

April 20, 2012

AQUASONIC® 100 SAFE FOR CONTINUED USE
*Recent seizure of ultrasound gel in Newark, New Jersey is NOT related to
Aquasonic 100 Ultrasound Transmission Gel or any other Parker Laboratories product.*

To our customers and the public:

In recent days you may have been informed that federal drug regulators seized thousands of bottles of ultrasound gel produced by a Newark, New Jersey based company after the product was blamed for infecting sixteen cardiac patients at a Michigan hospital with a dangerous bacteria.

Be assured, the product at the center of the investigation and seizure is NOT Aquasonic 100 Ultrasound Transmission Gel or any other Parker Laboratories Product.

Aquasonic 100 and all other Parker Laboratories products remain safe for continued use.

At Parker, we ensure product quality and reliability by adhering to the strictest quality control/infection control guidelines with each and every line. Furthermore, our commitment to quality is nowhere more evident than in our flagship, Aquasonic 100 Ultrasound Transmission Gel.

In response to inquiries made regarding possible microbial contamination, the following information is provided:

Parker Laboratories products meet the USP criteria for Antimicrobial Preservative Effectiveness.

Studies performed on Aquasonic 100 Ultrasound Transmission Gel show that the product remains free from microbial growth for more than five years from date of manufacture.

During the course of a 28-day study, samples of Aquasonic 100 were stored both at room temperature, and at 36 - 38°C to simulate conditions in a Thermasonic® Gel Warmer. Samples under both conditions met the USP criteria for preservative effectiveness.

As long as a bottle that has been opened is stored properly and not contaminated during use, the gel is expected to maintain its original shelf life.

Parker Laboratories stringent quality assurance procedures include the following:

- Environmental monitoring program routinely tests several areas of the manufacturing and production areas for microbial contamination, including manufacturing and packaging equipment.
- Microbial testing is performed monthly on the process water used to make all Parker products and results have shown no presence of bacteria at all points of use.
- Sanitization of entire process water system is performed quarterly.
- Continuous monitoring of water quality provides real-time indication of any system malfunction.
- Microbial testing is done on all Parker products during the routine stability program every six months throughout the life of the product. There have been no indications of microbial growth.
- Quarterly pathogen testing on Aquasonic 100 demonstrates product is free from pathogens when manufactured.

What this means for you is simple...

The quality and reliability you expect from Aquasonic 100 and Parker Laboratories is as strong and unwavering today as ever.

Lastly, I wish to express our sincere appreciation for your ongoing loyalty and support.

Neal Buchalter
President

