# How to Create a Feedback Loop for the Surgical Robot Life Cycle

In an ironic twist, surgical robotic firms often use old-school techniques to build new-school devices. There is a better way.

Engineering technologies and methodologies are improving rapidly. Now, you have access to extended reality, the Internet of Things (IoT), and digital engineering practices. You can use these tools to create a feedback loop (or digital thread) that connects the entire product life cycle of surgical robots.

#### "We can link products and their specifications and requirements together so you can unlock insights for continuous improvement. You're developing and commercializing the best products available, so why not use the most advanced technological tools to develop your technology?"

#### -Paul O'Connor, Director of Medical Development at Boston Engineering

By embracing the latest engineering tools, surgical robotics firms can improve throughput, upgrade existing robots, and make data-based decisions while designing the next generation of robots. That can boost your likelihood of success at every stage of the product life cycle, from ideation through the many procedures that surgeons perform with robotic assistance.

The product life cycle has three main phases. In the design and engineering phase, engineers develop concepts and create blueprints and prototypes. Next, manufacturers build the products. In the third phase, customers use the robot in the field. While these phases used to be linear, they are now an endless, connected cycle.

"The feedback loop takes usage information from the field and pipes it back into the design phase and beyond," explains Brian Kononchik, Director of Innovative Digital Technologies at Boston Engineering.

## Phase 1: Design and Engineering

When you consider the feedback loop from the beginning, you bake connectivity and digital engineering into every design. It starts with defining and documenting what the final system will do from the perspective of users (in this case, the surgeons and operating room staff).

There are several ways to use extended reality (or immersive technology) in each phase of the product life cycle. Different levels of immersion are appropriate at different stages. For example, virtual reality (VR) is a fully immersive experience that is useful for simulating various scenarios. Augmented reality (AR), on the other hand, is useful when you need to see the product in the real world but also want additional details to supplement that view.

Early in the design process, engineers can build VR experiences to show how surgeons will use the robot in the operating room. Your engineers can work out some details internally, such as figuring out the best

angle for a robotic arm. But VR also allows you to create and account for variables such as patient size, surgeon size, ambient temperature, and other environmental conditions.

Furthermore, you can provide the actual users with VR experiences to practice using the robot in ways that are more realistic and specific to their needs. Then you can run through the scenarios without physically building an expensive piece of equipment or wasting company resources on developing a prototype that gets changed at the last minute (e.g., in response to a last-minute client request). This enables you to gather detailed, personalized user feedback far earlier than would be possible with traditional engineering tools.



"When you gather feedback in the front end of the process, the rest of the design cycle is much more efficient," O'Connor says.

The next step is translating those clearly defined user needs (design inputs) into the product requirements and specifications (design output). Modern engineering tools simultaneously make the design process more efficient and enhance traceability, the post-market surveillance that regulatory bodies require. During the first design step, you must comply with design control requirements. You must also document the testing and validation that demonstrate how your design output matches your design input. In other words, you must show that your robot meets user requirements and is safe and effective.

Traditionally, engineers have used computer-aided design (CAD) software to design medical devices. Now, engineering firms that are on a path toward the next wave of manufacturing—called Industry 4.0—are adopting model-based practices. They are using advanced software to simulate every aspect of the robot's design, from the tiniest electrical components to subsystems, actuators, and the robot as a whole. Metadata about the product are attached to a 3D representation to create a digital twin of the physical product.

Digital engineering encourages innovation because testing new ideas is less risky than it would be with traditional tools. Engineers can use simulations to test various design iterations and explore every aspect of the design. This approach facilitates tasks such as choosing the right components, confirming electrical connections are strong, and ensuring all subsystems work together correctly.

"You can design and test while minimizing the amount of physical building you need to do," O'Connor explains. "This eliminates a very long and cumbersome part of the design process with many variables. With the right software, you can simulate those variables and then show that your system will still work within those parameters without having to build an actual system, test the system, make changes, and do it all again. Now you can iterate rapidly even the most complex electromechanical systems."

Because you already have a 3D model, you can take it further with AR for design review. "With goggles or a table, you see the model in front of you," Kononchik says. "You can zoom in, slice it, and do everything you would do in CAD software. But on this virtual model, you see and feel it from every angle."

Eventually, you will still build a prototype, either using conventional manufacturing techniques or, if your firm is farther along in Industry 4.0, with 3D printing for rapid prototyping. Then you will test the prototype and hope there are no unexpected issues. However, if you discover you need to adjust the design, you will need to build a new prototype, which costs money and valuable time.

"I've seen AR reduce design cycle time tremendously because it eliminates troubleshooting and iterating during the prototyping phase," Kononchik adds.

# Phase 2: Manufacturing

The feedback loop continues through the manufacturing phase. First, if you use connected equipment to build the robots, you can use an IoT platform to aggregate sensor information and analyze the data to avoid downtime. When you have a modern manufacturing environment, you can increase throughput and get robots out the door faster so they can begin to assist surgeons as soon as possible.

When the robots have sensors, the sensors feed information to your software so the digital twin truly represents the robot. For example, suppose you must swap a component at the last minute due to supply chain issues. Now, you can update the digital model to reflect this manufacturing change. Even if nothing changes, you can send IoT feedback through the digital thread to inform engineers who are making decisions about future upgrades or the next iteration of your surgical robot.

"When these systems are on the manufacturing floor and they encounter the inevitable challenges, you can immediately link those challenges back to design choices," O'Connor says. "This is an incredibly powerful tool."

You can also use AR on a manufacturing floor to facilitate manufacturing and assembly. Assembling complex robotics is challenging, but when you overlay instructions, label parts, and take measurements with AR, you can make the process easier and more consistent. This reduces the risk of human error and prevents delays that could occur with unclear manufacturing instructions. Similarly, field technicians can leverage AR when assembling, setting up, and troubleshooting the robots in operating rooms.

Finally, you can use VR to develop experiences to start training technicians and surgeons without waiting for delivery and assembly of the device.

## Phase 3: End Use in the Field

The feedback loop already assists with traceability during phase 1, but that is only the beginning. When you create a digital footprint throughout the entire life cycle, you automatically build an audit trail that eliminates human error and improves traceability.

The feedback loop continues even when the robots are in operating rooms. Incorporating sensors and connectivity into surgical robots turns them into IoT devices. The benefit is twofold: you can use this information to improve both the design and traceability.

Due to regulatory requirements, you already have procedures to track and monitor issues that arise in

the field and to feed those issues back to the manufacturer for continuous improvement. Now, you can use that data to improve the design and develop future systems and subsystems.

Because the IoT data pertain to the machine—not the patient—there will be no protected health information or any patient information whatsoever. Instead, the data will include key performance indicators such as:

- Power consumption
- Temperature (particularly of the electronics)
- Range of motion
- Force (from the user and of the end effector on the patient)
- Time of use (how long the system is on)
- Number of uses

Now, you will have real-world, real-time performance feedback about the system that you can reference while addressing challenging aspects of the design, such as haptic feedback. That means you can roll out upgrades to make the surgical robot better over time. For example, if a subsystem operates toward the top of its limits, this insight will aid with your component choice in the future.

IoT data can enable you to identify potential issues so technicians can proactively service the robot before it breaks, thus improving reliability and avoiding downtime. Again, technicians can use AR to overlay visuals on the machines for guidance during any necessary repairs or adjustments. You can also leverage the IoT data to identify abnormal use, such as when surgeons create workarounds for aspects of the robot that do not meet their needs.

"IoT data feed back into the beginning of the loop," Kononchik says. "Sometimes you identify that the end users are using your product in a way that wasn't intended. That's an opportunity to build a new product."

These technologies—digital engineering, extended reality, and IoT—are available today to provide deep insights into your surgical robot at any phase of the life cycle. The feedback loop is an endless cycle, so phase 3 feeds back into phase 1 and the cycle continues. Ultimately, robotics firms can use these technologies to develop the next generation of surgical robots to improve patient outcomes and modernize the healthcare system.

#### Ready to close the loop? <u>Start a pilot</u> and discover the impact of advanced engineering tools.

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