

TENA SmartCare Change Indicator[™]

Professional caregivers Instructions for use

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Warning

This guide is intended for professional caregivers, super users and managers using the TENA SmartCare Change Indicator™ in a nursing 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:

- The TENA SmartCare[™] Professionals dashboard that serves as an information hub for professional caregivers, super users and managers.
- An app named TENA SmartCare Professionals that is installed on the handheld devices of caregivers, super users and managers.
- A reusable Change Indicator made up of two parts: a sensor strip and a transmitter.
- A gateway that relays data from the Change Indicator to the Internet.

The TENA SmartCare Change Indicator is designed for professional caregivers, super users and managers who care for residents with urinary incontinence in a nursing home environment. It provides support by helping professional caregivers 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. Caregivers, super users and managers receive Information about increasing levels of saturation on their handheld devices via the TENA SmartCare Professionals app and on the dashboard.

TENA SmartCare Change Indicator is designed to alert caregivers, super users and managers when residents require care and to help them decide whether the TENA incontinence product needs to be changed or not. It also helps provide more effective, individualised incontinence care.

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 Professionals app and the TENA SmartCare Professionals dashboard.

Symbols used in this guide Technical description MARNING 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. Operating characteristics MOTE/TIP Important information or advice /tips. Lifetime Important information for the device to function. Disposable parts Labelling symbols Labelling symbols

Warning

- Ensure you have received training and/or have read and understood these 'Instructions for use' before using the product. Save these instructions for future reference.
- In the event of system failure or anticipated system failure, revert to a manual changing routine.
- TENA SmartCare Change Indicator is intended for 24/7 use.
- The system provides information on urine saturation levels to help guide decision making regarding when TENA incontinence products should be changed.
- TENA SmartCare Change Indicator does not replace normal safety checks and routines for repositioning residents, checking for faeces, administering medication, etc.
- Do not attach the Change Indicator to the inside of the incontinence product. TENA SmartCare Change Indicator should only be attached to the outside of the incontinence product.
- Do not use the Change Indicator system on residents who experience frequent faecal incontinence. TENA SmartCare Change Indicator does not detect faecal episodes.
- Do not use the same Change Indicator for multiple residents.
- If you encounter any problems, equipment failure or if any other incidents occur, report them to the manufacturer or TENA SmartCare support.

- 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 put the Change Indicator in an autoclave.
- 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.
- The Change Indicator is not intended for use in an aseptic environment.
- The Change Indicator is not magnetic resonance-safe and should not be brought into a magnetic resonance imaging environment.
- Do not use the Change Indicator where X-Rays are performed.
- If a defibrillator is used on a resident who is wearing the Change Indicator, the Change Indicator must be replaced.
- Ensure adequate disinfection procedures are followed for residents with infectious diseases.
- Only use the Change Indicator on a single user. If a resident is experiencing loose bowel movements or diarrhoea, wait until the condition has been treated before resuming use of the Change Indicator.
- 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.

Continues on next page

Warning

TENA SmartCare Change Indicator components

- 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.
- The Change Indicator and Gateway should not be used in an oxygen rich environment.
- The Change Indicator and Gateway should not be used in presence of flammable anaesthetics.



CONSUMABLES:

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

Your TENA representative will help you download the TENA SmartCare Professionals app, register your account and set up users in both the TENA SmartCare Professionals app and dashboard.

The dashboard is used by super users and nursing managers to: monitor the average response time for changes, add or remove residents from the system and create various reports.

Using the TENA SmartCare Professionals app

- 1 At the beginning of each shift, caregivers collect a handheld device and log in to the TENA SmartCare Professionals app to receive notifications. The password is provided by a super user or manager.
- 2 During their shift, caregivers receive notifications regarding urine saturation levels in residents' absorbent products.

To protect their privacy, residents are identified by their room numbers rather than their names. In the TENA SmartCare Professionals app, beside each resident's room number, caregivers will see a status icon for that particular resident.



The dashboard

The dashboard serves as an information hub for super users and managers. It provides access to real-time information as well as information saved from the previous 30-day period. This information includes notifications and details on incontinence product changes. Information on how long residents have spent in incontinence products after notifications have been sent, the status of the sensors and error notifications can also be accessed. There are three tabs on the home page: Home, Residents and Statistics. Nurses and Managers can log out or access "Help" from any of these pages.



The Home page provides an overview of of incontinence product changes throughout the nursing home. The Residents and Statistics pages allow super users and managers to monitor performance and levels of care in specific areas of the nursing home as well as for specific residents.

The Residents page page allows super users and managers to quickly view the average response time per shift over a 30-day period. It also allows them to access the status of a specific resident for the last 30 days. To see more information, click on the "History" button in the "Actions" column.

The Statistics page offers two different ways to view response times to "change" notifications – a bar chart and a grid. Both options enable the user to select a particular day or resident (by clicking on the "History" icon) and then view notifications and response times relating to this resident.





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





Assemble Change Indicator (transmitter + sensor strip)



See list of supported products on page 18–23 in this guide or in the app.



Press firmly to ensure the Change Indicator has full contact with the whole incontinence product.

(!)

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



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

Steady light for a few seconds: Continue to step 6

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TENA

SmartCare

Professional

app

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Blinking light: Change battery, see page 24

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You can read more in-depth explanations on page 9.





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Saturated

Some Urine

- Consider change. The resident's absorbent product is nearing saturation.

Some urine detected, but the surface of the product is still dry.

- No action needed.

- No action needed. Resident's absorbent product is dry.

Ok

Off

- Resident's absorbent product is not being monitored by TENA SmartCare Change Indicator.



- See TROUBLESHOOTING section of this guide for more information





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)



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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:

- 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 operator of this Change Indicator is 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 residents 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 both home and professional healthcare environments. The medical equipment is also compliant for professional healthcare facility environment use.

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 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
м	м
L	м !



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 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
м	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.



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 Comfort

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 SmartCare sensor strip length
S
S
S
м
м



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 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 25 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 4 weeks. However, the battery can be changed whenever needed.



NOTE

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

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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 disinfectant wipe and/or disinfectant spray when required, according to your local infection control protocol. 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.

Ensure adequate disinfection procedures are followed for residents with infectious diseases.

Do not clean in the washing machine.

Do not submerge in water.



Transmitter lights & buttons

Gateway installation

After attaching the Gateway 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.
- <u>`</u> • <u>`</u> -	Steady green light: Everything is OK.
0	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. 29–35 of this guide for more information.



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.



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

Change Indicator assembly

Once the transmitter has been attached to the sensor strip.

NS	LED LIGHT	WHAT IT MEANS
ect position. er to		Steady light for a few seconds: Everything is OK.
ears after a few or power by ttons simulta- econds.		Blinks five times: Transmitter is not attached properly or battery is low. Try re-attaching transmitter.
	0	No light: OK The light disappears after a few seconds. Check for power by pressing both buttons simulta- neously for two seconds.

Applying the Change Indicator to the incontinence product

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

LED LIGHT WHAT IT MEANS		
- <u>`</u> O <u>(</u> -	Steady light for a few seconds: Everything is OK.	
-;;;;;-;	Blinks five times: Transmitter is not attached prop- erly. Try re-attaching. Or: battery is low. Change battery.	
0	No light at all: Error. See TROUBLESHOOTING section, p. 29–35 of this guide for more information.	



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. While it is safe to clean the Change Indicator with running water, please follow your Infection Prevention and Control protocols. Use of an approved disinfectant spray product or wipe is recommended. Always clean the 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.

PROBLEM	ITEM	ACTION
Connection	Gateway	Caregiver:
error		 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.
		 If no light comes on after pressing the gateway button, check that the power cable and power adapter are both properly connected.
		4. If this does not help, contact a super user at your care facility and revert to a manual changing procedure for residents until the connection error is resolved.
		Super user:
		1. Repeat steps 1–4 above
		2. If this does not help, contact TENA SmartCare support.
Connection	Change	Caregiver:
error	Indicator	 Make sure the transmitter is properly attached to the sensor strip. (see p. 13 of this guide)
		2. Press both buttons simultaneously for two seconds. If this does not help, contact a super user at your care facility and revert to a manual changing procedure for residents' incontinence products until the connection error is resolved.
		Super user:
		1. Repeat steps 1–2 above
		 If there is no light, change the battery and re-attach to a sensor strip. Press both buttons simultaneously again. If there is a steady

PROBLEM	ITEM	ACTION
Connection error	Change Indicator	3. If there is a blinking light, check that the transmitter is properly attached to the sensor strip. Adjust if needed. Press both buttons simultaneously again. If there is a steady light for a few seconds, everything is OK.
		4. If this does not help, attach to a new sensor strip. Press both buttons simultaneously again. If there is a steady light for a few seconds, everything is OK.
		5. If this does not help, (no light or blinking light after attaching correctly to the sensor strip) consider changing the transmitter. If changing transmitter, make sure to register the transmitter and assign it to the resident in the administrative dashboard.
		6. If this does not help, contact TENA SmartCare support.
Connection	System	Caregiver
error	range	 Both the user and transmitter should be in range of the gateway – usually within 10 metres or 33 feet.
		 If the user is within range of the gateway, see "Connection error" in the TROUBLESHOOTING section of this guide.
		3. If this does not help, contact a super user at your care facility and revert to a manual changing procedure for residents' incontinence products until the connection error is resolved.

PROBLEM	ITEM	ACTION
Connection error	System range	 Super user: 1. Both the user and transmitter should be in range of the gateway – usually within 10 metres or 33 feet. 2. If the user is within range of the gateway, see "Connection error" in the TROUBLESHOOTING section of this guide. 3. If this does not help, contact TENA SmartCare support.
Connection error	Network failure	Occasionally, the network may go down. If this happens, inform a super user at your care facility and revert to a manual changing routine until the system is up and running again. Super user: Occasionally, the network may go down. If this happens, inform the person in charge of your network at your care facility.
Change Indicator falls off	Change Indicator	 Firstly, make sure you are using one of the supported TENA absorbent incontinence products with a textile-like backsheet (see p. 18–23 of this guide). The sensor strip 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.

ROBLEM	ITEM	ACTION
Change Indicator falls off	Change Indicator	 4. If this does not help, contact a super user at your care facility and revert to a manual changing procedure for residents' incontinence products until the problem is resolved. Super user: Repeat steps 1–3 above. If this does not help, attach a new sensor strip. 3. If this does not help, contact TENA SmartCare Support
l don't understand the notifications	Status indication	 Caregiver & super user: 1. The notifications are there to support your decision making regarding when to change the absorbent incontinence product without having to check manually. There are five different notifications: 2. "OK" The resident's absorbent product is dry – no action needed 3. "Some urine" Some urine detected, but the surface of the product is still dry. 4. "Saturated" The absorbent product is near.
		 Saturated The absorbent product is hear saturation – consider change "OFF" Resident's absorbent product is not being monitored "Error" Check "Connection error" in the TROUBLESHOOTING section of this guide.

PROBLEM	ITEM	ACTION
The system notifies me	Status indication	3. Make sure the Change Indicator is attached correctly (see p. 14 of this guide).
too late		4. If this does not help, please contact a super user at your care facility.
		Super user:
		1. Repeat steps 1–3 above.
		 If this does not help, make sure the right TENA product with the right absorption level is assigned to this resident in the administrative dashboard.
		3. If this does not help, please contact TENA SmartCare Support.
l don't receive any	Status indication	1. Check "Connection error" in the TROUBLESHOOTING section of this guide.
notifications at all		2. If this does not help, contact a super user at your care facility.
		Super user:
		1. Check "Connection error" in the TROUBLESHOOTING section of this guide.
		2. If this does not help, please contact TENA SmartCare Support.

PROBLEM	ITEM	ACTION
How often should the Change indicator be cleaned?	Change Indicator	Caregiver & super user: 1. 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 put the Change Indicator in an autoclave.
		 Ensure that adequate disinfection procedures are followed for residents with infectious diseases.
		 Follow your care facility cleaning routines when required, e.g. if Change Indicator is soiled.
		4. Remove lint from the Velcro-covered side when required. This will ensure the Change Indicator stays securely attached to the incontinence product.

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 uW 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

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	

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.

- 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.

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



Manufacturer



Instruction manual



WEEE-marking. Dispose of electrical components in accordance with your local regulations



Radio Frequency Radiation Symbol



Catalogue number



Serial number



Medical Device



IC:

UDI:

MR

CE

10°C



Unique Device Information

IP Classification



European Conformity mark









Temperature limit

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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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