



ULTRASONIC WELDING TECHNOLOGY

**MEDICAL**

## Ultrasonic welding technology. For medical engineering.

Increased life expectancy is made possible by continued progress in the field of medical engineering. Medical components and packaging, as well as hygiene products, significantly contribute to this progress while sustainably improving our quality of life. Such products are increasingly made of plastic materials and ultrasonically welded. Particularly for demanding applications in medical engineering with high quality requirements, ultrasonics has been proven to be a fast and reproducible welding technology. Critical process data is automatically captured and analyzed. Calibrated ultrasonic welding machines allow for traceability of processes, including systems at different manufacturing locations.

Herrmann Ultrasonics is a world-leading company in the field of ultrasonic welding. For our customers, we assume both the role of consultants and application problem solvers with regards to the ultrasonic joining of plastic materials, packaging and nonwoven products. In addition to leading-technology products, we provide excellent, in depth application consulting to solve joining tasks and problems, taking into account both quality and economic aspects.

Blister packs

Instruments

Wound dressing

Face masks

Film packaging

Drug delivery systems

Injectors

Filters



## Ultrasonic welding of medical components. As specific as the product itself.



Medical components

### Optimized solutions. For your specific requirements.

Nowadays, the requirements of medical products have become increasingly diverse and complex: In addition to tightness, strength and minimum particle formation, process validation and traceability are equally important quality criteria. In order to ensure high-quality manufacturing with maximum process safety, product design as well as selection of welding parameters play a decisive role, depending on individual application cases.

Ultrasonic welding systems by Herrmann Ultrasonics comply with the very high requirements for process monitoring, quality assurance and data acquisition. In this context, our DIALOG controller technology supports compliance with strictest calibration regulations according to FDA 21 CFR Part 11. High product safety and repeatability are provided in combination with application-related technical consulting in our local ultrasonic laboratories. Herrmann Ultrasonics provides ideal solutions for maximum quality in production – from small series systems all the way to fully automated manufacturing processes.



Medical packaging



Medical hygiene & wound healing

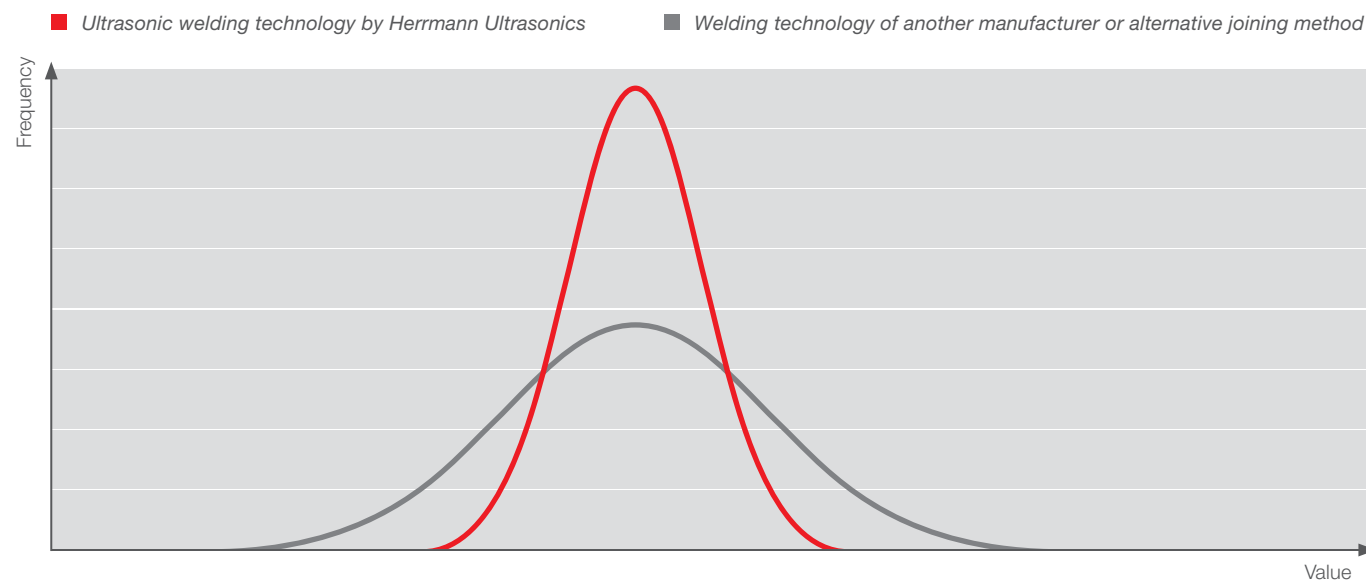
### Major product and process requirements. Possible with technology from Herrmann Ultrasonics.

- High strength
- Surfaces with impeccable visual appearance
- Reliable functionality of components
- Hermetic seal
- Prevention of particle flash
- Product safety due to cold sealing tools
- No adhesives or additives
- Statistical process monitoring
- Process data acquisition
- Data analysis
- Calibration for compliance with QS and FDA standards
- User authentication and audit trails
- Feasible for clean room applications

## Avoiding risks – increasing security. With outstanding process evaluation.

With ultrasonic welding, the properties of the machine and controller allow for unrivaled process monitoring and optimization, which is not attainable with other joining processes. Unique identification and traceability options facilitate and optimize the process validation throughout the entire production process.

### Statistical analysis of parameters



## Advantage through quality. With revolutionary technology.

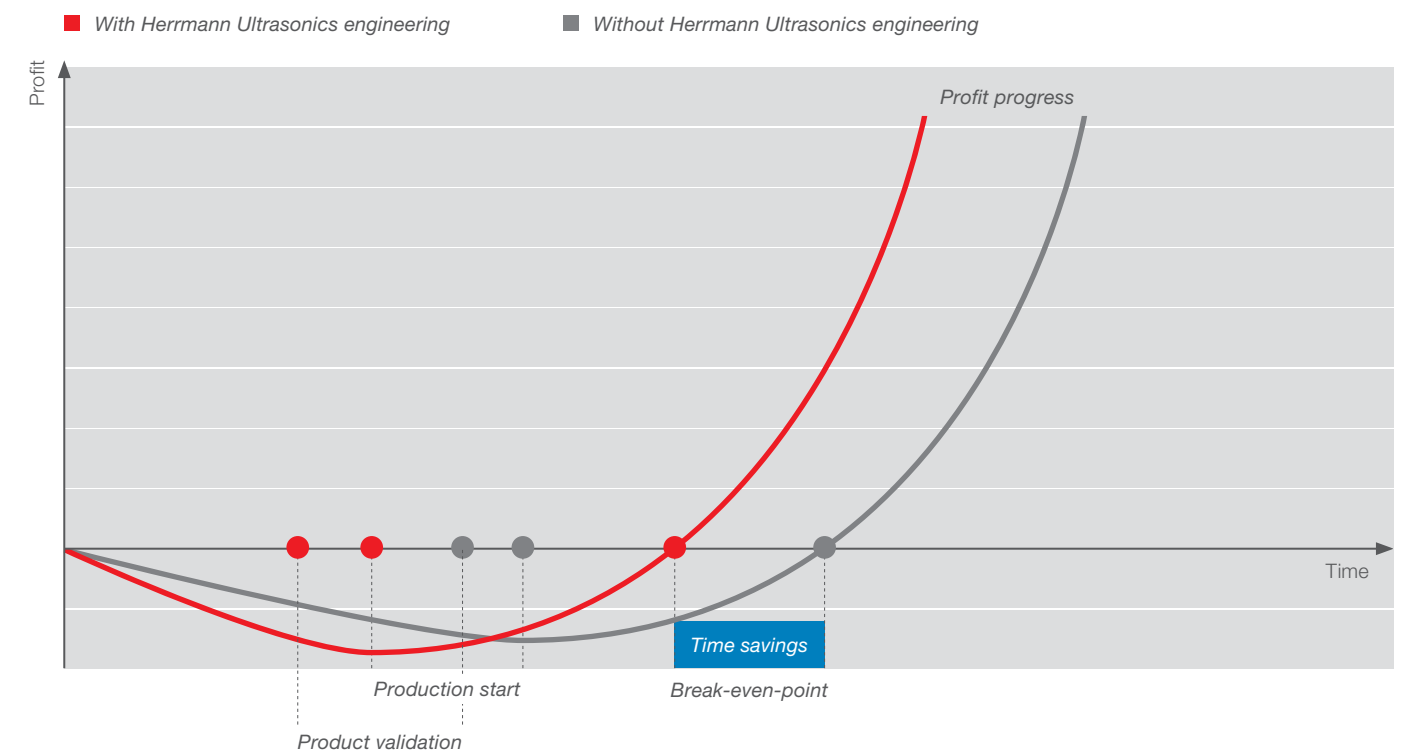
The ultrasonic technology by Herrmann Ultrasonics is capable of visualizing and analyzing up to 130 different process reference data. The FDA-compliant options for calibration of the welding systems allow for identical process synchronization at different production sites around the world. Thus the strict production environment requirements in medical engineering are optimally fulfilled.

### Cost reduction due to higher quality

- Support in process validation reduces product development phases
- Statistical analysis for high repeatability of the weld results prevents failed batches
- Low reject rate due to monitoring of weld quality criteria
- Electronic FDA user signature prevents faulty user inputs in production
- Production log facilitates traceability

## Outstandingly efficient. With technical application-oriented consultation.

Optimized product development phases are a crucial competitive advantage. By utilizing ultrasonic weld technologies from Herrmann Ultrasonics, break-even points can be met earlier and the required profitability can be achieved faster.



## Environmentally friendly and energy efficient



Ultrasonic welding technology is considered an environmentally friendly technology. In comparison with other thermal joining processes, its overall energy footprint is reduced by 75 %. This is due to power only being drawn during the actual weld time.

### Properties and advantages

- Very low energy required due to optimum efficiency
- Energy is focused specifically in the area to be joined and only during the actual weld cycle
- Efficient use of energy due to ultrasonics not requiring heat-up or stand-by cycles
- No power loss through heat radiation as with typical thermal processes



## Highest weld quality. Medical components.



### Membranes

Membranes are used for a large variety of tasks in medical and life science applications. These range from particle filtration in the field of infusion, to cell and tissue culture growth, to various aeration and ventilation requirements. Membranes can be welded or bound by means of ultrasonics.

### Fluid containers and hermetic housings

The major requirements for these components are assured weld tightness and dimensional accuracy, as well as their unrestricted and reliable functionality. Typical applications: Bottles, secretion containers and bags, transfer systems and tissue culture bottles.



### Adaptors and connectors

Unrestricted functionality, weld tightness, and particle purity, along with high outputs, are requirements for these medical components. Typical applications: Luer adapter, lock, connector, coupler, checkvalve and cuvette with luer lock fittings. In addition, plug valve housing, piercing membrane and needle embedding.



### Surgical tools

Strength, functionality and high-quality visual appearance are important requirements for surgical tools and devices. Typical applications: Grip plates of instruments, endoscopes, disposable clippers and devices for sclerotherapy.



### Functional components

Component protecting welds with strong and flawless weld seams and thin wall thicknesses are characteristics for medical functional components. Typical applications: Dental devices, hearing aid devices, implants, insulin pens and prostheses.



### Blood filters

The predominant requirement is cost optimization, particularly for these components. Therefore, process-transparent welding with ultrasonics is the ideal process compared to other joining processes. Typical requirements: Tightness, particle purity and unrestricted functionality of the filter.



## Highest sealing quality. Medical packaging.

### Top seal – Sachet/Pouch – HFFS

The vibrational motion of the ultrasonic tooling allows for obtaining reliable joint quality, despite the handling of powdered feed material. Burning of the packaging material during machine downtimes is safely prevented.



### Functional components on film

Functional components such as valves and discharge aids are frequently used in the field of medical packaging. Ultrasonic technology welds functional injection molded components quickly and safely on numerous types of film and maintains an attractive appearance of the packaging by avoiding film shrinkage. The barrier properties of the packaging are not compromised.



### Cross seal – Gel bags – VFFS

Ultrasonic welding achieves a hermetic seal, even with product contamination in the sealing area. The headspace volume can be significantly reduced; it is possible to produce completely air-free bags containing gels or liquids.

### Secondary packaging for disposable syringes

The use of ultrasonic welding guarantees a production process with extremely short sealing times and reproducible sealing parameters, yielding consistent welding results. The buildup of exhaust gases is also prevented.

### Secondary packaging for heat patches

The gentle sealing process with ultrasonic vibrations enables the use of thinner and more reasonably priced films for the packaging of the product. Because the ultrasonic sealing tools remain cool, additional heat sealing layers in the film are not required.



### Secondary packaging for inhalers

The digital ultrasonic generator ULTRAPACK enables 100% monitoring of the sealing process results for each weld, thanks to integrated process monitoring. All weld process data can be stored centrally, which allows for accurate traceability.

## Highest bonding quality. Medical hygiene and wound care.

### Respirator Face Mask

Thanks to ultrasonic technology, it is possible to create three dimensional shapes and very soft contour seams. The filtering properties of the material outside the weld seal are not influenced by this process. Shape-welding can be realized in a continuous ultrasonic process with intermittent attachment of the elastic straps. Special requirements: soft and strong seams, strong bonding of layers, sterility and high wearing comfort.



### Surgical Face Mask

Due to soft welding by means of ultrasonics, surgical face masks have a remarkably high wearing comfort. Strong bonding of the multi-layer structure and good breathing permeability are guaranteed by continuous processing, as well as providing for high production rates.



### Wound dressing/adhesive bandage

The main demand on modern wound dressing is optimized processing of various materials in a layered structure. Wound dressings laminated and perforated by means of ultrasonics are particularly breathable. Their absorbency is improved due to focused, low energy input. Special coating, antibacterial coating or coating that prevents adhesion of the dressing to the wound is not influenced by the ultrasonic process. Typical requirements: lint-free surfaces, high degree of absorbency, sterility, tightness, unrestricted breathability.

### Band-Aid

Sterile processing using ultrasonics allows for continuous perforation without residues, a soft hand feel and the desired breathability of the product.



## Versatile product portfolio. Leading in technology and precision.



### HiQ product line, systems and components

The standard machines of the HiQ product line allow for complex joining processes, ease of handling and are particularly designed for the special requirements of medical engineering. Due to visualization of the weld process and switch-over of weld forces, it is possible to realize even the most complex applications. Accumulation of all process parameters via fieldbus and easy integration of part identification systems facilitate process optimization and traceability. For integration in automation lines we provide a large variety of modular actuators.

- Validation functions for the entire weld process
- Archiving options for every single weld
- Integrated machine calibration functions
- Compliance with FDA CFR 21 Part 11 as part of the DIALOG software
- Minimum weld forces of only 10 N are possible for the smallest parts



### MICROBOND weld systems

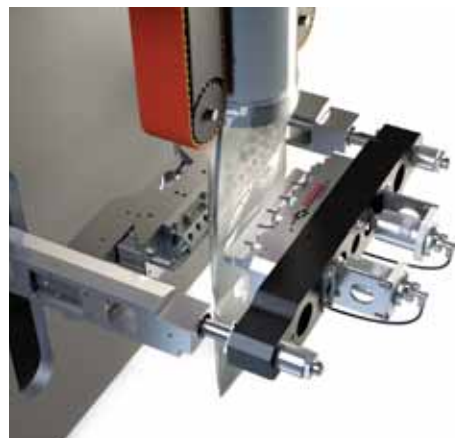
The patented MICROBOND technology provides an intelligent concept for continuous manufacturing processes with web materials. The compact module can be easily integrated in continuous high-speed production lines and ensures graphic analysis of important weld process data via touch screen. The low resistance of the rotating weld system minimizes the generation of particles. Modularity of the fixed weld tools (sonotrodes) allows for operating widths of up to four meters.

- ULTRABOND generators with high continuous ultrasonic power
- Continuous welding of delicate materials
- High production speeds

### ULTRASONIC PACKLINE weld modules

The flexible and modular system allows for easy and rapid integration in different types of packaging machines. Misallocations or double allocations and relevant process errors are safely recognized and the suspect pouches are rejected. Intelligent measuring and control technology, including a highly accurate distance measurement system, allows for this distinct advantage. High-cost quality returns from the market are thus prevented. All quality relevant sealing parameters are monitored and archived.

- Option for weld process archiving
- Safe recognition of faulty pouches
- Reduction of quality assurance costs



## Continued support. Consulting and services from the ultrasonic specialists.

The expert teams at Herrmann Ultrasonics will support you during every phase of your project. This includes understanding of customer requirements, joint design discussion, component optimization, pre-production prototype welding in application laboratories, weld parameter definition for verification of the required component properties, training/ instruction services and after-sales services. Close cooperation with the customer and efficient product development is the primary focus.



### Ultrasonic laboratory

#### Application consulting

- Support with various traceability options
- Early support for component design
- Support and direction for designing the geometry of the weld joint area
- Principle testing for feasibility

#### Application optimization

- Common trials and tests with the customer
- Determination and optimization of tooling profiles and process limits
- Complete documentation of the feasibility test results
- Verification of research results with the help of microscopy, tensile tests, sealing tests, burst tests, high-speed cameras and microtome cuts

### Training and customer services

- Beginner and expert seminars
- Practice-oriented application trainings
- Training on-site or at our local facilities
- Customer-specific trainings

### Technical project management

- Consistent implementation of customer requirements and test results in design concepts
- Support during the introduction phase of new component production at different manufacturing sites with equally validated parameters
- Central analysis of process data received from production plants located in different areas
- Mechanical and electrical interface definition for automation lines
- Guidance on integrating the weld process into the machine sequence

### Tech-Center on site

- Customer-oriented support for feasibility analyses
- Technical centers and application laboratories are strategically located in the major markets worldwide
- Experienced and native-speaking application specialists

### After-Sales-Service

- Optional 24-hour service hotline
- On-site service in the respective languages through our Tech-Center
- Preventative maintenance and servicing measures





North American Headquarters

Global Headquarters

Asian Headquarters

**FIRST CLASS TECHNOLOGY. WORLDWIDE.**



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