SKIIN | Operations and Safety Manual

Before using Skiin Underwear, please read this manual.

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LB00039
Rev. 001

Trademarks

Myant trademarks:
Skiin

Warranty information

The Skiin underwear Biomonitoring device and its accessories, when supplied and delivered new, in the original device to the original purchaser, are covered under a one-year warranty that covers damage due to defective materials and or failure of the equipment to operate in accordance with the information in this Operation and Safety Manual for Skiin Underwear.

Version information

System: Skiin Underwear
System Software: Skiin Connected Life App Version 1.0.0
Operation and Safety Manual for Skiin Underwear System Revision 1.0
original instructions PP002

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1. Introduction

This *Operation and Safety Manual* for Skiin Underwear System provides instructions for the safe and efficient use of the Skiin Underwear system for biometric monitoring Application.

Skiin Underwear uses textile electrodes embedded in the waistband with electronics in the Skiin Pod to measure and analyze your ECG. The underwear is machine washable and can be laundered with your other clothes (use the included wash bag).

Medical Version Only
Skiin Underwear continually tracks your activity, stress, and sleep quality to help you improve your wellness. It includes Health Canada Approved continuous ECG Monitoring. The underwear has been clinically validated and developed with doctors and users.

The ECG data captured from the Skiin Underwear system is to be used by qualified cardiologists, and trained clinicians to supplement ECG data captured by other methods. The data can also be used by individuals curious about their health and physiology. The Skiin System is used with a user-supplied compatible smart device.

WARNING EN-W1 ⚠	Unauthorized modification of this equipment is not permitted and may compromise the safe operation of the equipment.
NOTE EN-N1 !	Follow the instructions in this booklet to learn how to use and take care of your Skiin Underwear system.

Operators of the system will be able to benefit from the Skiin Underwear system's non-invasive form factor and ability to record continual data which can be analysed for cardiac abnormalities.

2. Essential Performance

The essential performance of the Skiin Underwear system is the ability to monitor and export ECG raw data to generate an accurate report of the patient's ECG through a 3rd party tool.

3. Indication for Use as a Medical Device (Medical Device Version Only)

The Skiin Underwear is indicated for users in need of remote monitoring and aiding the identification of potential cardiovascular issues by skilled medical professionals through a 3rd party reporting tool. The medical features for ECG monitoring of this product are not to replace traditional methods of diagnosis or treatment. Wellness features such as activity, temperature, respiration rate, sleep quality, mood and stress and not indicated to use as a medical device.

Contraindications

The Skiin Underwear is not for use by:

- Persons under 18 years of age
- Pacemaker and/or (ICD) implantable cardioverter defibrillator users
- Pregnant Women

⚠ *Risks for children and individuals requiring assistance*

This device is not intended for use by children. Do not leave the device near babies, infants or children. This device is not intended for use by individuals with limited physical capacities or limited experience and / or knowledge unless

they are supervised by an individual responsible for their safety or receive instructions from the latter as to how the device should be used.

4. Intended Use as a Medical Device (Medical Device Version Only)

1. The Skiin Underwear is intended for users 18 years of age or older, through over the counter or prescribed by a healthcare provider to record and monitor continual ECG data usable for a 3rd party reporting tool at static positions and shared with their circle of care, which includes skilled medical professionals.

2. The Skiin Underwear is intended for users 18 years of age or older, through overthe counter or prescribed by a healthcare provider to record and monitor continual ECG data usable for a 3rd party reporting tool at static positions and shared with their circle of care, which includes skilled medical professionals. The ECG viewer is to confirm the presence of signal and not to be used for diagnostic purposes

Circle of care consists of the user's trusted connections who have an interest in the user's health or wellbeing, for example, family members, friends, or health care professionals.

5. Safety Information

Before using the Skiin Underwear system, please become familiar with the information in this *Operation and Safety Manual* and the *Quick Start Guide.*

WARNING EN-W2	Failure to follow safety instructions and/or using the equipment for purposes other than those described in Skiin Underwear *Labeling* constitutes improper use.
NOTE EN-N2	Information pertaining to the use of the Skiin Underwear system to perform the biomonitoring

6. Contents

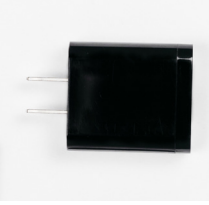
The standard configuration for the Skiin Connected Clothing System includes the following components:

(1) SKIIN POD

(2) USB CHARGING KIT

2.1 USB charging dock

2.2 A Micro-usb Cable



2.3 A Wall Plug

(3) SKIIN UNDERWEAR

Each kit has:

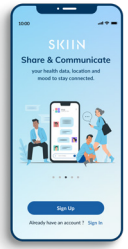
1. A 'Try me On' underwear that you must try first to check for fit before opening the other pairs.
2. PK0001 has 4 pairs of underwear

(4) WASH BAG

(5) QUICK START GUIDE

(6) SKIIN CONNECTED LIFE APP

The Skiin System is used with a user-supplied compatible smart device.



NOTE N-N4	Some features described in this guide may not be available with your configuration of Skiin Underwear.

WARNING: Use of accessories, and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

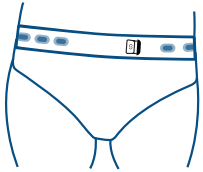
7. Concept of Operation

The Skiin System collects your bio-signals such as heart rate and steps. It is recommended to keep your smart device close to you whenever possible. When you put on the Skiin underwear, it can start sensing your heart rate and physical activity, which will be captured and stored as data by Skiin Pod and transmitted to the Skiin Connected Life App. As you use the Skiin underwear you become part of the Skiin Connected Clothing System and your health information is stored securely so you can view it from your App at any time.

8. Getting Started

STEP 1: TRY THE UNDERWEAR

Open the 'Try me On' box and put on the underwear to check the fit. It is important to ensure your underwear is the correct size, as good contact of the sensor zones in the waistband with the skin surface is required to get a good signal for ECG recording. Proper fit will ensure accurate heart rate readings. Your underwear should be snug, that means it will not ride up, twist, or slip down. When trying on the underwear, the band should not constrict or dig into the body. The waistband should sit comfortably on your body and not be too tight or too loose.



Located in the waistband are 5 sensor zones, 3 on the left hip and 2 on the right hip. Make sure the five sensor zones located in the waistband of the underwear are in contact with your skin. If your skin is too dry, it may affect the performance of the electrodes.

Apply a water-based (not glycerin-based) moisturizer to improve the performance. Wash your underwear after each wear as sweat, dead skin and dirt build up can prevent the electrodes from functioning properly. Ensure all components are dry prior to use, do not operate while wet or moist.

NOTE EN-N3 !	The underwear without the 'Try me On' label on the box, cannot be returned if opened.

If the underwear does not fit, visit www.Skiin.com/returns for instructions on how to return or exchange for the correct size.
You may return the unopened boxes of underwear to exchange for the correct size. Please visit www.skiin.com/faq/returns for more information.

The following sizing charts show waist measurement per size. The waist measurement should be taken around the hips, keeping a relaxed posture without holding in the abdomen.

Size	Range (Inches)
Women's	
XS	29.5-32
S	32-34.5
M	34.5-37
L	37-40.5
XL	40.5-45

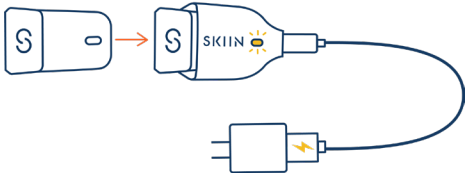
Size	Range (Inches)
Men's	
XS	30-32.5
S	32.5-35
M	35-37.5
L	37.5-41.5
XL	41.5-45

STEP 2: FIND & CHARGE THE SKIIN POD

Use the supplied charger to charge the Pod. Insert the Pod into the Charging dock. You should feel the magnets pulling the Pod followed by an audible "Snap". Connect the Charger and the Wall Outlet using the micro-USB cable and plug it into a power source. When the light on Pod shows magenta color, the Pod is activated. Take out the pod from the charger, you should see a blinking yellow light and it is ready to be paired.

NOTE EN-N4 !	It takes Approximately 1.5 hours for the Pod to be fully charged from a discharged state.

The blinking yellow light on the Pod indicates that it is now ready to be paired with your phone. Proceed to Step 3 to continue setup.

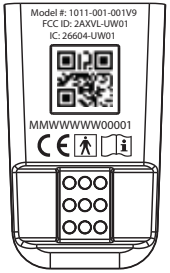


STEP 3: DOWNLOAD THE SKIIN CONNECTED LIFE APP

On your smartphone, download the Skiin Connected Life App from the Apple App Store or the Google Play Store. Open the App and follow the onboarding steps to setup and pair the Skiin Pod, start logging your health data and connect to the Skiin System.

Please refer to the Skiin website (https://www.Skiin.com/#compatibility) for the latest list of compatible devices and operating system versions:

1. Open the App on your phone.
2. Create an account, or login with your Skiin username and password.
3. Set up your account.
4. Activate your Skiin Pod by charging it. Your Skiin Pod should be partially charged when received. Charge the Skiin Pod using the provided charger (see Section 8, step 2,. Charging Instructions).
5. Ensure that Bluetooth has been enabled on your phone. In the Skiin Health App, proceed to the Devices Page and select 'Add a new device' on the screen. Connect the Skiin Pod to the App using QR Code or by using the Pod's ID. The App will indicate when the Skiin Pod is connected, and the light on the Skiin Pod will change from a blinking yellow light to blinking blue light.



Picture of Pod with Model Number, FCC, IC ID, Serial Number and markings

6. Slide the Skiin Pod into the Garment dock i.e. a small rigid pocket in the waistband of the underwear, located on the waistband of the underwear. The magnets will help automatically snap the Pod into the Garment dock.
7. The App should begin sensing your ECG signal. The Skiin App will show you a demo of this.

9. Skiin Underwear System Components

9.1 SKIIN POD

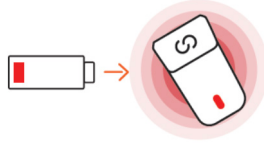
WARNING EN-W3	Only the components listed in this section may be connected to the Skiin Underwear system. If components other than those specified in this section are connected to the system, the Skiin Underwear software may fail and cause injury to the patient or operator.

Your Skiin Pod records and securely sends your health information to the Skiin Connected Life App. Pair it with your phone, then slide it into the Garment dock. The Pod will easily 'snap' with the magnets when inserted in the underwear dock. The Skiin Pod has an LED light that changes colours to indicate different states of charge and connection.

CAUTION EN-C1	Remember to remove the Pod from your underwear before washing.

Low battery

The Pod's LED blinks RED when the battery is low and the Pod should be charged. Use the Skiin Connected Life App to see the detailed Pod battery level.



9.2 SKIIN CHARGING KIT

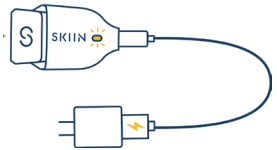
Charging The Pod

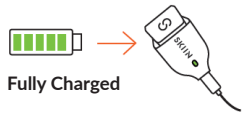
When the Pod is inserted into the charging dock and connected to a power source, the Pod's LED will Appear YELLOW to indicate that the Pod is currently charging. The Pod's LED will remain on and show a yellow light until the Pod has fully charged. We recommend that you fully charge the Pod for 1.5 hours before using.

Fully Charged

If the LED appears GREEN while charging, this indicates the Pod is fully charged and ready to use.

NOTE EN-N5	While the Pod is charging it will not indicate Bluetooth connection status through the LED light. Do not try to pair the device while charging.





- Magenta: The Pod is activated.
- Yellow: The Pod is not fully charged.
- Green: The Pod is fully charged.
- Blue: The software on the Pod is being updated.
- Red: A hardware issue is detected, contact support@skiin.com for assistance.

Pod Connected State

Once the Pod is connected to your phone via Bluetooth the Pod's LED turns into a BLUE blink, once every second, indicating that it is connected.

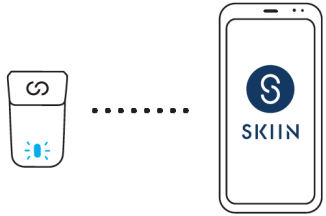
Pod Disconnected State

If the Pod has no Bluetooth connection the Pod's LED blinks yellow indicating that the Pod is not connected and is searching for a connection.

Please check your phone settings to ensure that Bluetooth is activated or launch the Skiin Connected Life App to check the connection status.

Turning the device on/off

The Skiin Pod is always "ON" as long as it is charged and has power. You cannot turn the Skiin Pod OFF, but you can unpair it from your phone in order to stop transmitting data. Refer above to Pod Disconnected State.
To unpair your Pod, on your Skiin App, in the Devices page please open the Device Settings for the chosen Pod and select unpair.



- Solid Blue: The software on the Pod is being updated.
- Single Blink Blue: The Pod is connected to the App.
- Single Blink Yellow: The Pod is NOT connected to the App.
- Single Blink Red: Low battery level & the Pod is connected to the App
- Rapid Blink Red: Low battery level & the Pod is NOT connected to the App

Data Storage and Syncing

Your Skiin Pod will automatically sync data to your smart device when it is within range and the app is opened or in the background.

When out of range or disconnected from your phone, the Skiin Pod will store ECG data for up to 45 minutes and wellness data for up to 24 hours depending on the amount of data saved. When your phone reconnects ,your data will continue to sync again. It is recommended to keep your smart device close to you whenever possible to avoid data loss.

Cleaning the Pod

Do not wash the Pod or Charging dock, USB cable or power cube, or immerse them in water.
The surface of the Pod can be wiped clean with a soft, moistened cloth. Do not use any abrasive or solvent based cleaners.

Storing Pod

Store the Pod in a clean, dry, safe location.
Do not store in extremely hot, cold, humid, wet, or bright conditions.

Resetting the Pod

Insert the pod into the charging dock, locate the pinhole under the charger. Use a pin to press into the hole and hold until the LED flashes to indicate it is reset.

9.3 SKIIN UNDERWEAR

Materials

Our Skiin garments can be washed just like regular clothing.
The underwear band includes Carbon and Silver yarns. Carbon yarn is used in the textile electrodes of the band and it serves as a conduit to human skin. Conductive silver yarn is used to connect textile electrodes within the band to the textile integration system.
Underwear bottoms are made of 95% Bamboo / 5% Spandex - 260 GSM – Single jersey fabric. Bamboo is naturally antibacterial, comfortable, very breathable, moisture-wicking, fast drying and thermal regulating. Bamboo fabric is also anti-static so it doesn't cling to other materials.

The Band is made of 69% Nylon, 26% Spandex and 5% of other fibres.

EN-W13 ⚠	**Warning:** If you have an allergic or skin reaction please discontinue use and contact customer support at support@Skiin.com. If necessary you should seek medical attention.
NOTE EN-N6 !	If the Skiin Pod is not inserted into the underwear you are wearing, no data will be collected or transmitted.

Laundering Instructions

EN-C1 ⚠	Remember to remove the Pod from your underwear before washing.

Do not wash the Skiin Pod. Please remove the Pod from the underwear dock in the waistband before putting the underwear for wash.

To care and maintain your Skiin underwear follow the wash instructions on the wash bag.

- Before wearing the underwear for the first time, please wash it.
- Please wash after wearing the underwear for 24-48 hours
- Washing: To wash, remove the Pod and put all the underwears in the washbag, use cold water when washing. Do not use bleach or fabric softener.
- Drying: To dry the underwear, keep them in the washbag and dry on low.
- When you change your underwear, take out the Skiin Pod and place it in a fresh pair.

Do not Wring the Garment	Do not Wring the Garment	No Bleach, No Softener
Tumble Dry on Medium	Do Not Iron	Do Not Dry Clean

NOTE EN-N7	Remove the Skiin Pod from the band of the underwear, before washing the underwear. Don't air-dry the underwear. A machine dryer should be used to ensure elasticity and long use of the underwear.

Storing the Underwear

Store the underwear in a clean, dry, safe location. Do not store in extremely hot, cold, humid, wet, or bright conditions.

9.4 SKIIN CONNECTED LIFE APP

9.4.1 Sections in the App

The Skiin Connected Life App is used to record, display and store your health information.
The Skiin Pod can be paired with any android mobile device with Android OS 5.0 or above and any iPhone with iOS 11.0 and above. We recommend you use a mobile device which is compatible with Bluetooth 4.2 for the best App performance.

NOTE EN-N8	Your smart device must be connected to the Skiin Pod and the internet for full functionality.

Home

The Home page for the app provides a summary of your timeline including all biometric data and manual logs.

Devices

The Devices page lets you add and manage your Skiin devices. The connected devices on this page help capture the biometric data points of heart health, activity, sleep, stress and more vitals. You can see the real-time connectivity and status of your Skiin device here.

Connections

The Connections page helps you to connect, share and communicate with your friends, family and health care professionals. You can connect with your connections individually and also as a part of a group, sharing all your captured biometric and contextual data. When connecting with your Family, Friends and/or HCP (healthcare professional), you will be able to specify and control the data which you would like to share with them.
You can also reach out to your Contacts using a quick access button to initiate a message, audio call and video call.

Metrics

The Metrics page is where system tracked biometric data (through Skiin devices) is presented to you. The main page is presented in the form of cards for each biometric data parameter that is captured. It gives you a quick view of the most recent system-captured biometric for Heart Health, Activity, Sleep, Stress, Location and More Vitals.

ECG

The user can use the App to monitor their ECG (non-diagnostic) and generate ECG data for a third party to generate reports.

9.4.2 Getting Help

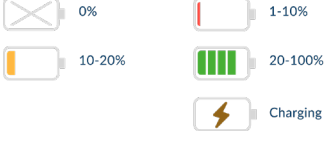
The *Preferences* > *System Information* screen allows the operator to access information including:

- Contact Information for Myant Technical Support
- Configurations for hardware, software, the activation key
- Message log export options

9.4.3 System State Messages

The Skiin Underwear software provides information to operators when unusual operating conditions occur that affect the *system state*. The type of condition determines the effect on the Skiin Underwear system state.

These are the symbols indicating battery level:



These are the symbols indicating garment signal quality:

These are the symbols indicating bluetooth connectivity:

NOTE EN-N9	For Technical Support contact us at: +1 (844) 501-0252 or support@skiin.com
NOTE EN-N10	In the event that an unexpected software error occurs, an error message will be displayed on the App.

10. Traveling with Skiin Garments

Flying while wearing a Skiin garment is straightforward. Simply show the security statement (below) during screening, and if required/or asked to remove the Skiin Pod from the Skiin garment dock to disable the Skiin System health data tracking for the time-being of travel. Skiin Pods contain lithium rechargeable battery and should not be included in checked luggages.

AIRPLANE MODE USAGE

To prevent the Skiin Pod from transmitting data, remove the Pod from the garment dock. Store it safely in your bag or pocket for use after your flight.

Post deboarding the airplane, to reconnect to the Skiin System again simply insert the Skiin Pod in the garment dock and make sure you turn on bluetooth service on your mobile device. Pair the Pod to the Skiin Connected Life App to get connected to the Skiin system again.

SECURITY SCREENING STATEMENT

This person is wearing a Skiin garment. This garment worn by the user tracks the user's ECG, heart rate, body

temperature, and other biometric data via the Skiin Pod. The Pod can be removed from the garment to stop the transmission of data to their Bluetooth connected mobile device for ease of screening while travelling if required.

If you have any questions, please contact the Skiin Customer support at support@skiin.com
24 hours/day, 7 days/week.

You're all set!
We love hearing from our users, send us an e-mail at feedback@Skiin.com or visit www.Skiin.com to let us know how we can improve your experience.
Want to order more pairs or see additional styles? Visit www.Skiin.com
For more information, visit www.Skiin.com

11. Limited Warranty

The underwear garment has a limited warranty of 30 days (on the date of purchase), and the Skiin Pod and accessories have a limited warranty of 1 year. If during this time the product malfunctions or does not perform as intended the user can request a new product to be shipped to them. Myant will only replace the defective part of the product after it has been returned and found to be defective due to normal use. Myant will not replace any products that have been tampered with or found to have been broken due to user negligence.
For information on how to submit a warranty claim please email support@Skiin.com.

12. Device Specifications

Performance Characteristics

ECG Channel.....3 Channels
ECG Dynamic Range.....+/- 400 mV Peak-to-Peak
Memory Recording Format .....64Mb Flash Memory
Warranty.....1 year
Frequency Range .....0.5 Hz to 40 Hz
CMRR.....80 - 100 dB
Input Impedance .....> 1 GOhm
Sampling Rate .....320 samples/second
ADC Resolution .....24 bits DC
Communication Interface Protocol.....Bluetooth Low Energy 4.2
Operating Frequencies.....2.4-2.48GHz
Frequency Deviation .....2 MHz/channel

Power Requirements

Battery Type .....Rechargeable Lithium Polymer
Battery Capacity.....200mAh, 2-3 days of use
Battery life .....minimum 24 Hours Operational Time, 1 year warranty

Physical Characteristics

Skiin Pod .....12.0 grams +/- 0.5g 27.9x46.5x10.6mm
Skiin Underwear .....Men's and Women's sizes range from 24" to 47"

Environmental Specifications

Operational Temperature .....5 to 45°C

Operational Humidity .....15% to 90%, non-condensing, water vapour partial pressure <50hPa
Operational Altitude.....700hPa to 1060hPa
Storage Humidity .....15% to 90%, non-condensing, water vapour partial pressure <50hPa
Storage Temperature.....-10C to 45°C (for 1 month) or -10C to 35C (for 6 months)

Ingress Protection Marking

Skiin Pod is IP22 rated, which means it is protected from touch by fingers and objects greater than 12 millimeters. It is also protected from water spray less than 15 degrees from vertical. Skiin Pod is compliant with standard IEC60601-1-11:2015.

Expected Service Life

The expected service life for the Skiin Pod is 2 years and 50 washes each pair of Skiin Underwear .

Warm up time

There is no warm up time but for optimal performance it is recommended that the user Applies moisturizer to the skin location where textile electrodes contact prior to use.

User Interface

Five textile electrodes are exposed on the inside of the waistband of the Skiin Underwear. These electrodes make contact with the user's skin. The Skiin Underwear Electrodes may be cold washed and tumble dried low 50 times without noticeable performance degradation.

13. Symbols Glossary

The tables in the following sections contain brief explanations of the safety symbols and other information used to label the Skiin Underwear system, its accessories, and its consumables.

Warnings, cautions, and notes are used to describe serious and non-serious conditions of the system. The symbols used to describe these safety conditions are:

WARNING EN-W#	Messages with this heading indicate serious adverse reactions, potential safety hazards, and limitations in use imposed by a condition. The warning will identify steps that should be taken if the incident occurs.
CAUTION EN-C-#	Messages with this heading indicate information regarding any special care to be exercised by the operator and/or patient for the safe and effective use of the device and to prevent damage. All caution statements should be followed to ensure data and system integrity.
NOTE EN-N#	Messages with this heading provide additional information that will increase the operator's understanding of the operation of the system.

Symbols on the Skiin Underwear System Device Label (Skiin Pod)

Symbol	Meaning	Symbol Reference
UDI	The unique device identifier (“UDI”); includes a production identifier segment that conveys serial number and manufacturing date	21 CFR 801.20
MMWWWWW 00001	Serial Number	
2AXVL-UW01	FCC Number	
26604-UW01	IC ID	
CE	CE Marking	
	Refer to operating instructions	ISO 15223-1, Clause 5.4.3 IEC 60601-1 symbol 10 in table D.2
	Type BF applied part	IEC 60601-1. Table D.1, Symbol 20 IEC 60417- 5333

Symbols on the Skiin Underwear System Package

Symbol	Meaning	Symbol Reference
	Legal manufacturer	ISO15223-1 symbol 5.1.1
	Date of manufacture	ISO 15223-1 symbol 5.1.3
REF	Manufacturer's catalog number	ISO15223-1 symbol 5.1.6
SN	Device serial number	ISO 15223-1 symbol 5.1.7
	Refer to instruction manual	IEC 60601-1 Table D.2, Symbol 10
	Indicates authorization under the FCC Declaration of Conformity procedure	FCC title 47, Part 18.209 b (symbol shown in 47 CFR 15.19 b)

	Temperature range limitation	ISO 15223-1 symbol 5.3.7
	Do not use the Skiin Underwear system if its packaging has been damaged	ISO 15223-1 symbol 5.2.8
NON STERILE	Non Sterile	ISO 15223-1, Clause 5.2.7 ISO 7000-2609
MR	MR Unsafe. Items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.	ASTFM F2503
	MR Unsafe. Items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.	IEC 60601-1-2:2007, Clause 5.1.1

14. Warning

EN-W4	Risks for children and individuals requiring assistance This device is not intended for use by children. This device is not intended for use by individuals with limited physical capacities or limited experience and / or knowledge unless they are supervised by an individual responsible for their safety or receive instructions from the latter as to how the device should be used.

EN-W5	Contraindication The Skiin Underwear is not for use by: Persons under 18 years of age. Pacemaker and/or (ICD) implantable cardioverter defibrillator users.
EN-W6	DO NOT expose the device to a magnetic resonance (MR) environment.
EN-W9	Do not ingest the Skiin pod, Skiin Charging Kit or Skiin underwear.
EN-W13	Warning: If you have an allergic or skin reaction, please discontinue use and contact customer support at support@skiin.com. If necessary, you should seek medical attention.
EN-W15	Do not operate the device if the device feels hot to touch

15. Cautions

EN-C2	Do not drop the device *It is important that the user takes care when handling the Pod. Repeated drops from 1m or over may damage and/or affect the performance of the Pod.*
EN-C3	DO NOT use in the presence of flammable anesthetics, drugs or pressurized oxygen.

EN-C6	The Skiin Pod contains magnets, use with caution around magnetic strips and metallic objects

16. General Safety Precautions

Explosion Hazard

WARNING EN-W8	The equipment is not designed to be used in potentially explosive environments. Do not operate the Skiin Underwear system in the presence of flammable liquids or gases.

Electrical Safety

CAUTION EN-C4	Do not spray or drip any liquid onto the Skiin Underwear system's Pod, as this could affect reliable operation.
CAUTION EN-C5	After a year of use, dispose of the Skiin Pod and Skiin Garments according to policies set out by your local governing authority
EN-W14	Do not use the Skiin Pod, or Skiin Charging Kit or Skiin Underwear if they are damaged in any way.

EN-W11 ⚠	Do not put your finger into the Skiin charger.
EN-W12 ⚠	Do not operate the device while wet or moist.
EN-W13 ⚠	Do not hold the Skiin pod, or Skiin Charging Kit directly to skin for extended periods of time

17. Other

HIPAA (the American Health Insurance Portability and Accountability Act of 1996) is a set of U.S. federal standards that ensure the privacy and security of all health-care related data. *Skiin underwear* is capable of preventing unauthorized access to patient data using password protection.

FCC Regulatory Statements

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.
(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the Federal Communication Commission (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 causes 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 doing 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.

NOTE: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

RF Exposure Warning

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED Regulatory Statements

This device complies with ISED Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

CAN ICES-3 (B)/NMB-3(B)

RF Exposure Information

This equipment complies with ISED RSS-102 radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Emissions Characteristic

NOTE The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table C.1 – Example Emission Class and Group Compliance

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.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The ME EQUIPMENT 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 ME EQUIPMENT 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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table C.2 – Example Immunity Test Level Compliance

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%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.

Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0,5 cycle 0% UT (100% dip in U_T) for 1 cycles 70% UT (30% dip in U_T) for 25 cycles 0% UT (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) 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 commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table C.3 – Example Immunity Test Level Compliance

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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz RF communication equipment inside 80 MHz to 6 GHz	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. **Recommended separation distance** $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.7 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 metres (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]
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 3 V/m.			

Table C.4 – Example Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications 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 communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.7 GHz**
w	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.12	0.12	0.24
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 metres (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.