INSTRUCTIONS FOR USE

zealacare

Smart Incontinence System

Table of Contents

Contents

Getting Started

About the Zealacare Smart Incontinence System

The Zealacare Smart Incontinence System is focused on creating comfort and peace of mind for individuals who are suffering from urinary incontinence. Our patented system offers notifications when a wet event has occurred, eliminating the guesswork and helping loved ones eliminate many of the negative side-effects of urinary incontinence. We are striving to lead the market with our unique products while allowing family members and patients to regain purpose in their lives.

The FDA registered Zealacare Smart Incontinence System consists of 3 different components:
1. Zealacare Comfort Briefs
2. Zealacare Smart Sensor and Inductive Charger
3. Zealacare Mobile Application

Zealacare Comfort Briefs
The Zealacare Comfort Briefs are the first smart briefs of their kind. While offering industry-leading quality, Zealacare Comfort Briefs contain two sensor strips that run the length of the diaper. These strips, when connected to the Zealacare Smart Sensor, are what allow individuals and caretakers alike to know when a wet event has occurred.

Zealacare Smart Sensor
The Zealacare Smart Sensor is a low power device that enables individuals and caretakers to receive real-time, customizable data surrounding wet events. Using Zealacare's proprietary technology, the sensor has the ability to not only recognize when a wet event has occurred, but the estimated saturation level of the diaper after the event has taken place. This allows individuals suffering from incontinence to gain a greater understanding of their incontinence needs while ensuring that care is given when needed.

Zealacare App
The Zealacare App is a simple and easy-to-use application that enables individuals and caregivers to track wet events and create a customizable experience. From customizable notifications based on estimated saturation levels, to our storefront integrated directly into

the app, the Zealacare App offers a variety of personalized features designed to enhance the user experience.

Setting Up The Zealacare App

Downloading and Creating an Account
1. Download the Zealacare App from the Google Play Store or the iOS Apple Store.
2. Follow prompts to sign up or log in to the app.
3. If signing up for the first time, a verification code will be sent to your email. After entering the code, you should receive a message telling you that your account has been verified.
4. You will be brought to a page that asks for "Account Owner Information":
5. Enter your first and last name into the marked boxes.
6. A congratulations screen will pop up. Proceed by clicking the "Get Started" button.

Creating a Home and Adding a Care Recipient
1. Enter a home name and the corresponding zip code of the home of the care recipient.
2. Enter required information for the care recipient.
3. Proceed to linking the Smart Sensor. If you have yet to buy a sensor, visit www.zealacare.com to purchase the sensor.
4. Refer to "Connecting my Zealacare Smart Sensor" for instructions on how to connect your sensor.

Adding Additional Caregivers
1. If someone other than the account owner is providing care to the care recipient, you may invite a guest caregiver by clicking the "Add guest caregiver" prompt on the home screen.
2. Enter the email of the guest caregiver.
3. A link will be sent to the caregiver allowing them to download the Zealacare App and create an account.
4. Once the guest caregiver goes through the sign-up process, they will automatically be linked to the account and will be able to begin providing care. You may need to click on the guest caregiver profile to adjust their permission settings and give access to specific care recipients.
5. To add additional caregivers or care recipients, click the + icon found in the top right corner of the screen.

Zealacare App Features

The Zealacare App has multiple features to help provide an enhanced and customizable level of care. These features can be toggled on and off in the notification window found on the app. The features highlighted in this document are:
- Wet Brief Notification
- Estimated Saturation Level Notifications
- Low Battery Notification
- Sensor Connection Notification
- No Brief Detected Notification

Wet Brief Notification

This feature notifies the user that a change is suggested at the estimated saturation level for the brief, as set by the app user. This feature can be customized by sliding the bar until it resides at the estimated saturation level that the app user would like to be notified that a change is needed.

Estimated Saturation Level Notification

This feature allows the caregiver or user to receive notifications at various estimated saturation levels, allowing them to track the estimated diaper saturation through multiple stages.

Low Battery Notification

Notifies the user of low battery levels of the Zealacare Smart Sensor.

Sensor Connection Notification

Notifies the user when the sensor and the app are no longer connected, resulting in the inability to recognize wet events.

No Brief Detected Notification

Notifies the user when the app detects that a sensor has not been connected to a brief for a certain amount of time.

Accessing the Zealacare Storefront Directly from the App

The Zealacare storefront can be accessed directly from the app. This allows users to easily place new orders without the need to be redirected to our storefront. Users can access the storefront by clicking the shop icon in the bottom left corner of the app.

Zealacare Smart Sensor

Preparing for Use: Zealacare Smart Sensor

1. Remove the contents from the packaging.
    a. Zealacare Smart Sensor
    b. Inductive charging mat & cable
2. Plug charging mat usb cable into any USB wall wart. (See "Zealacare Inductive Charger" for more details on charger)
3. Plug wall wart into wall receptacle.
4. Place the charging mat on a flat and level service.
5. Place Zealacare Smart Sensor on the center of the mat with snaps facing up.
6. A Red LED light located on the sensor will flash while charging.
    a. If after a few minutes you fail to see the flashing light, ensure the USB is plugged in properly and the charger has power.
7. Leave the sensor on the mat for approximately 60 minutes or until the LED stops flashing or turns green.

8. When the LED stops flashing or turns green, remove the sensor from the mat and proceed to the "Connecting my Zealacare Smart Sensor."

Connecting my Zealacare Smart Sensor

1. Open Zealacare app, follow steps outlined in the app to login or create a new account.
2. After creating a profile for the care recipient, you will be directed to a page where you can connect a sensor to that recipient.
3. If you have already created a profile for the care recipient but have yet to connect a sensor, click on the profile of the care recipient and you will be redirected to a page to connect the sensor.
4. Click "link sensor" and click on your device once it populates on the screen.
5. You will be directed to a page where you will provision the device to your local wifi. Make sure your device's bluetooth is enabled for this step.
6. You will select the device that matches the number found on the label of the device.
7. After entering the wifi password, you will be redirected to the user dashboard, signifying a successful connection.

If Sensor Does not Connect to Wifi

1. Ensure that the wifi is functioning correctly and reaches the room in the house that the patient resides in. Your device must be on the same wifi network and your device's bluetooth must be on.
2. If you are still unable to connect to the wifi, locate the wifi router and try to connect while standing next to it.
3. Please contact customer support if you continue to experience difficulties provisioning the device to the wifi.

If sensor is fully charged

1. Snap Zealacare Smart Sensor onto snaps located at the top of the Zealacare Brief.
2. Push Zealacare Smart Sensor onto diaper snaps firmly, you should feel the snaps engage.
3. Ensure snaps are securely fastened by gently tugging on the sensor.

7

4. If the sensor is well connected no movement should be noted.
5. Once the sensor is snapped onto the brief, the sensor will immediately begin sensing for wet events.
6. Follow steps in "Setting Up The Zealacare App" to customize your user experience.
7. To unclip the sensor, grasp onto the sensor and gently pull away from the brief until both snaps have released.

If charging is needed

1. Repeat steps found in "Preparing for Use: Zealacare Smart Sensor"

Cleaning the Zealacare Smart Sensor

1. Wipe down the sensor with a soft, barely-damp lint-free cloth to remove dust and fingerprints.
2. Spray or wet the cloth, not the sensor.
3. A small amount of mild non-abrasive soap can be used if needed.
4. Disinfecting wipes may be used.
5. Ensure the device is dry when finished.

Other Cleaning Details

Avoid the use of the following cleaning products as they could cause harm to the performance of the sensor:

1. Abrasive cleaners (for example powdered cleaners, toothpaste, polishing rouge, bathroom cleaner, etc.)
2. Acids (including vinegar)
3. Hydrogen Peroxide
4. Paint Thinner
5. Acetone/Nail Polish Remover
6. Degreaser
7. Solvents

If you need more information about cleaning and maintaining your sensor, please contact Customer Service.

Zealacare Comfort Briefs
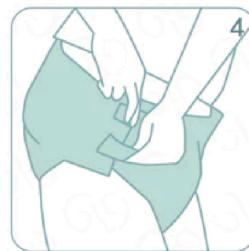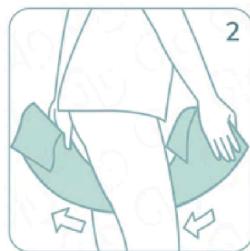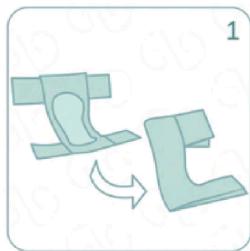
Putting on the Zealacare Comfort Brief

1. Remove Zealacare Comfort Brief from packaging, ensuring that the snaps are located at the front of the brief.
2. As seen from the diagram above, the easiest way to put the brief on is to fold it in half and place it in between your legs.
3. Adjust the brief up to the desired height while maintaining pressure with legs.
4. Attach adhesive fasteners onto one side of the diaper. For best fit, try to maintain the fasteners at an equal distance apart. There is a transparent plastic layer on the outside front of the brief where the adhesive fasteners must be placed for a secure hold.
5. Once one side has been securely fastened, repeat the process on the other side of the brief, adjusting until the brief is secure.
6. Attach the Zealacare Smart Sensor by firmly snapping it onto the snaps on the front of the brief.
7. In the Zealacare App, click the "Log brief change" button on the care recipient's dashboard to note the changed brief in the Zealacare App.

Changing and Disposing of the Zealacare Comfort Brief

1. Once the brief has been soiled, we recommend that the brief be changed as soon as possible.
2. To remove the brief, simply unfasten the adhesive straps and remove the brief.
3. The brief can then be rolled up and fastened using the same straps in order to secure the contents of the brief on the inside.
4. The brief can be thrown away into any trash can.
5. To place a brief back on, follow the steps found in "Putting on the Zealacare Comfort Brief."

Zealacare Inductive Charger

Specifications

Input	5V/2A, 9V/2A
Output	5W/7.5W/10W/15W
Quick Charge	QC3.0
Conversion	≥73%
Material	ABS
Color	Black

LED Indicators Information

- Power on: green light is on for 1s and then off
- Standby mode: no light
- Charging: green light
- When fully charged: green light will flash or turn off

Notes

- Do not disassemble the product at will.

- Do not use this product in a high temperature, damp environment.

Storage and Handling

To extend the use life of your device, when not in use, make sure the Zealacare Smart Sensor is properly cleaned and stored in a dry, safe location at room temperature.

Zealacare Comfort Briefs should similarly be stored in a clean, dry environment at room temperature.

Device Disposal

Dispose of the broken or damaged Zealacare Smart Sensor according to national and local regulations and guidelines for electrical medical equipment. The sensor device contains a Lithium-ion battery and should be disposed of properly.

Device Use Life

If the device is well maintained and cared for, an expected use life is approximately 2 years.

Technical Assistance

For Technical Assistance, please contact us through the Zealacare App or call Technical Support at the following telephone number: 801-981-2273.
Or visit us at www.zealacare.com

12

Our website contains a comprehensive range of support materials, including Questions and Answers to common questions. You can also post questions directly to Zealacare or email/call Zealacare support professionals.

Alternatively, send an email to support@zealacare.com. Please include the product name, serial number and a detailed description of the issue.

Warranty and Return Policy

Zealacare warrants its product to be free from defects in material and workmanship under normal use and service for a period of 12 months from the date of original purchase.

Zealacare's obligation under this warranty and any implied warranty is limited to the repair, replacement or refund of any product, or part thereof, which has been returned to it or its distributor within the applicable time period.

Exclusions and Limitations

This Limited Warranty does not apply to any product, or part thereof, which has been repaired or altered outside Zealacare's factory in a way so as, in Zealacare's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

This Limited Warranty does not cover: a) normal wear and tear such as scratches, abrasions, or alteration of the color and/or material, b) defects caused by rough handling, or c) defects or damage resulting from use contrary to intended or recommended use, improper care, negligence, and accidents such as dropping or crushing; d) printed materials and packaging; e) defects or alleged defects caused by use with any product, accessory, software and/or service not manufactured or supplied by Zealacare. Zealacare does not warrant that the operation of the product or accessory will be uninterrupted or error free, or that the product or accessory will work with any hardware or software provided by a third party.

This Limited Warranty is not enforceable if the product or accessory: a) has been opened beyond intended use; b) has been repaired using unauthorized spare parts; c) modified or repaired by unauthorized Service Center; d) the serial number has been removed, altered or made illegible in any way, as determined at the sole discretion of Zealacare; or e) has been exposed to chemicals (e.g. solvents).

Access to Zealacare warranty service

You must provide proof of purchase to access Zealacare warranty service. For instructions on how to obtain warranty service, contact your local authorized Zealacare retailer, or call the Zealacare Technical Support Center.

Limitation of Liability

To the maximum extent permitted by applicable mandatory laws, this Limited Warranty is your sole and exclusive remedy and is in lieu of all other warranties, expressed or implied. Zealacare shall not be liable for special, incidental, punitive or consequential damages, including but not limited to loss of anticipated benefits, loss of data, loss of use, cost of capital, cost of any substitute equipment or facilities, claims of third parties, damage to property resulting from the purchase or use of the item or arising from breach of the warranty, breach of contract, negligence, strict tort, or any legal or equitable theory, even if Zealacare knew of the likelihood of such damages. Zealacare shall not be liable for delay in rendering warranty service.

Technical Information

The sensor device complies with
ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
CSA C22.2 No. 60601-1:14 (R2022)
EN 60601-1:2006+A2:2021
IEC 60601-1-2:2014+A1:2021

TABLE 1: Zealacare Smart Incontinence System Technical Specifications	
Sensor	
Weight	0.9 oz (25 g)
Length	2.1 in (5.34 cm)
Width	1.5 in (3.175 cm))
Height	0.5 in (1.27 cm)

Operating Temperature	-0°C to 45°C/ -32°F to 113°F
Storage Temperature	-25°C to 25°C/ -13°F to 25°F
Water Resistance	Not to be used in water
Sensor Battery	
Battery Type	4V Lithium Rechargeable
Use Time	~120 hours
Radio Transceiver	
Transmission Frequency	2.4GHz-2.5GHz (2400MHz~2483.5MHz)
Max. Transmission Power:	17 dBm (Conducted)
Range:	~ 50 ft (15m)
General Info	
Type B Applied Parts	
Mode of Operation	Continuous
IPx4 Rating	4
Adult Diaper	
Weight:	3.6-4.7 oz (102.1-133.2 g)
Width:	24.8-31.5 inches (630-800 mm)
Length:	31.5-40.6 inches (800-1030 mm)

Size:	Body Size:
Small:	26-36 in (66-91 cm)
Medium:	34-50 in (36-127 cm)
Large:	48-58 in (122-147 cm)

Wireless Inductive Charging Pad	
Model OJD-Ql01	
Input:	5V/2A 9V/2A
Output:	5W-15W

TABLE 2: Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Zealacare Smart Sensor System is intended for use in the electromagnetic environment specified below. The customer or the user of the Zealacare Smart Sensor should ensure that it is used in such an environment.		
Emissions Test	Compliance	EMC Environment Guidance
RF Emissions CISPR 11	Group 1	The Zealacare Smart Sensor complies with FCC regulations for unlicensed transmitters. FCC ID: 2BF5N-SENS247 Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to

RF Emission (Radiated/Conducted) CISPR 11	Class B	operate the equipment. The Zealacare Smart Sensor complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: - Reorient or relocate the receiving antenna. - Increase the separation between the equipment and receiver. - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. - Consult the dealer or an experienced radio/TV technician for help.

TABLE 3: Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
The Zealacare Smart Sensor System is intended for use in the electromagnetic environment specified below. The customer or the user of the Zealacare Smart Sensor should ensure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	@ 2,4,8, 15 kV Air @ 8 kV Contact	Floor should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
Magnetic Field Immunity IEC 61000-4-8	@ 30 A/m 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

TABLE 4: Manufacturer's Declaration – Electromagnetic Immunity

The Zealacare Smart Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the Zealacare Smart Sensor should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	@ 10 V/m, 80-2700 MHz, 1 kHz 80% Amplitude Modulation, and 50% Pulse Modulation	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Zealacare Smart Sensor, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommended separation distance For 80 MHz to 800 MHz For 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 symbol:

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 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 Zealacare Smart Sensor is used exceeds the applicable RF compliance level above, the Zealacare Smart Sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Zealacare Smart Sensor.
[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 5: Recommended separation distance between portable and mobile RF communications equipment and the Zealacare Smart Sensor

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.117m	0.117m	0.233m
0.1	0.37m	0.37m	0.74m
1	1.17m	1.17m	2.33m
10	3.70m	3.70m	7.37m
100	11.7m	11.7m	23.3m

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

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

NOTE 2:   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

This product complies with FCC regulations for unlicensed transmitters.
FCC ID: 2BF5N-SENS247

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The equipment should be installed and operated with a minimum distance of 20cm between the radiator and your body.

TABLE 6: Symbols Used			
		IP 32	SN
Manufacturer	Refer to the instruction manual/ booklet.	Effective against tools, thick wires, etc. Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position. A total of four positions are tested within two axes.	Serial Number
	LOT	NON STERILE	MR
Type B Applied Part: Suitable for external application to the patient.	Lot or Batch Number	Non-Sterile	MRI Unsafe: Keep away from magnetic resonance imaging (MRI) equipment

Zealacare, LLC
4262 W. 4000 N.
Cedar City, UT 84721
www.zealacare.com

IFU-001 Rev. A