DOCUMENT NUMBER: 44U00149

DOCUMENT TITLE: Posey Wireless Toilet Sensor 8334WL IFU

DOCUMENT NOTES:

Rev 05: Through the Design Validation it was found that re-structuring of the IFU was needed/ MOC-2024-0218.
Rev 04: Updated IFU to include cleaning and disinfection instructions. Per MOC-2024-0218.
Rev 03: See redlines attached and DCO info.
Rev 02: Update list of active ingredients for cleaning and disinfecting products to better reflect what was tested.
Rev 01: Update to keep Spec revision consistent with artwork revision per MOC-2022-0085
Rev 00: Initial upload/ MOC-2022-0085

EFFECTIVE

Document Information

Revision:	05	Vault:	Regulatory Affairs-rel
Doc Type:	Labeling	Status:	Release

Date Information

Effective Date:	31 Jul 2025	Next Review Date:	
Release Date:	31 Jul 2025	Expiration Date:	

Control Information

Author:	TOLSON	Previous Number:	
Owner:	Engineering	Change Number:	DCO-6442

All dates and times are in US/Central

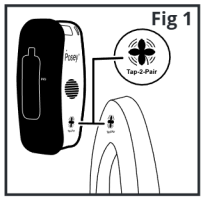
Posey Wireless Toilet Sensor 8334WL
Instructions for Use

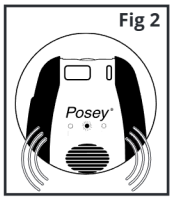
Description of Product: The Posey Wireless Toilet Sensor is compatible with the Posey On Cue® PRO Wireless Fall Monitor and is a 30-day sensor. Not for use with raised toilet seats, accessories or commodes.

Intended Use: The Posey Wireless Toilet Sensor is intended for use with the Posey On Cue® PRO Wireless Fall Monitor to alert caregivers when a fall risk patient exits the toilet.

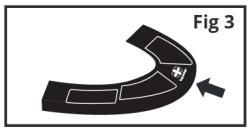
Contraindications: None

Instructions:



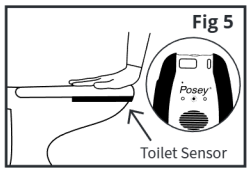


1. Pair Sensor to Fall Monitor
- Locate and align pairing icons face to face (Fig 1).
- Once beep is heard, the blue light above the toilet icon on fall monitor will illuminate (Fig 2).



2. Expiration Date
- Before first use, mark the expiration date using a **permanent marker** on textured surface below Tap-2-Pair symbol (Fig 3 and Fig 6).

3. Place Sensor
- Check that sensor is clean and not damaged. Discard and replace any damaged sensor.
- Raise toilet seat. Place toilet sensor on front of toilet bowl, centered on toilet bowl (Fig 4). Lower toilet seat. Tap-2-Pair® logo should be visible.
- If using specimen collectors (i.e. hats, specimen collector pans, collection hats), ensure toilet sensor is secure and seat is flat and stable. Do not use raised toilet seats, accessories or commodes.



4. Test Sensor
- Before each use, test system to ensure sensor and fall monitor are properly functioning.
  - Confirm fall monitor is on and sensor is paired.
  - Press firmly and continuously on toilet seat. Listen for beep and audio cue. Green means go (Fig. 5).
  - Release pressure from seat and listen for alarm tone from Posey Fall Monitor.
  - If Posey Fall Monitor fails to alarm, test with new sensor. If fall monitor still fails to alarm, reference Posey Fall Monitor's Instructions for Use.
  - If applicable, test that sensor functions with specimen collectors before placing the patient on the toilet.

5. Monitor patient
- Place patient on toilet, ensuring sensor is in place on front of bowl when seated.
- Confirm monitoring by looking for green status light and blue indicator light above toilet icon.
- Refer to the Posey On Cue® PRO Wireless Fall Monitor IFU for monitoring and transfer instructions.

6. Unpair Sensor
- To replace sensor, press HOLD button to pause monitoring. Repeat steps 1-5 with new sensor.
- To unpair inactive sensor, select from these options:
  - Press and hold the MODE button for 2 seconds. Listen for audio cue.
  - Turn off the fall monitor.

Fig. 6

7. Disposal
- Sensor contains a lithium manganese dioxide 3V non-rechargeable 20mm coin cell battery, not to be confused with rechargeable lithium-ion batteries.
- Per the US Resource Conservation and Recovery Act (40 CFR Part 261 Part C), non-rechargeable lithium manganese batteries are considered non-hazardous. They are not considered reactive, corrosive, ignitable, or toxic. Dispose of sensor per facility policy according to federal and state laws.
- Do not attempt to replace batteries.
- Recycling of unsoiled sensors is encouraged, please utilize electronic recycling programs. Some facilities and situations may arise that consider a sensor medical waste.
- Sensor cannot be reprocessed by third party reprocessors.
- Sensor can be reprocessed only as described in the Cleaning and Disinfection Instructions.

For California: Perchlorate Material - special handling may apply, See https://www.dtsc.ca.gov/hazardouswaste/perchlorate.

Storage: Store in ambient temperatures and humidity levels (10-50%).

Warranty / Useful Life: This product is warrantied and has a useful life of thirty (30) days from date of first use.

⚠ WARNING: Failure to follow these instructions could result in serious injury.

- Not for use on all toilet seats (split toilet seats only): ensure the sensor fits and functions on toilet before use.
- Do not hold pressure for testing or place patient directly on Tap-2-Pair® logo.
- The wireless toilet sensor may not be suitable for use with all accessories, as the weight of accessories could cause no alarm or uneven seating surface.
  - Never use raised toilet seats, accessories or commodes with wireless toilet sensor.
- Ensure all parts of the system are operational before leaving patient unattended.
- This system does not prevent falls or injury from falls and is not a substitute for patient care. This product should be used in conjunction with your facility's falls management program.
- Changes or modifications not expressly approved by TIDI could void the user's authority to operate the equipment.
- Discard sensor if:
  - Expired.
  - There is no expiration date.
  - Date cannot be clearly identified.
  - Used with a patient with an infectious disease in a shared room.
  - There is known contact with mucosal membranes and open wounds.
  - Used by patients under isolation precautions.
  - Sensor is submerged in liquid.
  - If there are any cracks, divots or grooves.
- Do not sterilize with any heat

⚠ This sensor may become contaminated as a result of normal use. Hospitals should follow their policies and procedures to minimize the risk of cross-contamination.

EFFECTIVE

TIDI Products, LLC • 570 Enterprise Drive • Neenah, WI 54956 USA
tidiproducts.com • Tel 1.800.521.1314

Learn more and access the Instructions For Use video by scanning the QR code.

The complete Posey Fall Monitor and sensor manuals can be found at **tidiproducts.com/IFU**

TIDI Support Caregivers. Protect Patients.

44U00149 Rev 05 2025-07-30

Posey Wireless Toilet Sensor 8334WL
Instructions for Use

Posey®

Cleaning and Disinfection:

Use one (1) of the tested and approved agents in Table 1 for cleaning and/or disinfection of the sensor. Follow cleaning and disinfection agent's manufacturer instructions for preparation and dry method.

Table 1. Both agents can be used for cleaning and/or disinfection.

Approved Agents	Approved Application Method	Cleaning Frequency	For Disinfection Only:		
			Disinfection Frequency	Wet Contact Time	Dry Method
PDI Sani-Cloth® Bleach Disposable Wipes	Disposable Wipes*	After each patient use	Twice Daily, when Visibly Soiled	4 minutes	Air Dry
Ecolab OxyCide™ Daily Disinfectant Cleaner (liquid solution)	Non-linting wipe or cloth*			10 minutes	

**As needed: soft-bristle nylon brush*

Note:

- The Toilet Sensor's external surfaces are made of polypropylene.
- Any deviation by the processor from the cleaning and disinfection instructions should be evaluated for effectiveness and any potential adverse consequences.
- Similar EPA registered products may be available and should be an intermediate level disinfectant with active ingredients including hydrogen peroxide and peracetic acid or sodium hypochlorite.

Manually Clean: After each patient use

1. Select agent from Table 1.
2. Keep the sensor on the toilet.
3. Wipe clean the top surfaces and edges of the sensor (Fig. 7).
4. Inspect sensor
   - If the sensor is soiled, complete manual disinfection steps listed on the right.
   - If the sensor has any cracks, divots or grooves, discard the sensor.

Fig. 7 - Arrows pointing to top surface and edges of sensor for cleaning.

Manually Disinfect: Twice Daily and when visibly soiled

Part 1

1. Select agent from Table 1.
2. Remove the sensor from the toilet.
3. Wipe clean all exterior surfaces (top, sides and bottom) until all visible debris is removed (Fig. 8).
   - As needed, replace soiled wipes or use a soft-bristle nylon brush.
4. Inspect sensor
   - Repeat step 3 until all visible debris is removed.
   - If debris cannot be removed or the sensor has any cracks, divots or grooves, discard the sensor.

Part 2

5. Using a new wipe or cloth, wipe all exterior surfaces of the sensor (top, sides and bottom) (Fig. 8).
6. Keep surfaces visibly wet for the **wet contact time** listed in Table 1 using as many wipes as needed.
7. Allow the device to air dry as per Table 1.

Fig. 8 - Wipe all exterior surfaces of sensor for disinfection.

EFFECTIVE

This sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.
FCC ID: 2AZB4-8309WL
May be patented: see tidiproducts.com/virtual-patent-marking

TIDI Products, LLC • 570 Enterprise Drive • Neenah, WI 54956 USA
tidiproducts.com • Tel 1.800.521.1314

TIDI Support Caregivers. Protect Patients.

44U00149 Rev 05 2025-07-30

Signature Manifest

Document Number: 44U00149 **Revision:** 05

Title: Posey Wireless Toilet Sensor 8334WL IFU

Effective Date: 31 Jul 2025

All dates and times are in US/Central.

Instructions for Use: Sitter On Cue Pro Wireless Toilet Sensor, Tap-2-Pair

Step 1

Name/Signature	Title	Date	Meaning/Reason
Mason Philemon (MPHILEMON)	Sr. Quality Systems Analyst	30 Jul 2025, 09:02:54 AM	Approved

Edit/ Collaboration

Name/Signature	Title	Date	Meaning/Reason
Sai Pooja Bajjuri (PBAJJURI1)	Senior Engineer, Product Development	30 Jul 2025, 10:07:06 AM	Complete

Doc Control Step

Name/Signature	Title	Date	Meaning/Reason
Hannah Heiter (HHUTMAKER)	Quality Systems Analyst	30 Jul 2025, 10:59:18 AM	Complete

Content Approval

Name/Signature	Title	Date	Meaning/Reason
Elizabeth Bloch (EBLOCH)	Quality Engineer II	30 Jul 2025, 11:09:34 AM	Approved
Amanda Altan (AALTAN)	Director, Regulatory Affairs	30 Jul 2025, 11:44:03 AM	Approved
Beth Hudson (EHUDSON)	Clinical Affairs Manager	30 Jul 2025, 12:35:04 PM	Approved
Merissa Mesi (MMESI)	Product Manager	30 Jul 2025, 01:00:24 PM	Approved
Samantha McCarthy (SMCCARTHY)	Engineering Manager, Product Development	30 Jul 2025, 03:06:02 PM	Approved
Sai Pooja Bajjuri (PBAJJURI1)	Senior Engineer, Product Development	30 Jul 2025, 03:17:35 PM	Approved

Release Approval

Name/Signature	Title	Date	Meaning/Reason
Sai Pooja Bajjuri (PBAJJURI1)	Senior Engineer, Product Development	30 Jul 2025, 03:17:47 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Hannah Heiter (HHUTMAKER)	Quality Systems Analyst	31 Jul 2025, 07:06:56 AM	Approved