FVL Spirometer Cleaning Instructions

Applies to all USA versions of the of the TransAir Multiple Flow ("FVL") spirometry testing systems distributed by Morgan Scientific, Inc running ComPAS version 1.10.XXXX software. All prior versions of the cleaning instructions are obsolete and superseded by the current version.

System Overview

The FVL spirometry system, like all other spirometry 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 FVL Pneumotach 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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FVL General Guidelines

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

The FVL 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 FVL 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 FVL 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 FVL pneumotach assembly and handle and any other 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 handle should be cleaned and disinfected; however, the Pneumotach Screen and its O-rings should be cleaned and disinfected or replaced.

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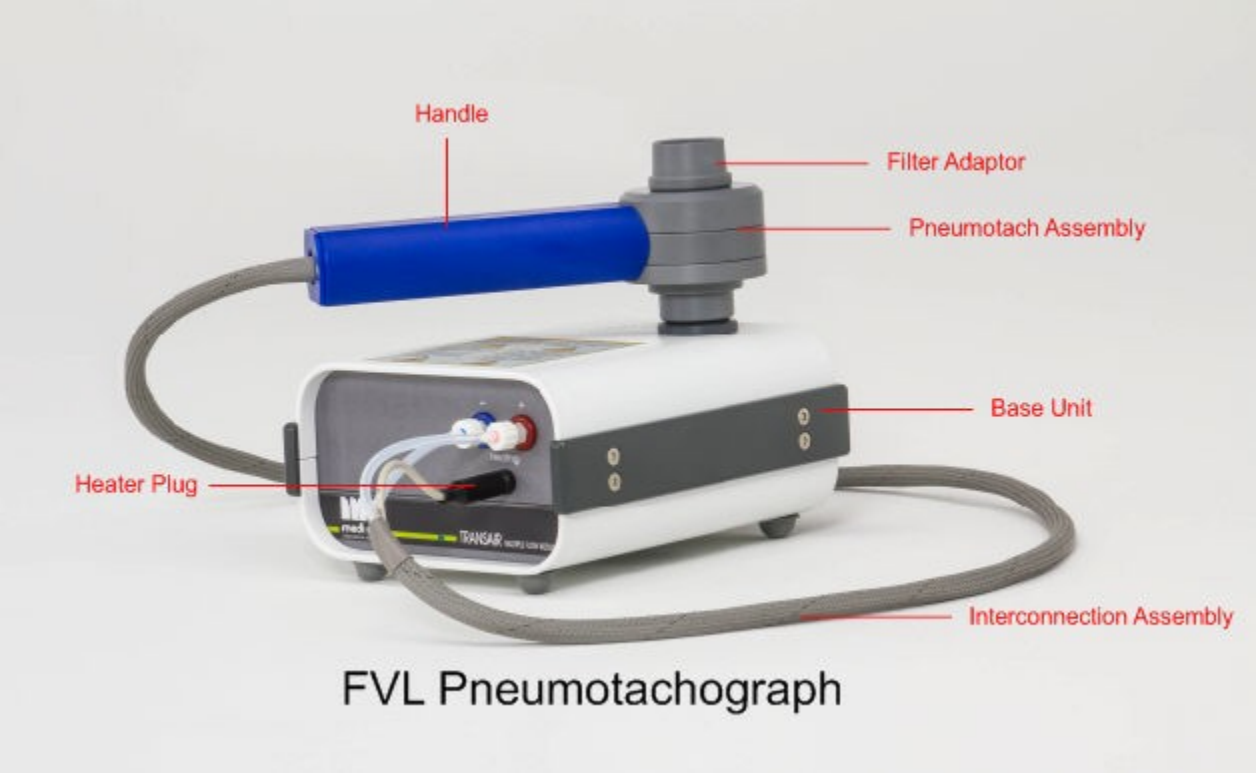
Cleaning & Disinfection Recommendations Chart



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Part	Material(s)	Level	Autoclave Possible?	Recommended Methods
Base Unit 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.
Handle	Polyoxymethylene (POM)	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	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	Polyoxymethylene (POM)	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.
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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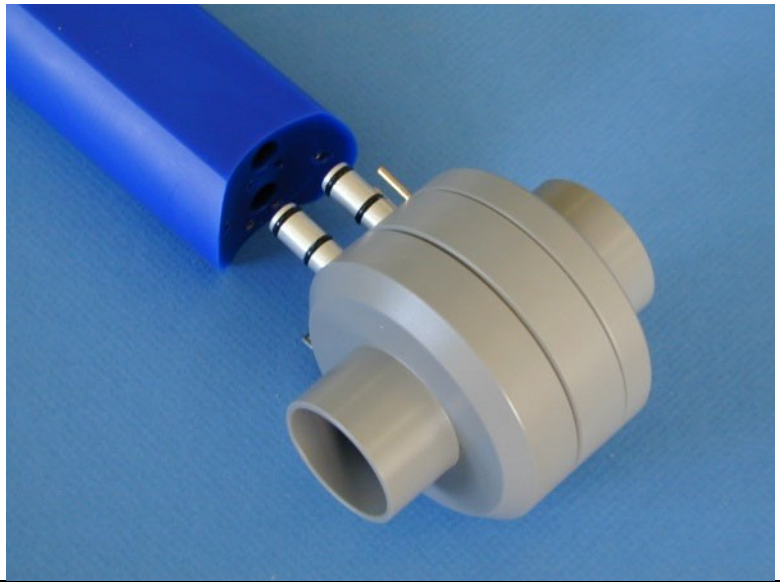
Part	Material(s)	Type	Autoclave Possible?	Recommended Methods
O-Rings	Buna-N (nitrile rubber), silicone	Clean & Disinfect	Viable	CLEAN: Clean with a wipe or cloth impregnated with a 70% Isopropyl Alcohol or follow the Facility's smooth/hard surface cleaning procedures. DISINFECT: Follow the Facility's chemical soaking or cold sterilization procedures

Instructions- Pneumotach Assembly

Step 1

Power off the device and unplug power supply cord.

Carefully remove the pneumotachograph from the handle by gently pulling the pneumotach straight out.



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Step 2

Place your thumbs on the two pressure fittings and gently turn against one another in an anti-clockwise direction.

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.

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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 FVL 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.	
Step 4 Once all the parts are cleaned, sterilized, and thoroughly dried, 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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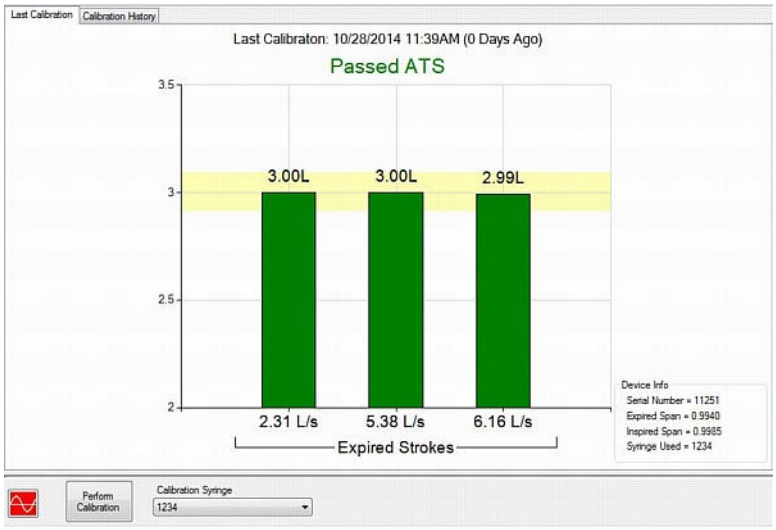
Instructions-Calibrations & Biological Controls

Step 1 Complete reassembly of <u>all</u> device components. 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.

References:

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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