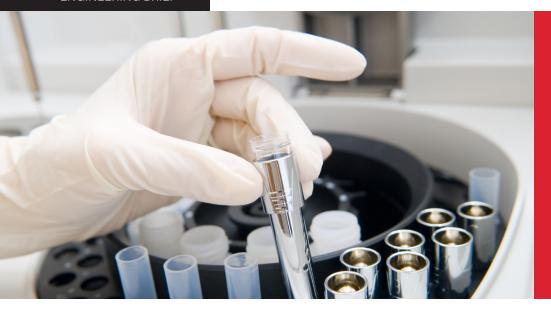
ENGINEERING BRIEF



Laboratory Instrumentation

Turning Technology into Products

Designing Laboratory Instruments for Volume Production

Introduction

Laboratory instruments are complex systems, often made up of multiple subsystems with unique requirements and sensitivities. Each subsystem presents numerous engineering challenges to solve. But when the subsystems are considered together, as a whole system, the true design challenges appear. At subsystem junctures, the difference between an elegant, integrated design and a disjointed one is exacerbated. By considering these interface interactions up front, and designing an initial architecture around the interactions of the subsystems, you'll produce a cost-effective, manufacturable product with reliable, repeatable results in fewer iterations.

Systems-level approach to design

Ideally, a top-down, holistic approach begins at the product architecture conceptualization phase. Acorn is frequently approached when a client is partway down the product development path. For example, the client has developed a proof-of-concept breadboard, consisting of building blocks—modular, functional subsystems. Some of these subsystems are off-the-shelf products that are connected together to provide many of the product's essential functions, such as temperature control, fluid control, vibration, mixing, and more.

The breadboard approach works well to prove out the process and deepen understanding of sensitivities to environmental and other variables. But to get to a reliable, manufacturable, and cost-effective solution, a more integrated systems-level approach is needed. Planned modularity may still be desirable for specific reasons, such as serviceability, future upgrades, enhancements, or the desire to build multiple products with different subsystem options. All of these requirements are considered during the initial architecture phase. Examples of modular (Figure 1) and integrated (Figure 2) product designs are included in the sidebar on page 2.

Plan for your product's system highway

The product's initial architecture should include a design plan for the handoffs and interactions between subsystems, including how they fit within the overall layout of the device.

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Laboratory instruments are complex systems. How do you develop and implement a systems-level architecture, ensure manufacturability, and meet both performance and cost requirements?



Modular Design



Example: Common product based on a modular design approach



Figure 1

Integrated Design



Example: Product based on an integrated design approach

Figure 2

Designing these interactions can be likened to designing a highway or a transportation system. The highway design team may consist of structural engineers, soil engineers, and construction crews—but it also needs someone to plan the traffic flow. A straight or even a curvy road design is pretty simple; bottlenecks, challenges, and accidents generally occur at the intersections, the entrances or exits, or where multiple roads meet and hand off cars. Road design also needs to take into account potential interference from connecting roads, such as by using dividers between lanes going in opposite directions. A successful systems-level approach relies on proactive interaction design; you don't want to be surprised by what occurs when subsystems are integrated at the final step.

Subsystem design and integration

Each subsystem has unique requirements, sensitivities, and considerations, both in its own design and when it interacts with other subsystems. The following subsystems are typically found in laboratory instruments:

- Sample movement and automation
- Thermal control system
- Fluid control subsystems
- Sensing and measurement subsystems

The items above represent only a subset of subsystems typically required in a laboratory instrument. Using this small subset as an example, we'll explore the complexity of subsystem interactions. Overlooking the importance of these interactions can lead to unfortunate architectural choices that would be hard to ameliorate after each subsystem is designed independently. Understanding some of the common considerations will lead to the development of a resilient architecture and skeleton up front.

Sample movement and automation

Take an example where a sample is placed at an entry point, moves into a controlled environment (or a controlled environment moves to it), undergoes processes, then moves back to an exit point. Moving the sample to each step in the process is relatively straightforward and can be easily automated. It's where the sample meets another subsystem that the biggest challenges occur, and the required motions are defined.

At the entry point, an operator may need to place and interact with the sample. Designing for ease of use, as well as protecting both the system and the operator against unscripted behavior, is required. For example, any movement near an operator needs to be designed to avoid impacting, pinching, or otherwise hurting the operator. This design requirement can be achieved through sensing or general layout and order of operations. Operator interactions also impact decisions about how motion is applied and what is exposed. The sample might need to be exposed at some point so the operator can interact with it, while the operator is simultaneously protected from dangerous or susceptible portions. These requirements may define the overall layout of the machine as well as how it will need to move.

At the exit point, the sample again interacts with an operator, producing similar concerns. An additional requirement might occur if the sample includes biologic material, which is often the case in lab equipment. In case of machine failure or servicing, the sample might need to be manually removed from the equipment before it can be sent elsewhere. This manual override removal should be easy for the operator to perform and should also guard against unsafe actions if mistakes are made.

Thermal control system

Laboratory instruments often have critical requirements for temperature control of samples, reactants, catalysts, and overall processes. Feedback loop control is generally required, along with some processing, to control temperature within a specified range. Insulation

may be needed for the samples to both manage the thermal loss (or gain), as well as to insulate the samples from contact with materials that could potentially interfere with the analysis process. Some processes not only are required to be run at specific temperatures, but also need to manage the ramp rate (up or down) to achieve those temperatures at various stages of the process, and not overshoot those ramps. Further considerations must also be given to parameters such as mass, thermal coefficients, and incidental effects from proximity to other nearby elements or subsystems.

For the cooling or heating element, there are generally trade-offs between initial temperature ramp time, thermal mass for even temperature profiles, and cost and power consumption that need to be considered during the design stage.

Fluid control subsystems

Laboratory equipment processes can include reactions requiring automated reactant or catalyst delivery. Delivery of fluids to the sample(s) often requires precise control of the volumes and flow rates in a protected environment to ensure that there is no leakage or contamination with other samples or parts of the system. In addition, waste or byproducts created as a result of the reaction need to be removed or neutralized, for safety and disposal reasons.

Sealing is another requirement that is important to consider. More than simply preventing leaks, sealing might be needed to make the sample and materials compatible within the operational temperature ranges (e.g., having compatible coefficients of thermal expansion). It might also be necessary to consider how the samples will interact with other materials under the specified conditions. If any of the processes require pressurization, exposure to UV, or other potentially harmful processes, material compatibility with those processes needs to be accounted for as well.

Some processes are optimized for a low-volume fluid transfer that requires accuracy on the order of microliters. Suppose you need to design a low-cost, solenoid-actuated piston that is built into a cartridge that will be used to push reagents in. Alignment of the various components in production, variability and stability over a range of temperatures, humidity, and process and component manufacturing variations will all play a significant role in how well the fluid flow meets the requirements.

Sensing and measurement subsystems

To measure the results, the processes inside laboratory equipment often involve applying a wave—such as light, electromagnetic, or ultrasound—and sensing the response. From a design perspective, it's important to consider how the waves reflect and refract within the system, and to manage these wave movements, particularly at the interfaces between materials. Designing interfaces to be manufacturable while ensuring the tolerances necessary to achieve accurate, repeatable measurements at a cost target is critical.

For example, systems that utilize a variety of critical components for optics, high- and/ or low-temperature environments, small parts, etc. for disposable, high-volume cartridges need to not only have a robust design, but also utilize manufacturing processes that can hold the tolerances needed to make the measurement system work. Working with suppliers early in the process to ensure that what you're designing can be manufactured at the volumes, cost, performance, and reliability you need is critical.

Sample interaction with fluids, thermal, and light guiding

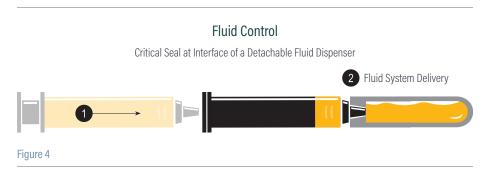
Take an example where the sample needs to interact with a fluid system in a controlled-temperature environment while a light guiding and sensing operation takes place. These actions all share the same space and operate on the sample at the same time, leading to proximal effects and concerns.

In our example, let's say a thermoelectric cooler (TEC), or Peltier device, is used to lower and keep the temperature of a sample below the ambient laboratory environment temperature (Figure 3). The TEC has a cold side applied to a spreader under the sample, and a hot side taking the waste heat to the ambient air through a heat sink and fan combination. The hot and cold sides of the TEC need to be well insulated from each other to avoid short-circuiting the thermal loop. The hot side of the TEC needs to be well connected to the heat sink, and the cold side of the TEC needs to be well connected thermally to the spreader and the sample. This layout requires that the sample and the TEC cold side to be effectively pressed together with even pressure to ensure good thermal contact, and it will define the final motion of the sample at that location.

Thermal Control Sample Bed • Temperature Controlled Below Ambient Sample Flow Thermal Barrier • TEC Hot Side Heat Sink Figure 3

Meanwhile, let's say the sample carrier is a high-volume injection-molded disposable with a critical fluids interface. A consumable will often drive up the cost of ownership of the instrument for the lab and create a good opportunity for recurring revenue for our client. As such, it requires special attention to the design to minimize material usage, increase yield, and work with automation equipment to meet the volumes required. Considering the manufacturing methods up front and designing within achievable tolerance ranges to increase yield will directly impact the bottom line.

For example, the sample could receive a fluid injection from a reservoir located inside the machine (Figure 4). The sample needs to travel into and be enclosed within the fluid movement system vial and seal. Among many factors it is necessary to consider the alignment of the sample to the fluid system, the full tolerance loop between them, what sensing is required to check for correct alignment, and what final direction of motion would keep it compatible with the temperature control system. What if the temperature range results in differential thermal expansions? Does the design accommodate those ranges or use that as additional constraints on location or isolation?



Two separate motions may be required to get a sufficient TEC contact and fluid seal. And, of course, the light guide needs to be considered. Perhaps the light needs to enter from the bottom side of the carrier, and be sensed from above. This requirement may drive the fluid entry point to be moved to a different location. There are a lot of different ways to solve the problem and many should be explored.

Figures 5a through 5d show just four examples of many possible ways to provide the required motion(s) for the fluid movement system. In the first example (Figure 5a), the fluid would connect first, then travel down with the fluid movement vial for TEC contact. Another example (Figure 5b) would have the fluid and TEC connection being made in the same motion. Alternatively, (Figure 5c) the TEC would contact first and the fluid vial would connect after that. A fourth way to do it (Figure 5d) would have the fluid connect first, and then in step 2, the TEC/cold-plate combination would raise up and away from the heatsink to make contact. These are only four of many alternatives. Don't settle immediately on the first ideas that come to mind.

There are also other factors to consider. As a disposable, the sample carrier is cost-sensitive in addition to having critical tolerances in sealing on a high-volume injection-molded part. Early interaction with vendors and processes used to define capabilities would be recommended to plan out what could be achieved or expected, from both cost and performance perspectives.

All of these factors, and others, are fighting for the same space, and the proximity of each subsystem to the other may also have an impact. Add in the required electronics and processing, and perhaps some waste heat from those components impacting the temperature control system from proximal effects, and the result is a multilayered challenge.

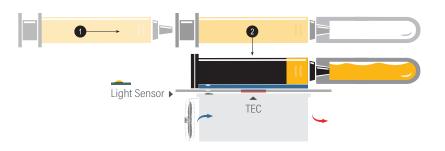
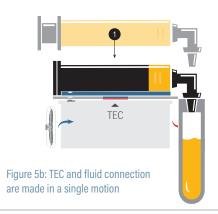


Figure 5a: (1) The syringe and fluid connection is made, (2) then together, they travel downward and TEC contact is made



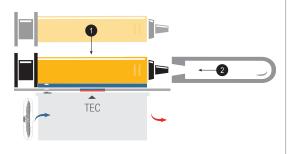
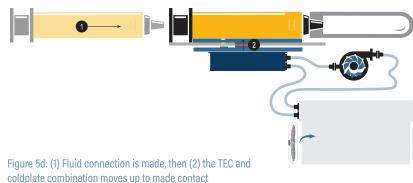
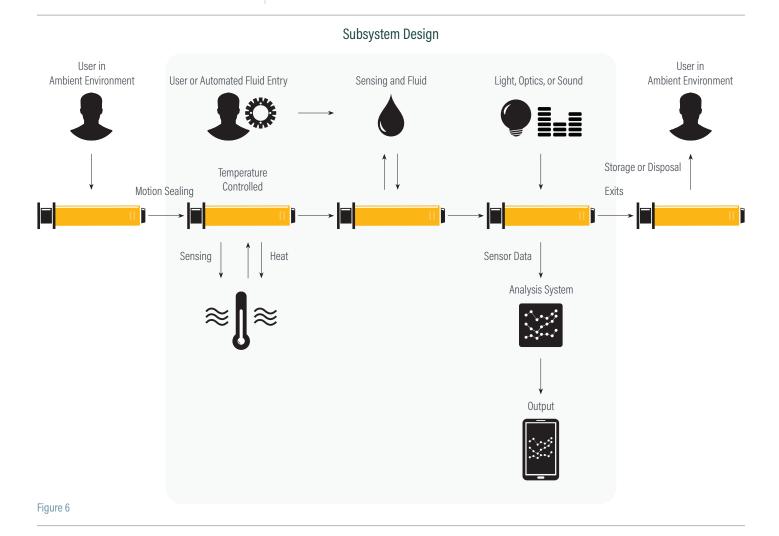


Figure 5c: (1) TEC contact is made, then (2) fluid connection is made



Managing overall design risk

Systems-level design may seem complex to approach with so many interactions (Figure 6). This is where concept exploration really helps—defining the hardest-to-achieve requirements, ideating on those problems, developing the concepts, and rating them on performance against metrics. Identify behaviors that are hardest to predict and plan a mock-up cycle to reduce risk.



In our experience of designing hundreds of products, one of the common temptations we see clients struggle with is the temptation to skip the product-level architecture layout stage after a breadboard proof of concept exists, and go straight to design. Often the reasoning involves schedule pressure or the feeling that a lot of work has been done already to get this far. It is important to remember that work performed already is now in the past, and that decisions should be made looking forward. If the foundation of the design has fundamental flaws, the fact that it appears 80 percent done on the outside is not going to help the product reach the finish line. It may be difficult to face, but an honest assessment of how far along the design really is and what it will realistically take to get it into production is recommended. The further along the project is, the harder it will be to stomach the reset.

To develop a reliable, cost-effective product, it's best to start fresh with a clean product architecture after the breadboard/proof-of-concept stage is complete—keeping the product requirements that have been fleshed out (e.g., process flow, design targets, and boundaries), but not necessarily the layout. Developing several potential architectures and choosing the best one is usually an effective approach. While reviewing the product schematic, start with the hardest, riskiest requirements and explore a variety of sketched concepts, and perform early analysis before selecting ones to mock up and test.

While it may be desirable to leverage existing designs and experience, it is necessary to identify the unique requirements and flexibilities of your technology compared with existing products. When leveraging an existing design, understand why a design choice was made and assess whether that choice makes sense for your design and requirements.

From a team perspective, we've found it's best to include a systems-level generalist with product development commercialization experience in addition to the technologists. The team must have subsystem design expertise, systems-level design experience, and experience with bringing products to market faster with few extraneous iterations and low manufacturing costs.

In our experience, optimal architecture reduces time-to-market. In fact, achieving optimal performance from suboptimal architecture can be extremely difficult and time consuming. So, if architectural changes are needed, make them. Finally, collaborate early and often—both internally and with outside suppliers and manufacturers—and product architecture, performance, and manufacturability will benefit significantly.

Summary

Laboratory instrument product design can be challenging, given its complexity. Start with a clear understanding of the process parameters and utilize a top-down design process. Starting at the architecture level, pay particular attention to handoffs between subsystems, and ensure that those handoffs are designed to support the process parameters and requirements. And design for manufacturability early and often, selecting and engaging with your supply chain to avoid any surprises and costly redesigns when transferring into production.

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Gwynn is the engineering manager in our Silicon Valley Design Center. She's a product development professional with more than a decade of experience bringing products to market at Acorn. She earned her bachelor's and master's degrees in engineering from Stanford.

About Acorn

Founded in 1993, Acorn Product Development is based in Silicon Valley with additional design centers in Atlanta, Boston, and DongGuan, China. We provide comprehensive product engineering services—from turnkey product development, subassembly development, and engineering analysis to materials cost analysis and manufacturing cost reduction—for leading companies around the globe.

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