



## **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**

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#### **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.

# SoClean®

## 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 new version of User Manual using the following links:*

[SoClean2](#)

[SoClean3](#)

To obtain a paper copy of the new version of 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>

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- *Confirmation of Receipt.* please go to the following link to acknowledge that you've read and understand this communication.

<https://www.soclean.com/field-correction>

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.

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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](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088<sup>®</sup> 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<sup>®</sup>

We truly appreciate your loyalty as a SoClean customer.

Sincerely,



George Peters

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VP, Quality Assurance &  
Regulatory Affairs