SpiroAir Cleaning Instructions

Applies to all USA versions of the SpiroAir pulmonary function testing systems distributed by Morgan Scientific, Inc running ComPAS 1.10.XXXX software. All prior versions of the cleaning instructions are obsolete and superseded by the current version.

System Overview

The SpiroAir pulmonary function testing (PFT) system, like all other PFT systems, is not designed to be a sterile system. A new Bacterial Viral Filter (BVF) should be used for every patient to prevent cross contamination. The BVF provides a barrier of protection between the patient and the reusable portions of the testing system. As such, under general use, the interior of the patient circuit does not require decontamination between patient tests. The exterior may be cleaned or disinfected according to the end user's organizational requirements.

Hygiene & Risk Management

Morgan Scientific offers the cleaning/disinfection recommendations herein as general guidelines to accommodate the average needs and requirements of most end users. State, Federal, industry, and other regulatory guidelines are varied in their requirements and rapidly evolving. End users should defer to the recommendations of their own Facility when considering the details of the cleaning and decontamination policies and procedures to be implemented.

A Risk Management approach should be taken by the Facility and a Risk Assessment carried out to ascertain the risks presented to both operator and subject. An action plan should be devised by the facility to minimize the chance of cross infection occurring, particularly where known infectious or immuno-deficient subjects are being tested. An Assessment should be made of methods of decontamination available to the end user and their effectiveness against the potential risks. Details are provided below to assist in this. Morgan Scientific recommends that cleaning and disinfecting should normally be carried out according to the guidelines of the user's facility or on an annual basis.

Morgan Scientific recommends cleaning and disinfection of equipment to be carried out after use on infected subjects or prior to use on immunocompromised subjects. The user's Facility must determine what level of disinfection is appropriate and acceptable in any particular circumstance.

It is recommended that, in cases of high risk with no effective disinfection methods available at the Facility, the contaminated parts be disposed of. For this device, this includes the following: the SpiroAir Patient Valve assembly.

Morgan Scientific has adopted the following definitions for use throughout this document from the United States Centers for Disease Control and Prevention's (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities (2008):

- Cleaning: The removal of visible soil from objects and surfaces, usually via manual or mechanic means. Typically precedes disinfection if it is to be performed.
- Disinfection: a process that removes many or all pathogenic microorganisms, except bacterial spores. Can be further subcategorized as: high-level (semicritical; comes in contact with mucous membranes or nonintact skin); intermediate-level (some semicritical and some noncritical items); low-level (noncritical items; intact skin).
- Sterilization: A process that destroys all forms of microbial life.

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SpiroAir General Guidelines

Specific guidelines and parts of the system are contained in the "Recommendations Chart" section. General guidelines are as follows:

The SpiroAir has a variety of smooth/hard surfaces and touchpoints. As a general rule, the end user should follow their facility's preferred method of cleaning and disinfecting smooth hard surfaces. Cleaning can be achieved using a wipe or cloth impregnated with a 70% Isopropyl Alcohol or other preferred method. Disinfection is typically achieved using chemical wipes that are used following the manufacturer's instructions. Commonly, PDI Sani-Cloth® products and Metrex CaviWipes™ are used; however, a variety of options are available. The CDC maintains a complete list of EPA-registered surface disinfectants and their characteristics. Morgan Scientific therefore uses the following terms to refer to cleaning and disinfection of smooth, hard surfaces: "Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures" and "Follow the Facility's smooth/hard surface disinfection procedures," respectively. Also note that the use of chemical wipes can sometimes be dual purpose, by design, when used according to their directions: cleaning and disinfecting.

Some parts of the SpiroAir are not easily accessed with chemical wipes and are more readily decontaminated using chemical soaking methods or cold sterilization, such as the STERRAD® system. These are parts comprised of polyoxymethylene, nitrile rubber, aluminum, nylon, silicone, and stainless steel. In these instances, Morgan Scientific uses the following term: "Follow the Facility's chemical soaking or cold sterilization procedures."

Some of the parts of the SpiroAir are viable for sterilization via autoclaving, noted below.

Routine Practices

It is vital for the user to set guidelines for protective hygiene measures whilst performing pulmonary function testing. There are three main potential sources of cross contamination, 1) skin contact; 2) aerosolized particles; and 3) saliva/body fluids. By far the most important is item 3; thus, a minimum requirement is to use a new Bacterial Viral Filter for each patient regardless of the test types being performed.

We also recommend that a delay of at least 5 minutes be allowed between subjects. This allows aerosolized organisms to be removed by gravitational sedimentation between tests. (American Journal of Respiratory and Critical Care Medicine, Vol 159. pp 610-612, 1999).

Between patients it is recommended that all exterior surfaces of the SpiroAir (pneumotach assembly and valve) and touchpoints be wiped down using the Facility's smooth/hard surface cleaning and disinfection procedures.

In the event of visible contamination: The Pneumotach Assembly and Pneumatic Valve should be cleaned and disinfected; however, the Pneumotach Screen and its O-rings should be cleaned and disinfected or replaced.

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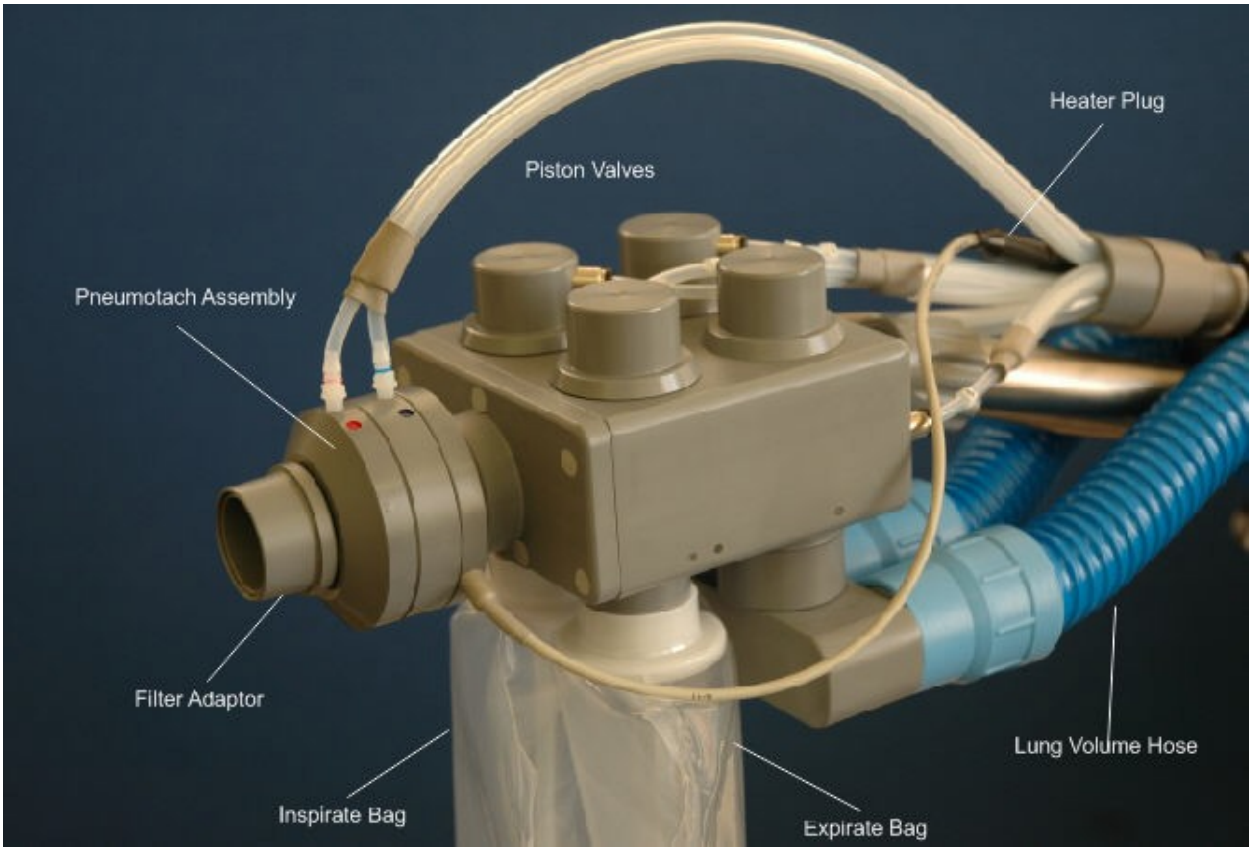
Cleaning & Disinfection Recommendations Chart



NOTE: Two different valve designs exist. Key differences are detailed below in the instructions.

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Part	Material(s)	Level	Autoclave Possible?	Recommended Methods
Main Instrument Exterior	Aluminum with epoxy paint	Clean & Disinfect	No	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECTION: Follow the Facility's smooth/hard surface disinfection procedures.
Piston Valves/ Pneumatic Valve Body	Polyoxymethylene (POM), aluminum	Clean & Disinfect	No	CLEAN & DISINFECT (Exterior): Follow the Facility's smooth/hard surface cleaning and disinfection procedures. CLEAN & DISINFECT (Interior): Follow the Facility's chemical soaking or cold sterilization procedures.
Interconnection assembly/ Umbilical	Nylon and silicone	Clean	No	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures.
Filter Adaptor	Polyoxymethylene (POM)	Clean & Disinfect	Viable	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures.
Pneumotach Assembly/ Pneumotach Body	Polyoxymethylene (POM)	Clean & Disinfect	Viable (Except heating element)	CLEAN & DISINFECT (Exterior): Follow the Facility's smooth/hard surface cleaning and disinfection procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures. See "Instructions- Pneumotach Assembly, Step 1" about removal of the heating element.
Pneumotach Screen	Aluminum, stainless steel	Clean & Disinfect	Viable	CLEANING: See "Instructions- Pneumotach Assembly, Step 3" below. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures. The pneumotach screen will also withstand autoclaving at 134°C for 3 minutes.

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Part	Material(s)	Level	Autoclave Possible?	Recommended Methods
Inspirate & Expirate Bags	Polyoxymethylene (POM), PVC	Clean & Disinfect or Dispose	No	CLEAN & DISINFECT (Exterior): Follow the Facility's smooth/hard surface cleaning and disinfection procedures. DISPOSAL: If contamination is suspected inside the bag, dispose and replace.
O-Rings	Buna-N (nitrile rubber), silicone	Clean & Disinfect	Viable	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures
Lung Volume Hoses	PVC over steel wire	Clean & Disinfect	Viable	CLEAN & DISINFECT (Exterior): Follow the Facility's smooth/hard surface cleaning and disinfection procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures.
CO2 Absorber Canister	Polyoxymethylene (POM), stainless steel, acrylic	Clean & Disinfect	Viable	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures
Rolling Seal	Silicone rubber	Clean & Disinfect	No	CLEAN: Follow the Facility's smooth/hard surface cleaning procedures. DISINFECTION: Follow the Facility's smooth/hard surface disinfection procedures. NOTE: To avoid degradation of the rolling seal, use *alcohol-free wipes only*.
Spirometer Drum	Stainless steel	Clean & Disinfect	No	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECTION: Follow the Facility's smooth/hard surface disinfection procedures.

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Instructions- Pneumotach Assembly

Step 1 Disconnect the heater cable and the red and blue hoses from the pneumotach. Carefully remove the pneumotach from the patient valve. Remove 3 mounting screws and separate the heating element from the pneumotach assembly before cold sterilization or immersion in liquid.	
Step 2A Place your thumbs on the two pressure fittings and gently turn against one another in a counterclockwise direction.	

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Step 2B This will open the pneumotach and gain access to the Lilly-style screen. When handling the screen, only handle the screen using the outside edges. Be careful not to touch the mesh part of the screen. Up against a back light, carefully examine the screen. Some bacterial/viral filters deposit a fine lint that can gradually clog the screen.	
Step 3 To clean the screen, gently soak and bathe it in sterile water, deionized water, or 70% isopropyl alcohol. Shake the screen vigorously to remove droplets and then let it air dry before re-assembling the pneumotach. With each Plethysmograph there are spare screens to use while others are drying. Follow the Facility's chemical soaking or cold sterilization procedures. The pneumotach screen will also withstand autoclaving at 134°C for 3 minutes.	

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Step 4 Once all the parts are cleaned, sterilized, and thoroughly dried, secure the heating element back to the pneumotach assembly then apply a small amount of DuPont™ Krytox grease on the two O-ring seals that secure the pneumotach back into the patient valve. Krytox is available from Morgan Scientific.	

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Instructions- Valve & Shutter Assembly

NOTE: Two different valve designs exist. They are easily identified by the color of the valve body. The white valve is referred to as the "original valve", and the gray as the "new valve." When substantially similar processes exist for both valves, the new gray valve is usually pictured below. Where there are appreciable differences, the two different valves are pictured and described separately.

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Step 1 Power off the device and unplug power supply cord. Close main valve on all gas tanks. Remove the pneumotach assembly. Unplug the heater cable and disconnect the red and blue pressure lines. Pull the pneumotach away from the valve body being careful not to put strain on the heater cable connection. Place the pneumotach aside for cleaning. There are separate instructions for the cleaning and maintenance of the pneumotach and screen above.	 

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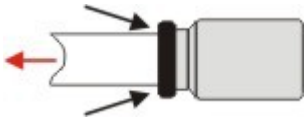
Step 2 Using the collar, remove the large inspirate bag and the smaller expirate bag. The bags simply pull-down to release. Also remove the blue spiral tubes from the valve body at this time by firmly pulling them away from the valve (not pictured).	
Step 3 Each of the pneumatic tubing connections are typically labelled for correct re-assembly. If not, label or mark them prior to disassembly. Disconnect all the tubing connections.  To release the high-pressure connections, hold the collar against the manifold and pull on the hose. Regular soft hose connections simply pull away from the retaining nipple.	

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Step 4 Remove the valve body from the adjustable patient arm. Note: the original style valve has a spring-loaded retaining pin located on the back of the valve body (not pictured). Pull the pin prior to removal. For both valves, slide the body upwards to remove it from the patient valve arm.	

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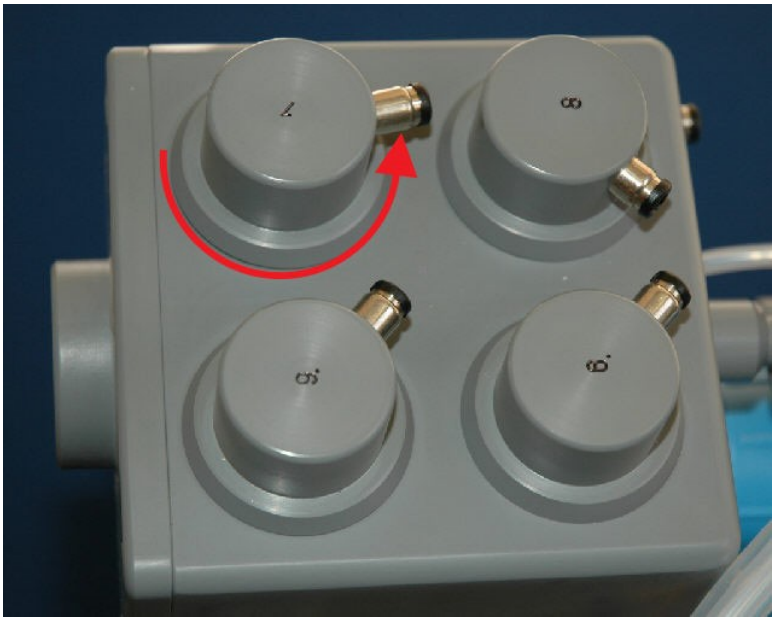
Step 5A- New Valve

Each of the four piston valves locks into place and can be removed by turning the valve in a counterclockwise direction to unlock.

The valves remain quite snug when released, so to remove each one from the valve body requires a firm pull.



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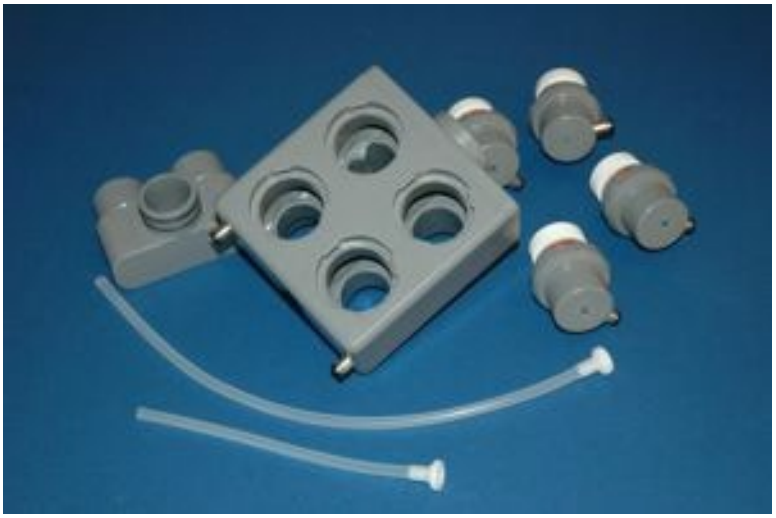
Step 5B- New Valve Remove the lung volume hose connection by pulling them straight out and away from the main body.	
Step 5C- New Valve The valve can now be cleaned and disinfected following the Facility's smooth/hard surface cleaning and disinfection procedures and/or by b following the Facility's chemical soaking or cold sterilization procedures.	

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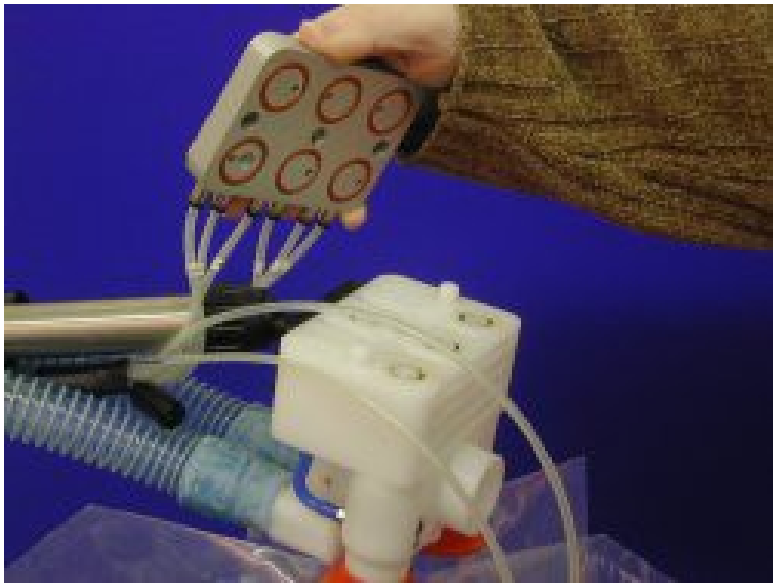
Step 5A- Original Valve Note: Pictures for Steps '5A to 5C- Original Valve' show valve body disassembly prior to completion of Steps 1-4. For ease of disassembly, we recommend that Steps 1-4 are completed first; however, either method will work. Remove the pneumatic connection manifold plate. Unscrew the manifold handle counterclockwise and store the handle in a safe place.	
Step 5B- Original Valve Lift the manifold plate carefully away from the valve body.	

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Step 5C- Original Valve The valve can now be cleaned and disinfected following the Facility's smooth/hard surface cleaning and disinfection procedures and/or by following the Facility's chemical soaking or cold sterilization procedures.	
Step 6 Once all the parts are cleaned, sterilized, and thoroughly dried, secure the heating element back to the pneumotach assembly then apply a small amount of DuPont™ Krytox grease on the two O-ring seals that secure the pneumotach back into the patient valve. Note: Various pneumotach and valve parts pictured for demonstration purposes.	

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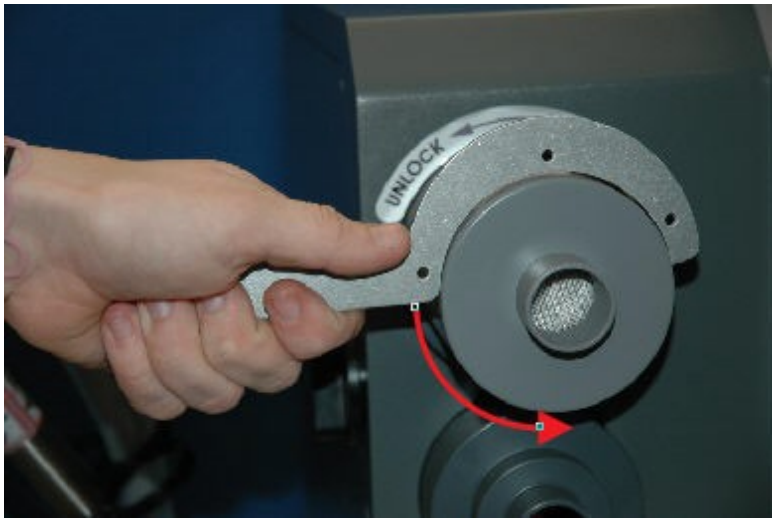
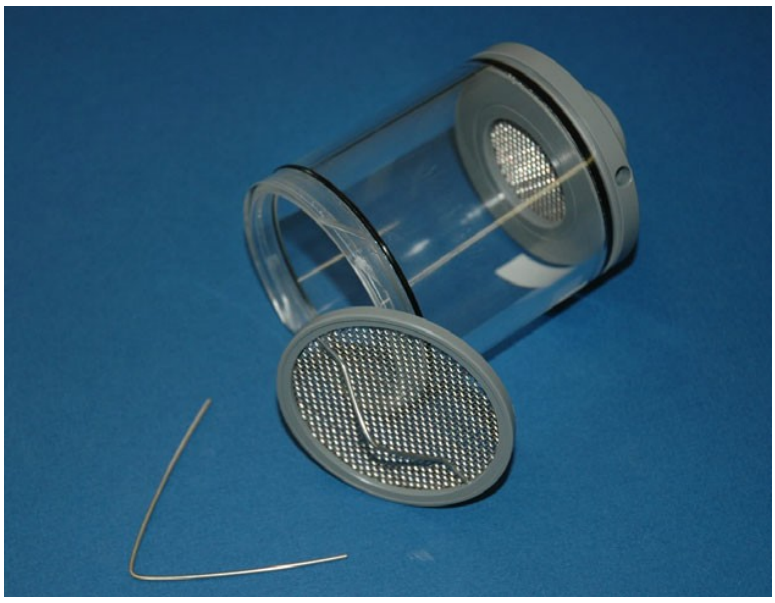
Instructions- Patient Circuit

Step 1 Remove the two spiral lung volume hoses from the CO2 canister and spirometer housing. Remove the CO2 Canister. Some models include a tool for ease of removal.	
Step 2 Squeeze the retaining spring and lift out the canister wire mesh. Discard the used CO2 absorbent granules and filter paper. The canister, along with the lung volume hoses, are now ready for cleaning or sterilization. To clean, use a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. To disinfect, follow the Facility's chemical soaking or cold sterilization procedures. Once decontamination is complete and all parts are dried, apply a small amount of Krytox grease to the O-ring seal. Replace filter paper on bottom, refill with absorbent, place filter paper on top, and reassemble.	

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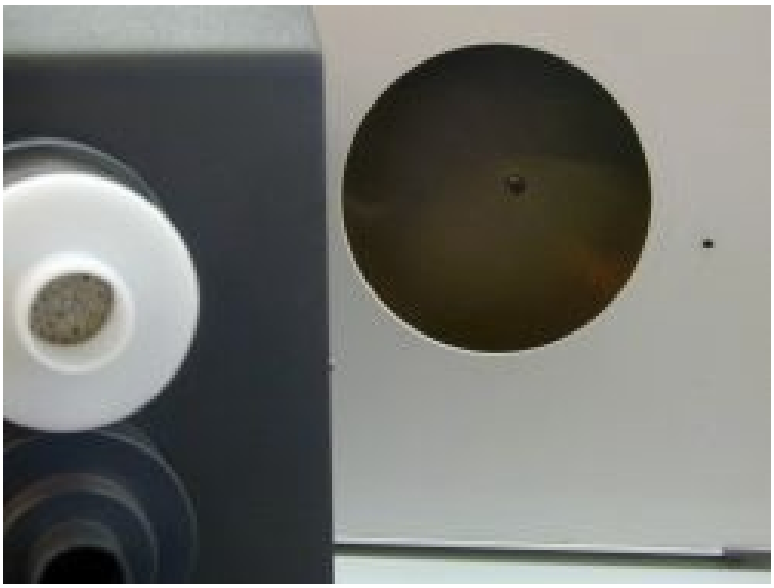
Instructions- Rolling Seal Spirometer

CAUTION*:* The SpiroAir is a complex instrument. To avoid incidental damage to components, cleaning and disinfection of the rolling seal spirometer should be conducted with extreme care by trained personnel only.

Step 1 Power off the device and unplug power supply cord. Close main valve on all gas tanks. Open the spirometer by turning the knob on the side of the turbine absorber unit.	
Step 2 Gently push the spirometer to its fully open position (away from the opening). Thoroughly and carefully clean the drum and rolling seal using the Facility's smooth/hard surface cleaning or disinfection procedures. NOTE: To avoid degradation of the rolling seal, use *alcohol-free wipes only*.	

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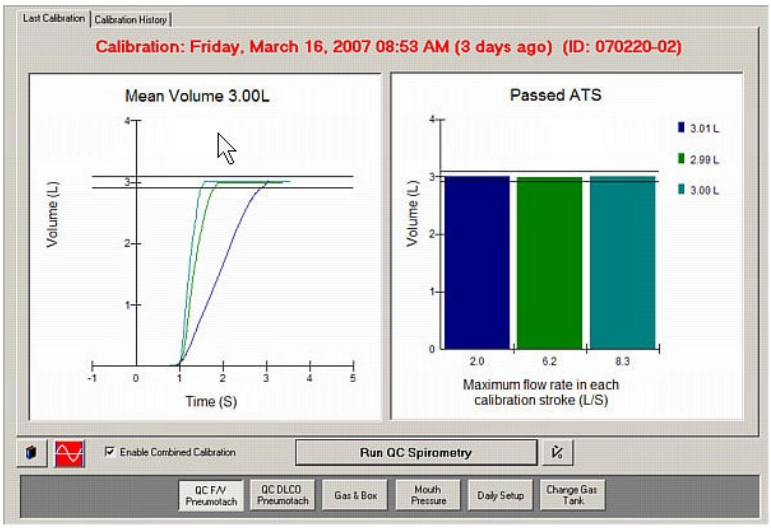
Instructions-Calibrations & Biological Controls

Step 1 Complete reassembly of <u>all</u> device components. Ensure absorber canisters contain fresh chemical absorbers and gases are turned on to the appropriate pressure. Enter ComPAS and run complete calibrations and biological controls.	

Support

Should you encounter any difficulties or have questions, or find yourself needing support in any way, please do not hesitate to contact as via phone at 978-521-4440 or email support@morgansci.com.

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Rutala, W. A., D. J. Weber and the Healthcare Infection Control Practices Advisory Committee (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities. Update: May 2019. Centers for Disease Control and Prevention, Accessed 12 April 2020, from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

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