

Deviation Report

**Record ID:** DEV\_20250808\_133946      **Generated:** August 08, 2025 01:40 PM

Report Information			
Title:	Continuous Particle monitoring instrument cut off due to unsecured charging cord	Priority:	Major
Status:	In Progress	Deviation Type:	Equipment
Date of Occurrence:	February 06, 2025	Department(s):	QA
Batch/Lot Number:	10000215	Quantity Impacted:	Complete Batch
Planned Deviation:	No	Initiator:	Matt

## User Input - Original Deviation Description

During Continuous Particle monitoring the particle monitoring instrument cut off. Upon Observation it was noticed that the charging cord was not securely pushed into the back of the Instrument. Instrument was restarted and completed the continuous monitoring through the end of batch. Started: 0733 - Results passed. 1st Vial Filled: 0757 Roughly 2 hours and 15 minutes elapsed. Instrument restarted: 1012 thru End of Batch - All samplings Passed. Batch was evaluated for established release criteria for subvisible particles and visual inspection. - All testing criteria for subvisible particles and visual inspection passed.

## AI-Generated Analysis

### Deviation Summary

During continuous particle monitoring on 02/06/2025, the monitoring instrument for batch/lot number 10000215 unexpectedly shut off due to an unsecured charging cord. The issue was identified when the instrument cut off, and it was subsequently restarted at 1012 hours. The complete batch was impacted, but all testing criteria for subvisible particles and visual inspection passed. The current status indicates that the batch meets established release criteria.

## Event Timeline

- 0733: Continuous particle monitoring began.
- 0757: First vial filled.
- Instrument cut off due to unsecured charging cord.
- 1012: Instrument restarted and continued monitoring until the end of the batch.

## Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Equipment: The particle monitoring instrument requires review of the charging connection to ensure it is securely fastened during operation.
- Personnel: Review the procedure for securing equipment connections to ensure compliance with relevant SOPs.

## Impact Assessment

- Product Quality: No impact on product quality as all testing criteria for subvisible particles and visual inspection passed.
- Batch Disposition: The batch does not require additional testing as it meets established release criteria.
- Risk Level: Classified as Minor due to no impact on product quality or batch disposition.
- Other Batches: No risk identified to other batches as the issue was isolated to the equipment setup for this batch.

## CAPA Plan

### Immediate Actions (24-48 hours):

- Securely fasten the charging cord of the particle monitoring instrument.
- Review and document the incident in the deviation management system.

### Corrective Actions:

- Recalibrate the particle monitoring instrument to ensure accurate operation.
- Conduct a training session for operators on the importance of securing equipment connections.

### Preventive Actions:

- Implement a checklist for equipment setup that includes verification of secure connections.
- Revise the SOP to include a double-check system for equipment setup before operation.