

Kingdom of Saudi Arabia  
Saudi Food & Drug Authority



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء

Medical Devices Sector  
Surveillance Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية  
الإدارة التنفيذية للرقابة والقياسات الحيوية

FSCA Weekly Update

17-Jul-22

Attached below is the weekly report of Field Safety Corrective Actions (FSCAs) for the period:

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية لإذارات السلامة للفترة:

From 26-Jun-22 من  
To 16-Jul-22 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمتأثرة بها المملكة والتي جاري متابعتها مع الممثلين المعتمدين لإتمام تنفيذ الإجراءات التصحيحية.

\* Role of contact officer:

\* مسؤولية ضابط الاتصال:

**\* Kindly respond to the weekly report in both cases either you are affected or not affected.**

**\* نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر.**

- Disseminate and share the information with other Departments within healthcare facility and Ensuring that the healthcare facility is free of any affected device/product.
- Communicate with the Authorised Representative of the manufacturer if there is any device/product affected by a FSCA

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من الإجراءات التصحيحية للسلامة الميدانية.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من الإجراءات التصحيحية لإذارات السلامة.

Hospital name:

اسم المستشفى:

Date:

التاريخ:

Hospital affected by any device/product in this report:

يوجد أجهزة/منتجات متأثرة بالمستشفى ضمن القائمة:

Yes

نعم

No

لا

- The yellow highlights indicates that medical devices subject to removal action.
- To identify the affected serial numbers/lots, please open the link.

- الإجراءات المظللة بالأصفر تشير إلى إجراء سحب الجهاز الطبي.
- لمعرفة الطراز أو الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Field Safety Corrective Actions (FSCA):

15

عدد الإجراءات التصحيحية لإنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Active Implantable Devices

HeartWare™ Ventricular Assist Device (HVAD™) System	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	
Medtronic Cobalt XT, Cobalt and Crome Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=16192">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=16192</a>	

### Anaesthetic and respiratory devices

Aisys CS2, Avance CS2, Avance CS2 Pro Anesthesia Systems	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	
Avance CS2, Avance CS2 Pro, and Aisys CS2 Anesthesia Systems	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	
Servo-air ventilator system, Servo-u ventilator system, Servo-u MR ventilator system, Servo-n ventilator system	Maquet Critical Care AB	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=161">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=161</a>	
Servo-air with High mobile cart	Maquet Critical Care AB	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	

### Diagnostic and therapeutic radiation devices

Sensis, Sensis Vibe Combo	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
SIGNA Premier	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
Various CT, PET, NM Tables	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### In vitro diagnostic devices

Calibration Serum Level 3	Randox Laboratories Ltd.	Bio Standards	<a href="#">cure/CA/CaViewRec</a>	
Cholesterol.	Randox Laboratories Ltd.	Bio Standards	<a href="#">cure/CA/CaViewRe</a>	

### Medical software

Centricity Universal Viewer Zero Footprint Client	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
Merlin Patient Care System (PCS) Software Model 3330 25.3.X or earlier and Merlin.net MN 5000 v11.7 Remote Monitoring Application	Abbott..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=16203">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=16203</a>	
Merlin Patient Care System (PCS) Software Model 3330 25.3.X or earlier and Merlin.net MN 5000 v11.7 Remote Monitoring Application	Abbott..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=16203">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=16203</a>	

### Single-use devices

Adsorba Hemoperfusion Cartridge	Baxter Healthcare	Baxter AG	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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