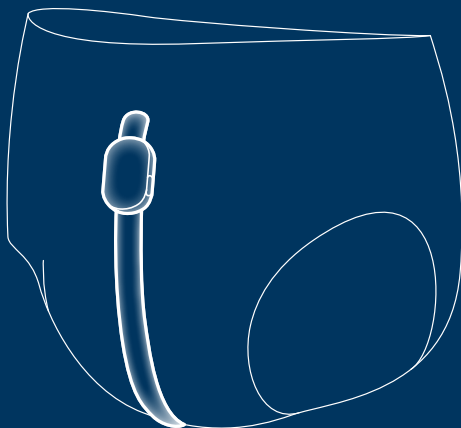




Instructions for use



For professional caregivers

This guide is intended for professional caregivers using TENA SmartCare Change Indicator™ in a professional care and home care environment.

TENA SmartCare Change Indicator is a digital health technology solution that helps caregivers decide when to change absorbent products without the need for frequent manual checks. Besides being less intrusive, it also helps provide more effective, individualized care.

The Change Indicator attaches to the outside of a TENA absorbent product and tracks the urine saturation levels within. Caregivers then receive information about the different saturation levels on their smartphones via the TENA SmartCare Professional app. The TENA SmartCare Change Indicator system tracks urine saturation but does not detect fecal episodes.

TENA SmartCare Change Indicator is a system consisting of:

- The TENA SmartCare Web portal, which serves as an information hub for nurses and administrators.
- The TENA SmartCare Professional app that is installed on the smartphones of caregivers.
- A reusable Change Indicator that consists of three parts: a sensor strip, a transmitter and protection lid.
- A gateway that relays data from the Change Indicator to a secure server.

In this guide, you will find instructions for how to use:

The TENA SmartCare Change Indicator system, including TENA SmartCare transmitter, TENA SmartCare gateway, TENA SmartCare sensor strip, TENA SmartCare Professional app and TENA SmartCare professional Web portal.

Model number

To verify that you are using the correct instruction material for your device, see instructions on p. 34.

Symbols used in this guide



WARNING Special care should be taken to ensure safety and efficiency. Failure to do so could cause damage to equipment or lead to the receipt of incorrect data.



NOTE/ TIP Important information or advice/ tips.



CHECK Important information for the system to function.

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Before starting to work with the TENA SmartCare system

- Ensure you have received training and/ or have read and understood these instructions for use before using the product. Save these instructions for use for future reference.
- Make sure to consistently update the SmartCare Professional app to the latest version available on the App Store or Google Play.

Change Indicator

- The Change Indicator is intended for use with TENA absorbent product.
- The system provides information on urine saturation levels to support decision making regarding when TENA absorbent product should be changed.
- The same Change Indicator sensor strip should never be used on more than one care recipient.
- TENA SmartCare Change Indicator™ is intended for 24/7 use.
- Do not attach the Change Indicator to the inside of the absorbent product. TENA SmartCare Change Indicator should only be attached to the outside of the absorbent product.
- TENA SmartCare Change Indicator does not replace normal safety checks and routines for repositioning care recipient, checking for feces, administering medication, etc.
- The Change Indicator is not intended to be used in direct contact with the skin.
- Only a CR2032 battery should be used in the Change Indicator. Using the wrong type of battery, including rechargeable batteries, can damage the Change Indicator.

Gateway

- The adhesive strip for attaching the gateway will not adhere well to dirty, dusty, or oily surfaces and may not adhere well to vinyl surfaces. Do not use tape on wallpaper, bare wood or on porous or painted surfaces.

In case of system failure

- In the event of system failure or anticipated system failure, revert to a manual changing routine.
- If you encounter any problems, equipment failure or if any other incidents occur, report them to the manufacturer or TENA SmartCare support.

Incorrect usage of Change Indicator

- Do not use the Change Indicator system on care recipient who experience frequent fecal incontinence. TENA SmartCare Change Indicator does not detect fecal episodes.
- If a care recipient is experiencing loose bowel movements or diarrhea, wait until the condition has been treated before resuming use of the Change Indicator.
- Do not swing the Change Indicator in the direction of people, pets, or nearby objects. Be aware of the risk of strangulation with the sensor strip.
- If a defibrillator has been used on a care recipient who was wearing the Change Indicator, the Change Indicator must be replaced.
- Do not use gateways and smartphone chargers with unapproved power supplies.
- Be careful not to use any sharp objects to remove the transmitter from the sensor strip.
- Be careful not to trip over the cord of the Change Indicator Gateway when plugged into the wall.

Incorrect use environment

- The Change Indicator and gateway should not be used in an oxygen-rich environment.
- The Change Indicator and gateway should not be used in the presence of flammable anesthetics.
- The Change Indicator is not intended for use in an aseptic environment.
- Do not use the Change Indicator where X-Rays are performed.
- The Change Indicator is not magnetic resonance safe and should not be brought into a magnetic resonance imaging environment.

Cleaning

- Cleaning of the Change Indicator during normal use, when transmitter is attached to sensor strip, should only be done when fully assembled to prevent water from entering the device. Do not submerge in water or clean in a washing machine. Do not put the Change Indicator in an autoclave.
- Ensure adequate disinfection procedures are followed for care recipient with infectious diseases.

- If the transmitter should be used on a new care recipient it is important that the protection lid is attached and that the instructions for how to clean the transmitter for reuse are followed. Do not submerge in water or clean in a washing machine. Do not put the Change Indicator in an autoclave.

Battery

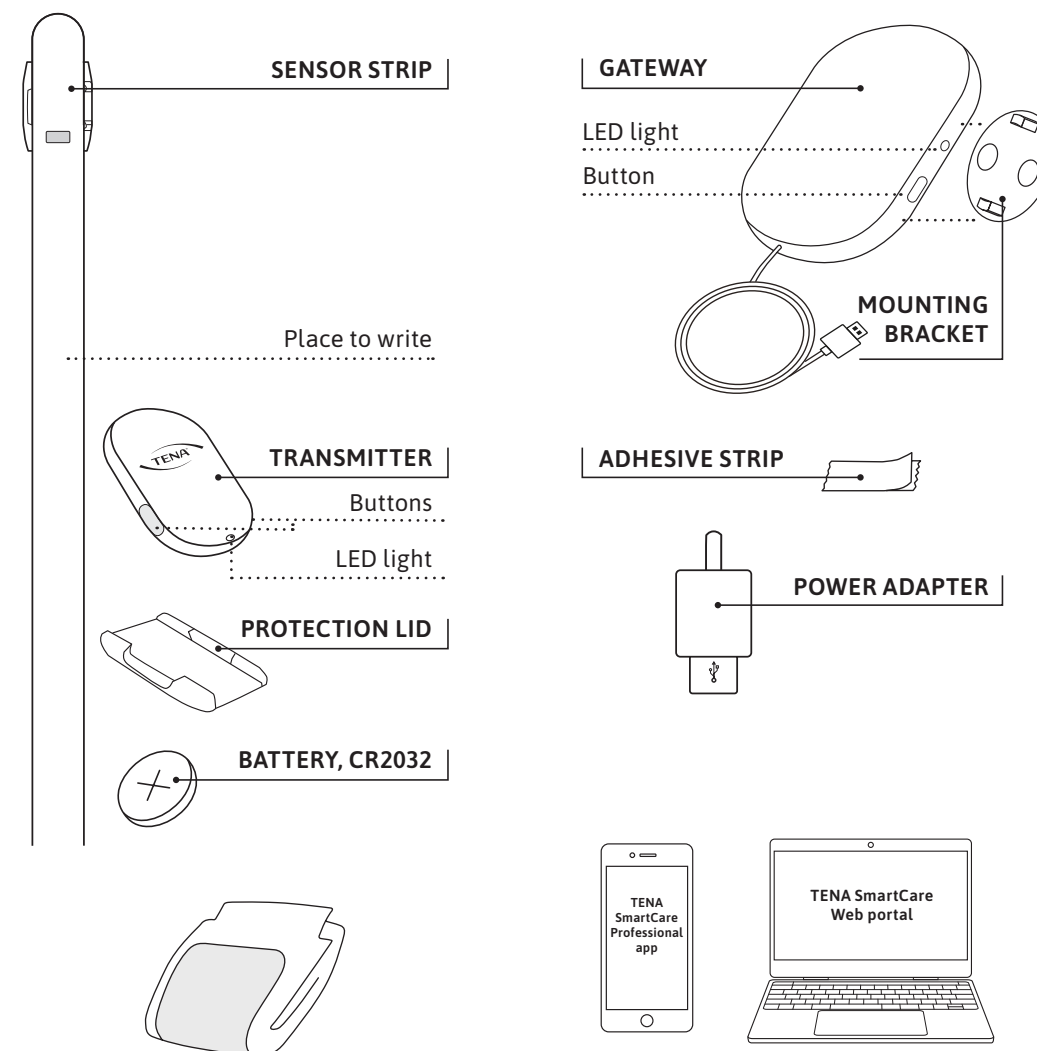
- Keep the Change Indicator and Change Indicator batteries away from children and pets.
- Seek immediate medical care if the battery is swallowed.
- Do not expose the battery to high temperatures, disassemble it, damage it mechanically or put battery into the fire as this can cause an explosion or a fire.
- Be careful when pulling the metal tab to not accidentally pinch your finger. If you are not able to use your finger to pull the tab you can use another item such as a pen to pull it back.

Maintainance

- Do not attempt to repair or modify the Change Indicator or a gateway by yourself.
- If any part of the Change Indicator system appears to be damaged or broken, it should not be used. Contact TENA SmartCare support in your country.

Sensitive skin

- If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.
- In case of any sign of skin redness stop using the device or apply a fixation pant or ordinary underwear on top of the Change Indicator to protect from chafing.



A supported TENA absorbent product (see supported TENA products on p. 17 of this guide or in the TENA SmartCare web portal).

CONSUMABLES:

Sensor strip and battery.

A handheld device (iOS 16 and later or Android 10 or later) with TENA SmartCare Professional app and a computer to access the TENA SmartCare Web portal.

TENA SmartCare Web portal

TENA SmartCare Web portal is an information hub for administrators in care facilities. It provides real-time and historical data on urinary patterns and product consumption, and enables users to:

- Set up and manage user and care facility settings.
- Monitor care recipient change routines and urinary patterns over time.
- View real time data on care recipients change status.
- Identify measures for improved care and sustainability efforts.



Using the TENA SmartCare Professional app

- 1 At the beginning of a shift, caregivers log into the app using the provided login details from an administrator or manager. This allows them to receive notifications and stay updated.
- 2 During the shift, caregivers receive notifications regarding urine saturation levels in care recipients' absorbent products.

Setup app

The TENA SmartCare Professional app is a useful tool for caregivers, providing real-time data and notifications regarding the care recipients they care for. To get started, caregivers can download the app from the App Store or Google Play.



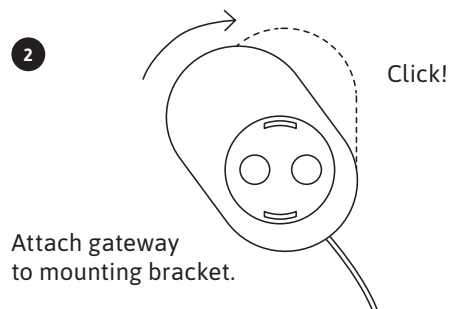
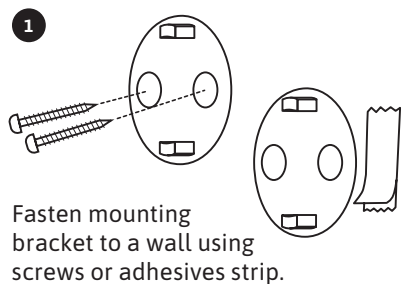
102A The care recipient bed number. NOTE To protect care recipients privacy, they are identified by their bed or room number rather than their names.	 xx min Time care recipient has had this status for.	
 OK means the care recipient absorbent product is dry.	 Some urine means that the Change Indicator has identified urine in the product. The surface of the product is still dry and the product has not reached saturation.	 Consider change means the care recipient absorbent product is nearing capacity. Consider changing the absorbent product.
 Inactive means the care recipient is inactivated for monitoring over a longer period of time. NOTE The care recipient will not be monitored until you activate him/her in the settings. (Only visible in the web portal.)	 Off means the care recipient absorbent product is not being monitored by TENA SmartCare Change Indicator. NOTE Care recipient will be back to monitoring automatically at the next shift.	 Error means there is an error with either the care recipient Change Indicator or the system. The caregiver should click on the icon to learn more. See p. 27–31 for more information on how errors can be resolved.



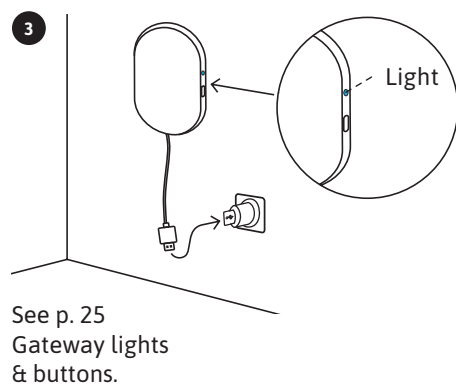
NOTE

The Change Indicator must be within 10 m/33 ft from a gateway to be monitored by the system.

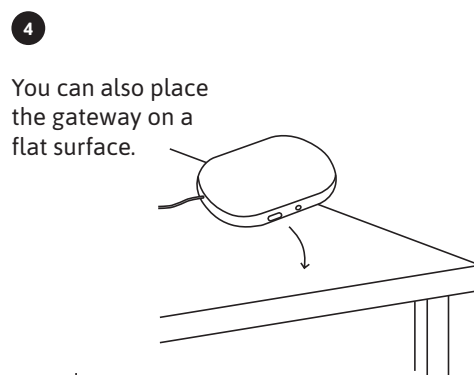
Wall mounting



Wall mounting

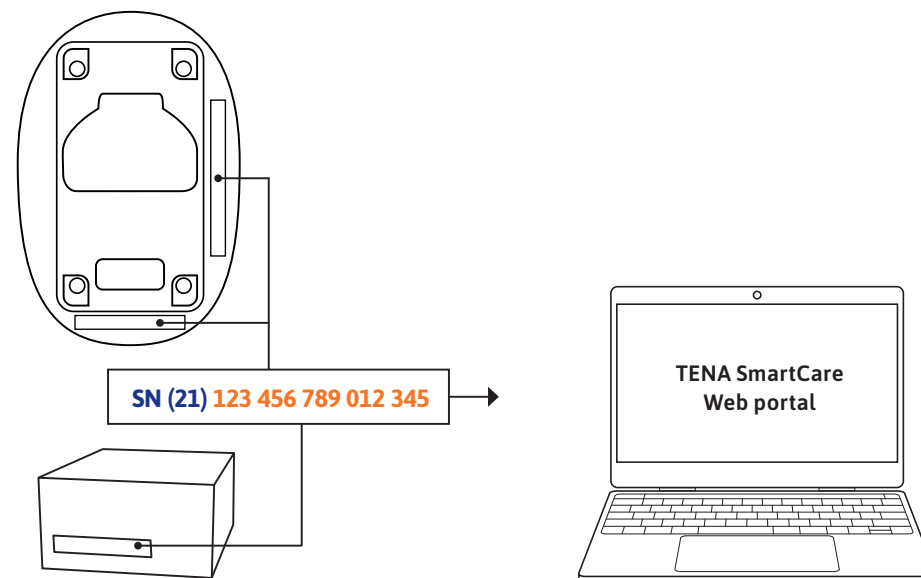
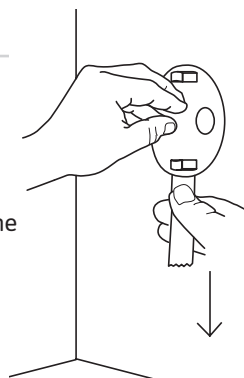


Surface mounting



Removal (wall mounting with adhesives)

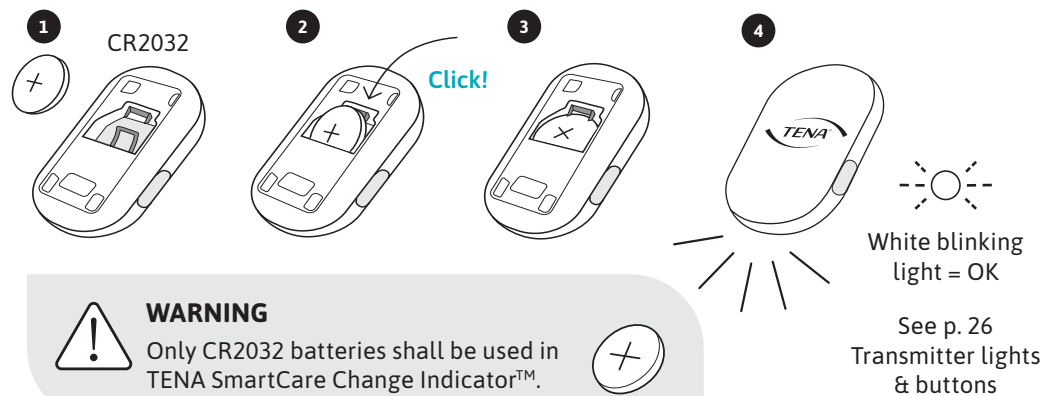
Removal of the mounting bracket: Grab removal tab and slowly pull the tab straight down against the wall stretching the tape at least 6 inches (15cm) until item releases from the wall.



1 Find the 15 digit code, which is located on the back of the transmitter and on the packaging.

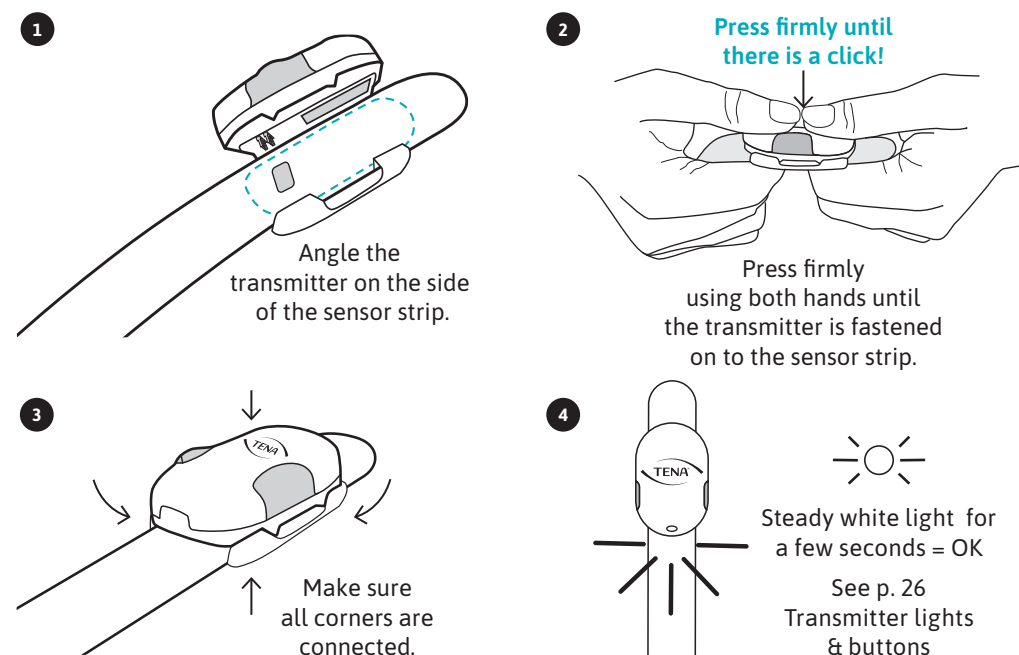
2 Enter the transmitter code on the care recipient page.

Install the battery

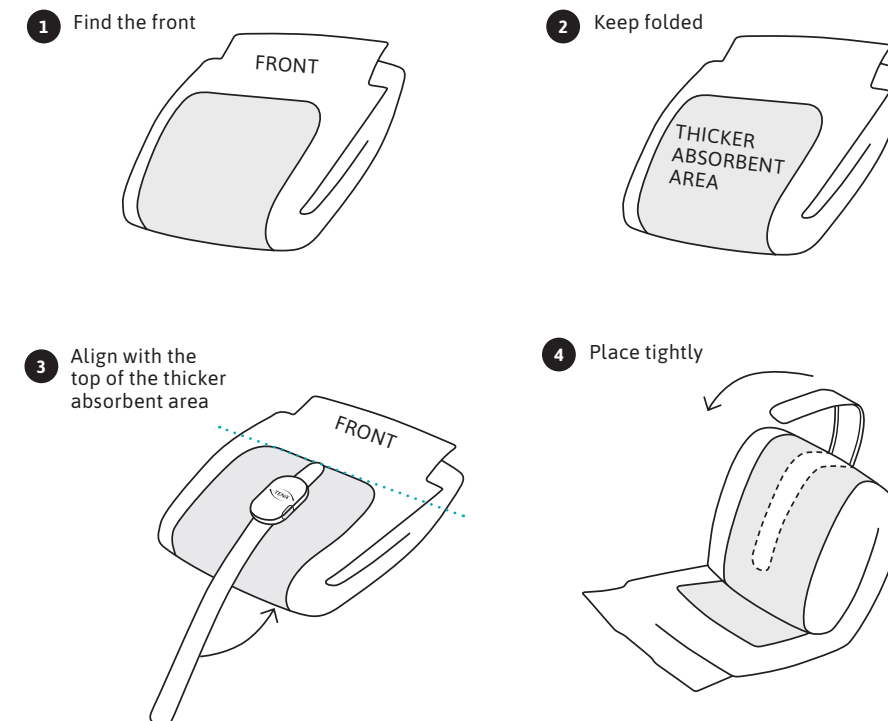


NOTE
The transmitter is delivered with a lid. The lid is only to be used during cleaning of transmitter. Remove protection lid and store for later use. See instructions on p. 24.

Assemble the Change Indicator (transmitter + sensor strip)

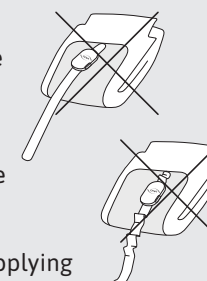


See list of supported TENA absorbent products on p. 17 in this guide.

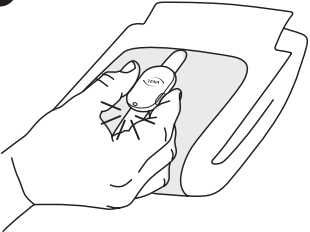


NOTE
Always attach the Change Indicator before you unfold the absorbent product. Start by placing the Change Indicator at the front of the absorbent product, on the thicker absorbent area, ensuring it is straight. Align the sensor strip with the top of the thicker absorbent area of the absorbent product. Press firmly to ensure the Change Indicator has full contact with the whole absorbent product.

If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.



1



Press both buttons simultaneously for two seconds at every change to register the change in the system.

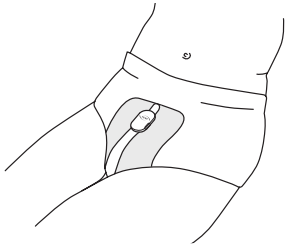
Steady green light for a few seconds:
The Change Indicator is ready to be applied to a care recipient.



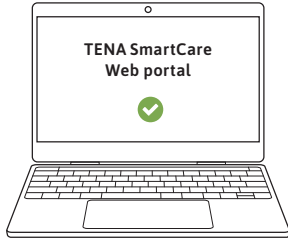
Blinking light:
Change battery, see p. 22



2



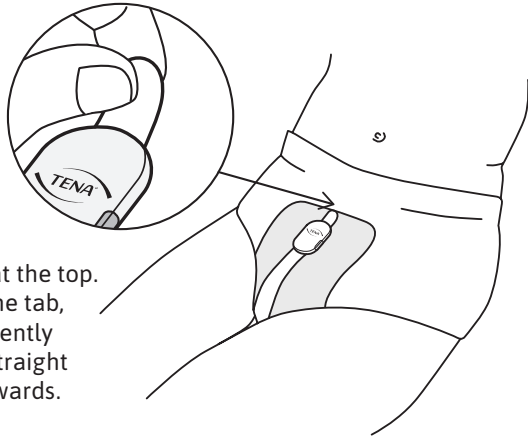
Apply the TENA product with the Change Indicator on the care recipient.

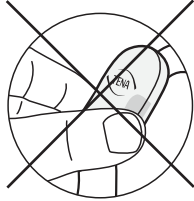
3

 OK No action needed. Care recipient absorbent product is dry.	 Some urine No action needed. Some urine is detected, but the surface of the product is still dry.	 Consider change The Care recipient absorbent product is nearing capacity.
 Inactive (web portal) The Care recipient is inactivated for monitoring over a longer period of time.	 Off Care recipient absorbent product is not being monitored by TENA SmartCare Change Indicator.	 Error See p. 27–31 for more information.

1



Start at the top. Grip the tab, then gently peel straight downwards.

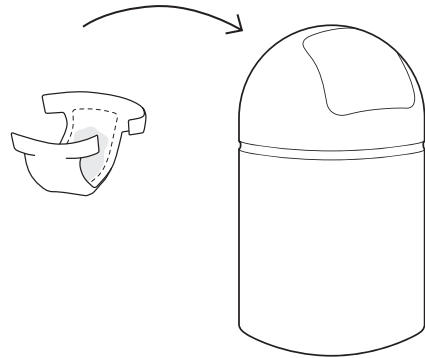


Don't grab and pull the transmitter.

NOTE

The Change Indicator should be removed while the user is still wearing the absorbent product. Gently pull the Change Indicator down from the top until removed.

2



Always make sure the Change Indicator has been removed before disposing of the TENA absorbent product.

Intended use:

TENA SmartCare Change Indicator™ is an accessory to absorbent products, intended for use on individual(s) suffering from urinary incontinence in a home or professional environment who are dependent on one or more caregivers to change the absorbent products. TENA SmartCare Change Indicator estimates the degree of urine saturation in the absorbent product and notifies the caregiver(s). This facilitates the caregiver decision regarding when to change the absorbent product.

Standard operation:

- The Change Indicator should not be in contact with the user's skin during normal use. It should always be attached to the outside of the absorbent product.
- The operator of this Change Indicator is the caregiver of the incontinent user. The user wears the Change Indicator in combination with a TENA absorbent product.
- Attaching the Change Indicator to the absorbent product is considered a primary operating function.
- Only the caregiver is intended to interact with the Change Indicator.
- To turn monitoring off for the Change Indicator for a longer period, change the status to "Inactive" in the web portal.
- The Change Indicator is intended for users with healthy skin.

Advanced operation:

- Changing the battery and sensor strip are operations that should be carried out infrequently.

Using the TENA SmartCare Change Indicator according to its intended use does not add any risk compared to not using it.

The medical device complies with emission and immunity standards and regulations. It has been tested and fulfills requirements for both home and professional healthcare environments. The medical equipment is also compliant for professional healthcare home environment use.

TENA Slip Plus, Super, Maxi, Ultima

TENA Flex Normal, Plus, Super, Maxi, Ultima

TENA Pants Normal, Plus, Extra, Super, Maxi

TENA Silhouette Underwear Plus (high waist)

TENA Men Pants Active Fit

TENA Comfort Normal, Plus, Extra, Super, Maxi, Ultima

**CHECK**

TENA Pants Discreet, TENA Silhouette Underwear Normal (low waist) and TENA Men Pants Premium Fit cannot be used with the Change Indicator.

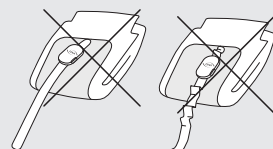
TENA Slip

TENA SmartCare Change Indicator™ should always be attached when the absorbent product is folded and before it has been applied to the care recipient.



NOTE

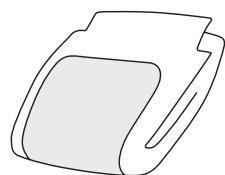
Ensure the Change Indicator is straight. Smooth any sensor strip wrinkles, then press firmly to ensure the Change Indicator has full contact with the TENA absorbent product.



1

Find the front

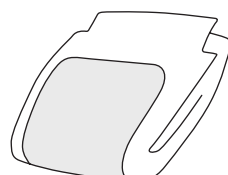
FRONT



2

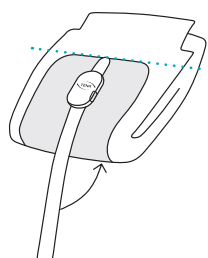
Keep folded

THICKER
ABSORBENT AREA



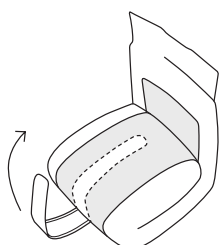
3

Align with the top of the thicker absorbent area



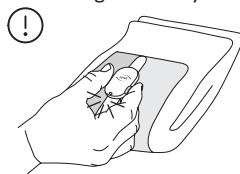
4

Place tightly



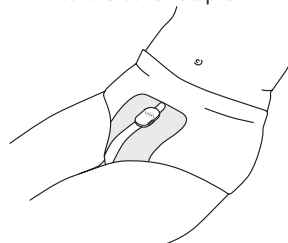
5

Every time you change an absorbent product, press both buttons simultaneously for two seconds to reset the transmitter and register the change in the system.



6

Apply the absorbent product with the Change Indicator to the care recipient.



NOTE

If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.

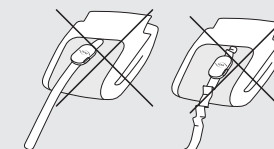
TENA Flex

TENA SmartCare Change Indicator™ should always be attached when the absorbent product is folded and before it has been applied to the care recipient.



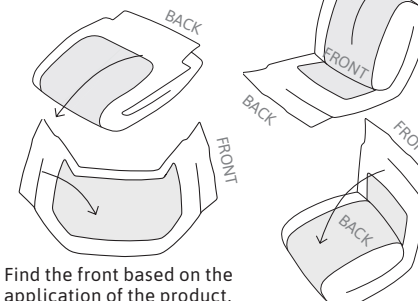
NOTE

Ensure the Change Indicator is straight. Smooth any sensor strip wrinkles, then press firmly to ensure the Change Indicator has full contact with the TENA absorbent product.



1

Find the front



Find the front based on the application of the product.

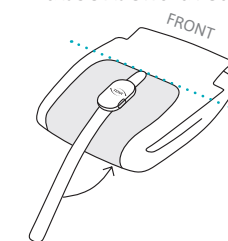
2

Keep folded



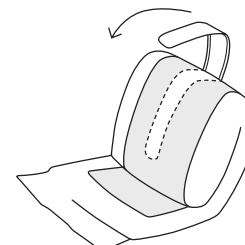
3

Align with the top of the thicker absorbent area



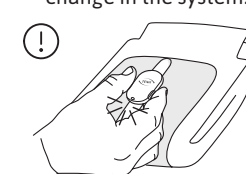
4

Place tightly



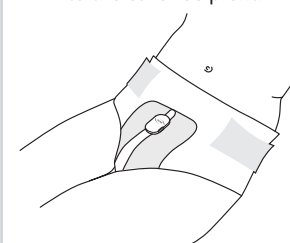
5

Every time you change an absorbent product, press both buttons simultaneously for two seconds to reset the transmitter and register the change in the system.



6

Apply the absorbent product with the Change Indicator to the care recipient.



NOTE

If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.

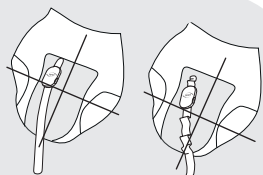
TENA Pants

TENA SmartCare Change Indicator™ should always be attached when the absorbent product is folded and before it has been applied to the care recipient.



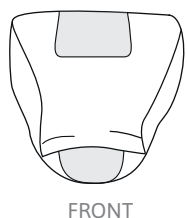
NOTE

Ensure the Change Indicator is straight. Smooth any sensor strip wrinkles, then press firmly to ensure the Change Indicator has full contact with the TENA absorbent product.



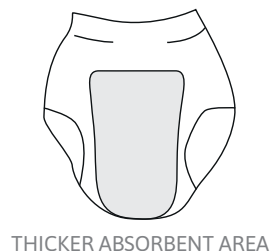
1

Find the front



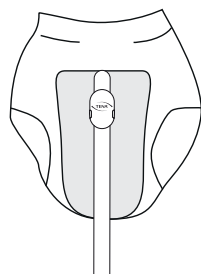
2

Fold up



3

Align with the top of the thicker absorbent area



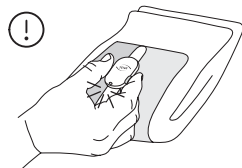
4

Turn around and place tightly



5

Every time you change an absorbent product, press both buttons simultaneously for two seconds to reset the transmitter and register the change in the system.



6

Apply the absorbent product with the Change Indicator to the care recipient.



NOTE

If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.

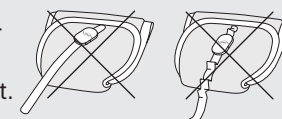
TENA Comfort

The TENA SmartCare Change Indicator™ should always be attached when the absorbent product is folded and before it has been applied to the user.



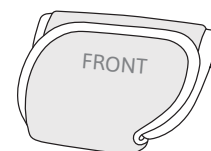
NOTE

Ensure the Change Indicator is straight. Smooth any sensor strip wrinkles, then press firmly to ensure the Change Indicator has full contact with the TENA absorbent product.



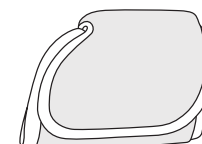
1

Find the front



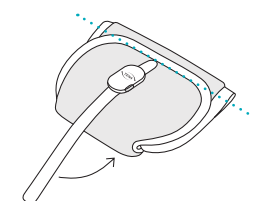
2

Keep folded



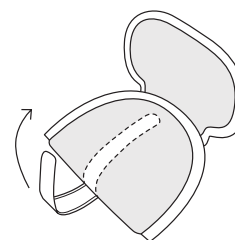
3

Align with the top of the thicker absorbent area



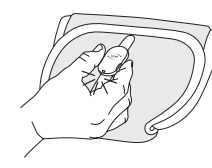
4

Place tightly



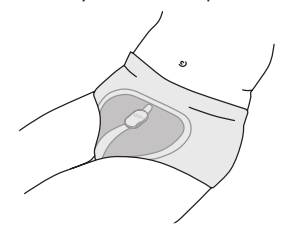
5

Every time you change an absorbent product, press both buttons simultaneously for two seconds to reset the transmitter to register the change in the system.



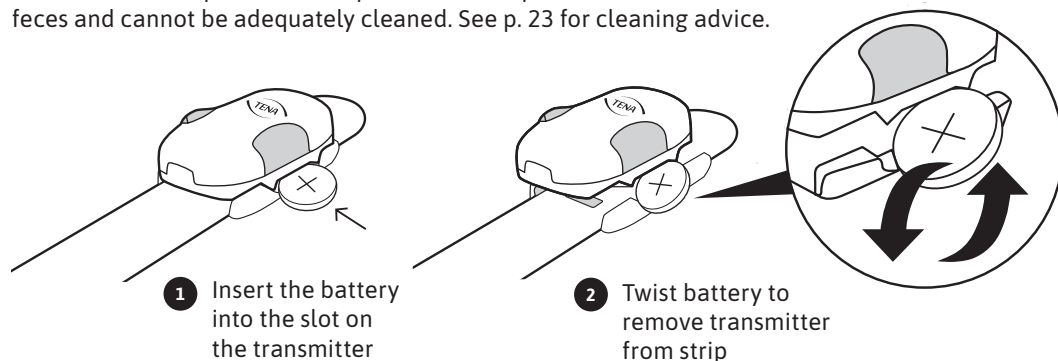
6

Apply the absorbent product with the Change Indicator to your care recipient.



Sensor strip replacement

The sensor strip is designed for up to 12 weeks of continuous use. However, if hooks get covered with fibers or lint, preventing attachment to the absorbent product, errors may occur, and the strip should be replaced. Also, replace it if it becomes soiled with feces and cannot be adequately cleaned. See p. 23 for cleaning advice.



WARNING

Be careful not to use any sharp objects to remove the transmitter from the sensor strip.

Battery replacement

If the LED light starts blinking with a white light during use, either the battery needs to be replaced or the transmitter is not properly attached to the sensor strip. The CR2032 battery will last for up to 12 weeks continuous use.

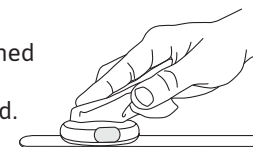


WARNING

Be careful when pulling the metal tab to not accidentally pinch your finger. If you are not able to use your finger to pull the tab you can use another item to pull it back.

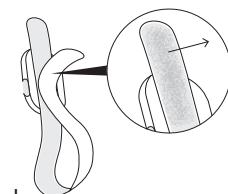
Cleaning Change Indicator during regular use

During regular use, the transmitter and sensor strip should never be cleaned separately – only clean the Change Indicator when it is fully assembled. Clean the Change Indicator using a cloth or a disinfectant when required.

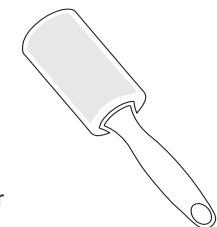


We recommend using:

- Pre-soaked, alcohol-based wipes without additives.
- Alcohol-based disinfection foam for the hooks on the back of the sensor strip.



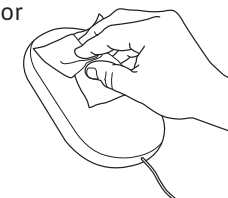
The assembled Change Indicator can be rinsed under a tap. Any fibers or lint attached to the hooks on the back of the sensor strip should be removed to ensure a secure fit between the Change Indicator and the absorbent product. Fibers can be removed using the free end of the sensor strip. If this method is not sufficient the strip can be cleaned with a lint roller.



Cleaning Gateway

Whenever the gateway is moved from one location to another it should be cleaned. Clean the front surface of the gateway with water and detergent or pre-moistened cleaning wipe by rubbing the surface for at least 1 minute. The backside of the gateway should only be cleaned using a dry cloth to prevent damaging the electronics. Dry the front of the gateway with a paper towel or disposable dry wipe. Proceed to disinfect the front of the gateway using a disinfectant suitable for low-risk equipment to inactivate pathogen microorganisms. Example disinfectant products are:

- 70% alcohol.
- Virkon® containing the active ingredient hypochlorous solution.

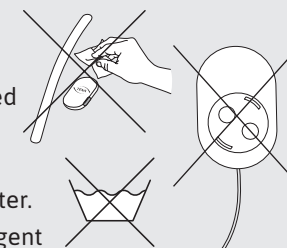


Let the gateway airdry.



WARNING

- Clean the Change Indicator when fully assembled to prevent water from entering the device.
- Ensure adequate disinfection procedures are followed for care recipients with infectious diseases.
- Do not clean in the washing machine.
- Do not submerge Change Indicator or gateway in water.
- Do not clean backside of gateway using water, detergent or disinfectant.



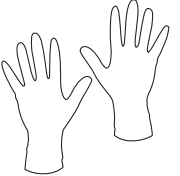
Cleaning Change Indicator for reuse

The Change Indicator transmitter is a reusable device that can be used on several care recipient. Before using the transmitter on a new care recipient, it is important to clean and disinfect the transmitter following the steps below.

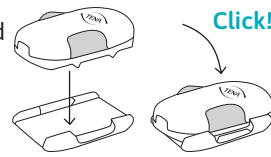
Standard operation:

- 1

Apply protective gloves before handling the transmitter and prior to cleaning and disinfecting.


- 2

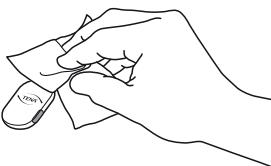
Attach protection lid to transmitter to protect the inside of the transmitter.


- 3

Clean the transmitter with water and detergent or pre-moistened cleaning wipe by rubbing the surface for at least 1 minute.


- 4

Dry the transmitter with a paper towel or disposable dry wipe.

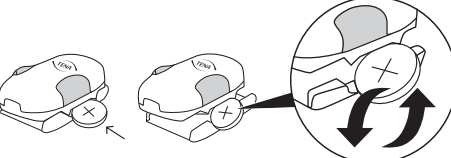

- 5

Proceed to disinfect the transmitter using a disinfectant suitable for low-risk equipment to inactivate pathogen microorganisms. Example disinfectant products are:
 - 70% alcohol
 - Virkon® containing the active ingredient hypochlorous solutionRub every surfaces including crevices and make sure surfaces and crevices are completely saturated with the disinfectant. Follow the manufacturer's recommended instructions for use of the disinfectant.


- 6

Let the transmitter airdry.
- 7

Remove the protection lid from the transmitter using a battery.


- 8

Now the transmitter is ready to be used on the next care recipient.

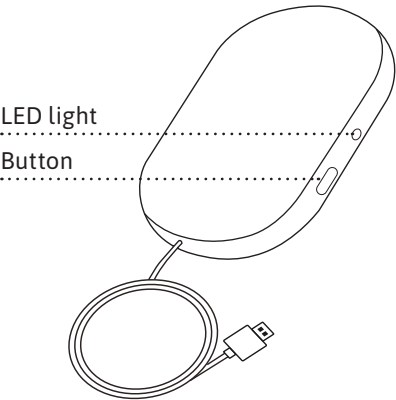


WARNING

- Only clean the transmitter when fully assembled to protection lid to prevent water from entering the device.
- Ensure adequate disinfection procedures are followed for care recipients with infectious diseases. Do not clean in the washing machine.
- Do not submerge transmitter in water.

Gateway installation

After attaching the gateway to a power outlet:

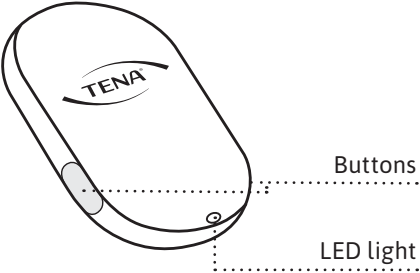


NOTE

The LED light can be difficult to see if exposed to a strong sunlight, for example. Try to block the sunlight to improve readability.

COLOUR LED LIGHT	WHAT IT MEANS
	Blinking blue light: Wait. The system is connecting. Allow up to 60 seconds for the light to start blinking.
	Steady green light: Everything is OK. Allow up to 60 seconds for the light to turn green.
	No light: Green light disappears after a while and the system goes into dark mode. Push the button to see if it has power and network connection. If no light appears, check the power connection.
	Steady red light: Error. See p. 27–31 for more information.
	Blinking blue-green-red light: pull out the power. Wait 30 sec. Insert the power. Wait 2 min. If the error persists, contact TENA SmartCare support.

Transmitter



Battery installation

Once the battery has been placed in the transmitter:

LED LIGHT	WHAT IT MEANS
	Blinking white light: The battery is in the correct position.
	No light: OK The light disappears after a few seconds. Check for power by pressing both buttons simultaneously for two seconds.

Change Indicator assembly

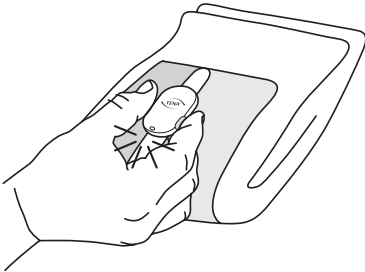
Once the transmitter has been attached to the sensor strip:

LED LIGHT	WHAT IT MEANS
	Steady white light: Everything is OK.
	Blinking white light: The transmitter is not attached properly or the battery is low. Try re-attaching the transmitter. If it does not help, change the battery.
	No light: OK The light disappears after a few seconds. Check for power by pressing both buttons simultaneously for two seconds.

Applying the Change Indicator to the absorbent product

Press both buttons simultaneously for two seconds at every change to register the change in the system.

LED LIGHT	WHAT IT MEANS
	Green steady light: Change has been registered, everything is OK.
	Blinking white light: The transmitter is not attached properly, or the battery is low. Try re-attaching the transmitter. If it does not help, change the battery.
	No light: Error. See p. 27–31 for more information.



Use this guide for general troubleshooting.
If the problem persists, contact TENA SmartCare support.

PROBLEM	SOURCE	SOLUTION
Connection error	Gateway	1. Check the power supply. Are the power cable and power adapter both properly attached? 2. Press the gateway button. If there is a steady green light, everything is OK. 3. If there is a blinking blue light, the gateway is trying to connect. 4. If the gateway fails to connect and the light does not turn green after 2–5 minutes, try moving the gateway to a position in the room where the network connection is stronger and wait for the green light. 5. If this does not help, contact a super user and revert to a manual changing procedure for care recipients until the connection error is resolved. 6. Occasionally, the cellular network may go down. If this happens, inform the person in charge of the network. 7. If there is a steady red light, please remove and re-connect the gateway to the power supply.
	Change Indicator	1. Make sure the transmitter is properly attached to the sensor strip and that the battery is properly inserted (see p. 12 of this guide). 2. Press both buttons on the assembled Change Indicator simultaneously for two seconds. A steady green light should appear.

PROBLEM	SOURCE	SOLUTION
Connection error	Change Indicator	1. If there is no green light when pressing the buttons for 2 seconds change the battery and reattach the transmitter to the sensor strip. Press both buttons simultaneously again for 2 seconds. If there is a green light, everything is OK. 2. If there is a blinking white light when attempting to register a change, check that the transmitter is properly attached to the sensor strip. Adjust if needed. Press both buttons simultaneously again. If there is a steady green light for a few seconds, everything is OK. 3. If this does not help, replace the sensor strip. Press both buttons simultaneously again. If there is a steady green light for a few seconds, everything is OK. 4. If this does not help (no steady white light after attaching transmitter correctly to the sensor strip or a green light after pressing the buttons for 2 seconds), consider changing the transmitter. When changing the transmitter, make sure to register the transmitter and assign it to the care recipient in the web portal.
Connection error	System range	1. Both the care recipient and the Change Indicator should be in range of the gateway – usually within 33 feet/ 10 meters. If possible, place the gateway closer to the care recipient.

PROBLEM	SOURCE	SOLUTION
Change indicator falls off or loosens from absorbent product	Change Indicator	1. Make sure you are using one of the supported TENA absorbent products with a textile-like outer lining. The Change Indicator does not attach to absorbent products with a plastic outer lining. 2. Make sure you attach the Change Indicator to a folded product, straight from its packaging, see instructions for attaching the Change Indicator on p. 18–21. Do not attach the Change Indicator when the care recipient is already wearing the absorbent product. 3. Check the hook-covered side of the sensor strip to see if it is covered with lint. Remove any lint, see cleaning instructions on p. 23. 4. If this does not help, attach a new sensor strip. 5. If this does not help, contact a super user and revert to a manual changing procedure for care recipients' absorbent products until the problem is resolved.
Sensitive skin		1. If the user is very mobile and/or with sensitive skin, consider applying a fixation pant or ordinary underwear on top of the Change Indicator. This will keep it comfortably in place and protect the skin from chafing.
Skin redness		1. In case of any sign of skin redness stop using the device or apply a fixation pant or ordinary underwear on top of the Change Indicator to protect from chafing.

PROBLEM	SOURCE	SOLUTION
The system notifies me too early / too late	Status indication	1. Make sure you are using one of the supported TENA products (see p. 17 of this guide). 2. Make sure the Change Indicator is attached correctly (see p. 18–21 of this guide). 3. If this does not help, make sure the right TENA product with the right absorption level is assigned to this care recipient in the web portal. 4. You can also adjust the Consider change notification timing in the web portal.

PROBLEM	SOURCE	SOLUTION
I don't receive any notifications	Status indication	1. Check “connection error” in the troubleshooting section of this guide. 2. Check that you have enabled notification on your smart phone. 3. Check that your smartphone is connected to a network. 4. Check the web portal. Is the proper transmitter assigned to the care recipient? 5. Ensure that the care recipient is “active” in the web portal.

Operating characteristics

The Change Indicator is classified as an internally powered device for continuous operation.

Electromagnetic Immunity

PHENOMENON	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TEST LEVELS. "HOME HEALTHCARE ENVIRONMENT"
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table below
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz

PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

TEST FREQUENCY (MHZ)	BAND (MHZ)	SERVICE	MODULATION	MAXIMUM POWER (W)	DISTANCE (m)	IMMUNITY TEST LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810 870 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
1 720 1 845 1 970	1 700–1 990	GSM 1 800; CDMA 1 900; GSM 1 900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2 450	2 400–2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5 240 5 500 5 785	5 100–5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

Electromagnetic Emissions

The TENA SmartCare Change Indicator is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an Electromagnetic Environment as the "Home Healthcare Environment" (defined in the IEC 60601-1-2) and "Residential areas" (defined in the CISPR 11).

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions (CISPR 11)	Group 1	The TENA SmartCare Change Indicator 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	Class B (lower emission limits, residential): Class B devices are devices that are suitable for use in residential areas and such areas, and they are connected to the public mains.

TENA SmartCare Change Indicator frequency band of transmission and the effective radiated power

Each frequency or frequency band of transmission:	BLE standard channels (2400–2483.5 MHz, in total 40 channels)
The type and frequency of the modulation:	BLE standard (Gaussian frequency shift keying)
The effective radiated power:	4 dBm

Processing units

Transmitter & gateway

CHARACTERISTICS	VALUE/ RANGE
Wireless technology	RF communication
RF frequency	2.4 GHz
Max. output level (ERP)	0 dBm
Electrical emissions	Class B, level 47 dB mV/m
Operating voltage	2.7–3.3 V
Power consumption	Avg. 135 uW Peak 75 mW
Remote communication range	At least 10 meters/ 33 feet in open environment, without obstructions

Battery module

TYPE	CAPACITY/ VOLTAGE
CR2032	220 mAh/ 3.0 V nominal

This value is with the recommended battery: CR2032

Product component dimensions (mm/ inch)

ITEM	LENGTH	WIDTH	HEIGHT	DIAMETER
Transmitter	52 mm/ 2.05"	34 mm/ 1.34"	13 mm/ 0.51"	N/A
Protection lid	43.05 g/ 1.69" oz	33.30 mm/ 1.31"	6.10 mm/ 0,24"	N/A
Sensor strip	485 mm/ 19.09"	33 mm/ 1.30"	7 mm/ 0.28"	N/A
Battery	N/A	N/A	3.2 mm/ 0.13"	20 mm/ 0.79"

Product weight (g/ ounce)

COMPONENT	WEIGHT
Transmitter	12.6 g/ 0.44 oz
Protection lid	5.4 g/ 0.19 oz
Sensor strip	26.6 g/ 0.94 oz
Battery	3.0 g/ 0.11 oz

Environmental conditions

CONDITION	MINIMUM	MAXIMUM
Storage & transport temp.	+10 °C/ 50 °F	+40 °C/ 104 °F
Storage & transport humidity	65% Rh	90% Rh
Operating temp.	+15 °C/ 59 °F	+40 °C/ 104 °F
Operating humidity (non-condensing)	15% Rh	90% Rh
Pressure	700 hPa	1060 hPa

After transporting or storing the device refrain from using the device for 30 minutes so it can reach room temperature.

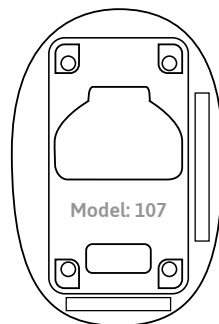
Model numbers

This Instruction for use is compatible with the following model numbers:

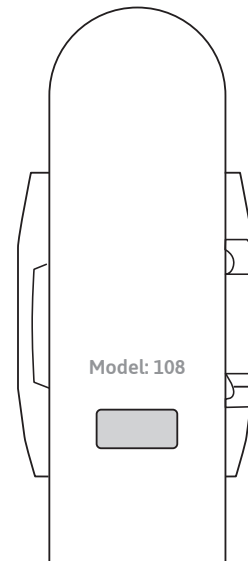
Transmitter: 107

Sensor strip: 108

The model numbers can be found on the following places on the devices:



Backside of Transmitter



Sensor strip surface covered by the transmitter

Electromagnetic compatibility (EMC)



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm/ 12" to any part of the TENA SmartCare Change Indicator. Otherwise, degradation of the performance of this equipment could occur. Interference may occur in the vicinity of equipment marked with this symbol.

Lifetime

- Expected lifetime of the transmitter is two years and the sensor strip is up to 12 weeks, after the first use.
- Expected shelf life (from the manufacturing date) for the transmitter and sensor strip is three years. See manufacturing date on respective pack.

Disposable parts



- Clean the Change Indicator before disposal transmitter and strip.
- Follow local regulations for disposal of the Change Indicator and the batteries. Please return gateway to Essity.



- This declaration relates exclusively to the radio equipment in the state in which it was sold and excludes components that are added and/ or operations carried out subsequently by the final user.

WEEE mark:

- This product has been designed with recycling, reuse and waste management in consideration. Essity will provide the necessary information to recycling facilities and government agencies as required by WEEE Directive. For more information, please contact the manufacturer at www.tena.com.
- The product will be labeled with the WEEE mark as shown on the side, in accordance with European Standard EN 50419.
- The proper disposal of WEEE products will conserve natural resources (through reuse and recycling) and protect environmental and human health through proper disposal.
- WEEE-labeled products must be kept separate and returned to a designated collection point for dismantling, recycling and/ or reuse.
- The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local government, your commercial, institutional and/ or municipal waste disposal service or the location where you purchased the product.

Labeling symbols

The following symbols may appear on your TENA SmartCare Change Indicator™, accessories and/ or packaging:



Manufacturing date



Manufacturer



Instructions for use



Warning



WEEE mark
Dispose of electrical components in accordance with your local regulations



Radio Frequency Radiation symbol



Reference / Article number



Batch number



Serial number



Medical Device



International Protection against contact and ingress of dust and against the effects of submersion in water



UK Conformity Assessed, UK Conformity mark



Swiss Authorized Representative



Not MR safe



European Conformity mark



Australian Regulatory Compliance Mark



Single patient – multiple use



Do not submerge in water



40°C
104°F
Storage & transport temperature



90% Rh
65% Rh
Humidity limitation



1060 hPa
700 hPa
Atmospheric pressure limitation



GS1 DataMatrix

Article list for IFU

EU1	
10592	TENA SmartCare transmitter
10619	TENA SmartCare sensor strip
8544	TENA SmartCare gateway
EU2	
10599	TENA SmartCare transmitter
10624	TENA SmartCare sensor strip
8545	TENA SmartCare gateway
NA	
91291	TENA SmartCare transmitter
91292	TENA SmartCare sensor strip
91290	TENA SmartCare gateway



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essity

TENA
an Essity brand

