



SBED Weekly Update

09-Oct-18

Dear,

SBED team is pleased to inform you that **33** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/2/2018 to 10/7/2018
In order to view more details, click the links and for ECRI alerts see the attachments

NOTE:

FSCA / Recalls are classified into three categories, representing the potential risk to public health:

Class I : High Risk, Class II : Medium Risk and Class III: Low Risk.

FSN (Field Safety Notice) : A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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Active Implantable Devices


#	New	Model 37604 Activa PC+S Implantable Neurostimulators	10/4/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	Attac hed	
#	New	TB-Temporary Bipolar Pacing Leads	10/7/2018	Oscor Inc.	Medical Technology Establishment	FSN	Attac	

Assistive products for persons with disability




#	New	Smith Press Machines	10/4/2018	CYBEX International Inc	N/A	2	ttache	
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Diagnostic and therapeutic radiation devices

New	CyberKnife® M6™ System	10/7/2018	Accuray Inc	Gulf Medical Co.	FSN	https	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	ddR Formula B xray system	10/2/2018	Swissray	Saudi Health Services Co. Ltd.	2	https	
New	DigitalDiagnost 4.1.9 / 4.2.6	10/2/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
# New	O-arm O2 Imaging Systems	10/4/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	Attac	

Electro mechanical medical devices



New	Aisys and Aisys CS2 Anesthesia Devices ,	10/7/2018	Datex - Ohmeda Inc	GE Healthcare	FSN	https	
# New	da Vinci Si Drapes and Disposable Accessory Kits	10/4/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	Attac	
New	da Vinci Si/X/Xi Surgical System	10/2/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	https	
# New	Li-Ion Battery Housings for DrillSaw Sports 400 Systems	10/4/2018	Arthrex, Inc	Medical Regulations Gate	2	Attac hed	
New	Medtronic MiniMed 640G Insulin Pump.	10/2/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
# New	Puritan Bennett 980 Ventilator Systems	10/4/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	Attac	
New	Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System	10/2/2018	Shockwave Medical, Inc.	N/A	2	https://nc	

In vitro diagnostic devices


New	ARCHITECT HAVAb-IgG Reagent Kit, ARCHITECT HAVAb-IgM Reagent Kit, Alinity i HAVAb IgG Reagent Kit	10/2/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc mdr sda	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Atellica® IM 1300 Analyzer, Atellica® IM 1600 Analyzer, Atellica® CH 930 Analyzer, and Atellica® Sample Handler Prime .	10/7/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr.sfga.gov.s	
New	G8 Analyzer	10/2/2018	Tosoh Bioscience Inc	N/A	2	A/Ca/	
# New	hs-cTnl Reagents Used with PATHFAST Type-D Analyzers	10/3/2018	Lsi Medience Corporation	Alinfrad Trading Est.	FSN	Attac hed	
New	Immunohistochemistry (IHC)	10/2/2018	Ventana Medical Systems	Al-Jeel Medical & Trading Co. LTD	1	https	
# New	Instrument Manager (IM) Abbott Alinity ci-series (abdicqii) Accessory Drivers	10/4/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	Attac hed	
Update	Troponin T, Liquid Cardiac Control	10/2/2018	Randox Laboratories Ltd.	Bio Standards	FSN	https	

Medical software

# New	Mobile Computers with Android Operating Systems	10/4/2018	Honeywell	N/A	2	Attac hed	
# New	N'Vision 8840 Physician Programmers	10/3/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	Attac	

Non-active implantable devices




New	Juggerknot Long Flex Drill Bit	10/2/2018	Zimmer, INC....	Medical Regulations Gate	2	https	
# New	Mitek Screw and Washer Depth Gauges	10/4/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia	FSN	Attac	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Ovation, Ovation Prime, and Ovation IX Abdominal Stent Graft Systems	10/4/2018	Trivascular Inc	N/A	2	Attac hed	
New	Vanguard 360 Revision Knee System..	10/2/2018	Zimmer, INC....	Medical Regulations Gate	2	https	
# New	Zilver 518 and Zilver 635 Biliary Stents	10/3/2018	Cook Medical	Majal Care for Trading Est.	FSN	Attac	

Ophthalmic and optical devices

New	Cflex Intraocular Lens	10/4/2018	ayner Intraocular Lenses L	bdul Latif Basha Medical	2	A/Cal	
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Single-use devices

New	ALARIS PCEA ASV Yellow Microbore, ALARIS PCEA ASV Yellow Microbore, ALARIS PCEA Kit ASV Yellow Microbore	10/2/2018	Becton, Dickinson And Company	Medical Regulations Gate	FSN	https://nc.mdr.sfda	
# New	CARDIOSAVE Intra-Aortic Balloon Pumps	10/4/2018	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	FSN	Attac	
# New	Occlutech Sizing Balloons	10/4/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	FSN	ttache	
# New	XIA 3 Instrument Trays and French Benders	10/4/2018	Stryker Spine SA	Arabian Medical Express Services (2	Attac	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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* The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI

*  Indicates that medical devices subject to removal and/ or destroyed action.

* SBED Team Recommend ensuring The listed Distributors in this report as they may differ from the distributors you are dealing with

SBED is devoted to receive the adverse event report and feedback information about any medical devices malfunction from hospitals and healthcare facilities all around KSA, studying them and collaborative working with manufacturers, authorized representatives and distributors to take the right action and assuring the proper safe performance.

To see recent recalls kindly visit the following link:

<http://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx>

In case you find an effected medical devices by any of the published FSN/Recalls, we urges you to contact the local representative and the National Center for Medical Device Reporting in order to ensure corrective or planed action been implemented.