الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector
National Center for Medical Devices Reporting

Safety Communication

رسالة سلامة

To: Healthcare Provider   إلى: مقدمي الرعاية الصحية

Title	A wiring problem with the speaker. This may result in a failure which will appear on the pump screen as Malfunction Code 16-0x20E6, also known as "Malfunction 16".	العنوان:
Medical Device Description	t:slim X2 Insulin Pump	اسم ووصف الجهاز/المستلزم الطبي:
Manufacturer	Tandem Diabetes Care, Inc.	اسم المصنع
Authorized Representative	Bio Standards	الممثل المعتمد

Medical Devices Marketing Authorization (MDMA)	MDMA-1-2021-0565	إذن التسويق
Potential /Associated risks	- Stop insulin delivery and disconnect the pump from the Continuous Glucose Monitoring (CGM) and mobile app. - Lead to hyperglycaemia if not addressed promptly. - Require patients to seek medical intervention or hospitalisation in serious cases. - Result in loss of real-time glucose data and trends.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	- If Malfunction 16 has <u>not</u> occurred: - Continue using your pump as per the user guide. - Install the Tandem t:slim mobile app and enable push notifications. This ensures that if the problem does occur, you will be notified by the app. - If using a Dexcom sensor, use the Dexcom mobile app as a backup source for CGM alerts and alarms. - If a Malfunction 16 occurs: - Acknowledge the alert by pressing "Silence Alarm."	التوصيات

	o Contact your supplier who will arrange for a replacement pump. o In the meantime, switch to your backup insulin delivery method. • You should continue to monitor your blood glucose levels regularly and ensure a backup insulin method is available as per the pump training and user guide.	

For Reporting	SFDA 19999 مركز الاتصال الموحد	National Center for Medical Devices Reporting المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية	للإبلاغ