



URGENT: SECURITAS HEALTHCARE RECALLS EN1221S-60 SENIOR LIVING PENDANTS MANUFACTURED BY INOVONICS WIRELESS CORPORATION DUE TO PREMATURE BATTERY DEPLETION PRESENTING RISK THAT ALARMS WILL NOT BE RECEIVED BY THE ARIAL® WIRELESS EMERGENCY CALL SYSTEM



Date of Recall: September 25, 2023

Affected Device Models: EN1221S-60 senior living pendants

Type of Action: Recall

Affected Device Lots:

Part Number	Manufacturing Date	Securitas Healthcare	Estimated Shipment
	Codes	Product SKU	Dates
US and Canada			
EN1221S-60N	23128 to 23251	59360, 2560-59360	May 8, 2023 to
EN1221S-60NBU		59360, 2560-59360	September 8, 2023
EN1221S-60W		59361, 2560-59361	
EN1221S-60WBU		59361, 2560-59361	
EN1221S-60WLBU		59362, 2560-59362	

Dear Valued Client:

Securitas Healthcare LLC ("Securitas Healthcare") is initiating a Recall of EN1221S-60 senior living pendants that were manufactured by Inovonics Wireless Corporation (the "Pendants") and shipped between May 8 and September 8, 2023 (the "Affected Lots").

Description of the Condition:

Securitas Healthcare was notified by the manufacturer of the Pendants, Inovonics Wireless Corporation, that a radio chip in the Affected Lots is causing greater current draft due to a change in the chip design, which in turn results in a shorter than expected battery life for the Affected Lots.

The shorter than expected battery life in the Affected Lots presents a risk that the Affected Lots will enter into storage mode before the 7-day countdown timer following a low battery alert has expired. When the Pendant is in storage mode, it will not transmit alarms or check-in messages (i.e., supervision messages) to the Arial Wireless Emergency Call System.

The Pendants are manufactured by Inovonics Wireless Corporation in Mexico. On September 19, 2023, Inovonics Wireless Corporation implemented a Pendant Refurbishment Program for the Affected Lots (see <u>Appendix 2</u>). Approximately 12,500 Pendants distributed by Securitas Healthcare are affected by this recall. The Affected Lots were sold between May 8 and September 8, 2023.



Potential Hazard:

The following potential hazard has been identified for residents using a Pendant in the Affected Lots:

• The Pendants in the Affected Lots have a shorter than expected battery life. Pendants from the Affected Lots may enter into storage mode before the 7-day countdown timer following a low battery alert has expired. When the Pendant is in storage mode, it will not transmit alarms or check-in messages (i.e., supervision messages) to the Arial Wireless Emergency Call System. Additionally, if the Pendant battery is not replaced promptly the Pendant may be rendered inoperable even after battery replacement.

To date Securitas Healthcare has received 6 complaints regarding the Affected Lots. No injuries or deaths have been reported.

Customer Required Actions:

1. Immediately replace Pendant battery upon Low Battery Alert.

Customers that have purchased and received Pendants from the Affected Lots should replace Pendant battery immediately upon receipt of a low battery alert and test the Pendant to ensure it is operational. Instructions for replacing the Pendant battery and testing the Pendant are attached as <u>Appendix 1</u>.

2. Customer should check Pendant battery status in Arial System application at least daily.

Customer should check the battery status of all Pendants at least daily using the "Low Battery Transmitters (Current)" report in the Arial Wireless Emergency Call System. To access the "Low Battery Transmitters (Current)" report, users must click on the "Reports" tab within the Arial application, select "Low Battery Transmitters (Current)" report from the list of "Systems Reports", and click the "View Report" button. This report will list any Pendants that are in a low battery status. Customer should immediately change the battery in these Pendants and test the Pendant to ensure it is operational. Instructions for replacing the Pendant battery and testing the Pendant are attached as Appendix 1.

3. Customer should check for Pendants that are no longer communicating with the Arial System at least daily.

Customer should also check the Arial application for Pendants that are marked as "missing transmitters". The Arial System will mark Pendants that are no longer communicating with the Arial System are marked as "missing transmitters". To access the "Missing Transmitters" report, users must click on the "Reports" tab within the Arial System application, select "Missing Transmitters" report from the list of "Systems Reports", and click the "View Report" button. This report will list any Pendants that are marked as "missing transmitters". Customer should immediately locate these Pendants and verify Pendant battery status. If these Pendants are located in the supervised area, the Pendant battery will be dead. Customer should immediately change the battery in these Pendants and test the Pendant to ensure it is operational. Instructions for replacing the Pendant battery and testing the Pendant are attached as Appendix 1.

Removal and Replacement of Affected Lots:

Securitas Healthcare will be replacing all Pendants from the Affected Lots with refurbished Pendants at no cost. See below for instructions on how to return Pendants from the Affected Lots:

- 1. If you purchased one or more Pendants from the Affected Lots from Securitas Healthcare, a representative from Securitas Healthcare will be reaching out to your facility to coordinate replacement of all Pendants from the Affected Lots.
- 2. If you have distributed the product further, immediately notify your accounts that received the product identified above of this notification and ask them to contact Securitas Technical Support at 1-800-824-2996 (8:00 AM 5:00 PM CT, M-F) to obtain a response form and coordinate replacement and return of affected devices.



Transmission of this Recall Notice:

This notice must be passed on to those who need to be aware within your organization.

Contact reference person:

For additional information or clarification, please contact: Garth L Jack, Director of Quality and Regulatory Compliance at 402-742-9335 or via e-mail at: garth.jack@securitas.com Monday through Friday, 8:00 AM to 5:00 PM, Central Time.

IMPORTANT! For customers who purchased Pendants from the Affected Lots from Securitas Healthcare, a person in authority at the facility must sign the acknowledgement form attached hereto as Exhibit A and return the same to:

Mr. Garth L. Jack
Director of Quality and Regulatory Compliance
Securitas Healthcare
4600 Vine Street, Lincoln, NE 68503
Phone: 402-742-9335

Securitas Healthcare appreciates your cooperation with this matter and apologizes for any inconvenience it may cause you. If you have any questions, please contact me at the number above or at garth.jack@securitas.com.

Sincerely,

Garth L Jack

Director of Quality and Regulatory Compliance



Appendix 1 Battery Replacement Instructions

4 Battery Replacement

Note: Inovonics has tested and recommends Panasonic®, Energizer® and FDK® (formerly Sanyo) CR2032 coin cell batteries.

The waterproof pendant uses one standard CR2032 coin cell battery. To change the battery:

- Use the ACC680 alarm clearance card or a quarter to turn the battery door to the unlocked padlock icon.
- 2. Remove the battery door.
- 3. Remove the old battery from the battery compartment.
- **4.** Place the new battery in the battery compartment, ensuring that the positive terminal (+) faces up.
- **5.** Seat the battery door over the battery so that the arrow on the battery door is lined up with the unlocked padlock icon.
- 6. Use the ACC680 alarm clearance card or a quarter to turn the battery door to line up the arrow on the battery door with the arrow under the locked padlock icon.
- 7. Press the activation button to initalize the transmitter.
- 8. Clear the resulting alarm per section 3.2, "Clear an Alarm".

Note: If the pendant is not activated after replacing the battery, the low battery indication will not clear until the next check-in interval.

6 Test the Transmitter

The transmitter should be tested after registration and then weekly to ensure operation.

To test the transmitter:

- Press the activation button for at least one second and ensure the red transmit LED lights, the vibration activates, and the alarm is received by the receiver or gateway.
- 2. Clear the alarm and ensure the red alarm transmission LED stops flashing, and the blue alarm clear LED flashes.





Appendix 2



PRODUCT NOTICE

EN1221 S-60 Pendant Refurbishment Program September 19, 2023

What's Happening

Inovonics is implementing a refurbishment program for EN1221S-60 senior living pendants manufactured and shipped between May 8 and September 8, 2023 to address a component issue. This is not a safety recall.



Affected Units

Part Number	Manufacturing Date Codes	Estimated Shipment Dates
US and Canada		
EN1221S-60N EN1221S-60NBU EN1221S-60W EN1221S-60WBU EN1221S-60WLBU	23128 to 23251	May 8, 2023 to September 8, 2023
New Zealand		
EN1221S-60ZNBU EN1221S-60ZWBU	23128 to 23251	May 8, 2023 to September 8, 2023

Why It's Happening

The radio chip used in these devices causes greater current draw due to a change in the chip design, which in turn results in a shorter than expected battery life for the affected units. We have not identified any safety issue with these radio chips, but are offering a refurbishment program to extend the battery life of these affected units.



Identifying Affected Units

	Product in Original Packaging	Product NOT in Original Packaging
What to Look For	Five-digit manufacturing date code	Five-digit manufacturing date code
Where to Look	EN1221S-60N, EN1221S-60W Label on side of carton, lower left corner EN1221S-60NBU, EN1221S-60WBU, EN1221S-60WBU Label on front flap of carton	Back of unit, lower right corner, laser-etched
What it Looks Like	23187 WITCHT PER MICHER A WITCH STORY	-0
	Individual carton date code label	
	Bulk carton date code label	

Doing Your Part

We are asking that you immediately take the following next steps:

- · Identify any affected units in your possession
- · Identify your customers that have deployed the affected units
- . Estimate the number of affected units at each installation site
- . Submit an Advanced Replacement RMA form available at this link

Please note that the Advanced Replacement form now includes a checkbox for the EN1221S-60 Pendant Refurbishment Program.

- To protect the internal battery, send affected units to Inovonics with the coin cell battery removed. Include the battery door with the returned unit.
- Affected units should be returned to Inovonics in minimum lots of 50 units

Due to manufacturing capacity limitations, we will fulfill the Advanced Replacement RMA with refurbished devices.

Refurbishment Program Details

Refurbished units will be fully tested and cleaned. Neck devices will be shipped to VARs with a new neck lanyard, battery door and coin cell battery. Wrist devices will be shipped to VARs with a battery door and coin cell battery.

Securitas Healthcare



Refurbished units with updated firmware will be marked on the battery connector as follows:



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Contact Us

Please contact <u>Inovonics Technical Services</u> or your account manager with any questions.

We greatly value your partnership and and apologize for the inconvenience this causes you and your feam.



Jess Cobb Sr. Product Manager Hardware & Wireless Infrastructure jcobb@inovonics.com



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