

Urgent Safety Communication

Nontuberculous Mycobacteria (NTM) Infections Associated with Heater-Cooler Devices

Device/ Product Name:	Heater-cooler devices
Lot numbers/Serials:	Not specific
Manufacturer:	Not specific
Problem:	<p>SFDA would like to bring your attention to the potential risks for organisms (including NTM) to grow in the water tanks of any heater-cooler device.</p> <p>On December 22, 2015, the SFDA issued a Safety Communication (see Below) to ensure customers were aware of the risk associated with heater-cooler device. This safety communication is to ensure that all relevant health care providers and health facilities are aware of these issues and take relevant actions.</p> <p>Contaminated water from the heater-cooler device has the potential to aerosolized (NTM) into the operating room during surgery.</p> <p>When the heater-cooler exhaust is directed toward the surgical field, the smoke is blown in the direction of the operating table. Therefore, (NTM) will aerosolized from the contaminated heater-cooler unit and it will able to contaminate the surgical field during the procedure. This may lead to infection, primarily in cardiovascular patients undergoing open-chest surgical procedures.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> • Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer’s device labeling. Ensure you have the most current version. • Do not use tap water to rinse, fill, refill or top-off water tanks since this may introduce (NTM). Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.

- When making ice needed for patient cooling during surgical procedures use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.
- Deionized water and sterile water created through reverse osmosis is not recommended.
- Direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolising heater-cooler tank water into the sterile field and exposing the patient.
- Establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturers' instructions.
- Develop and follow a comprehensive quality control program for maintenance, cleaning, and disinfection of heater-cooler devices.
- Regularly check for and immediately remove from service heater-cooler devices and accessories that show discoloration of internal surfaces or cloudiness in the fluid lines/circuits.
- Consider performing environmental, air, and water sampling and monitoring if heater-cooler contamination is suspected.

Be aware that heater-cooler devices are important in patient care, the benefits of temperature control during open chest cardiothoracic procedures outweigh the risk of infection associated with the use of these devices.

SFDA is monitoring this issue and doing further evaluation study to come up with more actions in order to protect patients from any of the potential risks may occur.

Consult your hospital infection control officials to perform the appropriate follow up measures and report events of device contamination to SFDA.

Report to SFDA any adverse events suspected to be associated with **Heater-Cooler Devices** 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.

You can read the complete Safety Alert that includes recommendations from ([HERE](#)).

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

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

Risks of infection with Nontuberculous
Mycobacterium associated with use of medical
heaters/cooler for patients.

مخاطر الإصابة بداء السل البكتيري (المتفطرة اللاسلية) مرتبطة
باستخدام أجهزة التسخين / التبريد الطبية للمرضى

Dear Healthcare Professional,

عزيزي المختص بالرعاية الصحية،

Saudi Food and Drug Authority (SFDA) would like to bring to your attention some safety precautions regarding the risks of infection with Nontuberculous Mycobacterium associated with using of medical heaters/cooler for patients, through potential contamination of the water used in the device through the vents.

تود الهيئة العامة للغذاء والدواء أن تلفت انتباهكم إلى تنبيهات السلامة بخصوص مخاطر الإصابة بداء السل البكتيري (المتفطرة اللاسلية) مرتبطة باستخدام أجهزة التسخين / التبريد الطبية للمرضى، من خلال التلوث المحتمل للمياه المستخدمة في الأجهزة من خلال فتحات التهوية.

For further information, please see attachments by [Click Here](#).

لمزيد من المعلومات، يرجى الإطلاع على المرفقات [بالضغط هنا](#).

The affected devices are:

الأجهزة المتضررة هي:

All Heater - Cooler Devices provide heated and/or cooled water to:

- 1) oxygenator heat exchangers,
- 2) cardioplegia (paralysis of the heart) heat exchangers,
- 3) warming/cooling blankets.

If you have these products, please be aware of the mentioned risks in the notice
Please share this information with Healthcare Professional

إذا كانت لديكم هذه المنتجات، يرجى أن تكونوا على دراية بالمخاطر المذكورة في هذا الإشعار.
يرجى مشاركة هذه المعلومات مع المختصين

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or any other Medical Devices) to:

ينبغي على المختصين بالرعاية الصحية الإبلاغ عن أي حادثة عكسية يشتبه في ارتباطها بالأجهزة المتضررة أعلاه (أو أي جهاز طبي آخر) إلى:

National Center for Medical Devices Reporting
([NCMDR Website](#)).

Saudi Food and Drug Authority
Postal Address: Saudi Arabia - (3292) North Ring
Road - Al Nafal Unit (1) Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ([رابط الموقع](#))

الهيئة العامة للغذاء والدواء
العنوان البريدي: ٣٢٩٣ الطريق الدائري الشمالي - حي
النفل-الرياض ١٣٣١٢-٦٢٨٨ المملكة العربية السعودية
هاتف: +٩٦٦ (١١) ٢٠٣٨٢٢٢ تحويلة: ٢٤٠٦

For latest published Recalls/Alerts, please visit
NCMDR website:

للحصول على آخر التحذيرات والاستدعاءات المنشورة يرجى زيارة
الموقع الإلكتروني لمركز البلاغات



Sincerely,
NCMDR Team

مع خالص التقدير،
فريق مركز البلاغات