SteriComp PFS™
User Manual

Introduction

Thank you for purchasing SteriComp PFS™, the first patented portable pneumatic pressure filtration sterilizer. This manual provides the essential information you need to use SteriComp safely and efficiently. SteriComp performs low volume pressure filtration sterilization using 0.2µm membrane filters with low-cost non-proprietary disposables. At the same time, it can be used for vial filling, intravenous fluid bag filling or elastomeric infusion pump filling.

SteriComp works by applying a precise adjustable pressure to a syringe plunger to force liquid in the syringe through an attached 0.2µm membrane filter. The sterile liquid which flows from the filter can be injected into a sterile vessel such as a sealed glass vial, intravenous fluid bag, or elastomeric pump.

SteriComp allows the user to perform the following functions:

- make custom injectables that are not readily available
- make custom injectables with short shelf-life on-demand
- make custom sterile ophthalmic or auricular drops in low volumes
- make off label injectables on demand
- make preservative-free injectables when commercial preparations are not readily available
- rapidly fill elastomeric pumps (with or without filtration sterilization)
- rapidly fill sterile vials or IV fluid bags with viscous medicines
- save labor by semi-automating low volume sterile compounding
- save time and money compared to volumetric filling pumps
- achieve US Department of Labor OSHA compliance with Ergonomic Guidelines by reducing the risk of repetitive strain injury compared to manually sterilizing by filtration
- avoid damaging 0.2µm filter with excessive pressure
- refresh injectables that have passed the beyond-use date (for medicines expired per sterility guidelines, not for stability reasons)
- split single-use sterile vials into multiple smaller vials to cut costs while preserving sterility

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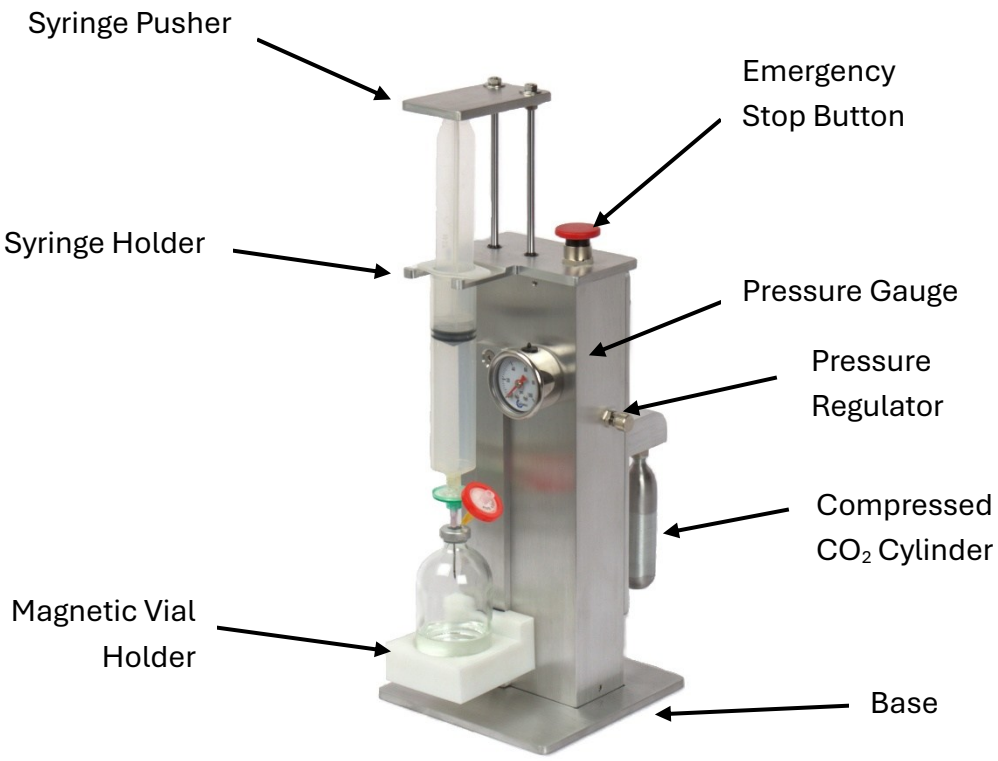

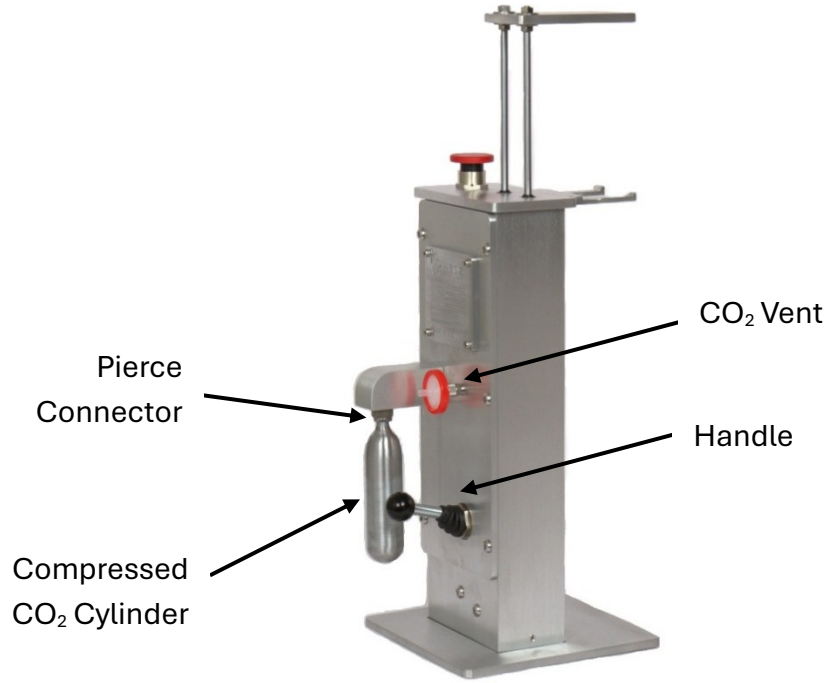

SteriComp PFS Description

Syringe Pusher – plate that pushes down on the syringe plunger to push liquids out of the syringe

Syringe Holder – slot where a syringe up to 60cc is placed (use Syringe Adapters when needed)

Magnetic Vial Holder – holds sterile vials, attaches to SteriComp by a magnet (internal)

Magnetic IV Bag Holder (not shown) – holds IV fluid bag, attaches to SteriComp by a magnet

Emergency Stop Button – rapidly releases all presure applied by syringe pusher

Pressure Gauge – measures internal CO_2 pressure (used to determine pressure applied to syringe)

Pressure Regulator – set internal CO_2 pressure that is used to move the Syringe Pusher

Compressed CO_2 Cylinder – cylinder containing compressed CO_2

Pierce Connector – threaded connector for CO_2 cylinder with stainless steel pierce fitting

CO_2 Vent – Luer connection point where exhaused CO_2 gas is released (a filter connects here)

Handle – 3 position handle (UP / STOP / DOWN), used to control the direction of movement of the pusher plate

Safety

CO_2 Cylinder Safe Handling and Use Information

Your safety is very important to us! Be sure you understand all safety precautions related to the use of CO_2 cylinders before use. Failure to follow the safety recommendations and safety precautions can result in equipment damage, bodily injury or death!

- Never expose CO_2 cylinders to temperatures over 120°F
- Always inspect CO_2 cylinders for damage before use
- When a CO_2 cylinder is connected to SteriComp, maintain the assembly at room temperature (70 - 75° F) or less. Do not freeze the SteriComp machine
- Always use CO_2 cylinders in the vertical position only, with the threaded portion at the top. Use in other positions will void the SteriComp warranty.
- Use caution while the CO_2 cylinder is in use, it can become very cold and cause skin injury or frostbite when touched. Handle with a rag, cloth gloves or wait for it to warm up.

General Safety

Be sure you understand all safety precautions related to the use of the SteriComp PFS machine before use. Failure to follow the safety recommendations and safety precautions can result in bodily injury, equipment damage, or sterility compromise.

- **DO NOT connect SteriComp directly to humans or animals! It is not an approved infusion device!**
- Ensure you are familiar with the Emergency Stop button usage since there is a pinch hazard during machine operation
- Always comply with applicable industry-standard protocols and procedures for sterilization
- Always set the correct pressure based on the size of syringe and type of filter being used (see Pressure Table in Appendix A)
- Do not use pressure settings that exceed the maximum rated pressure of the syringe/filter combination you are using
- Never operate SteriComp while under the influence of medications or other substances that affect judgement and concentration
- Do not modify SteriComp in any way, otherwise there is a possibility of operator injury, impairments or damage to the machine
- SteriComp does not contain any user-serviceable parts. Do not attempt to disassemble or service the machine. Malfunctioning systems must be sent back to Neos Medical for repair

- If SteriComp becomes damaged, set pressure regulator to zero and move handle to mid position (STOP position), then contact Neos for instructions
- If SteriComp has any observable sharp edges, contact Neos Medical for assistance
- To avoid the potential for cross-contamination between drugs, replace the sterile disposables when a new drug is to be compounded
- When using SteriComp to transfer liquid to containers such as vials or bottles, care should be taken to ensure the containers remain upright at all times by using the SteriComp Magnetic Vial Holders
- Always ensure containers are not pressurized when compounding (use venting)
- SteriComp should only be used with the manufacturer-supplied CO_2 cylinders; use of unapproved cylinders may cause internal contamination of the machine with particles of debris that will void the warranty
- Use aseptic techniques with syringes, filters, needles, vials etc. when inserting needles into containers, and making Luer lock connections
- Do not use sterile disposables if their sterile packaging has any sign of damage
- Sterile disposables should be changed within 24 hours of use
- When using SteriComp to compound hazardous liquids, use extra care to ensure they remain contained and do not leak or spray out of the sterile assembly
- No user calibration is required (except for high altitude use), SteriComp is factory-calibrated
- Save the original box and packaging. In the event that SteriComp needs to be sent in for servicing, return the machine in its original packaging. If the original box cannot be located, contact Neos Medical
- Service performed by individuals other than Neos Medical authorized agents may cause the warranty to be voided, at the discretion of Neos Medical
- Some metal parts might become cold or frosted during use; do not touch cold parts with bare hands
- Understand and consider the USP compounding guidelines when performing compounding
- Ensure SteriComp is placed on a stable surface
- During storage and use, avoid impacts and strong vibration
- Never immerse the machine in liquids for cleaning purposes, wipe or spray with disinfecting solution according to this manual
- Do not sterilize SteriComp using mechanical or steam sterilization equipment
- Always operate SteriComp in the **upright position only**, as other positions may cause internal damage due to liquid CO_2 entering the machine from the CO_2 cylinder (this will void the warranty)

Regulatory Compliance

SteriComp PFS is designed for use in Biological Safety Cabinets (BSC), Laminar Airflow Hoods and/or Safety Workbenches in clean rooms in a healthcare setting. The design includes joints sealed with NSF / FDA certified sealant, smooth non-corroding surfaces with minimal crevices that may be readily disinfected, and discharge of sterilized CO_2 outside the machine (requires a 0.2µm hydrophobic venting filter to be attached).

SteriComp is designed to allow the user to remain compliant with USP 797 and FDA guidelines. This requires the use of FDA-approved disposables such as syringes and membrane filters. Note that USP and FDA do not certify compounding machines or similar devices such as volumetric filling pumps. SteriComp PFS is not an FDA-classified medical device. SteriComp does not fall under the US Consumer Product Safety Commission.

DO NOT connect SteriComp directly to humans or animals! It is not approved as medical device or infusion device!

SteriComp meets CE standards. Compliance documents are on file at Neos Medical Systems.

The user is responsible for understanding and following industry standard practices and applicable laws for sterile medication compounding, such as USP 797 guidelines. The user must be trained in the operation and safe use of SteriComp according to the product manual. The user must follow published guidelines relating to work safety and accident prevention, and ensure professional diligence at all times. SteriComp is not an FDA-classified medical device and must never be used to infuse anything into a patient. For human-use medication sterilization, SteriComp must be used with sterile disposables that are approved by the FDA or other relevant health regulatory agency.

Operation

SteriComp PFS is designed to apply pressure to a syringe plunger to force liquid in the syringe through an attached 0.2µm membrane disc filter. The sterile liquid which flows from the filter can be injected into a sterile vessel such as a sealed glass vial, intravenous fluid bag or elastomeric infusion pump.

Calibration

The Pressure Gauge is the only SteriComp component that can optionally be calibrated. It is factory-calibrated at sea level. If the machine is being used above sea level, the pressure gauge will show an error of about 0.5 psi for every 1000 feet of elevation. For example, at 5000 ft elevation, if the pressure is set to 50 psi, the actual pressure will be 47.5 psi. Since the actual pressure will always be lower than the indicated pressure, there is no concern about damaging a membrane filter.

If SteriComp is being used at a significant elevation e.g. above 5000 ft, the gauge may be re-calibrated easily:

1. Set the Pressure Regulator knob to 0 psi (fully counterclockwise)
2. Set the Handle to the mid position (STOP position)
3. Press the Emergency Stop Button
4. Wait 5 Seconds
5. Briefly open the black stopper on the top of the Pressure Gauge, then push it back into place. The gauge will then be calibrated for the current altitude
6. Lift the Emergency Stop Button up

CO_2 Cylinder Use

SteriComp uses disposable sealed metal cylinders that contain compressed CO_2 (a mixture of gas + liquid at about 800 – 900 psi). When a cylinder is screwed onto the Pierce Connector, the cylinder is punctured. This allows CO_2 gas to enter the internal apparatus and provide power to operate the machine. Attachment and removal of CO_2 cylinders should be done outside of the Laminar Flow Hood or BSC, since some unsterile CO_2 will escape during this process. If a cylinder change must be performed inside the sterile environment, follow the correct steps below.

CO_2 Cylinder Attachment - Outside the Hood/BSC

1. Place the Handle in the middle (STOP) position.
2. Turn the Pressure Regulator knob fully counterclockwise (set the pressure to 0).
3. Screw a new CO_2 cylinder on the Pierce Connector gently until it just starts to become tight. At this point, further tightening will pierce the seal on the top of the cylinder. This will require a little more force.
4. Tighten the cylinder further firmly (and promptly to prevent CO_2 loss), until it stops. Tighten by hand only, do not use a wrench or other tools.
5. After tightening, listen for hissing (CO_2 leakage) and hand-tighten further if necessary.
6. Clean SteriComp with 70% isopropyl alcohol and place inside the Hood / BSC.

CO_2 Cylinder Attachment - Inside the Hood/BSC

1. Place the Handle in the middle (STOP) position.
2. Turn the Pressure Regulator knob fully counterclockwise (set the pressure to 0).
3. Clean a new CO_2 cylinder with 70% isopropyl alcohol and place inside the Hood / BSC.
4. Screw the new CO_2 cylinder on the Pierce Connector gently until it just starts to become tight.
5. Before further tightening to pierce the seal on the cylinder, soak a 4x4 gauze with 70% isopropyl alcohol and wrap around the top of the cylinder and Pierce Connector.
6. Tighten the cylinder further firmly with one hand while holding the gauze in place using the other hand. Tighten until the cylinder stops. Tighten by hand only, do not use a wrench or other tools.
7. After tightening, listen for hissing (CO_2 leakage) and hand-tighten further if necessary.
8. Discard the gauze and re-sterilize your gloves and SteriComp with 70% isopropyl alcohol.

CO_2 Cylinder Removal

When the machine can no longer maintain the user-selected pressure, as noted on the Pressure Gauge, the cylinder is nearly empty. It may now be removed and replaced. Do not unscrew a cylinder that is fully pressurized! CO_2 will escape forcefully and may cause the user to be startled or may cause injury! Cylinder pressure must be reduced first.

CO_2 Cylinder Removal (Outside the Hood/BSC)

1. If the cylinder is nearly empty, skip to Step 6. If you are uncertain, do not skip ahead.
2. Ensure the Syringe Holder is empty.
3. Turn the Pressure Regulator knob until approximately 20 psi is shown on the Pressure Gauge.
4. Place the Handle in the DOWN position and press the Emergency Stop Button.

5. Sterile CO_2 will be released from the CO_2 Vent until the cylinder is empty (look for the Pressure Gauge to show 0 psi or close to 0 psi).
6. Unscrew the cylinder. For near-empty cylinders, any remaining CO_2 will escape gently during this process (a brief hissing sound will be heard).
7. Discard the cylinder in the garbage or collect used cylinders and drop off at a metal recycling facility.
8. Lift the Emergency Stop Button up.

CO_2 Cylinder Removal (Inside the Hood/BSC)

1. Ensure the Syringe Holder is empty.
2. Ensure a 0.2µm hydrophobic disc filter is attached to the CO_2 Vent on the rear of the machine.
3. Turn the Pressure Regulator knob until approximately 20 psi is shown on the Pressure Gauge.
4. Place the Handle in the DOWN position and press the Emergency Stop Button.
5. Sterile CO_2 will be released from the CO_2 Vent until the cylinder is empty (look for the Pressure Gauge to show 0 psi or close to 0 psi).
6. Soak a 4x4 gauze with 70% isopropyl alcohol and wrap it around the top of the cylinder and Pierce Connector.
7. Unscrew the cylinder and keep the threaded portion covered with the gauze.
8. Discard the gauze and empty cylinder outside the Hood/BSC.
9. Lift the Emergency Stop Button up.

Emergency Stop Button

The Emergency Stop Button is used to stop the Syringe Pusher immediately if needed, while it is moving down only. IT WILL NOT STOP UPWARD MOVEMENT. This is necessary since your hand or finger can get pinched under the Syringe Pusher due to inattention while using the machine. To activate the Emergency Stop Button, simply push it down. Do not hit the button aggressively. Only a small movement of the button is required to stop the Syringe Pusher. Once the pinch hazard is resolved, put the Handle in the STOP position and lift the Stop Button back up.

Note that while the Stop Button is down, and the Handle is in the DOWN position, compressed CO_2 will be wasted. Leaving both controls in this position will empty the CO_2 cylinder. Therefore, be sure to lift the Stop Button up promptly once the pinch hazard has been addressed.

Cleaning and Preparation for use in Laminar Flow Hood or BSC

1. **First use:** lift the Emergency Stop Button up and move the Handle to the center (STOP) position. Turn the Pressure Regulator knob counterclockwise until it stops. Do not force the know beyond its stop point. Attach a CO_2 cylinder to the Pierce Connector on the back of the machine as described in the **CO_2 Cylinder Attachment** section.
2. Turn the Pressure Regulator knob to show around 20 psi on the Pressure Gauge.
3. Move the handle to the UP position. When the Pusher plate reaches the upper limit of travel, move the Handle to the center (STOP) position.
4. Clean SteriComp by spraying with disinfectant (e.g. 70% isopropyl alcohol) in the clean area (ante area). The machine components are sealed so it is possible to spray it with disinfectant. Avoid spraying disinfectant directly into the CO_2 Vent on the rear of the machine.
5. Alternatively SteriComp may be wiped down with a 4 x 4 gauze soaked with 70% isopropyl alcohol. Note that the 2 rods that connect to the Pusher Plate should preferably be lightly sprayed with disinfectant, instead of being wiped down. This will help maintain the thin layer of lubrication on their surface. This technique will increase the service life of the machine.
6. Place SteriComp in the Laminar Flow Hood or BSC*.
7. If needed, clean SteriComp with disinfectant again (e.g. if alcohol has dried before placing the machine into the Hood / BSC).
8. Attach a sterile 0.2µm hydrophobic disc filter to the CO_2 Vent Luer lock connector on the back of SteriComp.

** hood must be certified, disinfected and run according to accepted standard procedures*

Handling SteriComp

To lift the machine, hold it by the body and / or the base. Never lift it from the Stop Button, the Handle, the Pressure Gauge or the Syringe Pusher! Doing so may result in damage which will not be covered by the warranty.

When activating the Handle, it is best to support the machine base with 1 hand to prevent it from tipping.

Compounding into a Sterile Sealed Vial

1. Follow steps for cleaning SteriComp.
2. Disinfect all needed supplies and place in the Hood / BSC e.g. syringes, needles, filters, unsterile liquid medication container.
3. Confirm the Emergency Stop Button is up and the Handle is in the STOP position.
4. Adjust the Pressure Regulator knob to set the desired pressure on the Pressure Gauge based on the syringe size and maximum recommended pressure of the 0.2µm hydrophilic filter. Use the **Pressure Table** at the end of this manual to determine the maximum pressure setting. If SteriComp cannot produce the desired pressure, the compressed CO_2 cylinder is empty. It can be replaced with a new cylinder as described under **CO_2 Cylinder Use.**
5. Raise the Syringe Pusher to the UP position by moving the Handle to the UP position.
6. Fill the syringe (e.g. 60ml) with the medication to be sterilized.
7. Insert a filtered (0.2µm) venting needle, or short needle with an attached sterile hydrophobic 0.2µm filter into the sterile vial (e.g. #25 or #27 x ½" needle).
8. Attach a hydrophilic 0.2µm disc filter with needle (e.g. #18 or #21 x 1" needle) to the syringe Luer lock connector. Insert the needle into the vial.
9. Load the syringe with attached vial into the Syringe Holder. Use a Magnetic Vial Holder to support the vial at the correct height.
10. Move the Handle to the DOWN position to begin pushing the liquid medication under pressure through the filter into the vial. Medication will be sterilized as it fills the vial.
11. When the desired amount of liquid has been sterilized, move the Handle to the UP position briefly (to release pressure from the syringe) and then to the STOP position.
12. Remove the syringe and attached vial from the machine.
13. Remove the needles from the vial. The vial may be removed from the Hood and is now ready to use.

Using One Large Syringe to Fill Multiple Smaller Vials

Example: filling 6 x 10ml vials with a 60ml syringe.

When each vial is full, please ensure that the Handle is moved first to the UP position briefly before moving to the STOP position. This will ensure the vial is not overfilled. Moving the handle only to the STOP position will not stop the Syringe Pusher immediately since there will be some residual pressure in the internal machine components.

Compounding into an IV Fluid Bag

1. Follow steps for cleaning SteriComp.
2. Disinfect all needed supplies and place in the Hood / BSC e.g. syringes, needles, filters, unsterile liquid medication container, IV fluid bag.
3. Confirm the Emergency Stop Button is up and the Handle is in the STOP position.
4. Adjust the Pressure Regulator knob to set the desired pressure on the Pressure Gauge based on the syringe size and maximum recommended pressure of the 0.2µm hydrophilic filter. Use the **Pressure Table** at the end of this manual to determine the maximum pressure setting. If SteriComp cannot produce the desired pressure, the compressed CO_2 cylinder is empty. It can be replaced with a new cylinder as described under **CO_2 Cylinder Use.**
5. Raise the Syringe Pusher to the UP position by moving the Handle to the UP position.
6. Fill a syringe (e.g. 60ml) with medication to be sterilized.
7. Attach a hydrophilic 0.2µm disc filter with needle (e.g. #21-#23) to the syringe Luer lock connector. Insert the needle is inserted into the IV fluid bag.
8. Load the syringe with attached IV bag into the Syringe Holder. If needed, use the Magnetic IV Bag Holder to support the IV bag.
9. Move the Handle to the DOWN position to begin pushing the liquid medication under pressure through the filter into the IV bag. Medication will be sterilized as it fills the bag.
10. When the desired amount of liquid has been sterilized, move the Handle to the UP position briefly (to release pressure from the syringe) and then to the STOP position.
11. Remove the syringe and IV bag from the machine.
12. Remove the needle from the IV bag. The IV fluid bag is now ready to use.

Using One Large Syringe to Fill Multiple IV Bags

When the correct amount of medication has been injected into the IV bag, please ensure that the Handle is moved first to the UP position briefly before moving to the STOP position. This will ensure the IV bag is not overfilled. Moving the handle only to the STOP position will not stop the Syringe Pusher immediately since there will be some residual pressure in the internal machine components.

Compounding into an Elastomeric Infusion Pump

Follow the same steps as **Compounding into an IV Fluid Bag**, except connect the syringe to the elastomeric pump using the appropriate connector / tubing.

Maintenance

SteriComp requires minimal routine maintenance. The internal pneumatic cylinders are lubricated for life with FDA-certified lubricant and are sealed to prevent moisture from entering. No additional lubrication is routinely needed.

If medication is spilled on the machine, it should be wiped away and cleaned with water or alcohol.

Avoid corrosive cleaners such as sodium hypochlorite. These can damage the machine surfaces.

If the machine is removed from the Hood / BSC, the CO_2 Vent filter should be replaced with a new sterile filter when it is placed back into the Hood.

Do not aggressively turn the Pressure Regulator knob beyond its limits. This may cause the knob to loosen. If this happens, it can be re-tightened with a 1.5mm Allen key.

Storage

SteriComp should be stored at room temperature (70 – 75ºF) whenever a CO_2 cylinder is attached to it. Storage at high temperatues with a cylinder attached could cause the CO_2 to reach very high pressures and cause internal leakage within the machine. This is not covered by the warranty. If the machine must be stored above 90ºF, or there is a chance it may be exposed to such temperatures, the CO_2 cylinder should be removed as a precaution. Storage below room temperature is not a concern. Avoid freezing temperatures.

Warranty

SteriComp PFS product is warranted against defects in material and workmanship for a period of **twelve months** from the date of delivery. Neos Medical Systems will repair or replace, at its option, any product that proves to be defective during the warranty period, provided proper use and maintenance procedures have been followed as described in this user manual. If upon examination, Neos Medical Systems determines that abuse or misuse of the product is the cause for the repair, all labor, material, and shipping costs involved shall be paid by the Buyer.

All defective products or components shall be returned to Neos Medical Systems with a detailed explanation of the failure. The Buyer shall obtain a return authorization prior to return of the product and all transportation charges must be prepaid.

Limitations: The provisions above constitute Neos Medical Systems' sole obligation and exclude all other remedies or warranties, express, statutory or implied. This includes warranties of merchantability and fitness for a particular purpose, whether or not purposes or specifications are described herein. Neos Medical Systems further disclaims any responsibility whatsoever to the Buyer or to any other person for injury to person or damage to or loss of property or value caused by any product that been subjected to misuse, negligence, accident, misapplication or used in violation of product manuals, instructions or warnings, or modified or repaired by unauthorized persons.

Under no circumstances shall Neos Medical Systems be laible for any incidental, consequential or special damages, losses or expenses (even if Neos Medical Systems had been advised of the possibility of such damages) arising from the sales contract or its performance or in connection with the use of, inability to use or repair of Neos Medical Systems' product for any purpose whatsoever. The Buyer agrees that any recovery against Neos Medical Systems shall not be greater than the purchase price paid for the product as to which such claim is made. Neos Medical Systems' selection of repair or replacement shall be the Buyer's exclusive and sole remedy. No person is authorized to modify or amend the written warranty, product claims and specifications or to bind Neos Medical Systems to any term contrary to the terms herein.

Service performed by persons other than Neos Medical Systems or its authorized agents, may, at the discretion of Neos Medical Systems, be cause to void this warranty. Neos Medical Systems' supplied CO_2 cylinders are the only cylinders that may be used with the product. If other cylinders are used, it may (at the discretion of Neos Medical Systems) be cause to void this warranty.

Appendix A - Pressure Tables

How to Use the Tables

1. Based on the size of syringe you are using, refer to the appropriate table below.
2. Check the maximum rated pressure of the membrane disc filter that you are using.
3. Look under the maximum rated filter pressue to see what to set the SteriComp pressure to. Adjust the Pressure Regulator knob on SterComp to this pressure, or less.
4. Note: this is the highest pressure that can be safely used. Using a lower pressure will allow the CO_2 cylinder to last longer. Using the maximum allowable pressure will result in faster filtration sterilization.
5. Proceed with compounding and sterilization.
6. If a different type of filter is used or a different size of syringe, refer to the pressure tables again and change the pressure setting accordingly.

10 ml syringe (14.5mm internal diameter)

Membrane Filter Max Rated Pressure:	40 psi	50 psi	60 psi	70 psi	80 psi	90 psi
Set SteriComp Pressure Not More Than:	**21**	**26**	**32**	**37**	**42**	**48**

20 ml syringe (19.13mm internal diameter)

Membrane Filter Max Rated Pressure:	40 psi	50 psi	60 psi	70 psi	80 psi	90 psi
Set SteriComp Pressure Not More Than:	**37**	**46**	**55**	**64**	**74**	**83**

30 ml syringe (21.69mm internal diameter)

Membrane Filter Max Rated Pressure:	40 psi	50 psi	60 psi	70 psi	80 psi	90 psi
Set SteriComp Pressure Not More Than:	**47**	**59**	**71**	**83**	**95**	**100**

60 ml syringe (26.72mm internal diameter)

Membrane Filter Max Rated Pressure:	40 psi	50 psi	60 psi	70 psi	80 psi	90 psi
Set SteriComp Pressure Not More Than:	**72**	**90**	**100**	**100**	**100**	**100**

Tables refer to BD brand syringes. There is a 10% pressure safety margin included in the tables to account for variation in syringe sizes between manufacturers.