1.0 Steve's Equipment Design Tips

1.1 Overview

This guide provides an overview of the design process of semi-automated desk top or stand-alone machines used in the production of medical devices. It includes insights into the manufacturing process, machine design, machine materials, operating environment, and other issues required for designing and building a production machine.

1.2 Understanding the Manufacturing Process

The machines are manually loaded by operators and are usually direct substitutions for processes that are being done manually. The objective of each machine is to make the process more reproducible and less reliant on operator skill.

In 99% of the cases the machine should <u>not</u> change the process but only automate it. Process change is the responsibility of the involved R&D or process engineer, not the equipment design engineer.

The following tips help you understand the manufacturing process:

- Extract as much information as possible from the Process or R&D engineer.
- Watch and question the operator doing the process. They often understand the subtleties of the process more than the engineer.
- Try the process yourself.
- Get a bigger picture by expanding your view of the process and the engineer's equipment request by considering how this process fits into the overall processing flow. This might allow you to envision some extra machine features that add value.

1.3 Test the Functionality of the Machine Process

Break the manual process into a simplified model to find the major issue that will spell success or failure of the machine (I usually imagine the parts at a large size to help visualize the problem).

Make a mechanical model that will test that issue. This is usually a very simple mechanism but it must replicate the major issue.

1.4 Machine Design

It is best to start with the machine parts that handle the device parts (nest and clamps) and work out from there (bottom-up design). This and testing the functionality are <u>crucial</u> to success.

Cost is secondary when designing equipment that is made in small quantities. No one remembers the cost of a machine when it is complete but they appreciate the quality of the machine forever.

Let the design sit for a day or so before detailing the parts or doing a final design review. Good changes often come up during this period.

Because everyone loves color on a machine, go beyond black and clear anodize.

Be conservative in the design. Clients expect the machine to be correct the first time.

When designing, operator ease of loading and use are more important that a design that makes your life easier.

Use integrated off-the-shelf mechanisms whenever possible. As an example, pneumatic slides by SMC and FESTO combine cross roller slides, pneumatic cylinders, adjustable travel stops, and sensor holders in one compact unit. Integrated mechanisms make a cleaner design than mating many separate parts.

The following are specific recommendations for design considerations:

- Size the components at 1/3 to 1/2 of their design ratings.
- The nest that touches the device should have the edges radiused to eliminate lines on the device, unless a sharp edge is needed.
- Socket head cap screws seated in counter-bored holes give a clean look to a machine.
- Design for a pneumatic supply pressure of 80 psi, even though 100 psi is the normal supply pressure.
- Precision placement of the device by the operator can be achieved by using a securely mounted microscope with a reticule. A calibrating fixture should be used to confirm that the microscope is in the correct position with respect to the machine.

1.5 Machine Materials

Preferred components for a clean room are stainless steel, anodized aluminum, and most engineering plastics (Delrin, Teflon, etc.). Medical devices should touch only these, never mild steel or raw aluminum and especially not nickel plating, copper or beryllium copper. High chromium tool steels like D2 can be used if hardened 440 stainless steel is not hard enough.

If the machine touches a metal medical device (opposed to a polymer device), the mating parts should be made of stainless steel instead of aluminum to minimize wear particles.

1.6 Machine Environment

Keep the machine area between the operator and the process open, low, and as close to the front of the table as possible by putting clamping arms to the rear, etc. If the process needs a complex or crowded mechanical setup, the medical device must be moved into the processing area or the processing area must move onto the device. Either way the part nest must be very open during the loading process.

Right-hand placement of precision parts by the operator is best for operator convenience.

Find out how the part subassembly is passed around the production area. For example, if the distal end is usually to the right, have the machine accept the part in that orientation. This is especially important with long assemblies.

Provide clearance for a microscope if it is used.

1.7 Control Box Design

Keep control box design simple by accessing only the necessary operations. R&D may like options on all motions and pressures but production people want a start button and little else. If a touch screen is used, keep the interface simple on the first two levels and have the little-used options buried on a lower level.

It is preferable to have the start and E-stop buttons in a separate enclosure close to the operator, freeing the operator from reaching across the machine to start or stop it.

If using a PLC allow headroom of 10% to 20% on I/O.

1.8 Safety

The choices are: an interlocked door, two-handed no tie down interlocked buttons or light curtain. A two-handed tie down should not be used on a long process. It will drive the operator nuts.

1.9 Troubleshooting

Do not get too far into troubleshooting the machine until it is in its finished state and correctly adjusted. Often the trouble can be traced to some ‘kluge’ that has been performed on the machine to get it running quickly.