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Re: *Reprocessing flexible endoscopes using the Custom Ultrasonics System 83 Plus Washer-Disinfector and the S6 or S8 Pre-processing Sinks.*

Custom Ultrasonics's pre-processing sinks (models S6 and S8) automatically flush the endoscope's channels with Tergal 800,* an alkaline detergent that is automatically injected into the sink's basin at the correct dilution. While these pre-processing sinks supplement flushing these channels manually using a syringe, their use still requires that the endoscope's working channel and valves (and other accessible surfaces) be thoroughly brushed in accordance with both the endoscope manufacturer's instructions and published standards.

When using either the Custom Ultrasonics's S6 or the S8 pre-processing sink to pre-clean flexible endoscopes, please refer to the sink's operator's manual and to Custom Ultrasonics's endoscope adapter chart, which is available on Custom Ultrasonics's website. This chart lists the channel tubings, adapters, and fittings required by Custom Ultrasonics to ensure proper connection to, and thorough automated flushing with Tergal 800 detergent of, each endoscope model's internal channels. Please note that these same adapters are also used by the *System 83 Plus Washer-Disinfector* to ensure proper automated washing and high-level disinfection of the endoscope.

The S6 and S8 pre-processing sinks, like the *System 83 Plus*, are designed to be used exclusively with these listed adapters, connectors, and fittings – not those provided by the endoscope manufacturer (such as Olympus or Pentax), such as the all-channel irrigator – unless otherwise instructed by Custom Ultrasonics by way of its adapter chart.

A medical facility not using the S6 or S8 pre-processing sink to pre-clean flexible endoscopes prior to placing the pre-processed endoscope into the *System 83 Plus*, may ask whether it is necessary to use the all channel irrigator as the endoscope manufacturer recommends to flush the endoscope's channels manually with a detergent. In reply, it is not necessary to use this irrigator (or a comparable adapter provided by the endoscope manufacturer) during pre-cleaning of the endoscope in a medical facility's sink prior to the endoscope's placement into the *System 83 Plus*. Custom Ultrasonics has validated the *System 83 Plus* without the use of the all channel irrigator (see below).

Moreover, according to SGNA's guidelines (see: <http://www.sgna.org/Resources/guidelines/guideline6_print.html>), "the endoscope must then be immersed in fresh enzymatic detergent solution, which is flushed through all channels. Some automated reprocessors provide for irrigation of enzymatic solution. If not, this step must be done manually prior to beginning the automated cycle." The intent of this statement is to supplement manual flushing of detergent through the endoscope's channels with an automated reprocessor if and only if the reprocessor has been cleared by the FDA specifically for cleaning and automatically flushing the endoscope's channels (i.e., the reprocessor, like the Custom Ultrasonics's *System 83 Plus* (see: http://www.myendosite.com/fdabooklet_1.pdf), is labeled as a "washer-disinfector"). Ideally, the validation and verification data supporting this cleaning claim have been published.

Signed …

- *The System 83 Plus* has been validated for cleaning flexible endoscopes using Tergal 800 detergent. The use of an enzymatic detergent instead to clean the endoscope may be permissible, provided the alternative detergent satisfies a few criteria – namely: (a) that it is specifically formulated for ultrasonic cleaning; (b) that it has been demonstrated to be compatible with the materials and components of the endoscope *and* the *System 83 Plus*; and (c) for which validated simulated in-use data (e.g., microbiological or equivalent) demonstrate the detergent's effectiveness when used to clean flexible endoscopes during *worst-case* testing conditions.

  For further questions and assistance please contact:

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