MGC DIAGNOSTICS®

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Informational Product Bulletin

Applicable to:

√ **MGC Employee** √ **Distributor** √ **Customer**

Product(s): Platinum Elite Series, Ultima Series, CPFS/D, CCM Express

Date: January 13, 2020

Subject: Cleaning and Disinfection

Purpose: The purpose of this document is to give guidance on cleaning/disinfecting parts and supplies on the MGC Diagnostics systems. While some disinfecting methods are described below, this does not imply other methods may not be used. MGC Diagnostics makes no claims as to the efficacy of disinfecting products. Refer to the manufacturer of the disinfectant to determine the level of effectiveness of disinfection the particular product delivers. Exceeding recommended cleaning times or temperatures will degrade product integrity, or may reduce the accuracy of tests performed.

Note: None of the parts listed below are made with natural rubber latex.

The Centers for Disease Control (CDC) defines the following as:

Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

For pulmonary function testing, MGC Diagnostics recommends any of the following methods for infection control:

1. Use the preVent® flow sensor and BreathPath Patient Circuit once, then dispose after each patient.
2. Change the preVent flow sensor and BreathPath Patient Circuit between patients and replace with disinfected components. Clean the contaminated parts for reuse later. After changing the preVent flow sensor and BreathPath Patient Circuit, there is no warm-up time, and recalibration is not necessary.
3. Use MGC Diagnostics single-use preVent PF filter on the flow sensor and discard the filter after the patient test. The same preVent and BreathPath can be used on multiple patients.

Inspection

It is important to inspect all parts and supplies before patient testing, especially after being cleaned and disinfected. Parts that are cracked, torn or loose should be immediately replaced.

preVent® Filters & Filter Kits

P/N: 536713-002, -004, -005

P/N: 536719-001, -004

P/N: 536723-001, -004

MGC Diagnostics preVent filters and filter kits are the only filters recommended for use with MGC Diagnostics equipment. The preVent Series filters are high efficiency (99.98%) and fit directly onto the preVent flow sensor without the need for adapters.

Filters are single patient use and must be replaced after every patient. When using filters, MGC Diagnostics recommends disinfecting or disposing of the preVent flow sensor and BreathPath at least once every two weeks, or per the hospital's infection control policy.

Note: PF filters are not recommended for use with metabolic testing. Components must be disinfected or disposed of between patients.

preVent® & DirectConnect™ Flow Sensor Disinfection

P/N: 758100-004

P/N: 750066-003

MGC Diagnostics has determined that the preVent & DirectConnect flow sensors can be cleaned and disinfected at least 10 times according to the procedures outlined below. Under no circumstances may heat >120°F/49°C be used to disinfect or dry the flow sensors. The flow sensors are made of crystal polystyrene, which can be damaged by heat.

Note: These items are received in a clean, but not sterile condition.

Cleaning: Wash the flow sensor with soap and water, using a cleaning brush to loosen and remove any foreign matter.

Disinfection:

1. Soak the flow sensor in a solution up to 10% bleach and water for 60 minutes; OR soak in a 2.4% glutaraldehyde solution for 45 minutes; OR use the Sterrad Sterilization (hydrogen peroxide) system; OR use Cidex OPA; OR soak in a solution of Revital-Ox™ Resert® hydrogen peroxide.
2. Thoroughly rinse the flow sensor with tap or sterile water after soaking in a cleaning solution.
3. Thoroughly dry the flow sensor prior to use.

Note: To ensure test accuracy, no water may remain in the flow sensor before using. Fan drying at room temperature or low pressure air through holes in the flow sensor may be used to hasten drying. A drying chamber may be used as long as the temperature does not exceed 120°F/49°C.

Flow Sensor Inspection

Before using any flow sensor, visually inspect each unit. Look for obvious signs of damage, including cracks and chips. On the ***preVent flow sensor only***, check for loose screens using the following steps:

1. Insert a rigid device, such as a small rod, into any hole near the edge of the screen (see Figure 1).
2. Hold the rod in the hole and perpendicular to the surface of the screen while you attempt to rotate the screen within its frame.
3. If the screen rotates or moves at all or if there are obvious cracks or chips, dispose of the flow sensor immediately.

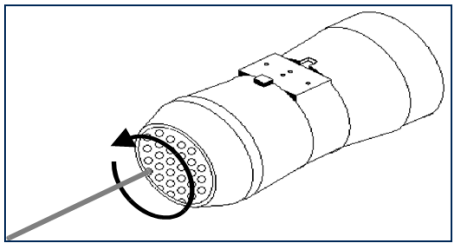

Figure 1

Breath Path Patient Circuit Disinfection

P/N: 758200-001

MGC Diagnostics has determined that the BreathPath patient circuit may be cleaned and disinfected according to the procedures outlined below. Under no circumstances may heat >120°F/49°C be used to disinfect or to dry the BreathPath Patient Circuit. The BreathPath patient circuit is made of Kraton™ that can be damaged by heat.

Note: These items are received in a clean, but not sterile condition.

Cleaning: Wash the patient circuit with soap and water, using a cleaning brush to loosen and remove any foreign matter.

Disinfection:

1. Soak the patient circuit in a solution up to 10% bleach and water for 60 minutes; OR soak in a 2.4% glutaraldehyde solution for 45 minutes; OR use the Sterrad Sterilization (hydrogen peroxide) system; OR use Cidex OPA; OR soak in a solution of Revital-Ox™ Resert® hydrogen peroxide.
2. Thoroughly rinse the patient circuit with tap or sterile water after soaking in a cleaning solution.
3. Thoroughly dry the patient circuit prior to use.
4. Before using any BreathPath patient circuit, you must inspect each unit. Look for obvious signs of damage, including tears, cracks and holes

Note: To ensure test accuracy, no water may remain in the patient circuit before using. Fan drying at room temperature or low pressure air may be used to hasten drying. A drying chamber may be used as long as the temperature does not exceed 120°F/49°C.

WARNING: Cleaning agents such as Cidex OPA may dramatically discolor and potentially shrink the patient circuit. Discoloration of the patient circuit may occur with continuous cleaning using any sterilization product. Unless there is material deterioration, the discoloration may be disregarded.

Mouthpiece (reusable) Disinfection

P/N: 758300-001

P/N: 758301-001

MGC Diagnostics has determined that the reusable mouthpieces may be cleaned and disinfected according to the procedures outlined below. Under no circumstances may heat >120°F/49°C be used to disinfect or to dry the mouthpieces. The mouthpieces are made of Kraton™ that can be damaged by heat.

Note: These items are received in a clean, but not sterile condition.

Cleaning: Wash the mouthpiece with soap and water, using a cleaning brush to loosen and remove any foreign matter.

Disinfection:

1. Soak the mouthpiece in a solution up to 10% bleach and water for 60 minutes; OR soak in a 2.4% glutaraldehyde solution for 45 minutes; OR use the Sterrad Sterilization (hydrogen peroxide) system; OR use Cidex OPA; OR soak in a solution of Revital-Ox™ Resert® hydrogen peroxide.
2. Thoroughly rinse the mouthpiece with tap or sterile water after soaking in a cleaning solution.
3. Thoroughly dry the mouthpiece prior to use.
4. Before using any mouthpiece, you must inspect each unit. Look for obvious signs of damage, including tears, cracks and holes

Note: To ensure test accuracy, no water may remain in the patient circuit before using. Fan drying at room temperature or low pressure air may be used to hasten drying. A drying chamber may be used as long as the temperature does not exceed 120°F/49°C.

WARNING: Cleaning agents such as Cidex OPA may dramatically discolor and potentially shrink the mouthpiece. Unless there is material deterioration, the discoloration may be disregarded.

Umbilical & Umbilical Clip Assembly Disinfection

P/Ns: 701080-102, 701066-015, -021, -024, -025, -027
(For all MGC Diagnostics systems)

1. Disconnect the preVent or DirectConnect flow sensor
2. Assure the vacuum pump is off or disconnect the umbilical from the system.
3. Wipe down the umbilical sheath with a disinfectant wipe such as Sani-Cloth or CaviWipes.

Warning: The umbilical sheath contains Nafion tubing which can be damaged by alcohol or wipes with excessive moisture.

4. Wipe down the stainless steel tubes, clip and DirectConnect Adapter if applicable.
5. The stainless steel tubes for flow are pressure sensing only, but for the purpose of ensuring that there is no moisture in the umbilical lines you may consider blowing compressed air into the back of the umbilical line to remove any moisture that may have been introduced. **Important:** Umbilical must be disconnected from the system; blow air from the end connected to the system towards the flow sensor connector. Place connector toward a paper towel to capture any moisture.
6. In the event that moisture accumulates in the gas sample line, back flush the sample line with compressed air.
7. In the event that secretions are aspirated into the gas sample line, back flush the sample line with compressed air or discard the umbilical.

Note: It is recommended that the umbilical assembly be replaced at least once per year.

preVent Mask Cleaning

P/Ns: 670009-001 thru -005

The preVent Mask is manufactured from neoprene. In rare cases neoprene has been known to cause dermatological reactions. Two known reactions are allergic contact dermatitis (ACD) and miliaria rubra (prickly heat). It is recommended that users be screened for a history of dermatological reactions to neoprene before wearing of the preVent Mask.

Note: This product is intended for single subject use only. The same mask may not be used on multiple subjects.

Cleaning

1. Carefully separate the neoprene preVent mask from the silicone coupler.
2. Wash the facemask separately in warm water with a mild detergent. Rinse well with cool water and allow to air dry.
3. After multiple washings, mask material may degrade and should be replaced.

Miscellaneous Parts & Supplies

The following parts & supplies are covered in this section

preVent Handle: 543370-001
preVent Retainer: 155203-001
Rubber Coupler : 536003-001
preVent Face Mask Silicone Coupler: 670010-003
Syringe/DirectConnect Adapter: 701240-001
DirectConnect Umbilical Adapter: 701067-001
FOT Filter Adapter: 543687-001


P/N: 543370-001


P/N: 155203-001


P/N: 536003-001


P/N: 670010-003


P/N: 701240-001


P/N: 701067-001


P/N: 543687-001

MGC Diagnostics has determined that the above parts & supplies may be cleaned and disinfected according to the procedures outlined below. Under no circumstances may heat >120°F/49°C be used to disinfect or to dry these items.

Note: These items are received in a clean, but not sterile condition.
Cleaning: Wash the items with soap and water, using a cleaning brush to loosen and remove any foreign matter.

Disinfection:

1. Soak the items in a solution up to 10% bleach and water for 60 minutes; OR soak in a 2.4% glutaraldehyde solution for 45 minutes; OR use the Sterrad Sterilization (hydrogen peroxide) system; OR use Cidex OPA; OR soak in a solution of Revital-Ox™ Resert® hydrogen peroxide.
2. Thoroughly rinse the items with tap or sterile water after soaking in a cleaning solution.
3. Thoroughly dry the items prior to use.
4. The DirectConnect adapter will require flushing with compressed air to dry the unit before it can be used again.
5. Before using any part or supply, you must inspect each unit. Look for obvious signs of damage, including tears, cracks and holes

Note: The affect of Revital-Ox on the gasket adhesive for Part 701067-001 is unknown.

Surface Cleaning

Surfaces that come in direct contact with patients should be cleaned/disinfected between patients. Cleaning and disinfection should be combined as part of the decontamination program. Detergents contain cleaning properties that remove soil and organic matter, and disinfectants contain active ingredients that remove microorganisms. Clean soiled areas (dirt and organic matter) if needed with liquid detergent & warm water or a neutral pH enzymatic detergent prior to using a disinfectant wipe. Powder detergents may not totally dissolve in the water and may scratch the surfaces of the equipment. After the removal of any debris (if necessary), use a disinfectant wipe to remove any microorganisms. Disinfectant wipes such as Sani-Cloth or CaviWipes can be used on the surfaces of the equipment. Refer to the manufacturer of the disinfectant wipe to determine the level of effectiveness of disinfection the particular wipe delivers.

Note: Alcohol based products should not be used on the glass of the Platinum Elite Plethysmograph. Alcohol can crack or etch the glass and make it look cloudy.

For more information, please visit our website www.mgcdiagnostics.com.