



## CLEANING AND STERILIZATION INSTRUCTIONS ETO 80%

**ATTN: PROBES ARRIVE NON-STERILE.  
CLEAN & STERILIZE BEFORE EACH USE**

### SUGGESTED CLEANING PROCEDURE FOR THE FOLLOWING KOVEN TECHNOLOGY, INC. SURGICAL PROBES:

VRP-08 / VRP-20	PP8M05N5A	P5M05S8A
VDP-08A / VDP-10A	PP10M5N5A	P8M05S8A
LRP-08	NP10M2S8AF	P10M5S8A
NRP-10H / NRP-20H	NP20M1S8A	BP5M05S8A
FDP-08	NP20M12S8AF	BP8M05S8A
CRP-20H1N	HP10M2N5AF	BP10M5S8A
CRP-10H / CRP-20H	HP20M1N5AF	

**CLEANING:** Probes must be cleaned to remove contaminating substances prior to sterilization. After each use, perform initial cleaning within the sterile field by wiping the probe free of blood and body fluids. Then, pass the probe out of the field. Disconnect the probe (and any adaptor) from the Doppler unit, clean the probe tip and housing thoroughly with a mild soapy solution, a soft cloth with an enzymatic cleaning solution, or an alcohol-based wipe. If using an enzymatic cleaning solution, wipe the probe again using mild soapy water or an alcohol-based wipe. Do not soak. Complete preparation for sterilization in accordance to hospital procedure using an approved probe cleaning agent.

**STERILIZATION 80%:** It is recommended that the intraoperative and laparoscopic probes be gas sterilized before each use with ethylene oxide (ETO) gas. The suggested mixture ratio is ETO gas – 20%, CO<sub>2</sub> gas – 80%. Exposure time should not be less than 1 hour and 45 minutes at a pressure of 0.75 to 0.8Kg/cm<sup>2</sup> and a temperature of 50° to 60° C. To achieve a Sterility Assurance level (SAL) of 10<sup>-6</sup> (the recommended minimum for direct contact with blood), an exposure time of 3 hours and 30 minutes is necessary. A biological indicator strip should be placed in the load to verify the effectiveness of the cycle selected.

**WARNING:** Do not sterilize the Doppler probes listed above by steam autoclaving. Steam sterilization is likely to damage the plastic probe tip and piezo-electric crystals. Utilize Koven/Hadeco probe number ACP-08 for steam autoclaving. Do not use an automatic washer/disinfector. Temperatures will cause probe electronics to melt.

**AERATION:** Follow hospital requirements with regard to aeration time to allow residual ETO gas to dissipate. The minimum recommended aeration time is 8 hours at 60° C, 40% to 60% humidity with an air change (ventilation) frequency of 25 times per hour. Note: aeration time should meet institution and FDA guidelines.

**COUPLING FOR INTRAOPERATIVE AND LAPAROSCOPIC USE:** During the examination, fluid coupling must be maintained for proper signal reception. If needed, irrigate the incision or laparoscopic portal with sterile saline to insure adequate coupling. Use of sterile gel is acceptable in all areas except the brain.

**CONTRAINDICATIONS:** Hospital policy takes precedence over this protocol.

*Failure to use approved cleaning & sterilization procedures may void the warranty*

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