



Australian Government
Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2022-RN-00627-1

DATE AGREED: 17/05/2022

PRODUCT: t:slim X2 Insulin Pump

Product code: 1006419

software version of 6.4.1 or prior

ARTG 304681

(Australasian Medical & Scientific Ltd - Infusion pump, insulin, ambulatory)

SPONSOR: Australasian Medical & Scientific Ltd

CONTACT INFORMATION: AMSL - 1300 851 056

REASON: There are potential risks when using the pump within its normal specifications resulting in a loss of therapy. Software updates are planned by the sponsor to mitigate these risks.

PROPOSED CUSTOMER ACTIONS: AMSL advises users that the Tandem pump may continue to be used as described in the User Guide. Users are advised to have an alternate means of insulin therapy available. Users should update their pumps to the latest software version as soon as possible.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 2050 Consumers

Product export status: N/A

This issue was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) –

<https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-00627-1>

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>