


## Safety Communication

### Recommendations for increasing the efficacy and reliability of FreeStyle Libre 14 Day Flash Glucose Monitoring

<b>Device/ Product Description:</b>	Continues Glucose Monitoring
<b>Brand Name:</b>	FreeStyle Libre
<b>Lot numbers/Serials:</b>	NA
<b>Manufacturer:</b>	Abbott Diabetes Care Ltd
<b>Problem:</b>	Amount of reported adverse events in the NCMDR is significantly increased, even though “FreeStyle Libre” is a safe and accurate device whenever the device is used as indicated by the manufacturer.
<b>Recommendation/Actions:</b>	<ol style="list-style-type: none"> <li>1- Although the product cannot be purchased without physician prescription, the Healthcare providers are recommended to assure that the patient have successfully completed the comprehensive training session first in order to prescribe the product.</li> <li>2- Healthcare providers are also advised to assess the patient eligibility to use the mentioned product based on technical, cognition, and health ability.</li> <li>3- Healthcare providers are also encouraged to explain the importance of the parents or caregiver roles in case the product is to be prescribed to patient under age of 18.</li> </ol>

<p><b>Devices/Products photo:</b></p>		
<p><b>Authorized Representative Details</b></p>	<p><b>Company name:</b></p>	<p>Abbott Diabetes Care Ltd</p>
	<p><b>Contact Person:</b></p>	<p>Bader Fahad Al Shabrain</p>
	<p><b>Phone:</b></p>	<p>+966 535000220</p>
	<p><b>Email:</b></p>	<p>SFDArecipients@mediserv.com.sa</p>

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

**[National Center for Medical Devices Reporting.](#)**

Medical Devices Sector  
Saudi Food and Drug Authority  
Postal Address: Saudi Arabia - Saudi Food and Drug Authority  
4904 North Ring branch rd – Hitteen Dist.  
Riyadh 13513 - 7148  
Tel: +966 (11) 2038222 Ext: 2995, 2952  
Fax: +966 (11) 2757245  
Or

[Saudi Vigilance](#)

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Sincerely,  
NCMDR Team