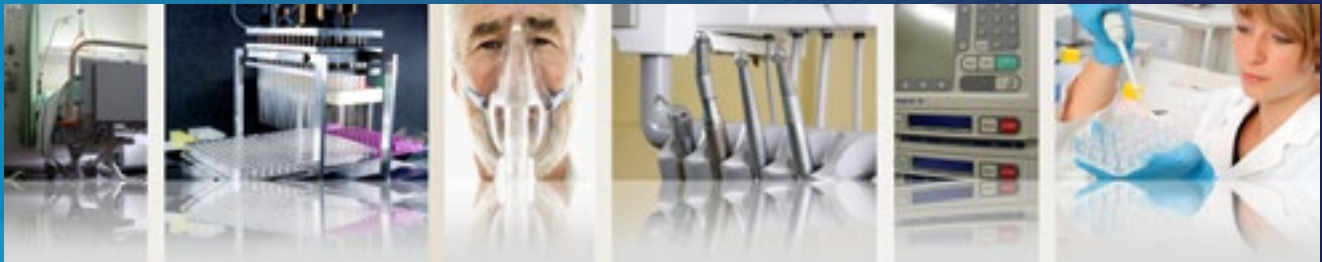


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# Designing Medical Devices for the 21st Century



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# Designing Medical Devices for the 21st Century

**H**ealthcare today is an ever-changing marketplace where technological advances fuel change and increase the demand for innovative ideas that often spawn a series of new applications. In today's medical device marketplace, the demand for reliable and safe medical device equipment instrumentation comes not only from the clinical end user, but the informed consumer. Today, health care safety is by far and away the number one concern among health care practitioners and consumers. Much of the impetus for cultural change and the focus on safety and quality in the U.S. Healthcare System can be attributed to a 1999 Report from the Institute of Medicine (IOM), entitled "To Err is Human: Building a Safer Health System." Since the publication of the groundbreaking IOM report, the transformation to building a safer healthcare system has been at the forefront of everyone's mind.

For those involved in the development and manufacturing of medical devices and equipment, the demand for safety and quality brings with it new and exciting challenges. How does one build equipment and devices that meet the hundreds of stringent needs of the clinical end user and health care consumer? How does one decide with whom to partner in this far-reaching world of medical device and equipment manufacturing?

You know caregivers require products that will assist them in achieving the best possible clinical outcomes for their patients. Patient's and clinicians require medication delivery pumps that deliver accurate safe doses of medications. While, devices that deliver continuous positive airway pressure must be powerful, quiet and capable of cycling quickly between functions. Where does an OEM turn to find motors capable of navigating the many demands of the health care industry? The capability of our medical device industry to build reliable and safe

medical devices has never before been so great. Yet the technological advancements in medication delivery and airway management have presented challenges to an OEM thriving to keep pace in today's marketplace.

## Medication Delivery

Thanks to the ever-growing body of research, the treatment for many diseases has evolved with time. Research has led to medical advances that prolong lives and allow disease sufferers to live longer more productive lives. Today, the key to prolonging life is not always found in the hands of a skilled surgeon, but in the medication used to treat illness and injury. Pharmaceutical advances have made medication administration the primary means of treatment of many conditions. Medications can be delivered by a host of routes and the safe appropriate administration of medications is the key to a successful recovery.

In healthcare today, the medications a patient receives are largely administered by a registered nurse. Medication administration is a skill that is taught based on five principles: the right drug, to the right patient, at the right time, via the right route in the right amount. With intravenous medications the key to safe, effective medication administration lies in administering the right amount at the right time. Simply put, some medications are most effective when given in timed, sequential, exact doses. Henceforth, these medications are infused via some type of medication infusion pump.



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Due to the intricacies of delivering precise amounts of medication over a particular period of time, infusion pump manufacturers have been facing increased scrutiny. From assuring free flow protection to keeping pace with software enhancements, the infusion pump market seems to present a new set of challenges daily.

Recently, the makers of a general infusion system called upon Danaher Motion to support their precise fluid delivery needs. Danaher Motion was chosen due to their ability to provide a small, highly accurate motor that offered precision in motion control. Danaher Motion worked with this manufacturer to supply a 16 mm/dia. DC coreless brushed DC motor with an integrated magneto resistive encoder, a reduction gearhead with spur gears (ratio 27:1)

and a rotor inertia  $1.60 \text{ kgm}^2 \cdot 10^{-7}$ . However, this motor was not chosen for the response time, but for low current draw, which would extend the device's battery life. The advantage this presented was an extremely quiet motor with a winding / gear reduction ratio that allowed the motor to work close to its peak efficiency point under the most common of the customer's application conditions.

Danaher Motion was involved from the initiation of the design process and quickly provided sample motors to assist engineers as they looked to develop a device that provided fluid management with extreme precision that minimized air bubbles during diaphragm operation. This infusion system provider remains extremely satisfied thanks in large part to Danaher Motion's quality control

process and ability to fulfill long-term motor needs as the infusion system demand increases.

## Bi-PAP

Twenty years ago most physicians's never offered up the diagnosis of sleep apnea to their patients. Many people suffered from chronic snoring that would not only torment their own night of rest but that of their spouse as well. Today, thanks to advances in modern medicine, physicians are not only more capable of diagnosing obstructive sleep apnea syndrome (OSAS), but capable of providing the cure. Through the wonders of modern medicine we have discovered that sleep apnea not only torments what should be a normal restful night, but that patients suffering from sleep apnea are at an increased risk for co-morbidities

such as high blood pressure, heart attack and stroke. This increased risk is derived from the fact that patient's suffering OSAS actually stop breathing several times during the night. This cessation of breathing denies the body's internal organs of the fresh oxygen they need to remain healthy. Thanks to today's medical advancements not only are physicians better at diagnosing OSAS; they are better at treating OSAS.



16mm Brush DC Coreless Motor with Gearhead and Encoder

The most common treatment for OSAS is positive airway pressure, or Bi-pap. During Bi-pap, airway pressure is utilized to "prop open" airway passages. This positive airway pressure is delivered via a device called a Bi-pap machine. The machine pumps room air or oxygen through a hose to a mask on the patient's mouth, nose or both, that the patient wears during sleep. This allows the influx of fresh air that eliminates the cessation of breathing by patient's suffering from OSAS. The key to success and patient compliance with any bi-pap machine is the ability of that machine to react to a patient's breathing pattern. Simply put, for maximum patient comfort, the device must be capable of quickly adjusting airflow pressure so as to avoid issuing a powerful breath while the patient is attempting to exhale.



## Brushless DC Motors at a glance

Details	Characteristics	Advantages
Permanent magnet DC design	Essentially linear torque/speed curve, with torque proportional to current and speed proportional to voltage	Ease of speed and position control
Brushless Design	Life is not limited by brush wear but only by wear in ball bearings	Very long life, high reliability, insensitive to environment. No arcing, dust free, reduced audible and electrical noise.
Static winding attached to motor housing	Improved heat dissipation	Overload capability
Slotless configuration	No detent torque	Excellent velocity smoothness
Versions without hall sensors	Typically used in spindle applications	Cost effective. Less sensitive to environment. Only three connecting wires.
Versions with hall effect sensors	Typically used in applications where speed or load variation are needed	Very simple commutation circuitry
Versions with encoder or resolver	Typically used in incremental motion	Very precise speed and position control

Recently, a U.S.-based bi-pap manufacturer who was developing a new family of Bi-pap devices approached Danaher Motion in search of a custom miniature motor that would attend to stringent application requirements for the new design. The OEM specification required the motor to adjust air-flow pressure in time intervals of 150 to 200ms. For this application, a 22mm Brushless DC motor was recommended.

Because Brushless slotless motors have an extremely low inertia characteristic, once the bi-pap device senses the patient's breathing pattern, the motor is capable of adjusting airflow pressure in 150-200 msec. This remarkable air-flow adjustment time is achieved thanks to an inertia of  $3.9 \times 10^{-7}$  kgm<sup>2</sup> and a mechanical time constant of 4.2 msec. The brushless motor offers a significant competitive clinical advantage by allowing the bi-pap device to make exceptionally quick airflow adjustments that truly enhance patient comfort, thereby directly improving patient compliance and outcomes.

The capabilities of the brushless motor do not stop with its ability to react quickly and capably to changing drive needs. This bi-pap manufacturer also added one more

request to the motor. Most patients require the use of bi-pap therapy while they sleep. Therefore, the motor must be capable of operating in near silence so as to allow the patient the maximum opportunity to rest. The brushless motor is not only packed with tremendous power, but has an extremely low operating noise of less than 30db. In today's growing bi-pap market the brushless motor provides the drive manufacturer's need to build the superior solution to patients suffering with obstructive sleep apnea.

### The right component provider with which to engineer a relationship.

As with all device projects, it is vital that the component provider be involved early in the design phase. Early involvement allows the solutions provider to work with device manufacturers to modify or customize motion control to suit the specific needs of the device.



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