



Fridingen, June 2009

## HIGH-END CLEANING

"State of the Art" was the objective when coming to the decision to guarantee our customers the optimal cleanliness of our products. We wanted to issue a well-founded cleaning and sterilisation instruction, not only for new instruments but also for long lasting practical use.

When cleaning the product at the end of the production process it has to be assured to remove all additives, like for example oil. There are many different technologies which can be applied for this reason. We opted for a fully automated ultrasonic plant with multiple-frequency technology on the basis of a hydrous solution with alkaline detergent. This cleaning method effectively removes soiling even from inaccessible spots - and yet it is eco-friendly.

The principle of ultrasonic is simple: Ultrasonic transducer systems transform electric energy into mechanical vibrations. These are transmitted into the cleaning liquid. In this process, tiny vacuum bubbles the size of micrometres are created which implode with high velocity (cavitation). The highly energetic flows (jets) created by cavitation thoroughly remove all kinds of contamination. After the cleaning bath, the instruments run through several rinsing baths, which are also equipped with ultrasonic. The cleaning parameters and the status of the cleaning process are being monitored continuously by a number of highly sensitive sensors. A data logger stores the specific information.





The reproducibility of the production process is requested by the DIN EN ISO 13485:2003 norm as well as by the American Health Authority FDA. The technical terminology calls this examination and documentation "**VALIDATION**".

**Validation** must demonstrate the process' ability to reach the intended results. An accredited laboratory examines the cleaning results. Extensive tests, e.g. determination of germ total, are accomplished with selected instruments which simulate the "worst case". In order to reach process reliability, these tests are repeated several times. Continuous tests during serial production serve as monitoring instrument.

To guarantee the created cleanliness of the products, the assembly and packaging process takes place in a cleanroom respectively under laminar air.



We guarantee that all delivered instruments have the optimal degree of purity and fulfill even the highest standards.

Please do not hesitate to contact us in case of any questions regarding the topic of cleaning and validation.

Read more concerning reprocessing of the instruments in our July issue of the Red-Flash!

Kind regards,

**Hermann Medizintechnik**