



To: Phil Griffin, Kansas Dept. of Health & Environment
Date: 7 July 2016
From: Corey Desmarais & Scott McDowell, Sensitech Inc.
Re: TempTale Monitor Replacements

Mr. Griffin,

The purpose of this letter is to inform you of the actions that Sensitech is currently taking to address the recent shipment of TempTale® 4 USB Multi Alarm monitors to the various sites as part of the Kansas Immunization Program received on June 23, 2016. The Sensitech case number for this issue is 21984.

There are 2 concurrent actions that Sensitech is taking: replacements and investigation.

Starting on July 11, 2016 each site will receive new stock as replacements. The replacement quantities will equal what each site is due based on a normal yearly swap. In an effort to reduce confusion of monitors, each site is welcome to return the units received on June 23, 2016 to Sensitech. Please contact Client Services to arrange the return and reference RMA#518542. Client Services can be reached by phone: 978-720-2658 or by email: clientservices@sensitech.com.

Sensitech's deviation process is currently underway to identify the root cause of expired stock during the June yearly swap. The deviation process consists of a thorough investigation followed by a CAPA if deemed appropriate. A report will be provided to you at the conclusion of this investigation.

On behalf of Sensitech we apologize for the many inconveniences this has caused you and each site as part of this program. In addition to the replacements we are addressing your concern with our service responses under Sensitech case number 22017.

Please do not hesitate to contact us if you have any further questions, comments, or concerns.

Kind Regards,

Corey Desmarais

Director, Client Services

Scott McDowell

Director Quality Assurance & Technical Support