المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
SFDA
Saudi Food & Drug Authority

Safety Communication

Cybersecurity Vulnerabilities Identified in Some Medtronic's Wireless Telemetry Technology

Device/ Product Name	Implantable Cardiac Devices, Programmers, and Home Monitors		
All Models	**Device**	**Model Name**	
	ICD and CRT-D	Amplia MRI CRT-D	
		Claria MRI CRT-D	
		Compia MRI CRT-D	
		Concerto CRT-D	
		Concerto II CRT-D	
		Consulta CRT-D	
		Evera MRI ICD	
		Evera ICD	
		Maximo II CRT-D and ICD	
		Mirro MRI ICD	
		Nayamed ND ICD	
		Primo MRI ICD	
		Protecta CRT-D and ICD	
		Secura ICD	
		Virtuoso ICD	
		Virtuoso II ICD	
		Visia AF MRI ICD	
		Visia AF ICD	
		Viva CRT-D	
	Programmer and Monitors	CareLink 2090 Programmer	
		MyCareLink 24950 Monitor	
		MyCareLink 24952 Monitor	
		CareLink 2490C Monitor	
Manufacturer	Medtronic		

Problem	SFDA would like to bring your attention that the Successful utilization of vulnerabilities (Improper Access Control, Cleartext Transmission of Sensitive Information) may allow access - to one of the affected products - to interfere with, generate, modify, or intercept the communication of some Medtronic Implantable Cardiac Devices; Programmers; and Home Monitors; potentially influencing product functionality and/or permitting access to transmitted sensitive data.
Recommendation	- Continue to use the CareLink programmers for programming, testing and evaluation of ICD and CRT-D patients. - Maintain control of CareLink programmers within your facility at all times according to your hospital Information Technology (IT) policies. - Use only home monitors, programmers, and implantable devices obtained directly from the manufacturer to ensure integrity of the system. - Remind patients to keep their home monitors plugged in: - The benefits of remote wireless monitoring of an implantable device outweigh the practical risk of an unauthorized user exploitating of these devices' vulnerabilities. - The monitor must remain powered on to ensure timely transmission of any wireless CareAlerts programmed by the physician, and to ensure automatically-scheduled remote transmissions occur at the specified time. - Operate the programmers within well-managed IT networks. Consult with your IT department regarding the security of your network. - Reprogramming or updating the affected devices is not required at this time. - Prophylactic ICD or CRT-D replacement is not recommended and should not be performed to solely address this vulnerabilities. - Discuss the risk of cybersecurity vulnerabilities with your patients prior to implanting ICDs and CRT-Ds along with other device risks and benefits, and take advantage of the latest software updates and improvements to devices. - Saudi Food and Drug Authority is seriously monitoring cybersecurity threats over medical devices. As an example, please check a previous notification about the same issue with ABBOTT products. - SFDA is also promoting best practices about Security-related Challenges for Network-connected Medical Devices in its guidance. - Report to SFDA any adverse events suspected about this matter through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.

النظام الوطني لبلاغات
الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical
Devices Reporting

الهيئة العامة للغذاء والدواء
SFDA
Saudi Food & Drug Authority

Devices/Products photo:			
Authorized Representative Details	Company name:	Medtronic	
	Contact Person:	Faisal Matbuli	
	Phone:	+966 555066900	
	Email:	faisal.matbuli@medtronic.com	

For further information, please see the letter issued by the manufacturer. (**Click Here**)

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for more clarification.

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 (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222   Ext: 2406, 2479
Fax: +966 (11) 2757245
Or
Saudi Vigilance

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team