Medical Device Assembly Process Key Factors to Consider

























LOCAL DISPENSING SOLUTIONS WORLDWIDE





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ABOUT TECHCON SYSTEMS

Techcon Systems was established in 1961 to service industrial manufacturing markets and has continued to be a leader in fluid dispensing systems.

In 1996 OK International acquired Techcon. This strategy provided Techcon with a strong global sales channel, with direct subsidiaries and distributors in North America, Europe and Asia.

Today, Techcon Systems represents OK International's Industrial Products Division. Currently focusing on fluid dispensing systems, Techcon's components are used in medical, automotive, telecommunications, aerospace and industrial applications throughout the world, helping improve manufacturing processes and increase customers' bottom lines.

Techcon offers a wide array of fluid dispensing products and provides dispensing components ranging from disposable accessories to complete microprocessor controlled dispensing systems, and precision valves.

Our products are in compliance with RoHS, WEEE regulations and are meeting or exceeding CE, TUV safety standards.

Whether your goal is cost savings or process improvement, we can tailor a solution for your application.



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1 – MEDICAL DEVICE FLUIDS AND APPLICATIONS

From the outside, most dispensing valves look the same. It's the finer details and workings that determine which application the valve is selected for. Let's start with the fluid:

Fluid thickness, referred to as "viscosity", is separated into three categories; low, medium and high viscosity.

- Low cyanoacrylate and anaerobic type fluids that are flow-able.
- Medium UV adhesive used in quick cure applications.
- High medical grade silicone type fluids that form a gasket seal.

Medical Device fluids

- UV Cure Adhesives
- Silver Epoxies
- Cyanoacrylates
- Silicones (silicone oil)
- Saline Solutions
- Monomers
- RTV Sealants
- Solder Pastes
- Lubricants
- Coatings
- Antibiotics
- Protein Solutions
- Reagents

Medical Device Applications

Catheters Bonding pacemakers Contact lenses and Packaging Syringe lubrication Stent Coating Membranes Surgical and tools Diagnostic equipment Respiration devices Defibrillators Pills coating Blood bag sealing with CA Needle hub bonding Filling vials Back plate assembly Spraying pill packs Bonding of medical plastics metals Hearing Aids Lubricating Equipment Solvent and Drug Coating Endoscope lense bonding Oil on diabetes syringe





2 – COMPLIANCE

Techcon Systems diaphragm valves are compact in size and feature a "sealess" design. The wetted components are manufactured from FDA-compliant materials, making it suitable for the medical assembly process. Materials include Teflon®, Delrin® and UHMWPE.

In addition, this design allows the valve to operate for many millions of accurate dispensing cycles. Any Techcon Systems Luer lock dispensing tips can be fitted to the diaphragm valve for fast and efficient fluid dispensing.

As a leading manufacturer of dispensing equipment Techcon Systems design engineers are experienced in using high quality materials to suit industry and application. Should you find that an existing Techcon product construction material doesn't meet your industries requirements, Techcon Systems can work with end-users and machine integrators to use an alternative plastic or metal material.

Our customisation service is second to none.



TS5621HD – Delrin® body.



TS5622VU – UHMWPE body.

3 – SELECTING THE CORRECT CONTROLLER

TS500R Multi-Purpose Digital Controller

The TS500R is capable of controlling all Techcon Systems valve series. With a universal power supply it is a fully 'plug and play' system and can be used immediately, anywhere in the world.

- 20 x 4 LCD digitally displays read outs.
- Digital timing range 0.008-60 seconds.
- 10 programmable memories.
- Rack mount rectangular design

Integration into semi-automatic and automatic equipment is made easy with the interface connector. The dispense cycle can be initiated, stopped and an end-of cycle signal can be fed back to the host PLC machine, in order to start the next dispense cycle.

TS350 Advanced Digital Controller

The TS350 Series dispenses all viscosities of fluids accurately and consistently from any size syringe barrel. It is immediately usable anywhere in the world with its accompanying tools, accessories and universal power supply.

- Includes all accessories to work out of the box.
- 2 options: 1-100psi (0.07-6.9bar) and 1-15psi (0.07-1.0bar).
- Rear DB9 I/O interface connector for integration.
- Can accommodate all syringe and cartridge sizes.

The user friendly firmware provides an option for programming up to 10 varied, sequenced or individual shots. These systems have a user programmable manual (purge) and automatic dispense cycle settings (program and time).



TS500R – for operating all dispensing valves.



TS350 – for operating all syringe barrels.

4 – SELECTING THE RIGHT DISPENSING VALVES

Diaphragm Valve for low to medium and difficult viscosity fluids

The TS5620 Series Diaphragm Valves are designed to dispense low to medium viscosity fluids with precision accuracy over a wide range of shot and bead sizes, down to a fraction of a micro litre.

- Short opening stroke provides extremely fast, positive shut-off.
- External stroke control adjustment for fine tuning shot sizes.
- Seal-less valve design features excellent moisture sensitive resistance.
- Incorporated diaphragm creates a barrier between the wetted parts and the air cylinder.

The compact design allows for mounting flexibility and easy integration into automated medical applications. With a choice of UHMWPE (Ultra High Molecular Weight Polyethylene), Delrin®, Teflon® and stainless steel fluid bodies, the TS5620 Series Valve can handle a wide range of medical adhesives.

Needle Valve for low to medium viscosity fluids

The TS5440 Series Microshot Needle Valves are a normally closed needle and seat dispensing valve, meaning the needle shuts off on the tip cannula. It is designed to dispense low – medium viscosity fluids. With a zero dead volume seat design, the TS5440 Series can dispense very precisely over a wide range of deposit sizes, down to a fraction of a micro litre.

- Needle shuts off on the tip cannula generating a "zero dead volume" design.
- Luer taper and tap provides a UV block for the dispensing tip.
- Short opening stroke provides extremely fast positive shut off.
- Fixed air cylinder and body position.

An internal spring return makes the valve fully adaptable with Techcon Systems controllers. Air pressure through the air inlet port retracts the needle assembly from the seat (tip cannula) allowing fluid to flow from the valve fluid inlet to the Luer outlet.

Miniature Spool Valve for medium to high viscosity fluids

The TS5322 Series Mini Spool Valves are based on a balanced spool design, to create a fast "ON/OFF" fluid dispensing function that is not affected by fluid input pressure.

- Automatic "suck-back" anti-drip feature after each dispensing cycle.
- Moisture prevent chamber provided with each valve.
- Optional version fitted with UV compliant wetted parts (TS5322D).
- Tip adaptor accepts any Luer lock style tip.

The valve is designed to be opened by air pressure and closed by a return spring (single acting). A port is provided so that the valve may be connected for air closing without the spring (double acting), that enables very high rate closure speeds.











Spray Valves for spray coating low viscosity fluids

The TS5540 Series Spray Valves are designed for precise spray applications of low viscosity fluids. Total control of the spray cycle is provided by precise management of the pre-spray, the atomizing air and the post spray, via the TS500R Multi-Purpose Digital Controller. The TS5540 Series features full stainless steel construction in both air cylinder and fluid housing.

- Extremely long working life of needle and seat.
- No overspray uniform spray pattern.
- Round or elliptical patterns.
- Microshot spray valve uses dispensing tips in place of a spray nozzle.

The TS5540-MS Spray Valve is designed to spray low to medium viscosity fluids, through disposable dispensing tips. The innovative design enables the valve to produce spray patterns ranging from 0.18" - 0.60" (4.6mm – 15mm) in diameter.

Disposable feed path rotary valve for "no cleaning" dispensing

The TS5000DMP valve has a hinged doorway that opens easily so the disposable feed path can be removed, disposed of, and replaced within seconds, while the production line is still in operation. No cleaning or refurbishment of the valve is required.

- Disposable fluid path no cleaning required.
- UV compatible Delrin® fluid paths.
- Optional rotating tip collar for bent and oval tips.
- Can dispense pre-mixed 2-part epoxy.

The TS5000DMP is the perfect valve for applications where removing the valve, for cleaning, is inconvenient and costly. With the ability to remove and replace the disposable feed path, the valve maintains its dispensing accuracy over a greater period of time. Techcon Systems TS5000DMP Series Valve has three options in pitch type: 8, 6 and 16 pitch and all pitch types are available with a fixed or rotating color coded Luer collar.

Interchangeable cartridge rotary valve for repeatable processes

The TS7000IMP Series modular design allows quick and easy replacement of the feed screw/chamber (cartridge assembly), without removing the valve from the machine. In addition, the valve cartridge assembly can be interchanged to be used with TS5000DMP feed screw inserts – The 7000-DMPBKIT retrofit kit is required.

- Interchangeable material path ensures fast cartridge changeover.
- Quick release cartridge removal.
- "divorced" wetted parts from motor assembly.
- Multiple syringe and encoder mounting options.

The TS7000IMP Series valve is available in 4 choices of feed screw types (8-pitch, high output 8-pitch, 16-pitch and 32-pitch), all made of precision hardened tool steel.













Non-Contact Jet Valves for all viscosity fluids

The TS9200D Jet Tech Valve is a non-contact dispense valve capable of jetting fluid viscosities up to 400,000 Cps. Jet Tech offers a fast jetting action producing hundreds of precise droplets in less than one second. The main feature of the valve is a single, easily replaceable diaphragm to eliminate dynamic fluid seals found in other jet valves. No longer is it necessary to disassemble, clean and replace worn seals, which translates into saving time and money. The diaphragm also allows fast cycle rates because of its very small mass. With this novel diaphragm design, the energy needed to eject a drop can be adjusted providing a wider process window.

- Non-contact dispensing method.
- Only 2 parts contact the fluid diaphragm and nozzle plate.
- Incorporated nozzle heater heats just the wetted area.
- No calibration required.

Conventional Jet valves can have as many as 8 parts requiring cleaning. With only two parts to clean, cleaning the TS9200D takes only minutes and there is no need to remove the Jet valve from the robot or its fixture. The TS9200D generates a very high drop velocity allowing a wide range of fluids and applications. In addition, the drop velocity can be easily changed to help fine tune the process and achieve a high process capability and wide process window.







Techcon Systems extensive dispensing valve offering can successfully dispense fluids as thin as solvents, through the range of viscosities, to thick fluids such as solder paste.

5 – HIGH QUALITY COMPONENTS



Syringe Barrels

Our syringe barrels feature a 0° draft construction of the inner diameter promoting high accuracy and stability. They are comprised of industry compliant silicone and chloride-free, low friction polypropylene. Available in natural for most generic applications, amber provides protection of UV/visible light (up to 520nm), but with the ability to see the fluid inside the barrel and black for total light block. Available in 3cc, 5cc, 10cc 30cc and 55cc.



Air Powered Pistons

Air powered pistons spread the pressure evenly across the fluid providing consistent dispensing even with high viscosity fluids. The tighter fitting white wiper pistons provide a complete seal for low viscosity fluids and are also used with the TS700 manual syringe barrel gun. The easy flow blue pistons require less pressure to dispense and prevent air from becoming entrapped during the dispensing process. Loose fitting red straight wall pistons prevent stringing and bouncing when dispensing high viscosity fluids. Made from silicone and chloride-free polyethylene.



Straight Dispensing Tips

The TE Series Premier dispensing tips consist of a stainless steel cannula with a double Helix polypropylene hub, for secure syringe barrel attachment. This premier line of dispensing tips is burr-free, and has an electro-polished cannula for unobstructed and consistent material flow. In addition they are silicone and chloride-free. Maximum operating pressure is 100psi (6.9bar).



Tapered Dispensing Tips - soft plastic for use with syringe barrels

Designed with a double Helix Luer lock connection to provide secure connection to syringes barrels. Recommended for applications where dispensing medium and high-viscosity fluids with a high degree of precision and consistency is required. The burr-free orifice ensures accurate and repeatable dispensing. Made of polyethylene with UV-light block additive. The tapered tip series are silicone and chloride-free with a maximum operating pressure 100psi (6.9bar).



Tapered Dispensing Tips – rigid plastic for use with dispensing valves Features all of the above benefits but manufactured from a rigid polyethylene. Rigid tips attach to Techcon valves to give an unobstructed flow of even the highest of viscosity fluids.



Premium Metal Tapered Dispensing Tips

Precision metal tapered tips deliver the best in high fluid flow rates, which are ideal for high speed dispensing, at a fraction of the cost of comparable precision tips, in the market. The smooth internal conical fluid flow path increases performance, reduces clogging and back pressure allowing for higher flow rates. The metal construction makes the MT Series ideal for use in robotic applications.

6 – FLUID FEED SYSTEMS

TS1254/TS1258 Pressure Tank

Techcon Systems pressure tanks are designed to accommodate fluids that are supplied in bottle/container form. Constant air pressure forces the fluid from the bottle through pre-installed tubing to the point of dispense. Black fluid tubing is available for UV applications. Compression fittings are located at the centre of the lid, of the pressure tanks, to ensure a continuous fluid path to the dispensing valve. Air-tight seals ensure there are no leak points or air entrapment problems and that fluid touches nothing but tubing from the pressure tank to the dispensing valve. Disposable polyethylene fluid lines can be changed quickly and easily.

- TS1254 (1.8L) for smaller bottle applications.
- TS1258 (5L) under bench version for larger containers.

Both pressure tanks can accommodate low to medium fluids, including solvents, adhesives, as well as medical grade Cyanoacrylates (CA). Equipped with a pressure relief (safety) valve, the pressure tanks provide safe and secure dispensing for all applications.



Adhesive bottle sits inside pressure tank with 1 continuous length of tubing connected to valve.

Typical System Set-Up

Permanently pressurised air - supplies both the controller and the pressure tank. Both parts of the equipment are fitted with air regulators and pressure reductions can be performed dependant on valve and fluid selection.

Ensure that the original source of air, or at least before the air influences the dispensing equipment, is equipped with an appropriate moisture trap. Failure to use a moisture trap will almost certainly damage internal controller parts.

Theory of Valve Operation – Diaphragm Valve

The Diaphragm Valves are normally closed, adjustable stroke valves. Input air pressure of 70-90 psi (4.8 to 6.2bar) through air inlet port (1) drives the piston assembly (2) back, opening the material path, allowing fluid flow from the material inlet (3) to the material outlet (4). Relieving the input air pressure allows the piston return spring (5) to close the diaphragm (6), ensuring rapid "fail-safe" shut-off of fluid flow.





7 – PREVENTING LEAKS AND DRIPS

From a syringe...

Ensure that a piston is used inside the syringe and that it is the correct type for the fluid being dispensed. For low viscosity fluids the double wiping white piston will prevent unwanted leakage out of the tip. For high viscosity or "stringy" fluids a red straight walled piston is recommended – the red piston also prevents "bouncing". A double wiping blue piston is made available for the medium viscosity fluids.

With some lower viscosity fluids there tends to be a small leakage after dispensing, even with a piston fitted. The TS250 and TS350 Series are equipped with a vacuum "suck back" adjustment to suspend the fluid at the end of the tip when the syringe assembly is not is use.

From a valve...

Each Techcon valve is fitted with a sealing design so that when the dispensing cycle is completed the fluid is suspended at the tip point until the next dispensing cycle. For needle and spray valves, a needle shuts off against a Delrin® seat. For the spool valves, a shaft retracts between 2 seals during opening and closing. Whilst in the closing phase a portion or fluid is sucked back into the dispensing tip to create a clean shut off, especially beneficial for stringy fluids. Diaphragm valves feature a moisture resistant barrier for moisture sensitive fluids such as medical grade cyanoacrylate. The diaphragm incorporates a domed end to shut off against the fluid body, creating a positive shut off.

The TS5440 Microshot needle valve is designed with an extended needle shaft to shut off the fluid flow at the dispensing tip to prevent dripping, caused by back pressure in the "dead volume area", in the hub of the dispensing tip.

8 – PRODUCING CONSISTENT SHOTS

Ensure **fluid pressure** and air pressure is not fluctuating. By using a high quality air regulator the source of air, supplying the dispensing equipment, is stable. All regulators should be fitted with a moisture trap to contain any moisture particles in the air source. Failure to use adequate filtration and moisture traps will result in contamination to the internal sensitive components of the dispensing controller.

Environment temperature plays a large part in fluid dispensing. Some fluids will become thinner as the room temperature increases, throughout the day, resulting in faster and uncontrolled dispensing deposits. Maintaining and stable room temperature will ensure the fluid stays at the true viscosity during use.

The final part, of the dispensing equipment, to touch the fluid, is the **dispensing tip**. Lower quality tips were found to have burrs and "flash" on the construction. Flash not only restricts flow rates but can break off into the dispensing fluid causing contamination. All Techcon Systems plastic consumable items are designed as a one use item. When the syringe is empty it should be discarded safely and new components should be used. Reusing plastic syringes increases the risk of contamination and inconsistency.





9 – PREVENTING AIR ENTRAPMENT

Entrapped air, in a syringe or fluid feed line, causes undesirable dispensing deposits. Before any live dispensing is initiated it is of paramount importance to purge and remove any air pockets otherwise adverse effects such as inconsistent deposit size, missing dots, bead breakage and drooling can occur.

From a syringe....

A syringe of fluid should be supplied, air free and ready to use. However, pockets of air can become entrapped during the filling process. If the fluid is thin enough, Techcon Systems stand up tip caps allow the air bubbles to slowly rise to the top of the syringe where they collect and can be purged out easily.

Alternatively, if the fluid is too thick for this method, the syringes should be placed inside a centrifuge, where the centrifugal forces will push all entrapped air to the top of the syringe for easy removal.



From a valve system...

The internal wetted area, inside a valve system, is greater than that of a syringe barrel meaning there is a higher risk of entrapped air throughout the system. If air is found in the fluid tubing or dispensing valve then it is possible that the fluid bottle, possibly by agitation, already contained the air which transferred through the system. If this event occurs the bottle will need time for the bubbles to escape, prior to dispensing.

Always start with the fluid pressure low and increase to the desired pressure gradually. If a dispensing tip is already attached then it may be necessary to remove, allowing the fluid to flow freely out of the valve. Once the tip is reattached check that a constant stream of fluid is observed, at the tip, with no breakages.

If air is still observed in the valve or tip area, a common method for removal is to invert the valve and place a cloth at the tip point. This method allows the air to migrate, under low pressure, out of the tip. The operator can activate the system and whilst tapping the tip and valve the air pocket will be disturbed, allowing for its removal.



Some fluids can generate air bubbles due to turbulent flow. The TS5622VU-DVD diaphragm valve is designed with a smooth fluid path to prevent this turbulent flow.

TS5622VU-DVD Diaphragm Valve

10 – PROCESS AUTOMATION

Techcon Systems bench-top dispensing robots are easy to program, simple to operate and compatible with all valve types and controllers. These versatile dispensing platforms deliver consistent, high performance dispensing results, at an affordable price.

Designed and configured specifically for fluid dispensing applications, Techcon Systems robots provide total control over fluid placement, from beads, arcs and circles to repeated timed dots. Programming is simple via a teaching pendant.

From a general assembly manufacturer, looking to automate an existing dispensing application, to an engineer designing a production process from scratch, Techcon Systems dispensing robots offer unsurpassed value in automated precision fluid dispensing.

The bench-top dispensing robot series are available in 3 platforms:

TSR2201: 200mm x 200mm x 100mm working area TSR2301: 300mm x 300mm x 100mm working area TSR2401: 400mm x 400mm x 100mm working area

All Techcon valves fit to the robot head (z-axis) by means of a universal mounting plate.



Note: To comply with CE regulations, a safety cover must be used in conjunction with the robot. Techcon Systems sell a range a light beam safety covers. Please contact Techcon Systems for more information.

11 – MAINTAINING AN ADVANTAGE

At some point, all dispensing equipment requires maintenance. Techcon Systems have made it as easy as possible to maintain the products. Techcon valves...

- All feature a low maintenance design.
- Require no special tools for maintenance.
- Can be maintained at the customer's premises.
- Can usually be maintained and returned to service within 30 minutes.
- Have recommended spare part kits. Individual spare parts also available.
- Have detailed exploded view drawings for easy part recognition.



12 – APPLICATION TESTING

Techcon Systems offer an application testing service where by a feasibility study will determine the suitability of a customer's fluid with our valve products. A sample of the fluid, with accompanying documentation and application details, will enable our testing team to conduct trails.

Once testing is completed, Techcon Systems will provide a:

- Detailed report.
- Application video.
- Application pictures.
- Glass slides of dispensed product.

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