

INTRODUCTION:

SOZO: A bioimpedance spectroscopy device for use on human patients, utilizing ImpediMed's patented BIS technology in a user-friendly format to allow quick and accurate measurement of fluid levels. This can be used as an "early warning" monitor for determining changes in the fluid status of patients with fluid management problems.

SOZO hardware is comprised of eight stainless steel electrodes (four hand and four foot) encased in a biocompatible polycarbonate plastic (Makrolon®).

ISSUE DESCRIPTION:

Cosmetic crazing or micro fractures/cracks have been observed on the surface of the SOZO hardware in the radius of the electrodes on both the hand and foot unit.



AFFECTED PRODUCTS:

- SOZO Analyzer
 Software Version: _____
 U400
 SFB7
 Electrodes (gel backed)
 Other

INSTRUCTIONS:

Refer to SOZO instructions for use regarding the Care and Maintenance of your SOZO hardware.

The external enclosure of the SOZO device should be cleaned between each use with non-bleach based disinfecting agents such as isopropyl alcohol 70% or Peridox® Concentrate Sporicidal Disinfectant and Cleaner.

ImpediMed does not recommend the use of cleaning agents containing Aldehydes, Phenols and Amines as these will degrade the polycarbonate plastic resulting in discoloration and cracking of the SOZO system. ImpediMed does not recommend the use of bleaching agents as these will result in damage to the electrodes.

The root cause of the cracking along the electrode radius is due to material and cleaning agent incompatibility coupled with stresses introduced through the moulding process.

Avoid cleaning agents with active ingredients in one or more of these categories:

Aldehydes	Phenols	Amines
Formaldehyde Acetaldehyde Benzoic acid Benzaldehyde Formic Acid	chlorobenzene nitrobenzene methylbenzene (chloromethyl)benzene benzoic acid (benzenecarboxylic acid) phenylamine phenylethene phenylethanone phenyl ethanoate	ammonia methylamine methanamine aminomethane ethylamine dimethylamine diethylamine Benzalkonium chloride

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