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Recommendations for Cleaning and Sterilizing:

Boehringer 3800 Series Suction Regulators



BOEHRINGER

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Introduction

The instructions contained herein describe methods by which Boehringer suction regulators can be processed. It is the responsibility of the hospital to ensure that any devices subjected to these guidelines have been appropriately processed. Of the possible processing options presented below, it is at the ultimate discretion of the hospital to determine which to employ, determined by regulator use conditions and degree of known or observable contamination.

Regulator Condition	Processing Option		Page
No evidence or fluid intrusion / gross contamination	1	Point of care external surface cleaning	Page 3
	2	Flush and optional autoclave	Page 4
Evidence of fluid intrusion / gross contamination	3	Partial disassembly, wipe down and optional autoclave	Page 5
	4	Full disassembly, clean and autoclave/sterilize*	Page 6

*Processing Option 4 is a validated process that when followed will render the suction regulator sterile (i.e. free of viable microorganisms). Regulators processed using options 1-3 will have reduced microorganism load, but cannot be considered sterile.

Applicable Regulator Models

ONLY BOEHRINGER SUCTION REGULATORS WITH THE "VSS-270" LOGO MAY BE PROCESSED USING THIS MANUAL.

This document contains recommended instructions for the safe care, handling and processing of the 3800 Series of Boehringer suction regulators, produced after December 31, 2010. This manual also applies to all Model 9100 Fluid Trap Bottles sold after March 2012.



3800 SERIES	9100 SERIES	3800 SERIES REGULATORS WITH
REGULATORS	TRAP BOTTLES	INTEGRAL TRAP BOTTLE INSTALLED.

Warnings and Cautions

- Boehringer suction regulators are intended to be cared for per the instructions in this manual as well as the instructions for use specific to each model.
- Suction regulators are used in a clinical setting on a variety of patients. Always utilize appropriate PPE when handling suction controls that have been in clinical use.
- Failure to ensure the suction regulator is functioning properly after processing can increase patient risk. Ensure suction controls function properly before they are returned to service.
- Boehringer suction regulators have not been validated for cleaning with high powered washers. Use of these cleaning tools may result in damage to the regulators, which will not be covered under warranty repair.
- Avoid solutions containing high chlorine content (>1%) as this may cause irreversible damage to the suction regulator components.
- All detergents used should have a neutral pH.
- Devices that are visibly contaminated must be thoroughly cleaned before processing to ensure the efficacy of the disinfection / sterilization process.
- Immediate use steam sterilization (IUSS) is not a recommended process for Boehringer Suction regulators.
- Any deviation outside of these processing protocols should be properly evaluated for efficacy and potential adverse consequences.

Option 1: Point of Care External Surface

- Clean the exterior surface of any gross visible debris/soil. Particular care should be paid to the adjustment knob and the mode selection knob as these are the two most commonly touched surfaces by caregivers.
- Wipe all exterior surfaces of the suction regulator with a surface disinfectant per manufacturer's instructions. Suitable hard surface disinfectants are:

ETHYL ALCOHOL-BASED	60%-90% Concentration
CHLORINE BASED	a 1:10–1:100 dilution of 5.25%–6.15% sodium hypochlorite (i.e., household bleach). (mix or use manufacturer-prepared chlorine based solutions or manufacturer-prepared wipes) Never use undiluted bleach on these instruments.
IODOPHORS	Mix per manufacturer's directions for use as a hard surface disinfectant.
Phenols	Mix or use manufacturer prepared wipes per manufacturer's directions for use as a hard surface disinfectant
QUATERNARY AMMONIUM Compounds	Mix or use manufacturer-prepared wipes per manufacturer's directions for use as a hard surface disinfectant.

Option 2: Flush and Optional Autoclave

This option may be considered for regulators where there is no evidence or fluid intrusion or gross contamination.

- Assemble a flush circuit as seen below:
 - Place 500cc distilled water in an open container
 - Connect the supply port of the regulator to the patient port of a suction cannister larger than 500 mL
 - Connect the suction cannister to any suction source, such as a portable suction pump or wall regulator
 - Connect a suction tube to the patient port on the regulator, and place the free end in the water



- Turn the adjustment knob of the regulator counter-clockwise until resistance is met
- Turn the mode selection knob to REG
- Turn on the suction source to maximum vacuum
- Place the end of the patient side tube in the distilled water and aspirate through the regulator
 Verify collection of the fluid in the suction cannister

CAUTION!

Failure to use a suction cannister larger than the volume of fluid to be aspirated will result in fluid intrusion of—and possible damage to—the suction source

- Once no liquid is observed in the line between the regulator and the suction cannister, continue to aspirate for an additional ten seconds to remove as much fluid from the interior of the regulator as possible
- Turn off the suction source and disassemble the flush circuit
- If autoclave is desired, follow "Autoclave Procedure" on page 6
- Verify performance of regulator as described on page 7 before returning to service

Option 3: Partial Disassembly, Wipe-down and Optional Autoclave

- Partially disassemble regulator following the procedures below. If multiple units are disassembled, take care to keep like parts mated.
 - For continuous models (3800, 3810, 3840), the control valve must be removed to allow cleaning of the control valve itself and the internal passageways of the regulator body
 - Remove valve retaining screw and washer with 5/32" hex wrench. During screw removal, it may be necessary to prevent the control valve from rotating with an adjustable wrench
 - Pull out control valve





- For intermitting models (3804, 3814, 3844), the control valve and spool must be removed to allow cleaning of the spool, control valve, dashpot knob and internal passageways of the regulator body
 - Remove the dashpot cover and filter
 - Unscrew the dashpot knob
 - Pull the intermitter control valve out of the regulator body



- Wipe down all internal and external surfaces with a disinfectant specified in processing option 1
- Reassemble the regulator in reverse order of the instructions above
- If autoclave is desired, follow "Autoclave Procedure" on page 6
- Verify performance of regulator as described on page 7 before returning to service

Option 4: Full Disassembly, Clean and Sterilize

The method below is part of a fully validated cleaning and sterilization process.

- Fully disassemble the regulator following all steps of the "Disassembly" procedure in the User Manual available for each regulator model, available on the Boehringer website (boehringerlabs.com)
- After the suction regulator is fully disassembled, all regulator components should soak for a minimum of 10 minutes in a solution of warm water and pH neutral detergent such as MetriZyme[®]. Refer to the detergent manufacturer's instructions for concentration recommendation.
- After soaking, thoroughly rinse components with warm tap water.
- Regulator components should be placed in a fresh solution of warm tap water and pH neutral detergent such as MetriZyme[®] and scrubbed with a soft bristle brush to remove deposits. Refer to the detergent manufacturer's instructions for concentration recommendation.
- The components should then be removed from the solution and rinsed with warm tap water.
- Components should be placed in an ultrasonic cleaner and completely submerged for a minimum of 10 minutes.
- Rinse components thoroughly with warm tap water.
- Inspect regulator components for visible soil. Repeat cleaning process again if visible soil is observed.
- Reassemble regulator as per user manual
- Follow "Autoclave Procedure" on page 6
- Verify performance of regulator as described on page 7 before returning to service

Autoclave Procedure

- Ensure all suction regulators are properly assembled and the control knobs are turned to the REG or CONT. mode.
- Ensure the adjustment knob is turned counterclockwise until it stops to keep the internal passageways as open as possible.
- Suction regulators can be packaged in a variety of ways for processing including a peel pouch, sterilization wrappers or instrument tray.
- The following are recommendations for autoclave processing of Boehringer Suction Controls

Cycle Type	Minimum Autoclave Exposure Time (min)	Minimum Sterilization Exposure Temperature	Minimum Dry Time*
Pre-vacuum	4	132° C (270°F)	10 Minutes

*Dry times will vary depending upon a number of factors including packaging materials, environmental conditions, steam quality, regulator mass and autoclave specification (cool down time and performance). The processor should visually inspect the regulator for signs of moisture.

• Ensure components are dry before reassembling the suction control. If using an automatic dryer, ensure the temperature does not exceed 132°C (270°F).

Verification of Performance

- After Boehringer suction controls are processed, it is imperative they be checked for basic function before returning to service. Please refer to each specific model's instructions for use for proper methods to check regulator performance.
- At a minimum check the following functions:
 - The regulator can maintain a constant level of vacuum.
 - The gauge properly indicates the vacuum level.
 - The regulator functions in all operating modes (e.g. continuous, intermittent and line).
 - The regulator flow rate is in compliance with the model's specifications.
- If you have questions at any time, please feel free to contact Boehringer at 1-800-942-4945.



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> For Customer Service Or Technical Support

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A free trial evaluation of any of our suction regulators can be arranged by calling (800) 642-4945