

Urgent Safety Communication

Urgent FSN of Bio-Cal Temperature Controller 370 and 370I Manufactured by Medtronic

Device/ Product Name:	Bio-Cal Temperature Controller
Lot numbers/Serials:	Model Number 370 and 370I
Manufacturer:	Medtronic
Problem:	Saudi FDA would like to bring your attention to the published Field Safety Notice (FSN) about that Medtronic is issuing an Urgent FSN for the Bio-Cal Temperature Controller model number (s) listed above are no longer used for clinical procedures .
Recommendation/Actions:	<ol style="list-style-type: none"> 1. Medtronic is recommending that BIO-CAL Temperature Controllers Models 370 and 370I are no longer used for clinical procedures. An updated cleaning protocol will not be developed by Medtronic. 2. If you have the affected devices mentioned above and haven't been contacted yet from the distributor, you should contact the Authorized representative listed below for corrective action. 3. Make sure to read the FSN. (Attached below)

<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>Company name:</p>	<p>Medtronic Saudi Arabia Co.</p>
	<p>Contact Person:</p>	<p>Quality and Regulatory Affairs dep.</p>
	<p>Phone:</p>	<p>+966 114048884</p>
	<p>Email:</p>	<p>ksa.ra@medtronic.com</p>

For further information, please **see the FSN below** or [Click Here](#).

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, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team