# Linear Motion Design Considerations for Medical Device OEMs

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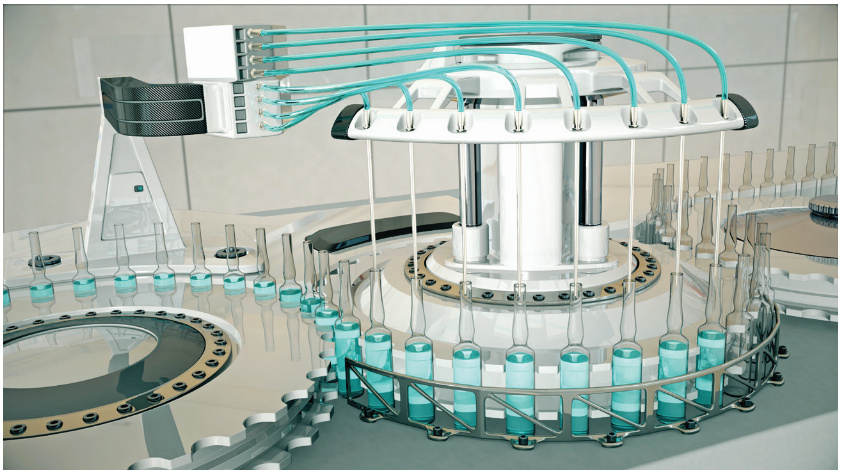
## Introduction

Linear actuators, in particular, electromechanical linear actuators, have become integral components of modern medical devices because of their high precision, accuracy, and ability to deliver repeatable motion control. Patient comfort, positioning and mobility, robotic surgery, imaging equipment, infusion, and pumping are just a few of the applications where the use of linear actuators has revolutionized the way medical devices are designed, improving patient outcomes and enhancing the overall quality of care.

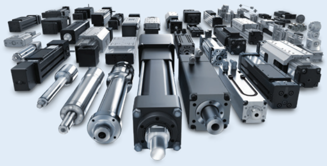
For medical device and equipment designs using electric linear actuators for motion control, detailing exact requirements for performance and reliability will help ensure successful outcomes. In addition, an understanding of how the motion control partner meets these requirements, as well as how they engage along the development and validation process, will be critical to meeting budget and time constraints.

This white paper explores some of the unique product and partner considerations to ensure successful device design.



**The precision, control and performance capabilities of electric linear actuators are facilitating rapid advances in discrete medical devices, clinical and lab equipment and medical manufacturing solutions.**

### About Tolomatic



Tolomatic has been designing and manufacturing innovative electric linear actuators, pneumatic actuators, and power transmission products for factory automation for over 60 years. These solutions are designed to simplify motion control for industrial applications. Available in in-line or reverse-parallel motor/drive configurations, Tolomatic products can be used as a direct replacement for pneumatic and hydraulic cylinders in a wide variety of packaging, material handling, machine tooling and general industrial automation applications. For more information on Tolomatic products: Please visit www.tolomatic.com or call Tolomatic toll free at 800-328-2174 or 763-478-8000.

*A rod-style electric actuator in this Rehabilitation Chair application provides smooth, quiet vibration and controlled force to counter muscle atrophy in recovering patients.*

## Advantages of Electric Linear Actuators

Electric linear actuators offer significant and game-changing advantages in many medical device and equipment applications over conventional manual or fluid power driven solutions:

- They are more precise and provide greater accuracy and control.
- In many cases they can offer a smaller footprint to aid in creating more mobile, more elegant design solutions.
- Electromechanical solutions are also more reliable and less maintenance intensive, reducing downtime and costs.
- In addition, they will also be quieter to support improved patient experience.
- Finally, they can improve the efficiency and speed of medical procedures, reducing wait times and improving patient flow.

## Linear Motion Design Considerations in Medical Devices

In any new design exercise, whether for a device destined for use in a procedure room or a new piece of medical equipment, an essential first phase is gaining a thorough understanding of the performance demands for the electromechanical components, balanced against the usage requirements.

When a linear actuator is designed and purpose-built in-house or through an external design/manufacturing resource, attention to details, integration, and application considerations that reach beyond basic actuator performance will have a significant impact on the success of the overall solution. A comprehensive view of requirements can seem daunting, but organizing considerations into key categories can help simplify the design specification process:

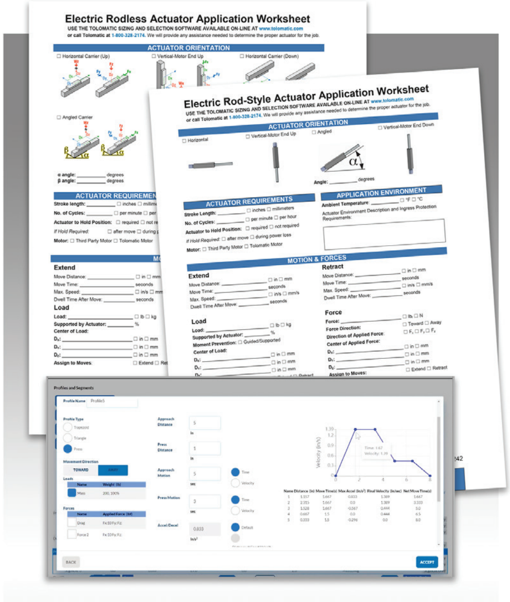
1. Performance Requirements
2. Service Life and Reliability
3. Operation and Usage
4. Operator and Patient Safety
5. Device Serviceability
6. Manufacturability
7. Comparison and Selection

## Performance Requirements

Typically, the initial application considerations and requirement set to be evaluated are the mass and forces to be managed. Linear actuators must meet the specific performance requirements for each aspect of device movement and often with multiple interactions, including target accuracy, motion precision, speed, force, and linear travel.

For example, in infusion pumps the speed and force of the linear motion is needed to ensure system can provide the proper the flow rate for the procedure. Delivery must be precise and reliable to ensure the correct dosage is delivered to the patient. Accuracy and repeatability ensure that the dosage from procedure to procedure is in alignment with dosage accuracy. In the cause of surgical robots, the accuracy and precision of the motion control system determine the accuracy of the surgical tool's placement, which is critical for achieving surgical objectives while minimizing trauma to surrounding tissue.

For design engineers, the use of Application Worksheets and Electromechanical Sizing Software assists in identifying, collecting, and calculating actuator specifications that will perform successfully in their application. It's critical that calculations be performed correctly to deliver the expected performance. Thus, understanding of system-wide loads and forces is essential, as well as velocity / speeds and the required level of movement accuracy.



**Electric Rodless Actuator Application Worksheet**

USE THE TOLOMATIC SIZING AND SELECTION SOFTWARE AVAILABLE ON-LINE AT www.tolomatic.com
or call Tolomatic at 1-800-328-2174. We will provide any assistance needed to determine the proper actuator for the job.

ACTUATOR ORIENTATION

☐ Horizontal Carrier (Up)
☐ Vertical-Motor End Up
☐ Horizontal Carrier (Down)
☐ Angled Carrier

α angle: __________ degrees
β angle: __________ degrees

ACTUATOR REQUIREMEN

Stroke length: __________ ☐ inches ☐ millim
No. of Cycles: __________ ☐ per minute ☐ per
Actuator to Hold Position: ☐ required ☐ not re
If Hold Required: ☐ after move ☐ during
Motor: ☐ Third Party Motor ☐ Tolomatic Motor

MO

Extend
Move Distance: __________ ☐ in ☐ mm
Move Time: __________ seconds
Max. Speed: __________ ☐ in/s ☐ mm
Dwell Time After Move: __________ seconds

Load
Load: __________ ☐ lb ☐ kg
Supported by Actuator: __________ %
Center of Load:
$D_x$: __________ ☐ in ☐ mm
$D_y$: __________ ☐ in ☐ mm
$D_z$: __________ ☐ in ☐ mm
Assign to Moves: ☐ Extend ☐ Ret

**Electric Rod-Style Actuator Application Worksheet**

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or call Tolomatic at 1-800-328-2174. We will provide any assistance needed to determine the proper actuator for the job.

ACTUATOR ORIENTATION

☐ Horizontal
☐ Vertical-Motor End Up
☐ Angled
☐ Vertical-Motor End Down

Angle: __________ degrees

ACTUATOR REQUIREMENTS

Stroke Length: __________ ☐ inches ☐ millimeters
No. of Cycles: __________ ☐ per minute ☐ per hour
Actuator to Hold Position: ☐ required ☐ not required
If Hold Required: ☐ after move ☐ during power loss
Motor: ☐ Third Party Motor ☐ Tolomatic Motor

APPLICATION ENVIRONMENT

Ambient Temperature: __________ ☐ °F ☐ °C
Actuator Environment Description and Ingress Protection Requirements:

MOTION & FORCES

Extend
Move Distance: __________ ☐ in ☐ mm
Move Time: __________ seconds
Max. Speed: __________ ☐ in/s ☐ mm/s
Dwell Time After Move: __________ seconds

Retract
Move Distance: __________ ☐ in ☐ mm
Move Time: __________ seconds
Max. Speed: __________ ☐ in/s ☐ mm/s
Dwell Time After Move: __________ seconds

Load
Load: __________ ☐ lb ☐ kg
Supported by Actuator: __________ %
Moment Prevention: ☐ Guided/Supported
Center of Load:
$D_x$: __________ ☐ in ☐ mm
$D_y$: __________ ☐ in ☐ mm

Force
Force: __________ ☐ lbs ☐ N
Force Direction: ☐ Toward ☐ Away
Direction of Applied Force: ☐ $F_x$ ☐ $F_y$ ☐ $F_z$
Center of Applied Force:
$D_x$: __________ ☐ in ☐ mm
$D_y$: __________ ☐ in ☐ mm
$D_z$: __________ ☐ in ☐ mm
Assign to Moves: ☐ Extend ☐ Retract

Profiles and Segments

Profile Name: Profile5

Profile Type: ○ Trapezoid ○ Triangle ● Press

Movement Direction: TOWARD AWAY

Loads

| Name | Weight (lb) |
|---|---|
| Mass | 200, 100% |

Forces

| Name | Applied Force (lbf) |
|---|---|
| Drag | Fx:10 Fy: Fz: |
| Force2 | Fx:10 Fy: Fz: |

Approach Distance: 5 in
Press Distance: 1 in
Approach Motion: 5 sec ● Time ○ Velocity
Press Motion: 3 sec ● Time ○ Velocity
Accel/Decel: 0.833 in/s² ● Default

| Name | Distance (in) | Move Time(s) | Max Accel (in/s²) | Final Velocity (in/sec) | Net Move Time(s) |
|---|---|---|---|---|---|
| 1 | 1.157 | 1.667 | 0.833 | 1.389 | 1.667 |
| 2 | 2.315 | 1.667 | 0.0 | 1.389 | 3.333 |
| 3 | 1.528 | 1.667 | -0.567 | 0.444 | 5.0 |
| 4 | 0.667 | 1.5 | 0.0 | 0.444 | 6.5 |
| 5 | 0.333 | 1.5 | -0.296 | 0.0 | 8.0 |

*Application Worksheets and Sizing Software helps designers identify and collect the essential data to needed to calculate the specifications for their unique application requirements. These tools are available freely to designers at Tolomatic.com*

## Linear Actuator Types

As is most often the case in medical devices, designers may choose to utilize efficient electromechanical actuators over less practical solutions with pneumatic, or in select cases, hydraulic cylinders. With the selection of an electric linear actuator, the more detailed the understanding of the motion profile and loading profiles, the more refined a solution can become relative to the overall objectives of the project.

It's not uncommon for designers to think about motion as simply traveling a distance over time. However, there are instances where a constant velocity is required to support a process or procedure, versus simply moving from point A to B in a fixed amount of time. Processes can also be influenced by the acceleration and deceleration rates relative to resistance or mass, which combined with the mechanical system, will influence the motor and control equation, or even play into power budgets and requirements for system-level certifications.

## Rod-style or Rodless Actuators.

An application's requirements will most often guide the selection of a rod-style or rodless actuator.

Rod style actuators are ideal for situations where linear thrust only is required. The pushing and pulling action of an electric rod actuator works well in many applications like fluid compression, dispensing or injecting procedures. Rod style actuators offer limited stroke length but support higher forces designed for pushing, pulling, or pressing with up to 50,000 lbf force. However, they do not provide

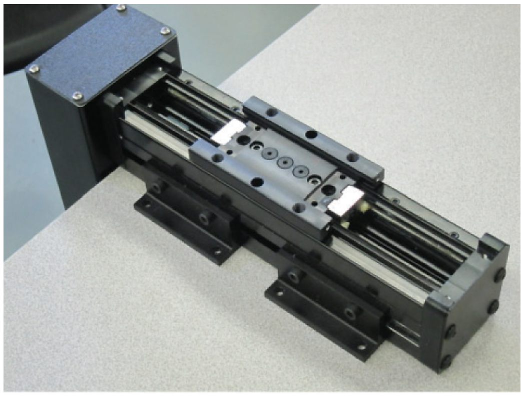
*The developer of a fluid injection device required very precise, consistent movement (speed & thrust) to meter injection of fluid. To achieve the required performance and reduce the overall footprint a modified rod-style actuator with a ball screw and RP (Reverse Parallel) motor mount was chosen. The finished actuator was also outfitted with a linear encoder to increase the overall resolution and position feedback of the system.*

support to a load. In the event that the load is cantilevered or overhung, it can deflect the rod, causing wear on seals and bearings and even triggering major positioning problems.

In contrast, rodless actuators have an inherent advantage over rod-style actuators for being able to support and carry loads. This reduces costs and design time by eliminating the need for additional load-bearing and guiding elements. In contrast to rod-style actuators, a rodless actuator's stroke lies completely within the length of its body, resulting in a smaller working footprint and a more efficient design that supports frequent cleaning, aesthetic requirements or even decontamination processes. Rodless actuators commonly use one of two main drive train types to convert a motor's rotary motion to linear motion: a power screw drive or a timing belt. While both drive trains offer efficiency, reliability, and long life, each has characteristics that may influence selection.

## Rodless Cylinder Loads and Forces

Rodless actuators carry the load, as opposed to rod-style actuators that push or pull the load. This difference makes it necessary to calculate the various moments (torques) that are being placed on the actuator's bearing system, based on the position, size, and weight of the load. For off-center or side loads, determine the distance from the center of mass of the load being carried to the center of the actuator's load-carrying platform and calculate the resulting bending moment. For example, if the distance from the center of mass of the load to the center of the cylinder's load-carrying device is 3 in., and the load is 30 lb., then: My (pitch moment in the Y axis) = 3 in. X 30 lb. = 90 in.-lb.; carrier mounted to extrusion rides on guides.



*Designed for advanced research in nanomaterials and molecular electronics, a custom-engineered electric screw drive actuator with a ball screw controls tungsten blades that monitor an electron beam used to generate an ultra-high resolution X-ray light source. The solution required tolerance of intense gamma ray radiation (capable of disintegrating any polymer load bearing components), shielding of all magnetic components and fields, low backlash positioning, along with moment and axial loading.*

Moment loading should also be calculated for the Mx axis (roll) and the Mz axis (yaw). The farther a load is from the center of the load-carrying device, the larger the resulting moment. Published bending moments are usually maximums and assume only one type of moment is being applied. In addition, dynamic bending moments are created by end-of-stroke acceleration or deceleration. Some applications contain compound moments that involve two or more of the moments described above. Each must be evaluated and calculated to determine whether the actuator can handle the combined moment forces.

## Proper Sizing

Appraisal of the precise loads, inertias, moments, duty cycles, and the operating environment, along with numerous other design considerations, are fundamental in proper actuator sizing. Careful attention to these and other parameters in the design phase of a project will provide the best performance, highest efficiency, and longest life in a given actuator application.

While it's common practice to factor a margin of additional movement capability and capacity into any design, this can be needlessly compounded as more functional layers and requirements are added. If outside vendors or design firms are engaged in this portion of the design process, the more defined or accurately these requirements are articulated to all parties involved, a more optimized end design will result. Thus, it's important to properly calculate essential control and movement factored to the design requirements of the overall system, rather that applying compounding levels of redundancy into individual components that may introduce complexity and unwanted variables.

## Service Life and Reliability

*Motion control to 1 micron via a custom electric actuator allows Radiation Treatment devices to precisely focus radiation beams in the treatment of cancerous cells.*

Identifying the actuator's duty cycle is a key component of sizing and technology selection. Duty cycle is defined as the ratio of operating time to resting time of an electric actuator, expressed as a percentage. Essentially, how much work an actuator is doing. For example, an actuator that is moving for two seconds and stopped for two seconds has a duty cycle of 50 percent. Underestimating the impact of duty cycle on an actuator can lead to overheating, faster wear, and premature component failure. Overestimating the impact of duty cycle can lead to higher initial costs due to oversizing. Overly-conservative duty cycle estimates often stem from an incomplete understanding of the application. This is another advantage of using sizing software programs as they can factor in duty cycles, move times, and velocities.

High-duty cycle applications move frequently, 50-70% of the time, or in the case of critical applications may only move a few times a day. In medical applications, where the demands of continuous operation and demanding environments can exist, high-duty actuators are often specified because of the need for mission-critical reliability, less than movement frequency.

Screw or belt and carrier bearing life are greatly affected by load, bending moments, speed, duty cycle, and environment. The useful life of any actuator depends on the durability of the components that perform the most mechanical work or carry the most load. Screw driven actuators are a typical example. The useful service life of a screw can be defined as the actual life achieved by a screw before it fails for any reason. Among possible reasons for its failure are fatigue, excessive wear, corrosion, contamination, insufficient structural strength, incorrect or improper maintenance, or loss of any function required by the application. In general, life expectations are closely associated with dynamic loads. To achieve maximum life of an actuator, total load must be kept within the actuator's design parameters.

## Operation and Usage Environments

Medical environments require low-noise operation to ensure patient comfort and minimize interference with sensitive equipment. Noise and vibrations can also affect the accuracy and precision of the linear actuator technology. Actuators should be designed to operate quietly and produce minimal vibrations, particularly in devices used during patient examinations or procedures. Intangible aspects like noise, vibration, or other aspects including visual appearance can at times be the most challenging and hardest to quantify and manage throughout a design exercise.

From a usage experience standpoint, designers may only know what they are trying to avoid, rather than what they are seeking to achieve, prior to a working prototype. At times, these more challenging and intangible aspects can drive over-specification in an effort to avoid undesirable unknowns. Here, it's most valuable to have strong collaborative partners in their given areas of expertise to help mitigate undesirable outcomes through design experience and know-how, rather than through over-specification.

*A custom rod-style actuator facilitates cardiac catheterization, injecting contrast, saline, performing aspiration and purging that free physician's hands while performing surgical procedures. The device requires preset or customized parameters for reproducible injection.*

The size and weight of the linear motion and actuator technologies are also vital design considerations for medical devices. In many cases, medical devices are designed to be compact and lightweight for portability, function, operational environments, and ease of use, while other applications may be fixed installations, quite large, heavy, and demand upmost levels of stability for accuracy and movement precision. Even in the largest, heavy-duty applications, there are often underlying objectives to produce desired performance outcomes while minimizing the physical footprint and weight to deliver a more practical and functional execution.

Beyond superior functionality, other top-of-mind considerations for the finished product package throughout the design process include creating a compact, aesthetically clean, and quiet solution. In cases where external partners are to be engaged, finding a partner that can employ technical flexibility on mechanical travel, mounting, motor selection/integration, or if needed, complete custom capabilities, can provide the designer greater latitude in creating a prioritization and balance between design criteria that optimize the design outcomes.

## Operator and Patient Safety

In medical devices and equipment, the importance of human factors cannot be overstated. From functional considerations for operators to essential safety aspects for the patient, consistency and fail-safe performance are of the utmost importance. Linear actuators and motion systems may be required to incorporate safety features such as position feedback sensors, limit switches, and emergency stop mechanisms to prevent accidents or injuries during operation. These safety features can help ensure proper device functionality while protecting patients and healthcare professionals.

## Device Serviceability

Ease of maintenance and serviceability is crucial for medical devices, as they often require periodic inspections, repairs or component replacements. Electric linear actuators should be designed with accessibility in mind, allowing for straightforward maintenance procedures and minimizing device downtime.

No less important, another critical consideration in medical settings is the maintenance of a sterile environment to protect patients, staff and to prevent healthcare-associated infections (HAIs). As key moving components, when appropriate, linear actuators should be designed with materials and finishes that are both low maintenance and compatible with OSHA-mandated and CDC-recommended cleaning and decontamination processes – and potentially sterilization processes. Smooth and easy-to-clean surfaces are also important to prevent the accumulation of dirt or contaminants. Specification of IP-rated actuators (such as IP55, IP67, or IP69K) not only protects the performance and life cycle of the component but helps ensure the device itself is tolerant of real-world cleaning and maintenance practices.

## Manufacturability

Once the proper performance specifications have been calculated, and operation, safety, service, and life cycle characteristics have been identified, the design process then turns to evaluate the viability of a solution.

*An electric screw-drive rod-style actuator provides precisely controlled, consistent delivery of saline in a thermal-ablation needle in a saline-enhanced radio frequency ablation system. This new technology dramatically improves procedure success rates and efficiency, offering treatment of a variety of life-threatening or debilitating conditions including VT (ventricular tachycardia).*

When considering a vendor for your medical device or equipment design, a designer may evaluate the partner's breadth of product line, engineering and solution expertise, and experience. If a standard, off-the-shelf product does not fully satisfy the performance specifications, it's best to identify a vendor with the expertise, agility, and willingness to make modifications. It's important to remember that "build to order" does not immediately involve a complex and costly custom development cycle. Among select, design-driven actuator providers, a wide array of product platforms coupled with engineering capabilities can yield the exact solution being sought. Here, collaboration is key.

Sometimes, innovation is required and it may be necessary to start with a "clean sheet of paper". This may involve combinations of speed, force, stroke length, mounting, size, integration, or any number of criteria. Again, the development partner you select should be not only qualified but collaborative, with demonstrated capabilities, engineering capacity, and spirit of willingness to engage in a robust customization dialog and process.

Other selection considerations for a successful design vendor partnership include but are not limited to: ISO quality management, supply chain management, complete design-to-prototype capabilities, design verification and testing, safety validation, U.S. and global regulatory compliance, and proven experience, with case studies, references and a formalized process for working with medical device developers.

The right partner can also help identify the critical design requirements and work with you to evaluate iterations of the finished product with consideration given to budget impacts and lead times. For significant design efforts, be certain to choose a partner that will stand by you for the long haul. In medical device development, it's not uncommon for product development efforts to span 5-7 years or more, with ever-evolving requirements. An agile, skilled, and collaborative partner that understands the often-lengthy process for development, validation, and regulatory approval should be highly considered as selection criteria that will offer both realized and intangible value.

## Comparison and Selection

When it comes to selection, a product that has the highest output rating – in loads, moments, or thrust – can have a distinct competitive advantage. Often the product that has the highest rating is seen to be the superior, most robust choice. However, what matters most is how long the actuator performs (useful life). How can you use manufacturers' published specification ratings to make a meaningful comparison? To compare components, the specification values need to be normalized to the rated life of travel the actuator is capable of when external forces are applied. Then the resulting data can be evaluated in the same units of measure.

A library of online tools for design engineers is available from Tolomatic, as well as "A Resource on Electric Linear Actuators", a designer's guide that explores the numerous design considerations of electrical actuators including position control, accuracy and repeatability, rod vs. rodless solutions, screw and motor selection, system installation, applications and more

## Conclusions

The trends for integration of advanced motion control utilizing electric linear actuators in medical devices will continue to surge. The continued development of emerging technologies ranging from surgical, procedural, and diagnostic devices to more advanced iterations of patient positioning, ergonomics, and mobility assistance, will propel the use of an enlarging scope of electric linear actuators to provide both simple and complex controlled movements.

Medical device designers must consider several factors when selecting the appropriate technologies and evaluating their development partners. By considering the factors that reach beyond performance specifications to address the larger impacts of the operating environments, human factors, and long-term serviceability and maintenance, designers can ensure that their medical devices are safe, reliable, and effective in meeting the growing needs of patients and healthcare professionals.

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