

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَة عُمان
وَزارة الصِّحة
والدَّيْرَة العامَّة للصِّدائِك
والسَّرْقابَة الدَّوائِيَّة
مِسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

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)

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 PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. ٥٠٠٦..... dated ١٥/٥/١٤٢٢. Regarding NCMDR Field Safety Notice of Disposable Humidification Flask from (mfr: Cook Medical Europe Limited).

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
- Supdt. of Central Drug Information

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سلطنة عمان
وزارة الصحة
المديرية العامة للأجهزة الطبية
والرقابة الدوائية
مسقط

Circular No. 06 / 2021

27-05-1442 H

10-01-2021

Field Safety Notice of Disposable Humidification Flask from Cook Medical Europe Limited.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15494
Product	Disposable Humidification Flask.
Description	Incubators, Laboratory, Aerobic.
Manufacturer	Cook Medical Europe Limited.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Reference part No. K-MINC-CTS-S Order No. G32707 Lot No. All lots
Reason	A manufacturing defect that can cause the silicone stoppers to dislodge or gas to leak from the flasks, impeding gas flow to the incubation chambers of the Mini Incubator.
Action	1. Please refer to "Action to be taken by the user" section in the attached FSN. 2. Contact the local agent for remedial action.
Product image	
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 through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
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WWW.COOKMEDICAL.EU

Customer Communication

Commercial name of the affected product: Disposable Humidification Flask K-MINC-CTS-S
Manufacturer : William A. Cook Australia Pty Ltd
Cook Reference Numbers: 2020FA0008 , QCR-106

Date: 14 December 2020

Attention: Chief Executive Officer, Director of IVF Unit and Purchasing Officers/Stores Manager.

Cook Medical is initiating this notice in relation to its Disposable Humidification Flask (K-MINC-CTS-S), which is used in conjunction with the Mini Incubator, K-MINC-1000 for cell culture. Our records indicate that you may have received affected product.

Details on affected devices:

PRODUCT NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Disposable Humidification Flask	K-MINC-CTS-S	G32707	All lots

Description of the problem:

A small percentage of K-MINC-CTS-S Disposable Humidification Flasks may have a manufacturing defect that can cause the silicone stoppers to dislodge or gas to leak from the flasks, impeding gas flow to the incubation chambers of the Mini Incubator.

Risk to Health:

Inadequate gas flow to the incubation chambers may result in degeneration or loss of embryo. This may have psychological impacts to the mother (e.g., anger, depression, grief), and may lead to additional egg collection from the mother.

The defect rate at the time of issue of this letter, based on data from complaints received, is 0.12%. There have been no reports of harm to the mother, and one report of embryo loss.

Action to be taken by the user:

As a precautionary measure, we recommend that users **perform two in-house checks** prior to using a new flask to improve detection of the manufacturing defect.

1. Visual Inspection

Check the flask assembly: when the stopper is placed on the flask, the tab on the silicone stopper should engage with the indent in the flask. Flasks that have the defect will not allow the stopper to be fully pushed into the indent of flasks, as shown in Figure 1.

2. Leak Test

Check for leaks: Flasks that have the defect will cause a gas leak that will impede gas flow into the Mini Incubator.

- a. Prepare the Mini Incubator by removing any flasks.
- b. Fill the flask to be tested with sterile distilled water (to the fill line) and insert it into the incubator.
- c. Set the flow rate to 15mL/min and wait for the purge cycle to complete.
- d. Block the gas flow from both tubes exiting the flask by kinking and holding the tubes as shown in Figure 2.
 - i. When the tubes are folded, the area around the folds may appear white – this is OK and does not indicate that the silicone tubing has been damaged.
- e. If the gas flow does not fall to zero within 45 seconds, the flask may be defective.



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- f. Unblock the tubes as soon as the flow reaches zero; blocking the tubes for more than two minutes may cause pressure to build up in the flask and the silicone stopper to suddenly pop off.
 - i. Gas flow may be greater than 15mL/min immediately after the tubes are unblocked. This is normal – the incubator will gradually adjust the gas flow rate to the correct value.
- g. If a potential defect is discovered, please **take a photo** and report this to your local Cook Medical Sales Representative, quoting reference number '**QCR-106**', in order to obtain a credit for the faulty product.
- h. If no irregularities are detected, the flask may be used in the Mini Incubator as per the IFU.

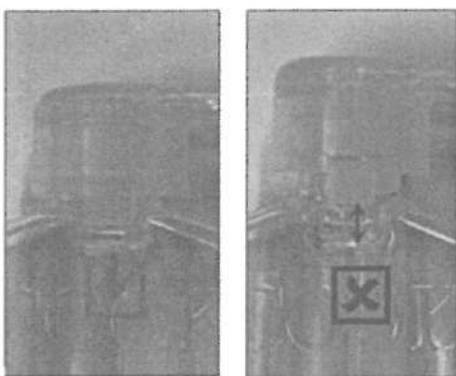


Figure 1: Assembly: no defect (left), defect (right)

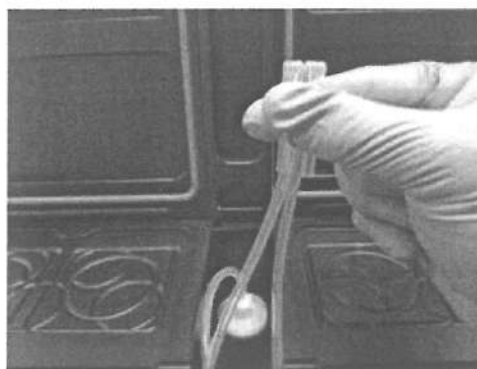


Figure 2: Leak test: blocking tubes

Additional Actions:

1. Please maintain a copy of this notice with the product(s) in your inventory.
2. If you have affected product in inventory, you may continue to use these products with the recommended testing as described above. **Cook Medical is not asking for product to be returned.**
3. Photograph flasks that may be defective, and send these, citing reference number **QCR-106**, to your local Cook Medical Sales Representative.
4. Report suspected defects and adverse events to your local Cook Medical Sales Representative or to Cook Medical Customer Support using telephone numbers in attached Country Contact List.

Transmission of this Customer Communication:

Please pass this notice on to the appropriate personnel, including down to the user level, within your organisation or to any organisation where the affected devices have been transferred. Please retain this letter in a prominent position for one month should there be any devices in transit.

Thank you for your attention to this matter. We recognise this disrupts your normal operations and for this, we sincerely apologise. Should you have any questions or concerns, please contact your local Cook Medical Sales Representative, or call Customer Support using telephone numbers in attached Country List or Customer Relations at European.FieldAction@cookmedical.com.

Regards

Jodi McCann
2020.12.14 16:00:09 +10'00'
Jodi McCann
Quality Assurance Manager
William A Cook Australia Pty Ltd