 217 Hz	0,2	0,3	9					
5500											
5785											
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.											
<p>(a) For some services, only the uplink frequencies are included.</p> <p>(b) The carrier shall be modulated use a 50% duty cycle square wave signal.</p> <p>(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p>											

Common EM Emitters

Specific common emitters may interfere with the function of the Health Patch. Users should avoid close proximity to EM emitters such as radio-frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), nearfield communications (NFC) systems, wireless power transfer and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. In the unlikely event of EMI, it is recommended that the user moveaway from EM emitter.

Disclaimer

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1. Privacy Policy
2. Service Level and Support Terms
3. Website, Application, and Product User Terms of Use.

You can find these policies at: www.perinhealth.com/terms

By using the Product(s), you indicate you have read these terms and policies and that you agree to them, including the limitations and disclaimers of liability. In particular, you understand and consent that use of the Product(s) measures and records personal information about you, including vital sign and other physiologic measurements. That information may include respiratory rate, heart rate, temperature, activity level, sleep duration, body position, step count, gait analysis, coughing, and other symptomatic or biometric data. You understand that the Product(s) do not render medical advice or diagnose or prevent any specific disease, including any communicable disease or virus. If you have any concerns about your health, including whether you have been exposed to or have contracted any disease or virus, immediately contact your healthcare provider.

Contact Us

For non-urgent support or questions about our product, please contact us through the Perin Health mobile application, email support@perinhealth.com or call xxx.xxx.xxxx (US).

 Manufactured for

Perin Health Devices, LLC (DBA Perin Health)

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