Compressed Gas in Pico-Cylinders as a Single Use Medical Device Energy Source

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Why use compressed gas?

When choosing an energy source for a single-use medical device, compressed gas cylinders offer several advantages: high energy and power densities, compact size, light weight, simple integration into a mechanical actuator, and low cost.

While a battery can be a very energy dense storage medium, the power density is actually very low. If a device needs to act energetically over a short period of time (seconds), a large battery or capacitor storage is required. The electrical energy also needs to be converted into mechanical energy in many cases, meaning motors or other actuators as well as electrical circuits for controlling them are needed; increasing the size, weight, complexity and cost of a new device.

Springs offer a very simple and inexpensive energy storage option. The power density is high, meaning the energy can be released very quickly. However, the energy density is very low. If much work needs to be done, the spring can get large. It is also difficult to control the energy release once it is started and some potential energy is converted to kinetic energy by the spring mass, which can pose challenges at the end of the motion.

Compressed gas cylinders offer several advantages over batteries, motors, and springs. The energy density is higher than springs and the power density is higher than batteries. No additional devices are required to convert the energy into mechanical work, simplifying device designs.

	Specific Energy, J/g	Specific Power, W/g [2]
Lithium Battery, AAA [1]	924	0.24
Compression Spring	0.3	0.6
Pico-cylinder .7 mL, 205bar Ar	30	60
Pico-cylinder .7 mL, CO2	56	112

1. Energizer L92, 0.8V cutoff.

2. Spring and Pico-cylinder assume device actuation time 500ms, energy to 0 pressure or spring force.

What is a pico-cylinder?

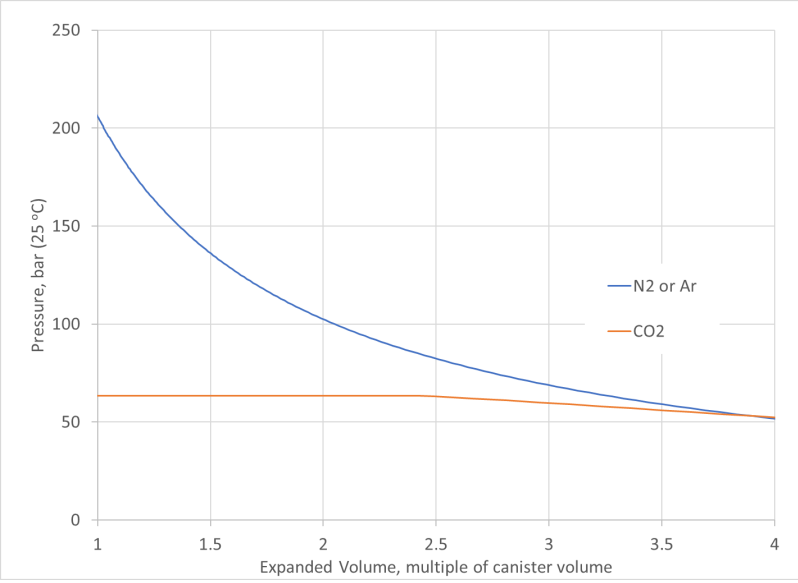
Compressed gas pico-cylinders are very small metal cylinders containing gas or liquified gas under pressure. The volume may range from 0.5 to several mL. A variety of gas types can be used, and the pressure can be as high as 205 bar (3000 psi). The pico-cylinder is filled under controlled conditions, weighed before and after filling assuring a tight tolerance of the fill mass. The closure is most often a welded cap with a thin septum to be punctured during device actuation. The empty canisters and caps can be made from stainless steels to resist corrosion, eliminating the need for plating or other coatings to be applied after filling and sealing.

Gas Options

There are different gases available for the pico-cylinders. The largest distinction in characteristics is between vapor only and dual phase (vapor and liquid) gases (at room temperature).

Vapor only phase gases, such as Nitrogen or Argon, are often utilized. These gases can be provided with high fill mass accuracy and are less sensitive to temperature variation. Argon has the advantage of being heavier than Nitrogen, which improves the filling weight measurement resolution.

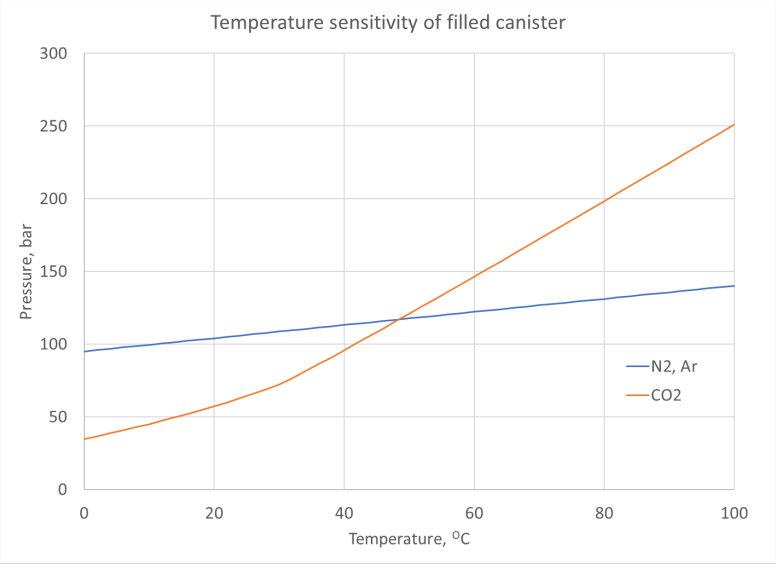
Liquified dual phase gases, such as Carbon Dioxide or refrigerants (HFC-134a), can be filled to a higher density and provide consistent pressure over a large volume change when a portion of liquid phase is maintained.



When using a vapor only phase gas, the energy is released much like a spring (without any of the inertial issues). As the gas vapor is released from the pico-cylinder, and first expands into the “dead volume” of the device, the pressure decreases. As the gas acts on a mechanism to do work, (for example on a piston in a piston/cylinder actuator), the pressure continues to decrease proportionally, as the piston moves in the cylinder, further increasing the gas expanded volume. The result is that there will be a difference in start and end of stroke piston force. This may or may not be advantageous in an

application. If not, one technique to reduce the difference in piston force, is to increase the "dead volume" of the device so that the volume expansion resulting from piston motion is a smaller fraction of the total expanded volume. The pico-cylinder would be filled to a higher pressure (up to 205 bar) to compensate for the greater pressure decrease resulting from the added "dead volume" required.

Actually, when vapor only phase gas is used, the piston, in this example, never actually sees full compressed gas pressure. On initial activation, the gas rapidly expands to fill the initial volume, then further expands as the working member (often a piston) is moved.



To maximize the value of the constant pressure characteristic of a dual phase gas, it is important to minimize the "dead volume". In this way, there is less expansion upon initial release of gas from the cylinder and the pressure can be held constant through the greatest working volume change possible.

Liquified gases have the unique advantage that they maintain a consistent pressure as volume is removed from the cylinder when a portion of liquid phase gas is present. This can be useful if a constant force is required. The flip side is that the pressure of these gases is more sensitive to temperature variation, so if a device needs to be used over a wide temperature range, the force changes resulting from temperature must be considered.

Leak Detection / Shelf Life

Pico-cylinders are sealed by welding a cap onto the cylinder body during filling. This is a very reliable process and results in a virtually leak free seal. This enables long shelf live performance.

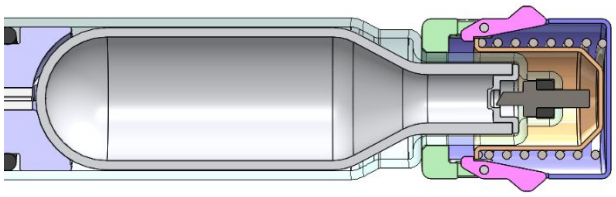
Every filled pico-cylinder is heated to above the expected maximum use and storage temperature in order to assure elevated pressure integrity. Mass spectrometry is most often used to detect any

possible leaks as it is much more sensitive than methods based on change in weight. In some cases, helium is added in low quantities as a tracer gas which is easily detected.

Many filled pico-cylinders may be tested at the same time, with the total possible leak assured to be less than the specification for a single cylinder. In addition, a gross weight can be marked on the cylinder body at the time of filling enabling a spot check later in the device manufacturing process further assuring minimal gas loss, within the error tolerance of scales.

Pico-cylinder Closure

The most common and economical way to close a pico-cylinder is to weld a cap onto the fill neck. The cap incorporates a thin septum which can be punctured when the device is actuated. This results in a low puncture force while providing the longest shelf life, supporting some of the most demanding medical device requirements.



Manufacturing Considerations

To be a viable medical device energy source, strict adherence to medical device manufacturing controls is mandatory. Pico-cylinders are filled in an ISO Class 8 clean room to ensure cleanliness and particulates are controlled so that downstream cleanroom assembly of the finished medical devices is seamless. Rigorous in-process testing ensures that the correct gas is filled at the correct mass. The filled pico-cylinder mass and leak-tight integrity are verified in multiple 100% in-process inspections to ensure that the finished device will perform as intended through the full shelf life of the product. Adherence to ISO 13485 and GMP requirements ensures that the quality standards are met today and in the future.

Conclusion

Effectively applied, a compressed gas pico-cylinder is a compact and effective way to provide energy to power a single use device. There are many options available to optimize the compressed gas cylinder for your application. Contact Picocyl for more information.