

Recall Notice – Labelling Amendment

May 6, 2022

Dear Sir/Madame:

Re: SoClean 2 Labelling Amendment in Canada

We are writing to notify you of a recent important change to the label and instructions for use applicable to the SoClean 2 device (Medical Device Licence No. 100197) in Canada.

We are notifying SoClean 2 users of the following labelling changes, which were approved by Health Canada in June 2021:

- Running the SoClean 2 for a 12-minute cycle time duration obtains a 99.9% reduction of microorganisms. Independent lab testing with SoClean 2 demonstrates that, when set at the 12-minute cycle time duration, it kills 99.9% of the following microorganisms comprised of the following bacteria: *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus epidermidis*, and yeast: *Candida albicans*. Previous labelling did not specify to run SoClean for a 12-minute cycle.
- SoClean 2 is not an Automated PAP disinfecting system but rather an Automated Supplemental PAP Maintenance Device.
- Users must follow the CPAP-manufacturer's instructions for cleaning their PAP accessories. The SoClean 2 is intended for use as a supplement to that cleaning.
- The SoClean 2 is intended for use with single-user, personal at-home-use PAP device accessories.

This labeling amendment was made in consultation with Health Canada. Health Canada considers the re-labelling to be a recall, so we are writing to you today to notify you of the action taken and to provide you with the following link to the updated label and instructions for use for the SoClean 2: [SoClean2 CA IFU](#). This notice applies only to Canada.

No action is required in connection with the SoClean 2 device itself and it can continue to be used safely and effectively in accordance with the updated label and instructions for use linked above. All new orders and/or new customers will be provided with the new label/instructions for use.

If you have sold or otherwise distributed the SoClean 2 device, please forward this communication to your customers with instructions that they do the same. **In addition, please acknowledge your receipt of this notice by reply email (SC2CanadianRecall5-2022@soclean.com), fax (1-603-446-6845) or by contacting the undersigned.**

Thank you very much for your attention to this matter, and please do not hesitate to contact us with any questions or concerns. We appreciate your support and thank you for your business. Rest assured that SoClean continues to stand behind the SoClean product.



Sincerely,

A handwritten signature in black ink that reads "George Peters". The signature is written in a cursive, flowing style.

George Peters
VP, QA/RA
SC2CanadianRecall5-2022@soclean.com

