



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies, MOH
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Director General of Quality Assurance Centre, MOH
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL MEDICAL DEVICE SUPPLIERS
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. **212/2021** dated **21/12/2021** regarding GHC Field Safety Corrective Action of Synergy Cranial S7 and Stealth Station Cranial from Medtronic Navigation, Inc.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Head of Central Drug Information





Circular No. 212 / 2021

المتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040

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21 -12-2021

Field Safety Corrective Action of Synergy Cranial S7 and Stealth Station Cranial from Medtronic Navigation

Source	GHC-Gulf Health Council.			
Product	Synergy Cranial S7 and Stealth Station Cranial.			
Manufacturer	Medtronic Navigation, Inc.			
Local Agent	Advanced Medical Instruments CO. (AMICO)			
The affected products	Navigation System	Software Name	Model#/CFN	Version
	StealthStation S7/i7	Synergy Cranial S7	9733763	2.2.8
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.1
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.2
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.3
Reason	Software can enter a state where the Biopsy Depth Gauge is no longer synchronized with the rest of the navigational information on the screen and displays an inaccurate position of the biopsy needle. This issue can potentially lead to resection of normal brain tissue or eloquent anatomical regions of the brain. When this software anomaly is encountered, it may result in a prolonged procedure, the need for an additional surgical procedure, tissue injury, including potential for life-threatening injury (hemorrhage, unintended tissue damage, permanent neurological injury).			
Action	<ol style="list-style-type: none"> 1. Medtronic will provide a warning and instructional placard to be applied to impacted systems to maintain visibility to the mitigations until a software fix is available. 2. The Mitigation Steps should be utilized to prevent this software anomaly from occurring and to restore normal function if this anomaly is observed. 3. Contact the local agent for remedial action. 			
Product Picture				
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om			

Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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