Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 G **dated** 28/1/24 **Regarding NCMDR Field Safety Notice of SoClean 2 and SoClean 3 from (mfr: SoClean, 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**
- **Supdt. of Central Drug Information**

PADC
ص.ب ٣٩٣ مسقط - الرمز البريدي ١٠٠ - هاتف ٢٢٣٥٧١١١ - فاكس ٢٢٣٥٨٤٨٩
P.O Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 6 / 2024

16 -07-1445 H

28 -01-2024

Field Safety Notice of SoClean 2 and SoClean 3 from SoClean, Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19892
Product	SoClean 2 and SoClean 3.
Description	Automated PAP Disinfecting System.
Manufacturer	SoClean, Inc.
The affected products	SoClean 2, REF SC1200 System, UPC: 187293000860 SoClean 3, REF SC1400, UDI: (01)00858242007147
Reason	Revising labeling of above SoClean products to incorporate: (i) additional warnings and contraindications; and (ii) proper and consistent device set-up instructions including use of a hose and mask adapter, thereby reducing potential risks associated with the previous device design and labeling.
Action	1. Actions to be Taken by Customers: - User Manuals: Download the new version of the User Manual using the link found in the attachment. - Hose and Mask Adapter: If you recently purchased a SoClean filter and only want to obtain a no cost Hose and Mask Adapter, please contact to SoClean Customer Care team, please refer to the attachment for more details. 2. Contact the local agent for remedial action.
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 the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
ISO

ص.ب ٣٩٣ مسقط - الرمز البريدي ١٠٠ - هاتف ٢٢٣٥٧١١١ - فاكس ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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SoClean®

URGENT Medical Device Field Correction
SoClean2 (SC1200) and SoClean3 (SC1400) Automated Supplemental Sleep Equipment Maintenance Systems
Clarifications to User Manuals
Hose and Mask Adapter Availability
Attention to Customers

The Purpose of this Letter

The purpose of this letter is to advise you that SoClean is conducting a voluntary field action intended to update and clarify the user manuals for all units of the SoClean2 and SoClean3. This voluntary field correction does not require you to stop using or return your SoClean unit.

The Reason for Voluntary Field Correction

SoClean has received approximately 7,417 complaints (equating to 0.33% of all SoClean2 and SoClean3 units sold) resulting from improper set-up, unauthorized device modifications, and use by individuals for whom the device is not recommended as indicated in the user manual. Of those complaints, 334 (0.015%) were FDA reportable adverse events and zero (0) deaths were reported. Common complaints include (i) the customer not being able to set up or turn on the device; (ii) mildew smell in the hose; (iii) excessive ozone smell; (iv) cough; and (v) exacerbation of preexisting condition(s).

As stated in the user manual, persons with underlying lung diseases, such as asthma and chronic obstructive pulmonary disease (also known as COPD, which includes emphysema and chronic bronchitis), and those with cardiovascular disease, may be sensitive to ozone and should consult with their health care professional before using a SoClean2 or SoClean3.

SoClean is revising its labeling to incorporate: (i) additional warnings and contraindications; and (ii) proper and consistent device set-up instructions including use of a hose and mask adapter, thereby reducing potential risks associated with the previous device design and labeling.

Risk to Health

Risks from ozone exposure may include cough, difficulty breathing, nasal irritation, headaches, asthma attacks or other breathing issues.

Actions Taken by SoClean

SoClean is revising the existing labeling to provide clarifying instructions for both the SoClean2 and SoClean3, as follows:

- Incorporated additional warnings and set-up instructions to enable appropriate use.
- Additional instructions for events in which a user is unable to smell residual ozone.
- Additional clarity and consistency regarding that the SoClean2 and SoClean3 are not intended to replace CPAP manufacturers' cleaning instructions but rather are to be used to supplement cleaning procedures for home use CPAP masks and tubing.
- With each SoClean filter purchase, SoClean is supplying a complementary (no additional cost) Hose and Mask Adapter, which facilitates use of the SoClean2 and SoClean3 equipment without ozone entering the CPAP. Set-up Instructions for the Hose and Mask Adapter are included in the updated manuals.

How to recognize if the device is not properly set up

Note that improper set-up of your SoClean can be detected by the machine not turning on and/or the smell of ozone. As noted above, the updated manuals contain instructions for users that are unable to smell ozone.

Products Affected

Product	UPC/UDI Number
SoClean2	UPC 187293000860
SoClean3	UDI (01)00858242007147

Actions to be Taken by You

- User Manuals: Download the new version of the User Manual using the following links:

SoClean2 SoClean3

To obtain a paper copy of the new version of the user manual, simply contact Customer Care at 866-501-3705.

As noted above, this voluntary field correction does not require you to stop using or return your SoClean unit. Instructions for next steps are provided below.

- Hose and Mask Adapter:
  If you recently purchased a SoClean filter and only want to obtain a no cost Hose and Mask Adapter, please contact our Customer Care team at 866-501-3705 or visit the SoClean website: https://www.soclean.com/field-correction
- Confirmation of Receipt: please complete the form to acknowledge that you've read and understand this communication.

This notification is being performed with the knowledge of the Food and Drug Administration (FDA) and other appropriate regulatory authorities.

We at SoClean understand that your time is valuable. Therefore, after acknowledging this communication by following the link above, you will be supplied an offer code to receive 20% off your next SoClean filter purchase.

Adverse events or quality problems associated with the use of SoClean 2 and SoClean 3 may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

We truly appreciate your loyalty as a SoClean customer.

Sincerely,

George Peters
VP, Quality Assurance &
Regulatory Affairs

User Acknowledgement

☐ I acknowledge that I have read and understand the above letter.

☐ I confirm receiving a copy of the Updated User Manual

Device Name and Model Number	SoClean® 2 (SC1200)
Serial Number	

Name	
Address	
Phone/Mobile Number	
E-mail	
Signature	