Vibration Isolation Solutions at the FDA's New Lab

When it was decided that the FDA's OSEL would be moving, officials sought to address vibration isolation in the new building upfront so they wouldn't bring this issue with them from the previous facility. This article reviews the steps they took in order to ease concerns over this significant problem while also examining the solutions selected.

By Ben McKelway

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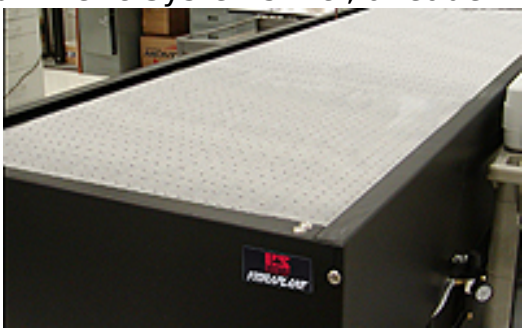
When the Office of Science and Engineering Laboratories (OSEL), part of the U.S. FDA, recently moved to new quarters in suburban Washington, its ability to perform precision research dramatically improved, thanks to advanced planning. Officials of the federal agency researched and installed vibration-isolation equipment manufactured by Boston-based Kinetic Systems Inc., a leader in the field of vibration-isolation technology.



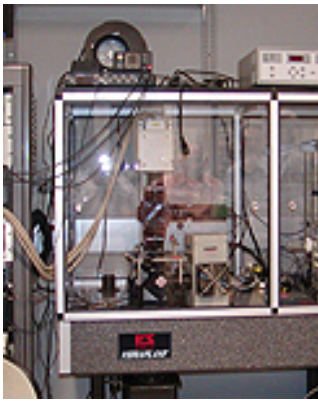
A newly delivered Kinetic Systems optical table awaits outfitting and use by scientists at the FDA's Office of Science and Engineering Laboratories. The stainless steel top skin has mounting holes at regular intervals.

The OSEL conducts research, testing, and risk assessments of medical and radiation-producing products to ensure they meet federal safety standards. It also establishes performance standards and develops standardized product-evaluation methods to support the regulatory decision-making of the FDA's Center for Devices and Radiological Health (CDRH).

"If We Need To Move, Let's Do It Right"

At the OSEL's old facility in Rockville, MD, the main vibration source was traffic. "Many of our operations couldn't be conducted until 7:30 or 8:00 at night because

the traffic on the street a block away generated so much vibration through the ground and into the labs," explains Charles Warr, OSEL's associate director for laboratories. "We saw an opportunity to fix that when the word came down that we would be relocating. 'If we need to move, let's do it right,' we said, so even before the blueprint stage, we placed a great emphasis on vibration isolation."



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"First, vibration-isolation consultants evaluated the soil characteristics of the building site," recalls Warr, who is trained in nuclear physics with specialties in medical and solid-state physics. "Based on their advice, the foundation of our main facility was poured up to 14 feet thick. We even went as far as writing our own isolation specifications for the air conditioning system. Normally, the architectural engineers get to do that in a back room somewhere."

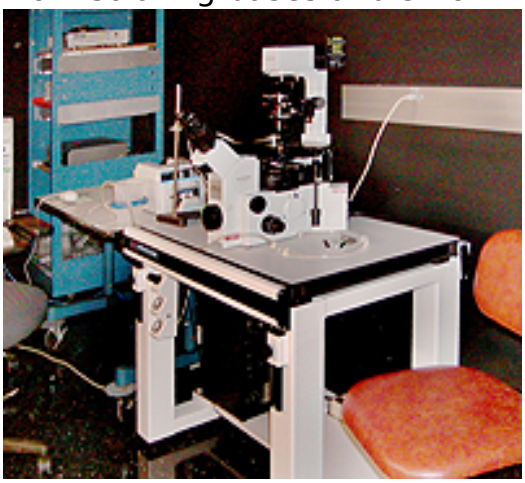
Vibrations

Whether from traffic, wind, in-house machinery, or something simply known as natural resonance frequency, all buildings vibrate. In laboratories, vibrations don't have to be obvious for performance to suffer. Day-to-day magnification problems may include excessive signal noise, low-frequency jitter, high-resolution image blur, and the appearance of line thickening. At their worst, uncontrolled vibrations can cause excessive wear and even structural damage to microscopes and other sensitive electromechanical and optical equipment.

With technological advances demanding greater precision in many fields, vibration isolation becomes more important and more difficult. To meet the needs of laboratories around the world, there is now an array of new sophisticated vibration-isolation workstations, optical tables, benchtop platforms, and related equipment, much of which did not exist 20 years ago.

Isolating the OSEL

Because the OSEL's electron microscopes magnify up to 170,000 times, the slightest instability can cause an image to blur. For the new facility, Warr and his colleagues specified a vibration-isolation "island"&#151a 1.5-ton concrete block that "floats" flush with the surrounding floor supported by heavy-duty, automatic-leveling isolation mounts supplied by Kinetic Systems. The microscopes have their own vibration-isolating bases and sit on the island, which provides even greater isolation.



The Kinetic Systems Personal Vibration Isolation Workstation is ideal for applications where floor space is limited. At the FDA's Office of Science and Engineering Laboratories, this one is used for steadying a microscope.

The consultants also recommended a good deal more workstation vibration-isolation equipment for the new labs. Warr had expected this. OSEL already had equipment from various suppliers, including a Kinetic Systems active-air workstation, but all of the new vibration-isolation equipment purchased was supplied by Kinetic Systems.

"We asked around, consulting scientists from all over the world," Warr recalls. "For research, we weren't just looking for something good enough; we wanted the best performance&#151the best equipment available for our new modern laboratories."

The OSEL made the decision to procure from Kinetic Systems a total of 14 optical tables for use in optics and as isolation workstations, two variable-height vibration-isolation workstations, and a benchtop platform. Most of these systems use "Active Air" technology.

Warr says the new Kinetic Systems equipment will enable the OSEL to more confidently support the review of proposed medical devices, assess the manufacture and use of existing devices, and conduct the research necessary for "technology forecasting." Key to these missions are the OSEL's many microscopes, each of which requires vibration isolation. In addition to the agency's two electron microscopes mounted on the two new vibration-free islands, the OSEL has confocal florescence microscopes, atomic force microscopes, and many others which will benefit from the new vibration-isolation equipment. The OSEL is diligent about

keeping up with, or even a few steps in front of, advances in medical science, backed by documented, repeatable lab work.

OSEL Testing

The OSEL reviews a wide variety of products, and uses that knowledge going forward. For example, from previous tests of defibrillators, scientists already know that the human heart muscle responds to different electronic waveforms in different ways, Warr explains, and expect these devices to be designed to minimize the strain they cause the body.

The OSEL's electron microscope gains extra protection against image-blurring vibrations because beneath the assembly is a concrete "island" flush with but not abutting the surrounding floor, supported by heavy-duty isolation mounts supplied by Kinetic Systems.

Various forthcoming electrophysiology experiments, some of which require the insertion of microprobes into single cells, will be conducted on a Kinetic Systems workstation outfitted with a Kinetic Systems Faraday cage to create an "RF dark" environment free of radio frequencies in order to help researchers isolate the important variables.

"Active Air" Systems

"Active Air" systems are self-leveling. Connected to a compressor or other pressurized air source, they have servo valves that automatically feed or bleed air from the appropriate isolator as needed to maintain the tabletop at a pre-set zero-deflection level as the load increases, decreases, or is moved. Vibration-isolation efficiencies can approach 99%

for vertical and 95% for horizontal.

The Kinetic Systems "Active Air" equipment uses frictionless, rolling-diaphragm air seals in conjunction with dual air chambers. With this design, stiffness is a function of the combined air volume of the dual chambers. Very low stiffness is needed to obtain the desired low natural frequency and thus, high vertical isolation efficiency. Some Kinetic Systems equipment also includes pistons to enhance horizontal isolation.

Improvements in optics and in other sciences have increased demand for precision. This has resulted in the manufacture of optical tables that are ultra-sensitive to vibrations. Kinetic Systems optical tables perform so well that they are also used for lab work unrelated to optics, as illustrated by the OSEL's choice to use 8 of its 14 new optical tables for research in other fields. These tables provide a large surface area, very high isolation capabilities at very low frequencies (2 Hz and lower), and quick response to micro disturbances. Performance is achieved through a vibration-isolation support system that incorporates passive and active isolation concepts. These high-quality optical workstations offer quad-tuned as well as broadband vibration damping using individual absorbers (tuned to the two lowest natural frequencies, bending and torsion, of each table)

embedded in all four corners of the table. This narrow-band selective damping provides four frequency-tuned, mass-spring resonators dry-damped and tuned to resonate 180 out of phase with the lowest natural frequency of the table. The out-of-phase inertial forces induced in each resonator mass act to cancel or absorb the motion of the table at its natural frequency and lower the resonant amplification.

The "Active Air" workstations provided are ergonomically designed, variable-height units. There's no point in eliminating blur and jitter from microscope work, for example, if the operator cannot sit comfortable and alert. Good design and appropriate construction materials can make vibration-isolation equipment user-friendly. Variable-height workstations reduce user fatigue and back stress. They are remotely activated with a quiet electrohydraulic mechanism that allows the user to smoothly raise or lower the tabletop in order to maintain a posture that is ergonomically correcta major benefit when accommodating different operators on different shifts.

Tabletops are typically constructed of aluminum, steel, or composite with plastic, anti-static, or stainless-steel laminate. Corrosion-resistant metals and layered composites can be combined to provide lightweight, rigid, highly damped surfaces. And, although tabletops need to be

supported by low-frequency support systems, the tops themselves should have high internal natural frequencies. Tabletops can even be built with honeycomb-type cores of hexagonal cells for reduced weight without sacrificing rigidity. In fact, such cores can provide natural frequencies higher than those attainable with either ribbed cast iron or solid granite block of the same size.

Vibration-isolation equipment is available with many accessories to add convenience to workstations or optical tables. They include shelves, drawers, electrical outlets, monitor supports, lighting, guard rails, padded armrests, retractable casters, Faraday cages to protect sensitive operations from electromagnetic interference, and other tabletop enclosures to protect against harsh environments.

In the OSEL's materials testing lab, scientists test the long-term biostability and biocompatibility of pacemakers, artificial hip joints, and other medical implants, using Kinetic Systems vibration-control equipment. With the use of new polymer coatings to encapsulate implants, new techniques must be developed to simulate and evaluate their long-term performance in the human body.
In the fluid dynamics lab, a Kinetic Systems optical table and benchtop platform help scientists test the flow of blood. "For some of these experiments, we need to make sure we are measuring what we think we are measuring," says Warr, who cites the example of testing the filters that surgeons put into patients' arteries to catch blood clots. "With a simulated artery, it is important to have a vibration-stable platform, or else we might shake a clot out of the filter without planning to. The body is rather resilient and does not conduct high-frequency vibration well, so blood clots in a body wouldn't be subjected to that problem, but blood clots in the laboratory might be, and we would never know it. It's important to isolate the variables." Another example is the testing of optical fibers and wave guides that may be used in the surgical removal of plaque from arteries. The amount of energy delivered through a particular fiberoptic can be estimated with a computer simulation, he explains, but the accuracy of the simulation must be compared with

a laboratory verification on a vibration-isolation platform to discover any potential problems.

The OSEL's medical-imaging laboratory is using a Kinetic Systems optical table to take ultra-precise measurements of images on flat-panel monitors. According to Warr, a monitor that is used for viewing an MRI image, for example, affects the quality of the image and therefore should be part of the review for medical use. As part of the "imaging chain," it becomes, in effect, part of a diagnostic medical device subject to FDA oversight. "We mathematically characterize the performance of the monitor with respect to various imaging figures of merit and overall uniformity," says Warr, adding that this work also fulfills another of OSEL's missions: public education. The test methodologies developed are published, so that manufacturers can make use of them.

In another lab nearby, OSEL optical specialists are using four Kinetic Systems optical tables to ensure the reliability of measurements and calibrations involving optical interferometry and optical holography. Experiments in both of these fields require ultra-stable platforms, and for this work the OSEL expects to reach American National Standards Institute "Curve A" performance, the most stringent specification for vibration isolation. "Very few places in the health research world have this kind of facility," says Warr.

Medical research is primarily with animal tissues, but OSEL scientists expect optical nanoprobes&#151optical fibers only a few microns in diameter&#151to someday supply diagnostic information when inserted into the human body through veins, arteries, or surgical openings. Through a nanoprobe, a doctor should be able to irradiate, with intermediate frequencies of infrared light, several square centimeters of a tumor and receive a 3D image for a closer look.

The OSEL will use the results of its optical experiments and other research to develop frameworks for evaluating the safety of many nanotechnology-based medical devices, some of which have already been approved for use. The OSEL will publish recommended testing protocols in the hope that the manufacturers will adopt those techniques and supply the data in the preferred format when applying for approval of their products.

Despite all this research, it is unusual for the OSEL to actually test a new product&#151there are just too many of them. Typically, agency scientists review test results submitted by manufacturers and re-run tests only when there is a need to verify the information supplied.

Detective Mode

"But when things go wrong with a product that's already out there on the market, it's a different story," notes Warr. "That's when we shift into detective mode." If, for instance, doctors were to notice that a statistically significant number of patients with a certain type of artificial heart valve were having unexpected problems, they might be invited to send samples of explanted valves to the FDA. The OSEL might then obtain several new valves from the manufacturer and begin tests to compare them with the failed valves to learn the cause of the failures.

"You can see why we have to be prepared," Warr says. "In a compliance situation, especially with something like a heart valve, we don't have a lot of time. If we know there are tens of thousands of people with these heart valves, we need to make a decision fast, and it has to be the right decision. It takes about two years to create a

laboratory and staff it and get it operating, but we don't have two years, so we have to look ahead. We need to forecast which technology areas are going to be problematic, and to begin operations in those areas to become familiar with the technology, so that if a problem arises, we are ready to go."

The Future

"We need to be ready to evaluate proposed devices as soon as applications are received," Warr explains. "We have to be able to verify that the products are effective as claimed, and don't present a safety hazard. We deal with a lot of controversial subjects. The public-health and economic impacts of our decisions are worldwide, so we have to know what's happening in the medical-device business worldwide. It's quite a stretch, and in our particular Center, we deal with pretty much the whole range of human technology. We have to know about super-conductive magnets. We have to know about carbon-fiber materials technology. And there are unprecedented things going on&#151it's a very exciting time to be in this business."

Summing up, Warr stresses that the OSEL has no desire to hinder the process of getting new medical devices to the people who need them. In fact, he asserts, the more in touch FDA laboratory scientists are with the latest scientific developments, and the more reliable the research, the more efficiently the OSEL can review new products and the more reliable those products will be.
Asked for comment, Alan Gertel, president of Kinetic Systems Inc., adds, "The science of vibration isolation, too, is constantly improving, and KSI is fully prepared to meet these changes and the expanding needs of the OSEL and other high-precision laboratories."
"Because medical science is moving so rapidly, there are going to be plenty of surprises," says Warr. "We hope most of them will be good surprises, but we know some will not be. We're here for both kinds of surprises."
Online
For additional information on the technologies and products discussed in this article, see *Medical Design Technology* online at www.mdtmag.com [1] or Kinetic Systems Inc. at www.kineticsystems.com [2].

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