Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

## **Safety Communication**

رسالة سلامة

## Detectors may fall - Discontinue system use until further notice

<b>Device/ Product Description:</b>	Gamma Camera Systems	
AFFECTED PRODUCTS:	Forte, Forte JETStream, Forte JETStream upgrade, Forte JETStream AZ, Forte JETStream AZ upgrade, Diamond Select Forte, Diamond Select Forte JETStream	
Manufacturer:	Philips Healthcare	
Problem:	The manufacturer identified an issue affecting the mentioned products of gamma cameras that could result in either detector 1 or detector 2 falling unimpeded vertically to the end stops of its travel limit during detector radius movement.  Possible contact with a patient could result in entrapment, serious injury, or death.	
Recommendation/Actions:	<ul> <li>Discontinue use of the system until further notice.</li> <li>Inform those who need to be aware within your organization</li> <li>Maintain this notice with your system Instructions for Use (IFU) until the correction is made to the system.</li> <li>Communicate with the authorized representative to perform the required corrections.</li> </ul>	

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Devices/Products photo:		
Authorized Representative Details	AR name:	Philips Healthcare Saudi Arabia Ltd.
	Assigned Contact Person:	Mohammed AlSamhan
	Mobile/Phone:	0558685708
	Email:	sfda.sa.met@philips.com

SG-1912-156-H 03/12/2019