




Date: 4 July 2024

Reference Number: SG-2407-422-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
Title	Potential of an issue related to the construction of the power cord not meeting the insulation rating per country-specific requirements and international electrical standards.	العنوان
Medical Device Description	Power cords used with the Welch Allyn Connex ProBP 3400 Digital Blood Pressure Device and Welch Allyn Spot Vision Screener	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Welch Allyn Inc. (Baxter)	اسم المصنع
Authorized Representative	FAROUK, MAAMOUN TAMER & COMPANY	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2019-0442	إذن التسويق
Potential /Associated risks	Non-compliant cords are more susceptible to physical damage incurred over time due to the insulation being slightly thinner than the compliant cords. If a user is exposed to a visibly damaged power cord, the injury incurred would most likely be minor to moderate, such as discomfort, tingling, or a minor burn; more serious adverse health consequences may occur in rare situations and higher-risk populations.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ol style="list-style-type: none"> 1. Inspect the condition of the power cords. If fraying or other damage is observed, users should discard the power cord immediately. 2. Healthcare providers may continue to use the affected power cords after they are inspected for damage. 3. Healthcare providers should regularly inspect the power cords for fraying or other damage. 4. Once Baxter has replacement power cords, a follow-up notification will be sent with additional instructions on how to request replacement power cords. 	التوصيات
For Reporting	  	للإبلاغ