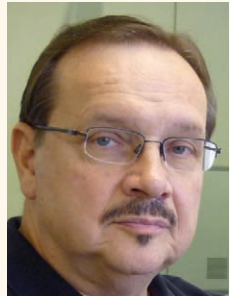


# OUTSOURCING OUTLOOK

## Cleanroom Manufacturing and Assembly



By partnering with a manufacturer that specializes in cleanroom services, OEMs can cut costs and rely on the supplier's specialized expertise, according to Harold Faig, CEO of **MedPlast** (Tempe, AZ).

**MPMN:** What advantages do medical device OEMs enjoy by partnering with contract manufacturers that offer cleanroom capabilities?

**Faig:** OEMs enjoy numerous benefits by partnering with outsourcing companies with cleanroom expertise. Operating a medical device manufacturing cleanroom requires capital equipment and expenses, annual certifications and maintenance, regular testing, cleanroom attire, and personnel trained to maintain and operate within the cleanroom environment. By bearing these expenses, the contract manufacturer can help the OEM to reduce costs while providing specialized services beyond the OEM's range of expertise.

**MPMN:** What cleanroom infrastructure, systems, and equipment skills should the medical device OEM expect of a contract manufacturer?

**Faig:** While cleanroom infrastructure and mechanical systems are common in the manufacturing world, they differ depending on the cleanroom class. In most cases, the contract manufacturer builds and certifies the cleanroom, but only then does it prove its true expertise and skills by developing maintenance and environmental testing programs and by training cleanroom personnel. The OEM should expect that the contract manufacturer has implemented a robust monitoring program, a thorough cleaning schedule, regular training programs, and competency assessments.

**MPMN:** What trends and advances in cleanroom manufacturing should the medical device OEM bear in mind when seeking a vendor?

**Faig:** The first question an OEM should ask is what cleanroom class is required to manufacture the medical device in question. Depending on the function, regulatory requirements, and sterility demands of the device, different levels of cleanroom manufacturing may be required. While flexible, modular options have been developed for less-stringent environments, modular cleanrooms are not an option for more-demanding operations. The medical device OEM should also be aware of the latest trends in measurement and filtration equipment, which are continuing to improve as new materials and methodologies are developed. Nevertheless, despite improvements in mechanical efficiency, physical design, and filtration, the need to filter and pressurize cleanroom air results in high energy-consumption levels. Hence, the most noticeable trend in the cleanroom manufacturing and assembly space is the emergence of efficient 'green cleanrooms' and advances in smart cleanrooms—computer-monitored facilities in which mechanical equipment can be adjusted as necessary to optimize performance.

### Medical device and electronics assembly services

Operating two Class 100,000 cleanrooms totaling 1700 sq ft, Coastline International focuses on medical part and electronics assembly operations. The ISO 13485- and ISO 9001-certified company also plans to double its Class 100,000 cleanroom capacity this spring. Equipped with SMT and through-hole wave-soldering equipment, the company's facility provides RoHS-compliant and surface-mount manufacturing services, in addition to such full-contract manufacturing services as parts procurement.

**Coastline International Inc.**  
SAN DIEGO

[www.coastlineintl.com](http://www.coastlineintl.com)



### Cleanroom molding

**MackMedical/Mack Molding** has added Class 100,000 cleanroom molding to its portfolio of medical device manufacturing services. Dedicated to the production of reusable and disposable medical devices for orthopedic applications in particular, the company's modular cleanroom injection molding facility features removable panels to accommodate future expansion. Dual-air-lock, rapid-roll-up doors facilitate product flow and quick tool changes. The facility houses six high-precision, energy-efficient 110-ton electric injection molding machines. The service provider is equipped with 121 injection molding machines in total, ranging from 28 to 4000 tn in clamping force and from 0.6 to 800 oz in barrel size. It also has a Class 100,000 cleanroom dedicated to sonic-welding assembly, functional testing, and nonsterile packaging of disposables.



**MackMedical/Mack Molding**  
ARLINGTON, VT

[www.mack.com](http://www.mack.com)

### Contract manufacturing and assembly

Full-service, FDA-registered, and ISO 13485-certified contract manufacturer Sanbor Medical offers production and assembly of Class I and Class II medical devices. Services include full-system box build and the manufacture of handheld devices and single-use disposables. In addition, the company conducts assembly and packaging operations in a Class 10,000 cleanroom and provides sterilization services through its FDA-registered partners. It produces electromechanical subassemblies and plastic molded components, as well as finished devices. The service provider is equipped for high-volume production but has no minimum-volume requirement.

**Sanbor Medical**  
ALLENTOWN, PA

[www.sanbormedical.com](http://www.sanbormedical.com)



### Cleanroom leasing

A full-service medical device contract manufacturer registered with FDA and operating a facility certified to ISO 13485:2003 standards, Life Science Outsourcing Inc. has 10,000 sq ft of Class 10,000 cleanroom space used primarily for the manufacture of Class II and Class III devices. The company can lease cleanroom space to OEMs on a daily, weekly, or monthly basis, providing allocated spaces for confidential or special projects. The cleanroom houses equipment, tooling, and assembly fixtures for ultrasonic component cleaning, ultrasonic welding, tray sealing, and such microprocesses as soldering. Providing a turnkey outsourcing solution for both startups and large medical device companies, the company offers sterilization, packaging validation, and warehousing services as well.



**Life Science Outsourcing Inc.**

BREA, CA

[www.lso-inc.com](http://www.lso-inc.com)

### Production, assembly, and testing services

Outsourcing partner MedPlast is a full-service custom medical device manufacturer equipped with Class 100,000 cleanrooms for molding and assembly. It also offers extensive product testing capabilities. Its in-house laboratory services include monitoring of the production environment for microbial contaminants that could compromise the final sterilized product. The company also performs bioburden and Limulus amoebocyte lysate testing. In addition to lab tests, it conducts a variety of in-process and final testing during the manufacturing process, including customized pull testing, drop testing, leakage testing, flow testing, and electrical testing. The ISO 13485- and ISO 9002-certified and FDA-registered contract manufacturer offers capabilities in injection molding, blow molding, silicone materials, and silicone processing.

**MedPlast**  
TEMPE, AZ

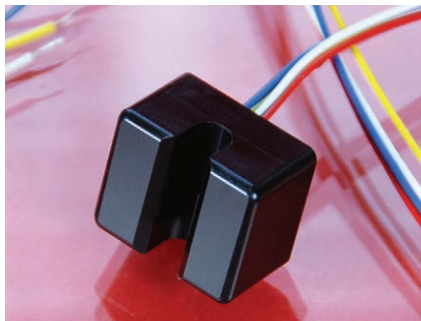
[www.medplastgroup.com](http://www.medplastgroup.com)



# MD&M WEST 2013

## Ultrasonic Air-Bubble Sensors

Compact Sonocheck ABD07 clamp-on ultrasonic sensors for quick, reliable contactless air-and gas-bubble detection in liquid-filled tubes are supplied by Sonotec Ultraschallsensorik Halle GmbH to manufacturers of miniaturized and



portable medical devices. Measuring 25.40 x 19 mm and 15.75 mm high, the minisensors offer performance comparable to much larger conventional air bubble detectors, according to the manufacturer. Bubble-size sensitivity and other parameters can be specified by the user. The manufacturer can also produce custom devices as necessary. Equipped with a programmable microcontroller, the sensors additionally perform liquid-level monitoring and full-empty detection. Their measurement cycle is 200 microseconds, typical response time is 1 millisecond, and guaranteed detection capability extends down to bubbles sized at one-third of any tube's inner diameter.

**Sonotec Ultraschallsensorik Halle GmbH**  
HALLE, GERMANY  
www.sonotec.de  
**Booth #3593**

## Pumps for Surgical Ablation

The OEM pumps in the 400RXMD family have been specifically designed by Watson-Marlow Pumps Group for the surgical ablation market. The pumps are suited for equipment employing radio-frequency ablation. They can also be used to pump cooling fluid for precise temperature control in surgical systems for the treatment of cardiac arrhythmia, cancer, and other procedures. The pumps are offered in a range of precision pressure settings to suit specific applications, feature a mechanism engineered to improve flow accuracy as compared with that of a predecessor line, and have a tube holder that ensures correct positioning of a newly loaded tube each time the safety lid is closed. Available in 10 variants, the pumps provide flows up to 500 ml/min at 550 rpm and deliver pressures up to 8 bar. The offer of two stepper motors and one brushless-motor option enables pump users to set pressure, flow, and rotation direction.

**Watson-Marlow Pumps Group**  
WILMINGTON, MA  
www.watson-marlow.com  
**Booth #1713**

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THINKING MEDICAL SYSTEMS®



## Engineering Exceptional Results

For over 15 years, Minnetronix has combined design and manufacturing, and our own innovative IP solutions, to help customers transform ideas into commercial success. Our teams expand the boundaries of device performance to create sophisticated medical devices that reliably meet regulatory and market needs.

FDA Registered ■ ISO 13485 Certified

Visit us at [www.minnetronix.com/mpmn](http://www.minnetronix.com/mpmn)

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Medical Device Innovation concept → commercialization+

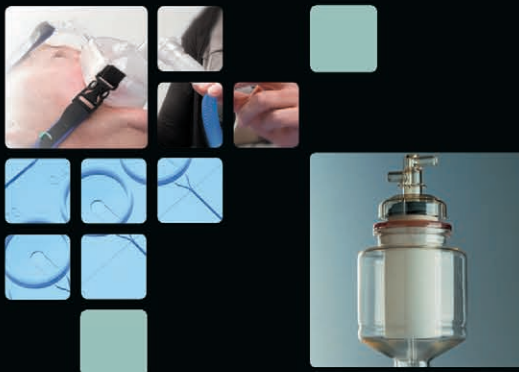
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- Process Validation
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- Optics
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