

TENA SmartCare Change Indicator™

Family caregivers
Instructions for use

This guide is intended for family caregivers using the TENA SmartCare Change Indicator™ in a home environment. The Change Indicator system tracks and displays urine saturation levels in absorbent TENA incontinence products.

TENA SmartCare Change Indicator is a system consisting of:

- An app named TENA SmartCare™ Family that can be installed on one or more smartphones.
- A reusable Change Indicator made up of two parts: a sensor strip and a transmitter.

The TENA SmartCare Change Indicator is designed for people with urinary incontinence who use TENA absorbent incontinence products in a home environment. It provides support to family caregivers by helping them decide when it is best to change absorbent incontinence products without frequent manual checks. The TENA SmartCare Change Indicator system tracks urine saturation but does not detect faecal episodes.

The TENA SmartCare Change Indicator is attached to the outside of the incontinence product and tracks the urine saturation levels within. Information about increasing levels of saturation is then delivered to caregivers’ smartphones and viewed in the TENA SmartCare Family app. This information helps caregivers decide whether the TENA incontinence product needs to be changed or not.

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

The TENA SmartCare Change Indicator system including TENA SmartCare Starter Kit, TENA SmartCare transmitter, TENA SmartCare gateway, TENA SmartCare sensor strip and TENA SmartCare Family app.

The TENA SmartCare Change Indicator system is designed to be intuitive, with family caregivers in mind. It does not require special training.

Symbols used in this guide



WARNING Care shall 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 Important information or advice/tips.



CHECK Important information for the device to function.

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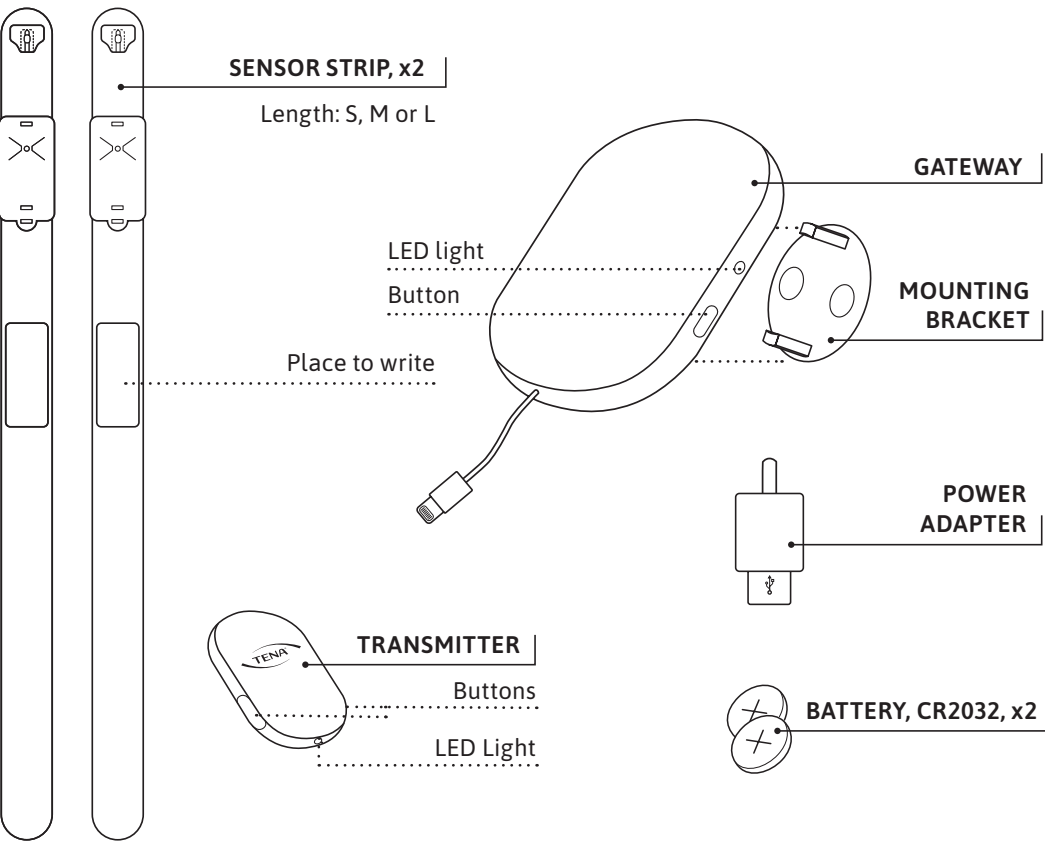
Important information

- Ensure you have read and understood these 'Instructions for use' before using the product. Save these instructions for future reference.
- If you encounter any problems, equipment failure or if any other incidents occur, report them to the manufacturer or TENA SmartCare Support.

Warning

- Keep the Change Indicator and Change Indicator batteries away from children and pets.
- 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.
- The Change Indicator should be attached to the outside of the incontinence product.
- The Change Indicator is not intended to be used in direct contact with the skin.
- Clean the Change Indicator when fully assembled to prevent water from entering the device. Do not submerge in water or clean in a washing machine.
- 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.
- Seek immediate medical care if the battery is swallowed.
- Do not attempt to repair or modify the Change Indicator or gateway by yourself.
- If any part of the Change Indicator system appears to be damaged or broken, it should not be used. Contact TENA for support.
- Do not expose the battery at high temperatures, disassemble it, damage it mechanically or put battery into the fire as this can cause an explosion or a fire.
- Do not use gateways and handheld device chargers with unapproved power supplies.

TENA SmartCare Change Indicator components



You also need (not included):



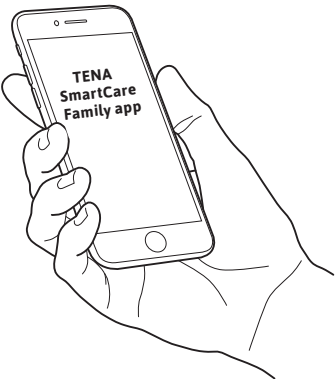
CONSUMABLES:

Sensor strip short, sensor strip medium, sensor strip long, battery.

Download app and set up account

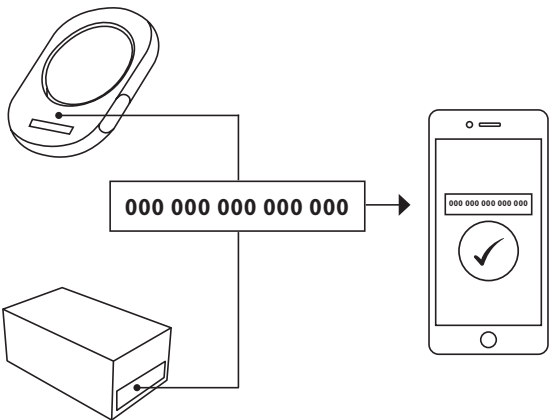
1 DOWNLOAD TENA SMARTCARE FAMILY APP

Download the TENA SmartCare Family app from App Store or Google Play and then register your account.



2 REGISTER THE TRANSMITTER

Follow set-up instructions on the TENA SmartCare Family app. The transmitter code is located on the back of the transmitter or on the packaging.

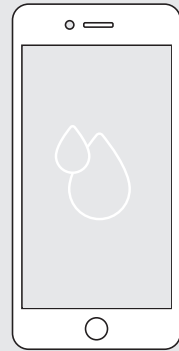


3 INVITE OTHER CAREGIVERS

Invite others who care for your loved one. This will give them access to the TENA SmartCare Family app.



Explanation of app during use



1 DRY – no action needed

The absorbent core of the TENA product is dry and the surface feels dry to the skin.



2 SOME URINE – no action needed

There is some urine in the absorbent core of the TENA product. However, the surface still feels dry to the skin. If the absorbent product has been on for an extended period and the user has sensitive skin, you may want to consider changing it.

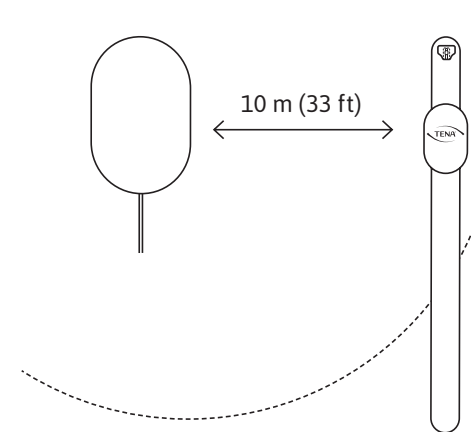


3 WET – consider change

There is a large amount of urine in the absorbent core of the TENA product. The surface probably still feels dry to the skin, but you should consider a change – especially if the absorbent product has been on for an extended period and/or the user has sensitive skin.

Set up gateway

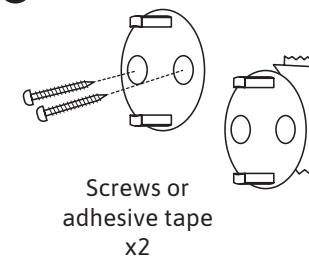
Placement



NOTE

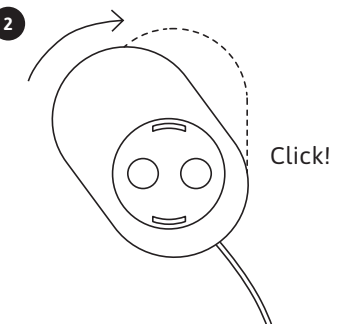
The gateway should be placed within 10 m (33 ft) of the user and connected to an electrical power outlet.

1

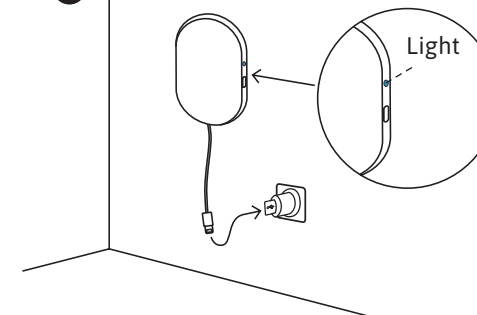


Screws or
adhesive tape
x2

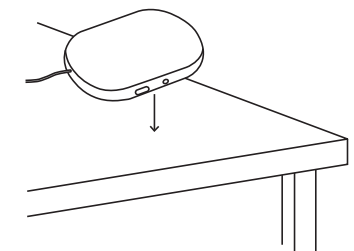
2



3

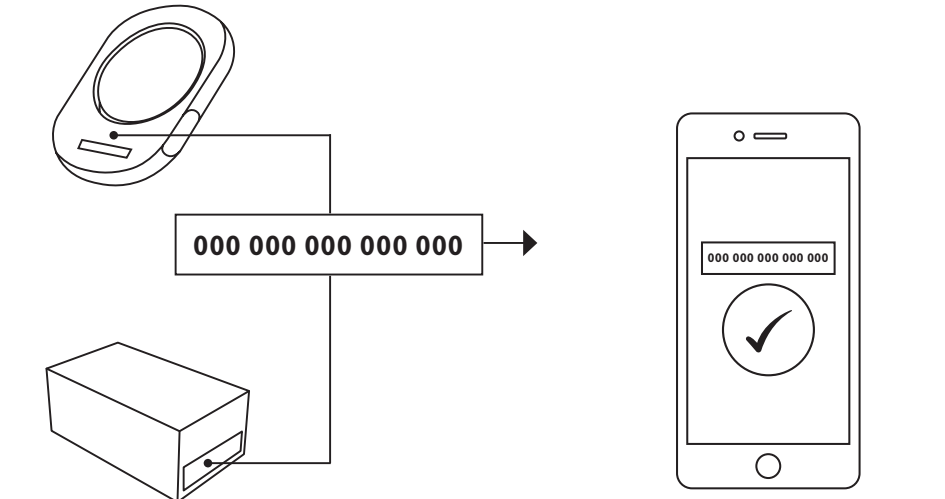


You can also place the gateway on a flat surface



See page 23
Gateway lights & buttons

Register transmitter code

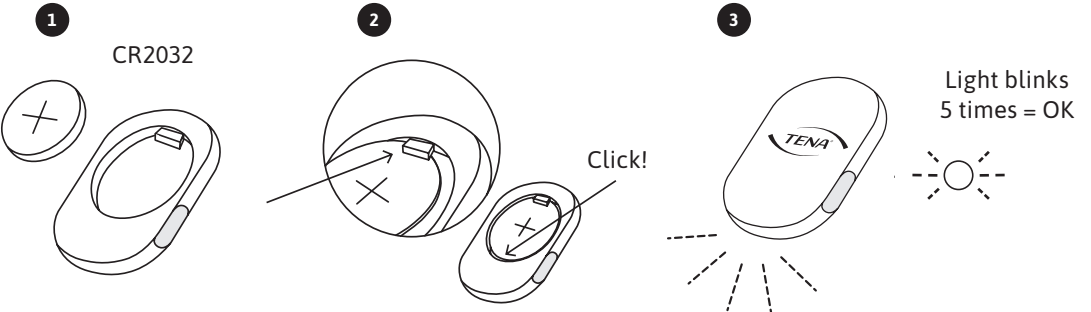


1 Find the transmitter code, which is located on the back of the transmitter or on the packaging.

2 Enter the transmitter code in the TENA SmartCare Family app to register.

Install battery & assemble Change Indicator

Install battery



1 CR2032

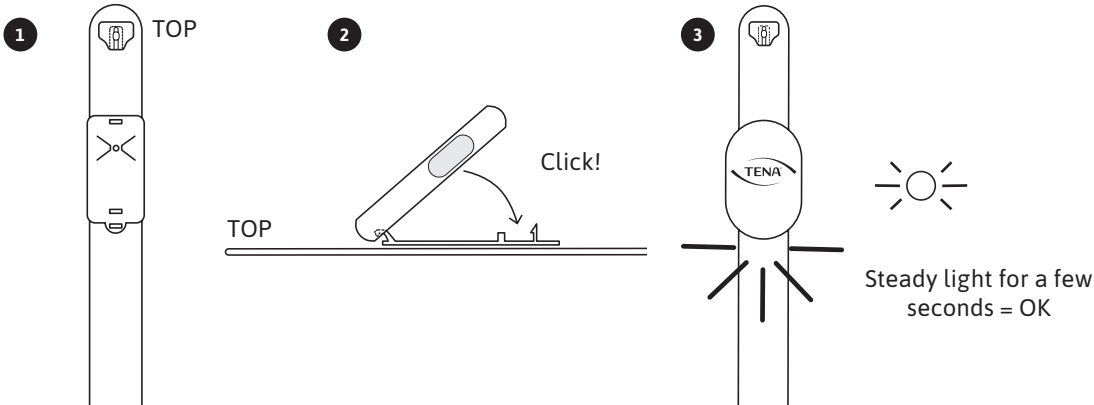
2 Click!

3 Light blinks 5 times = OK

See page 24
Transmitter
lights & buttons

WARNING Only CR2032 batteries shall be used in the TENA SmartCare Change Indicator.

Assemble Change Indicator (transmitter + sensor strip)



1 TOP

2 Click!

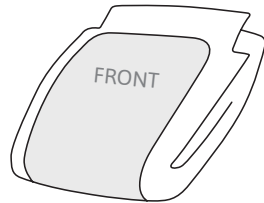
3 Steady light for a few seconds = OK

See page 24
Transmitter
lights & buttons

Attach Change Indicator

See supported products on pages 16–20 of this guide or in the TENA SmartCare Family app.

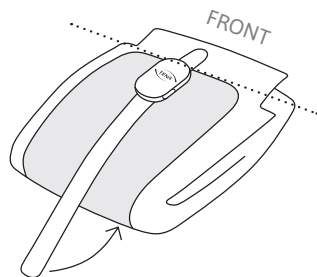
1 Find the front



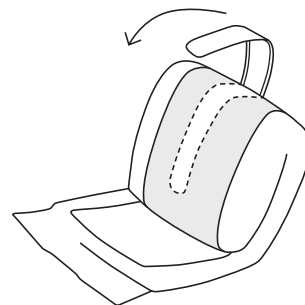
2 Keep folded



3 Align with top of thicker absorbent area



4 Place tightly



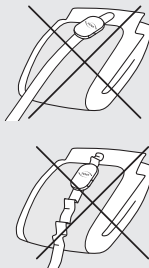
⚠ Please note that product size and sensor strip length do not always match.



NOTE

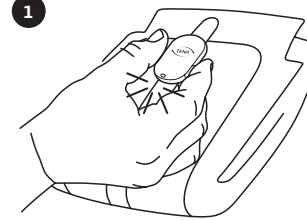
Always attach the Change Indicator before you unfold the incontinence product. Start by placing the Change Indicator at the front of the incontinence product, on the thicker absorbent area, ensuring it is straight. (1) Press firmly to ensure the Change Indicator has full contact with the incontinence product.

Align transmitter with top of the thicker absorbent area of the incontinence product.



Use Change Indicator

1



Press both buttons simultaneously for two seconds at every change. This records the change of incontinence product in the TENA SmartCare Family app and resets the system.

Steady light for a few seconds:
Continue to step 6

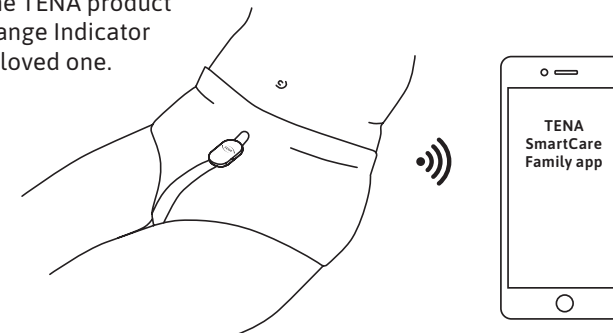


Blinking light:
Change battery, see page 21



2

Apply the TENA product with Change Indicator on your loved one.



3

For explanations of app notifications, see page 8.



DRY

– no action needed



SOME URINE

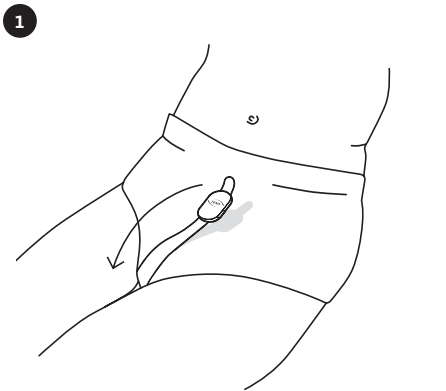
– no action needed



WET

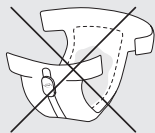
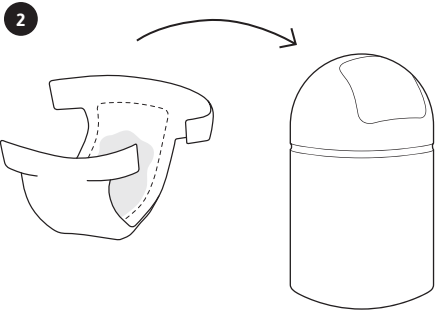
– consider change

Remove Change Indicator

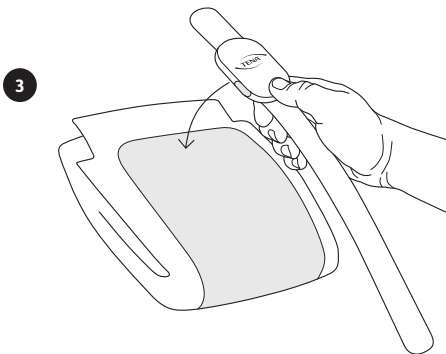


NOTE

The Change Indicator should be removed while the user is still wearing the incontinence product. Gently pull the change indicator down from the top, then roll the user onto his/her side before completing removal. (1)



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



Intended use

Intended Use:

The TENA SmartCare Change Indicator is an accessory to absorbent incontinence 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 incontinence products. The TENA SmartCare Change Indicator estimates the degree of urine saturation in the absorbent incontinence product and notifies the care giver(s). This facilitates the care giver decision regarding when to change the absorbent incontinence product.

Standard operation:

- If the Change Indicator is broken, it should be replaced, not repaired.
- 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 incontinence product.
- The Change Indicator is operated by the caregiver of the incontinent user. The user wears the TENA Change Indicator in combination with a TENA incontinence product.
- Attaching the Change Indicator to the incontinence product is considered a primary operating function.
- Only the caregiver is intended to interact with the Change Indicator.
- To turn the Transmitter OFF, remove the battery.
- The Change Indicator is intended for one user only 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 fulfils requirements for home healthcare environments.

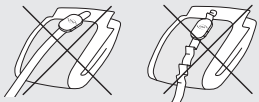
Attachment instructions for supported TENA products

TENA Slip

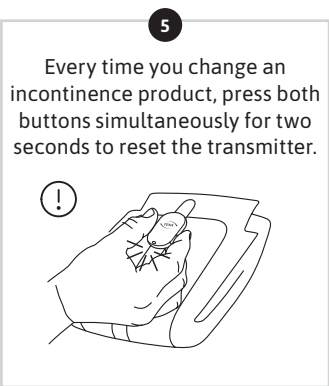
Plus, Super or Maxi

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

TENA Slip	TENA SmartCare sensor strip length
S	S
M	M
L	L



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.

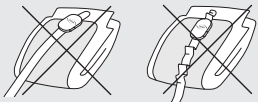


TENA Flex

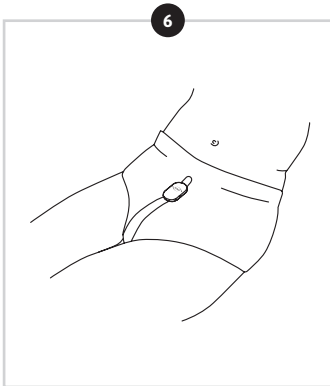
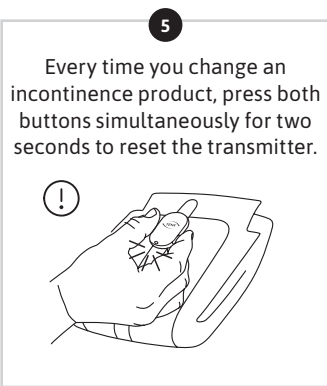
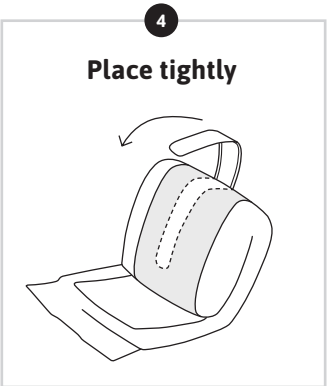
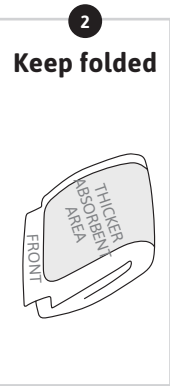
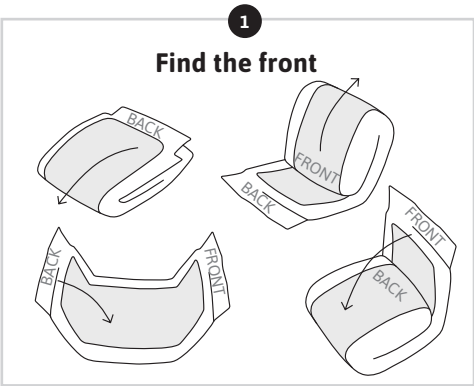
Plus, Super or Maxi

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

TENA Flex	TENA SmartCare sensor strip length
S	S
M	M
L	M !



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.



TENA Stretch Brief

Super or Ultra

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

TENA Stretch Brief	TENA SmartCare sensor strip length
M/R	M
L/XL	L !



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 top of thicker absorbent area

Please note that product size and sensor strip length do not always match.

4

Place tightly

5

Every time you change an incontinence product, press both buttons simultaneously for two seconds to reset the transmitter.

6

TENA Pants / TENA Protective Underwear

Plus or Super

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

TENA Pants	TENA SmartCare sensor strip length
S	S
M	S !
L	S !



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 top of thicker absorbent area

Please note that product size and sensor strip length do not always match.

4

Place tightly

5

Every time you change an incontinence product, press both buttons simultaneously for two seconds to reset the transmitter.

6

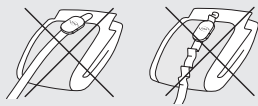
Attachment instructions for supported TENA products

TENA Brief

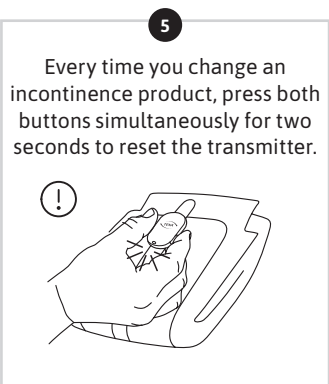
Super or Ultra

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

TENA Brief	TENA SmartCare sensor strip length
R	M !
M	M
L	L
XL	L !



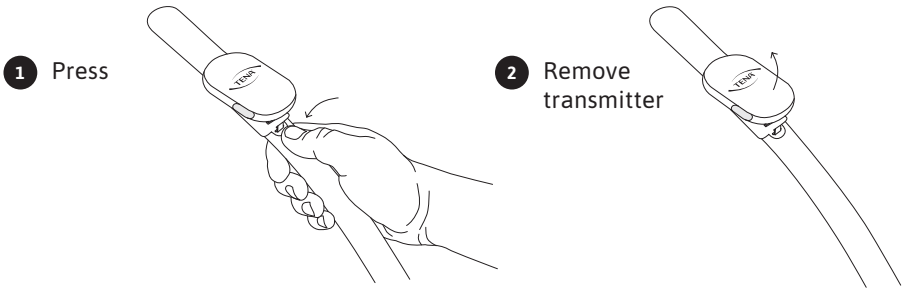
Ensure the Change Indicator is straight. Smooth any sensor strip wrinkles, then press firmly to ensure the Change Indicator has full contact with the TENA absorbent product.



Change sensor strip & battery

TENA sensor strip

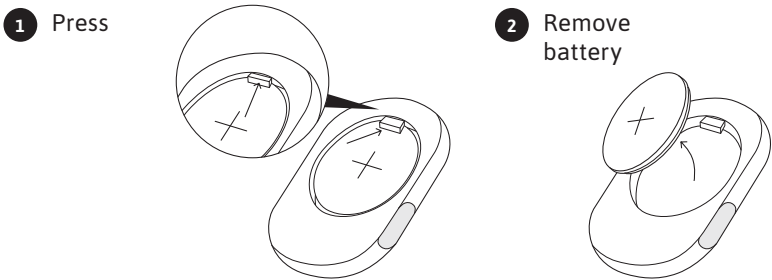
The sensor strip is designed to withstand approximately 4 weeks continuous use. Sometimes, however, the hooks on the back of the sensor strip can become covered with fibres or lint. This prevents the hooks from attaching to the incontinence product. If the fibres or lint cannot be removed, the sensor strip should be changed. The sensor strip should also be changed if it becomes soiled with faeces and cannot be cleaned sufficiently. For cleaning advice, see page 22 of this guide.



2 Remove transmitter

Battery replacement

If the LED light starts to blink, 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 4 weeks. However, the battery can be changed whenever needed.



2 Remove battery



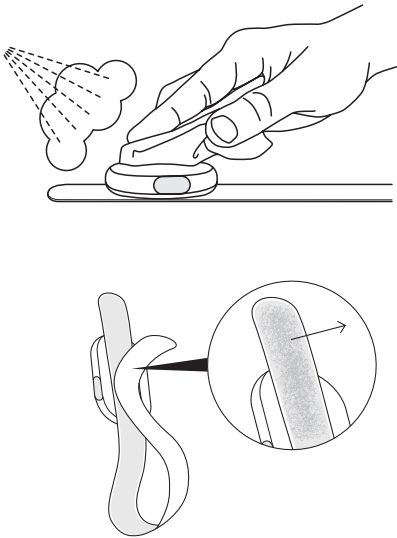
NOTE
If you have difficulty removing the battery, tap the transmitter in your hand until the battery falls out.

Cleaning

Change Indicator

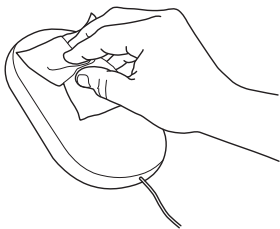
Only clean the Change Indicator when it is fully assembled. The transmitter and sensor strip should never be cleaned separately. Clean the Change Indicator using a cloth and disinfectant when required. The device can be rinsed under a tap.

Any fibres or lint attached to the Velcro should be removed to ensure a secure fit between the Change Indicator and the absorbent incontinence product. Fibres can be removed using the end of the sensor strip or gently with a lint roller (adhesive paper).



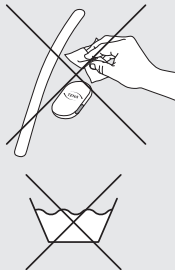
Gateway

Clean the gateway with a dry cloth when needed.



WARNING

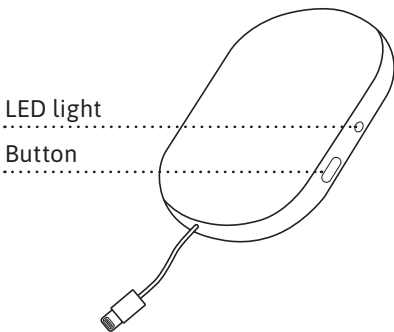
Clean the Change Indicator when fully assembled to prevent water entering the device.
Do not clean in the washing machine.
Do not submerge in water.



Gateway lights & buttons

Gateway installation

Once the gateway has been connected to a power outlet.



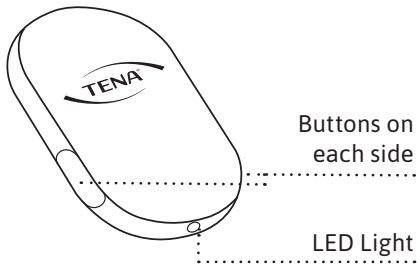
NOTE




The LED light can be difficult to see if exposed to strong sunlight, for example. To improve visibility, try blocking out any strong sunlight.

COLOUR LED LIGHT	WHAT IT MEANS
	Blinking blue light: Wait. The system is connecting. Allow up to 60 seconds for light to start blinking.
	Steady green light: Everything is OK.
	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 connection. If no light comes on, check the power connection.
	Steady red light: Error. See TROUBLESHOOTING section, p. 26–34 of this guide for more information.

Transmitter lights & buttons







NOTE

The LED light can be difficult to see if exposed to strong sunlight, for example. To improve visibility, try blocking out any strong sunlight.




Battery installation

Once the battery has been installed in the transmitter.

LED LIGHT	WHAT IT MEANS
	Blinks five times: Battery is in correct position. Attach transmitter to sensor strip.
	No light: OK The light disappears after a few seconds. Check for power by pressing both buttons simultaneously for two seconds.




Change Indicator assembly

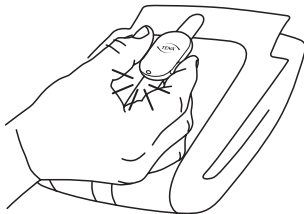
Once the transmitter has been attached to the sensor strip.

LED LIGHT	WHAT IT MEANS
	Steady light for a few seconds: Everything is OK.
	Blink five times: Transmitter is not attached properly or battery is low. Try re-attaching transmitter.
	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 incontinence product


Press both buttons simultaneously for two seconds at every change of incontinence product. This records the change of incontinence product in the TENA SmartCare Family app and resets the system.

LED LIGHT	WHAT IT MEANS
	Steady light for a few seconds: Everything is OK.
	Blinks five times: Transmitter is not attached properly. Try re-attaching. Or: battery is low. Change battery.
	No light at all: Error. See TROUBLESHOOTING section, p. 26–34 of this guide for more information.



Water, sand and dirt

The Change Indicator (when fully assembled with transmitter and sensor strip) has a classification of IP54. IP54 indicates that it is protected against small objects and splashing water. Use of an approved disinfectant spray product or wipe is recommended. Always clean Change Indicator when fully assembled – never attempt to clean individual parts separately.



WARNING

If water has entered the sensor strip or transmitter, ensure it is completely dry before use.

Troubleshooting

PROBLEM	ITEM	ACTION
Connection error	Gateway	<ol style="list-style-type: none">1. Press the gateway button. If there is a steady green light everything is OK.2. If there is a blinking blue light, the gateway is trying to connect.3. If the gateway doesn't connect after five minutes, try moving it to a position in the room where the Internet connection is stronger.4. If this does not help, please contact TENA SmartCare support.5. If no light comes on after pressing the gateway button, check that the power cable and power adapter are both properly connected.6. If this does not help, please contact TENA SmartCare support.

PROBLEM	ITEM	ACTION
Connection error	Change Indicator	<ol style="list-style-type: none">1. Make sure the transmitter is properly attached to the sensor strip. (see p. 11 of this guide)2. Press both buttons simultaneously for two seconds.3. If there is no light, change the battery and re-attach the transmitter to a sensor strip. Press both buttons simultaneously. If there is a steady light for a few seconds, everything is OK.4. If there is a blinking light, check that the transmitter is properly attached to the sensor strip. Adjust if needed, then press both buttons simultaneously. If the light continues blinking, change the battery. If there is a steady light for a few seconds, everything is OK.5. If this does not help, attach to a new sensor strip. Press both buttons simultaneously. If there is a steady light for a few seconds, everything is OK.6. If this does not help (no light or blinking light after correctly attaching to the sensor strip), please contact TENA SmartCare Support.

PROBLEM	ITEM	ACTION
Connection error	System range	<ol style="list-style-type: none"> Both the user and transmitter should be in range of the gateway – usually within 10 metres or 33 feet. Try moving the gateway to a place where it is within range of the transmitter.
Connection error	Network failure	Occasionally, the cellular network may go down. If this happens, revert to a manual changing routine until the system is up and running again.
Change Indicator falls off	Change Indicator	<ol style="list-style-type: none"> Firstly, make sure you are using one of the supported TENA absorbent incontinence products with a textile-like backsheet (see p. 16–20 of this guide). The Change Indicator does not attach to absorbent products with a plastic backsheet. Make sure you attach the Change Indicator to a folded product, straight from its plastic packaging. Do not attach it when the user is already wearing the absorbent product. Check the Velcro-covered side of the sensor strip to see if it is covered with lint. Remove any lint.

PROBLEM	ITEM	ACTION
I don't understand the notifications	Status indication	<p>The notifications are there to support your decision making regarding when to change the absorbent incontinence product without having to check manually. There are three different notifications:</p> <ol style="list-style-type: none"> Dry – two empty drops: The absorbent core of the TENA product is dry and the surface feels dry to the skin. Some urine – One filled and one empty drop: There is some urine in the absorbent core of the TENA product. However, the surface still feels dry to the skin. If the absorbent product has been on for an extended period and the user has sensitive skin, you may want to consider changing it. Wet – two filled drops: There is a large amount of urine in the absorbent core of the TENA product. The surface probably still feels dry to the skin, but you should consider a change – especially if the absorbent product has been on for an extended period and/or the user has sensitive skin.

PROBLEM	ITEM	ACTION
The system notifies me too early	Status indication	<p>You experience that the “consider change” notification shows when an absorbent product is still dry or has not been worn for long.</p> <ol style="list-style-type: none"> 1. Make sure you are using one of the supported TENA products (see p. 16–20 of this guide). 2. Make sure you are using the correct sensor strip length for your TENA product (see p. 16–20 of this guide). 3. Make sure the Change Indicator is attached correctly (see p. 12 of this guide). 4. If this does not help, please contact TENA SmartCare Support.

PROBLEM	ITEM	ACTION
The system notifies me too late	Status indication	<p>You experience that the “consider change” notification shows when an absorbent product is already too wet to be comfortable or the product has been worn for a long time.</p> <ol style="list-style-type: none"> 1. Make sure you are using one of the supported TENA products (see p. 16–20 of this guide). 2. Make sure you are using the right sensor strip length for your TENA product (see p. 16–20 of this guide). 3. Make sure the Change Indicator is attached correctly (see p. 12 of this guide). 4. If this does not help, please contact TENA SmartCare Support. 5. In cases of a clinical reaction, e.g. skin irritation, please revert to a manual changing routine and consult a healthcare professional.
I don't receive any notifications at all	Status indication	<ol style="list-style-type: none"> 1. Check the “Connection error” section of this troubleshooting guide. 2. Check that you have entered the correct transmitter code. The transmitter code you entered can be found under “account/hardware” in the TENA SmartCare Family app. 3. If this does not help, please contact TENA SmartCare Support.

PROBLEM	ITEM	ACTION
How often should the Change indicator be cleaned?	Cleaning	<ol style="list-style-type: none"> 1. As a rule-of-thumb, clean the Change Indicator as frequently as you change the bed linen. 2. Clean when needed, e.g. if soiled. 3. Remove lint from the Velcro-covered side when required. This will ensure the Change Indicator stays securely attached to the incontinence product.

PROBLEM	ITEM	ACTION
How do I clean the Change Indicator?	Change Indicator	<ol style="list-style-type: none"> 1. Always clean the Change Indicator when fully assembled, i.e. with the transmitter properly attached to the sensor strip. Never clean the individual parts separately as liquids or dirt may damage the electronics. 2. Clean on a regular basis, using a damp cloth or paper. 3. For more thorough cleaning, use an ethanol-based sanitizer for disinfection. 4. Use the free end of the sensor strip to remove lint from the Velcro.

PROBLEM	ITEM	ACTION
The user's skin has become irritated and turned red	Clinical reactions	If the user's skin becomes irritated, please revert to a manual changing routine and consult a healthcare professional.
The incontinence product was filled with faeces, but the system did not notify me	Faeces	The system does not detect faeces. In case of frequent faecal episodes, please revert to a manual changing routine.

Operating characteristics

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

Processing unit

Transmitter & gateway

CHARACTERISTICS	VALUE/RANGE
Wireless technology	RF communication, BLE
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 μ W Peak 75 mW
Remote communication range	At least 10 metres (33 feet) in open environment, without obstructions

Battery module

TYPE	CAPACITY / VOLTAGE
CR2032	220 mAh/3.0 V nominal

This value is with recommended battery: CR2032

Operating characteristics

Product component dimensions (mm/inch)

ITEM	LENGTH	WIDTH	HEIGHT	DIAMETER
Transmitter	51.8 mm / 2.04"	34.5 mm / 13.58"	13 mm / 0.51"	N/A
Sensor strip (S, M, L)	510–690 mm / 20.08–27.16"	27.5 mm / 1.08"	7.6 mm / 0.30"	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
Sensor strip (S, M, L)	12.6–15.9 g / 0.44–0.56 oz
Battery	3.0 g / 0.11 oz

Environmental conditions

CONDITION	MINIMUM	MAXIMUM
Storage & transport temp.	+10 °C	+40 °C
Storage & transport humidity	65% Rh	85% Rh
Operating temp.	+15 °C	+45 °C
Operating humidity (non-condensing)	15% Rh	90% Rh
Pressure	700 hPa	1060 hPa

Electro magnetic compability (EMC)

RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12") to the Change Indicator. Otherwise, degradation of the performance of this equipment could result.



Interference may occur in the vicinity of equipment marked with this symbol.

Lifetime

- Read best before date on accompanying packaging.
- Expected lifetime of the transmitter is two years and the sensor strip is 4 weeks, after the first use.
- Expected shelf life (from the manufacturing date) for the transmitter is three years and the sensor strip three years.

Disposable parts

- Clean the Change Indicator before disposal.
- Follow local regulations for disposal of the Change Indicator, the gateway and the batteries.
- 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-marking:

- This product has been designed with recycling, reuse and waste management as a consideration. Essity will provide the necessary information to recycling facilities and government agencies as required by WEEE Directive. For more information, please contact Essity at www.tena.com.
- The product will be labelled with the WEEE marking as shown on the side, in accordance with European Standard EN 50419.
- The proper disposal of WEEE products will conserve natural resources (through re-use and recycling) and protect environmental and human health through proper disposal.
- WEEE-labelled 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	IP54	IP Classification
	Manufacturer	FCC ID:	FCC ID number
	Instruction manual	IC:	IC ID number
	WEEE-marking. Dispose of electrical components in accordance with your local regulations	UDI:	Unique Device Information
	Radio Frequency Radiation Symbol		Not MR safe
	Catalogue number		European Conformity mark
	Serial number		Single patient – multiple use
	Medical Device		Do not wash
			Temperature limit

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.



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