



October xx, 2019

Urgent Field Safety Notice: t:slim X2 Insulin Pump - A/C Power Adapter Damage

A potential safety issue has been identified with the A/C power adapter that was originally supplied to you along with the t:slim X2 Insulin Pump. This issue involves the A/C power adapter breaking apart, thus exposing the metal prongs contained within the adapter, which could cause injury if the exposed metal prongs were touched when the adapter was plugged into an electrical wall outlet.

Tandem has worked in conjunction with the supplier that manufactures the power adapter to investigate the cause for the defective adapters, and to implement a change to the manufacturing process to enhance the power adapters to prevent the issue from recurring. The supplier has implemented corrective actions to resolve the product quality issue and along with this letter you will find a replacement adapter that has been manufactured under the new process.

Devices and Adapters Affected:

Device Type: Ambulatory Insulin Infusion Pump, Electronic

Commercial Name(s): t:slim X2 Insulin Pump, G5; t:slim X2 Insulin Pump, G6

Unique Device Identifier(s) (UDI-DI): [To be entered for specific country]

Device Model / Part Number(s): [To be entered for specific country]

Affected Serial Number Range: All t:slim X2 G5 and G6 Insulin Pumps distributed internationally

Associated Devices: A/C Wall Power Adapters

Please see the visual representation of the adapter involved:

[Insert photo(s) here]

Action Requested:

Please discard or destroy the three (3) power adapters that you received when you initially received your Tandem insulin pump. We ask that you go to www.TBD.com to complete a short online form for us to maintain records of the disposal process. If you cannot complete this form, please contact your local Tandem distributor to report completion of disposal.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective actions. The undersign confirms that this notice has been notified to the appropriate National Competent Authorities.

Tandem sincerely apologizes for any inconvenience that this matter creates, and we truly appreciate your assistance with completing the actions requested.

Sincerely,

Mick Trier
Director, Global Post Market Surveillance

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<<insert local distributor contact info?>>