

TENA SmartCare Change Indicator[™]

Family caregivers Instructions for use

www.tena.com

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This guide is intended for family caregivers using the TENA SmartCare Change Indicator™ in a home environment.

The TENA SmartCare Change Indicator is a digital health technology solution that helps family caregivers decide when to change absorbent products without the need for frequent manual checks.

The Change Indicator is attached to the outside of the absorbent product and tracks the urine saturation levels within. Family caregivers then receive information about the different saturation levels on their smartphones via the TENA SmartCare Family Care app. This information is then used to decide whether the absorbent product needs to be changed or not. The TENA SmartCare Change Indicator system tracks urine saturation, but does not detect faecal episodes.

TENA SmartCare Change Indicator is a system consisting of:

- An app named TENA SmartCare Family Care that can be installed on one or more smartphones used in a family.
- A reusable Change Indicator that consists of two parts: a sensor strip and a transmitter.
- A gateway that relays data from the Change Indicator to a secured 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 and TENA SmartCare Family Care 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 informatio
 - NOTE Important information or advice/tips.
- (!) **CHECK** Important information for the system to function.

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Important information

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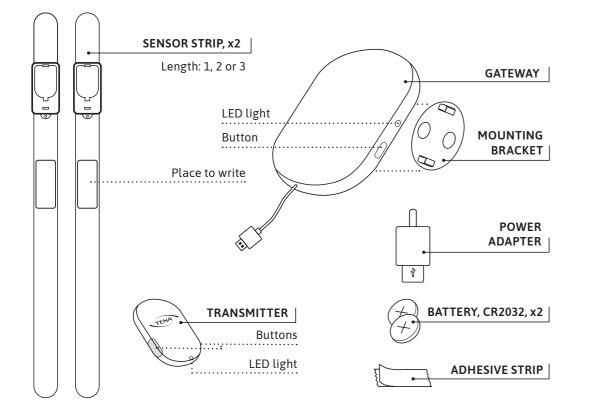
- Ensure you have read and understood these instructions before using the product. Save these instructions for future reference.
- If you encounter any problems, equipment failure or if any other incidents occur, report them to the manufacturer or TENA SmartCare Support.
- The Change Indicator is intended for use with TENA incontinence products.
- 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.
- The Change Indicator is not intended to be used in direct contact with the skin.
- Do not use gateways with unapproved power supplies.

- Keep the Change Indicator and 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.
- 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 a gateway by yourself.
- If any part of the Change Indicator system appears to be damaged or broken, it should not be used.
- 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.

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Included in the TENA SmartCare Change Indicator[™] starter kit

Download the app and set up the account



1 DOWNLOAD APP AND REGISTER ACCOUNT

Scanning the relevant QR code will take you directly to the App Store or Google Play, where you can download the TENA SmartCare Family Care app.

Once you have downloaded the app, start setting up the Change Indicator using the instruction films in the app or this quick quide.

° — To App Store (iOS) TENA TENA SMARTCARE FAMILY CARE APP To Google Play (Android) ►A

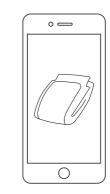
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REGISTER YOUR LOVED ONE'S PRODUCT IN THE APP 2

For the most accurate results, register the absorbent product your loved one is currently using in the app.

the packaging.



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A SUPPORTED TENA **INCONTINENCE PRODUCT** (see supported TENA products on p. 16 of this guide or in the TENA SmartCare Family Care app).

You also need:

A SMARTPHONE with TENA SmartCare Family Care app, iOS 11 / Android 7 or later.

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CONSUMABLES: Sensor strip 1 (short), sensor strip 2 (medium), sensor strip 3 (long), battery, TENA incontinence product.

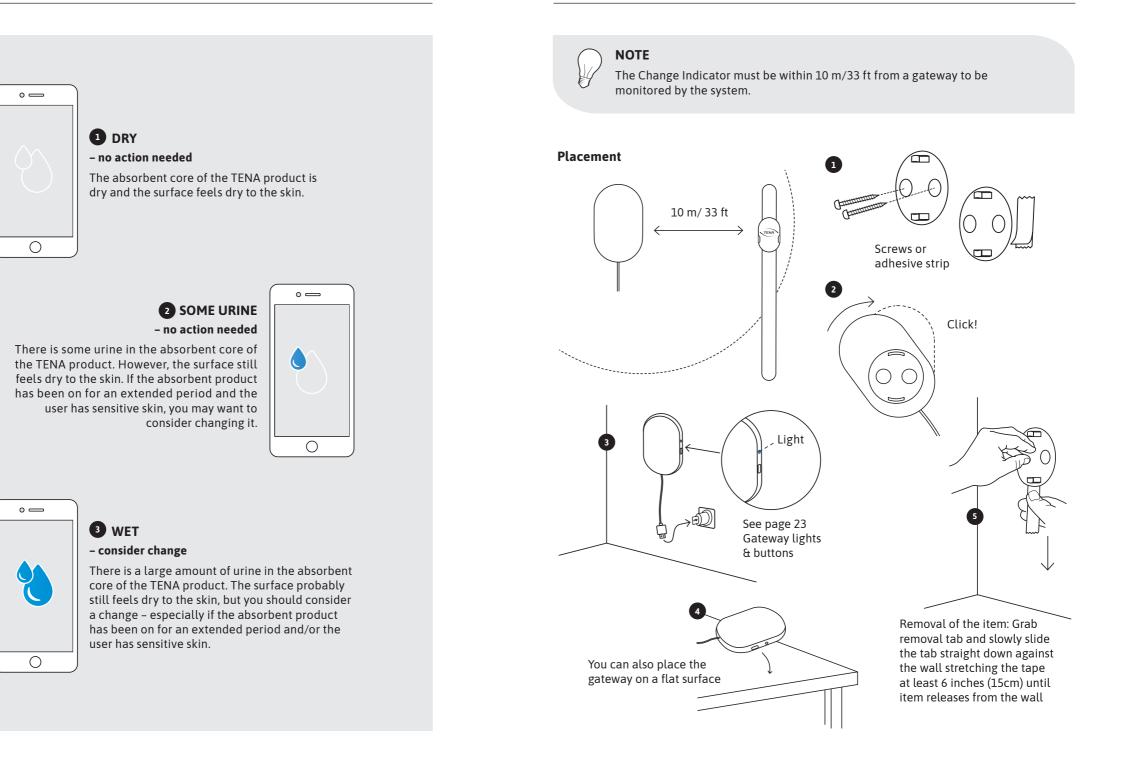


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Explanation of the app during use

Set up the gateway

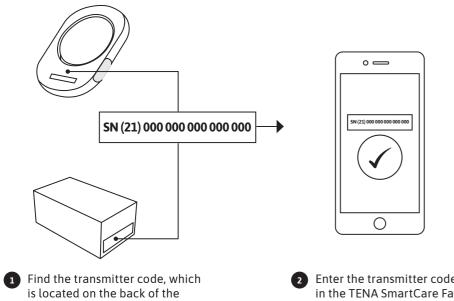


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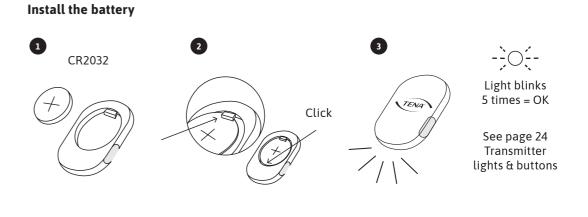
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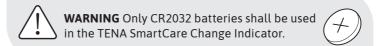
Register the transmitter code

Install the battery & assemble the Change Indicator en

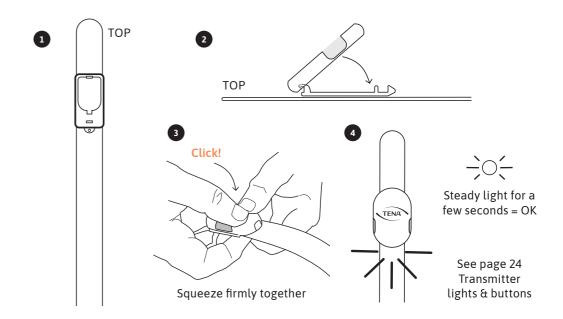


- transmitter and on the packaging.
- 2 Enter the transmitter code in the TENA SmartCare Family Care
 - app to register.





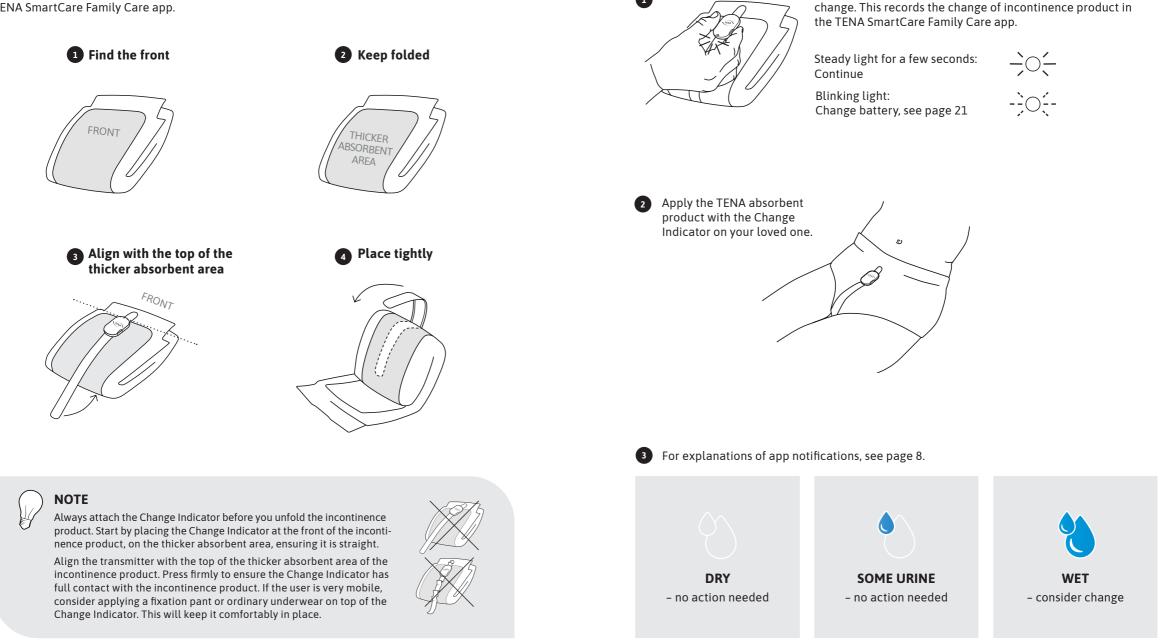
Assemble the Change Indicator (transmitter + sensor strip)



Attach the Change Indicator

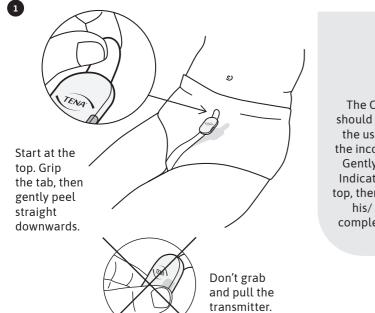
Press both buttons simultaneously for two seconds at every

See supported TENA absorbent products on p. 16 of this guide or in the TENA SmartCare Family Care app.



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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 the removal.



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

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 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 persons 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.

List of supported TENA products

Attachment instructions for supported TENA products

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CHECK Ensure you have the correct sensor strip length for your TENA product. Only products with a textile-like outer lining can be used with the Change Indicator.

TENA Slip Plus, Super, Maxi, Ultima

Size	XS	S	м	L	XL	2XL	3XL
Sensor Strip length	1	1	2	3	3	3	3

TENA Flex Normal, Plus, Super, Maxi, Ultima

Size	S	м	L	XL
Sensor strip length	1	2	2	3

TENA Pants Normal, Plus, Extra, Super, Maxi

TENA Silhouette Underwear Plus (high waist)

TENA Men Pants Active Fit

Size	xxs	XS	s	м	L	XL	2XL
Sensor strip length	1	1	1	1	1	1	1

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

TENA Comfort

Absorbency	Normal	Plus	Extra	Super	Maxi	Ultima
Sensor strip length	1	1	1	1	2	2

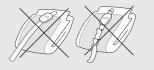
TENA Slip

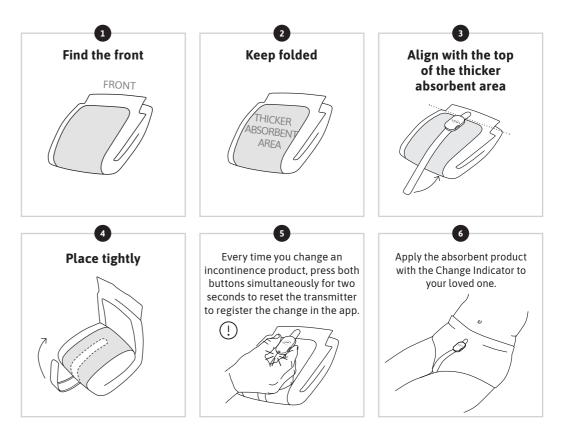
The TENA SmartCare Change Indicator[™] should always be attached when the incontinence product is folded and before it has been applied to the user.



) NOTE Ensure

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.



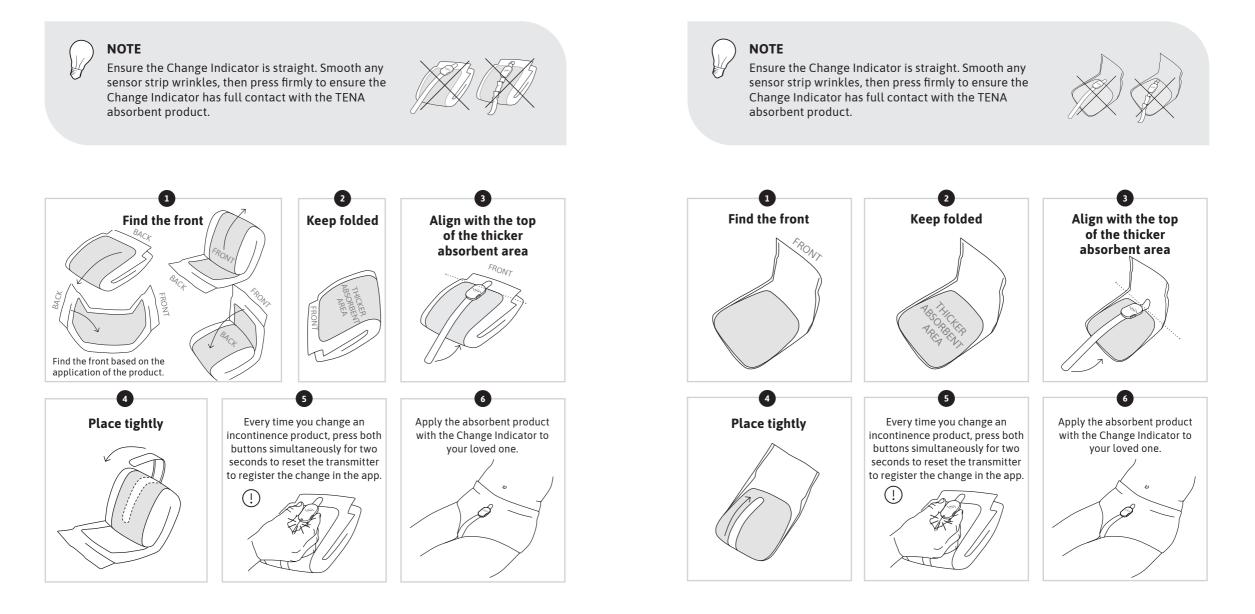


TENA Flex

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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

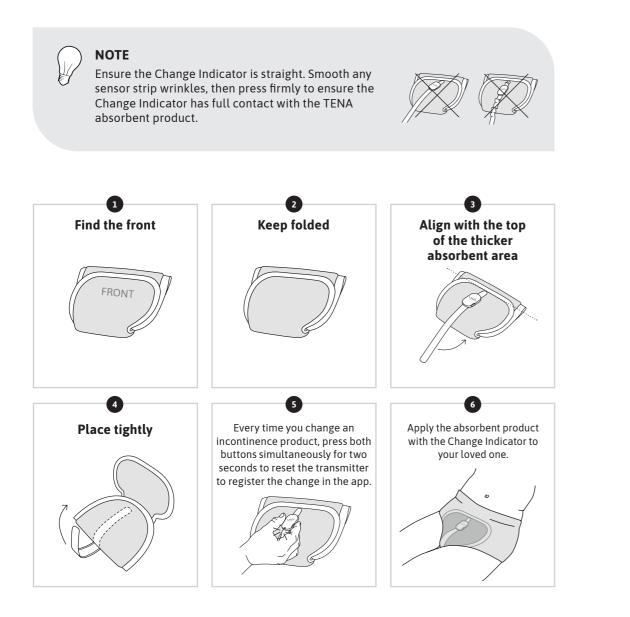
The TENA SmartCare Change Indicator™ should always be attached when the

incontinence product is folded and before it has been applied to the user.

TENA Comfort

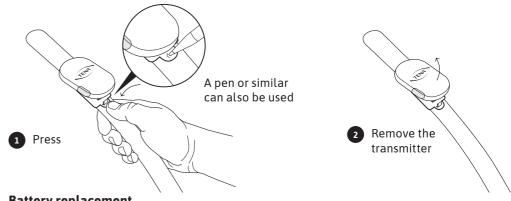
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The TENA SmartCare Change Indicator[™] should always be attached when the incontinence product is folded and before it has been applied to the user.



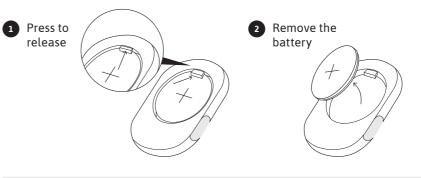
Sensor strip replacement

The sensor strip is designed to withstand up to 12 weeks of 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 replaced. The sensor strip should also be replaced if it is physically damaged in any way, if it becomes soiled with faeces and can not be cleaned sufficiently. For cleaning advice, see page 22 of this guide.



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 12 weeks. However, the battery can be replaced whenever needed.



CHECK

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If you have difficulty removing the battery, first press the locking tab, then tap the transmitter in your hand until the battery falls out. The transmitter is designed to withstand attachment and removal from a sensor strip four times per year over two years. With more frequent attachments/ removals, the system may not work as intended.

Cleaning

Change Indicator

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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.

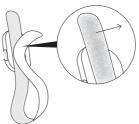


We recommend using:

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



Any fibres 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 incontinence product. Fibres can be removed using the free end of the sensor strip.



Gateway

Clean the gateway with a dry cloth when needed.

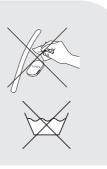


WARNING

Clean the Change Indicator when fully assembled to prevent water from entering the device.

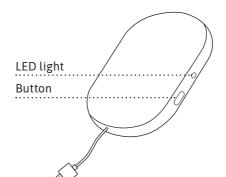
Do not clean in the washing machine.

Do not submerge 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 pp. 25–29 for more information.
-;•(;•(;•(-	Blinking blue-green-red light: pull out the power. Wait 30sec. Insert the power. Wait 2min. If the error persists, contact TENA SmartCare support.

Transmitter lights & buttons

NOTE

Change Indicator assembly

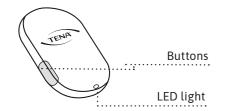
the sensor strip:

The LED light can be difficult

to see if exposed to a strong sunlight, for example. Try to block the sunlight to improve readability.

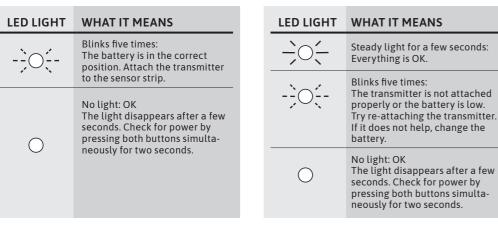
Once the transmitter has been attached to

Troubleshooting



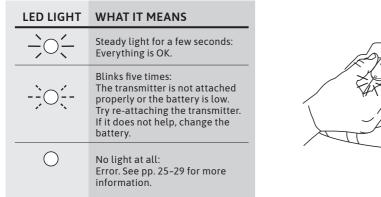
Battery installation

Once the battery has been installed in the transmitter:



Applying the Change Indicator to the incontinence product

Press both buttons simultaneously for two seconds at every change of incontinence product to register the change in the app.





lost)		 Press the gateway button. If there is a steady green light, everything is OK. If there is a blinking blue light, the gateway
		3 If there is a blinking blue light the gateway
		is trying to connect.
		4. If the gateway fails to connect and the light doesn't turn green after one minute, try moving the gateway to a position in the room where the network connection is stronger and wait for the green light.
		 Occasionally, the cellular network may go down. If this happens, revert to a manual changing routine until the system is up and running again.
		6. If this does not help, please contact TENA SmartCare support.
		 If the gateway blinks in three colors (red-blur-green), there is a technical error inside the electronics. Contact TENA SmartCare Support for replacement.

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PROBLEM	SOURCE	SOLUTION
Connection error (signal lost)	Change Indicator	1. Make sure the transmitter is properly attached to the sensor strip and that the battery is properly inserted. (see p. 11 of this guide).
		2. Press both buttons on the assembled Change Indicator simultaneously for two seconds.
		a. If there is no light, change the battery and re-attach the transmitter to the sensor strip. Press both buttons simultaneously. If there is a steady light for a few seconds, everything is OK.
		b. 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.
		c. If there is a steady light for a few seconds, everything is OK.
		3. If this does not help, replace the sensor strip. Press both buttons simultaneously.
		If there is a steady light for a few seconds, everything is OK.
		4. If this does not help (no light or blinking light after correctly attaching to the sensor strip), please contact TENA SmartCare Support.

PROBLEM	SOURCE	SOLUTION
Connection error (signal lost)	System range	 The Change Indicator should be in range of the gateway – usually within 10 metres or 33 feet.
		2. Try moving the gateway to a place where it is within range of the Change Indicator.
		3. If this does not work, check the "connection error" section above.
Change Indicator falls off	Change Indicator	1. Make sure you are using one of the supported TENA incontinence 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 plastic packaging. Do not attach it when the user is already wearing the absorbent product.
		 Check the hook-covered side of the sensor strip to see if it is covered with lint. Remove any lint.
		 If this does not help, replace the sensor strip.

PROBLEM	SOURCE	SOLUTION
The system notifies me too early / too late	Status indication	 a) You receive the "consider change" notification when an absorbent product is still dry or has not been worn for long. b) You receive the "consider change" notification when an absorbent product is already too full of urine to be comfortable.
		 Make sure you are using one of the supported TENA products (see p. 16 of this guide).
		 Make sure you are using the correct sensor strip length for your TENA product (see pp. 16 of this guide).
		3. Make sure the Change Indicator is attached correctly (see pp. 17-20 of this guide).
		4. Check the settings in the TENA SmartCare Family Care app. Is the proper absorbent product selected?
		5. If this does not help, please contact TENA SmartCare Support.

PROBLEM	SOURCE	SOLUTION
I don't receive any notifications at all	Status indication	 Check "connection error" in the troubleshooting section of this guide. Check that you have entered the right transmitter code in the TENA SmartCare Family Care app. If this does not help, please contact TENA SmartCare Support.

Technical descriptions

Operating characteristics

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

Processing units 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 uW Peak 75 mW
Remote communication range	At least 10 metres (33 feet) in open environment, without obstructions

Battery module

CR2032

TYPE CAPACITY / VOLTAGE

220 mAh/3.0 V nominal

This value is with recommended battery: CR2032

Product component dimensions (mm/inch)

ITEM	LENGTH	WIDTH	HEIGHT	DIAMETER
Transmitter	51.8 mm / 2.04"	34.5 mm / 1.36"	13 mm / 0.51"	N/A
Sensor strip (1, 2, 3)	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 (1, 2, 3)	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	90% Rh
Operating temp.	+15 °C	+40 °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

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- · Read best before date on accompanying packaging.
- The transmitter is designed to withstand up to two years of continuous use and the sensor strip are designed to withstand up to 12 weeks of continuous use.
- Expected shelf life (from the manufacturing date) for the transmitter is three years and for the sensor strip is three years.
- The transmitter is designed to withstand attachment and removal from a sensor strip four times per year over two years. With more frequent attachments/ removals, the system may not work as intended.

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 mark:

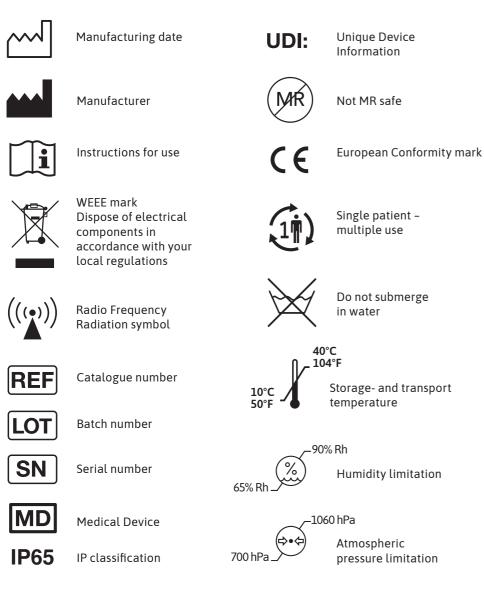
- This product has been designed with recycling, reuse and waste management in consideration. Essity will provide the necessary information to recycling facilities and government agencies as required by WEEE Directive. For more information, please contact the manufacturer at www.tena.com.
- The product will be labelled 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-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.

Labelling symbols

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



Assortment overview

ARTICLE LIST FOR IFU

- 8537 TENA SmartCare transmitter
- 8541 TENA SmartCare sensor strip 1
- 8542 TENA SmartCare sensor strip 2
- 8543 TENA SmartCare sensor strip 3
- 8545 TENA SmartCare gateway

SmartCare Support, UK: support.smartcare@tena.co.uk

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