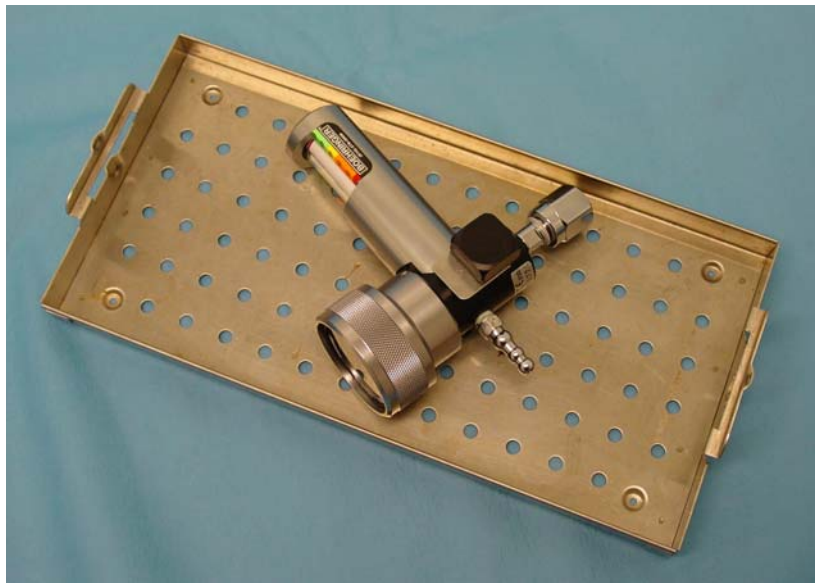


Suction Regulators

Boehringer Suction Regulator Recommendations for Decontamination and Autoclaving



BOEHRINGER®

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Definition of Terms and Symbology

VACUUM	Air or other gases at sub atmospheric pressure typically expressed as mm Hg or cm H2O
WARNING	Alerts user to actions or conditions that could result in injury to user or patient
CAUTION	Alerts user to actions or conditions that can cause damage to the device or may result in substandard performance of the device or system.
IMPORTANT	Indicates an action that is emphasized to ensure proper operation of equipment
CONTAMINATED	State of having been actually or potentially in contact with microorganisms
DECONTAMINATION	The use of physical or chemical means to remove, inactivate, or destroy blood borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or items is rendered safe for handling or disposal.
DISINFECTION	A process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling use.
STERILIZATION	A validated process used to render a device free from all forms of viable microorganisms
STERILIZABLE	Term used to describe devices that possess the characteristics required to withstand various sterilization processes
Process(ing)	Act of subjecting medical devices to the various routes used for disinfection and sterilization

Safety Information

WARNING!

- Boehringer suction regulators are intended to be cared for per the instructions in this manual as well as the Instructions for Use that are provided with your specific suction controls. Failure to follow the guidelines herein may result in unsatisfactory levels of decontamination.
- Suction regulators are used in a clinical setting on a variety of patients. The mechanisms that allow the regulators to function can result in biological contamination of the device though there are no apparent signs of contamination. Always utilize appropriate PPE when handling suction controls that have been in clinical use.
- Failure to ensure that the regulator is properly working after decontamination/disinfection/sterilization can increase patient risk. Ensure that suction controls work properly before they are returned to service.
- Though this manual provides instructions for appropriate decontamination and sterilization procedures, the hospital is responsible to ensure that proper disinfection and/or sterilization has been achieved.

CAUTION!

- Hydrophobic filters, gravity shut offs, and gravity safety traps provide a barrier to gross biological contamination but do not prevent microbiological pathogens from entering the suction control. Be mindful that these measures alone do not ensure a pathogen free device will be returned to clinical service.

Purpose

This decontamination guide provides instruction for the recommended care and cleaning of Boehringer suction controls. The instructions herein are meant to assist in the development of safe handling and effective reprocessing procedures for Boehringer suction controls. A variety of personnel in the hospital will interact with suction controls including clinical and support personnel. Hospital directors and management in charge of any departments that may be responsible for handling these devices should be informed of these recommendations to ensure the safety of hospital employees and patients while preventing the damage or misuse of these devices.

Scope

MODELS

This document contains recommended instructions for the safe care, handling and decontamination of the entire line of Boehringer suction controls, including all 7700, 3700, 7800 & 3800 series designs. This instruction sheet is an addendum to, and not a replacement for the complete instructions for use for your suction control. Please refer to our website www.boehringerlabs.com

DECONTAMINATION

The decontamination protocols described herein are intended to be used on regulators that have been grossly contaminated. Devices that show no signs of gross fluid intrusion may not require decontamination and may have sufficiently low bio-burden such that they may only require processing through a sterilizer. It is the responsibility of the hospital to determine whether or not gross decontamination is required¹, see page 5 for inspection instructions.

DISINFECTION

Routine disinfection at patient turnover may be prudent as a regular practice. Whether or not disinfection is required depends on the risk associated with the contaminated device for the particular clinical application.

PROCESSING

Processing through a sterilizer is recommended to ensure that the maximum numbers of infectious agents are inactivated. The instructions contained herein describe processes by which Boehringer suction controls can be processed. It is the responsibility of the hospital to ensure that any devices subjected to these guidelines have been appropriately processed.

¹ Gross contamination of suction equipment is an extraordinary event. Normal precautions such as the appropriate use of collection canisters, gravity trap bottles, and hydrophobic filters reduce, but do not eliminate the probability of such events.

Considerations

The instructions contained herein describe the procedure for effective processing of certain Boehringer suction regulators. Refer to the detailed instructions in this manual to determine which models are suitable for which type of processing.

The end user / individual / department responsible for processing these devices should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

Suction regulators are generally not considered sterile instruments and are not often stored in sterile containers before use. The hospital is responsible to determine in what cases processed suction controls are required over disinfected controls.

Healthcare systems are responsible for determining an appropriate protocol for the scheduling of regulator decontamination. Regulators that have been in contact with high risk patients may require immediate decontamination, whereas those that have been in contact with low risk patients may be able to be reused with disinfection only.

Instructions

Note: Refer to Appendix A for a detailed flow chart indicating the recommended steps for the processing of suction controls.

PRECAUTIONS

- All hospital personnel are recommended to observe universal precautions when handling contaminated or potentially contaminated medical devices.
- In exercising universal precautions, healthcare employees are recommended to wear personal protective equipment (PPE) while handling contaminated or potentially contaminated medical equipment.
- Suction regulator components should be cleaned with soft-bristled, nylon brushes and pipe cleaners. The use of metal brushes and scouring pads should be avoided to prevent damage to surface finishes on the devices.
- Unfortunately current suction regulator decontamination practices generally allow for the drying of contaminants within the regulators and unintentional gross contamination may go unnoticed until a scheduled service event. In the event that a regulator presents with dried contaminants, ensure that all dried debris are completely removed from all regulator surfaces during the decontamination process.

POINT OF USE PREPARATIONS

- Wipe all exterior surfaces of the regulator with a surface disinfectant per manufacturer's instructions. Appropriate disinfectants are:
 - o 3M Quat®
 - o Cavacide®
 - o 1:10 bleach solution (wipe, but do not soak in bleach)
- Refer to the instrument's user manual for instruction on internal disinfection via back-flushing the unit.

INITIAL ASSESSMENT

- To determine whether or not the unit has been grossly contaminated, loosen the set screw (2 turns max) on the control knob with a 1/16th Allen key and remove the adjustment knob (refer to the user manual for more detailed instructions).
- o Visually inspect the piston/stem assembly for signs of gross contamination.
- o If the unit shows no visible contamination, the adjustment knob should be reattached so that the unit can be processed.
- o If visible contaminants are present, the unit requires complete disassembly and gross decontamination (refer to the device's user manual for detailed instruction on this process).



DECONTAMINATION

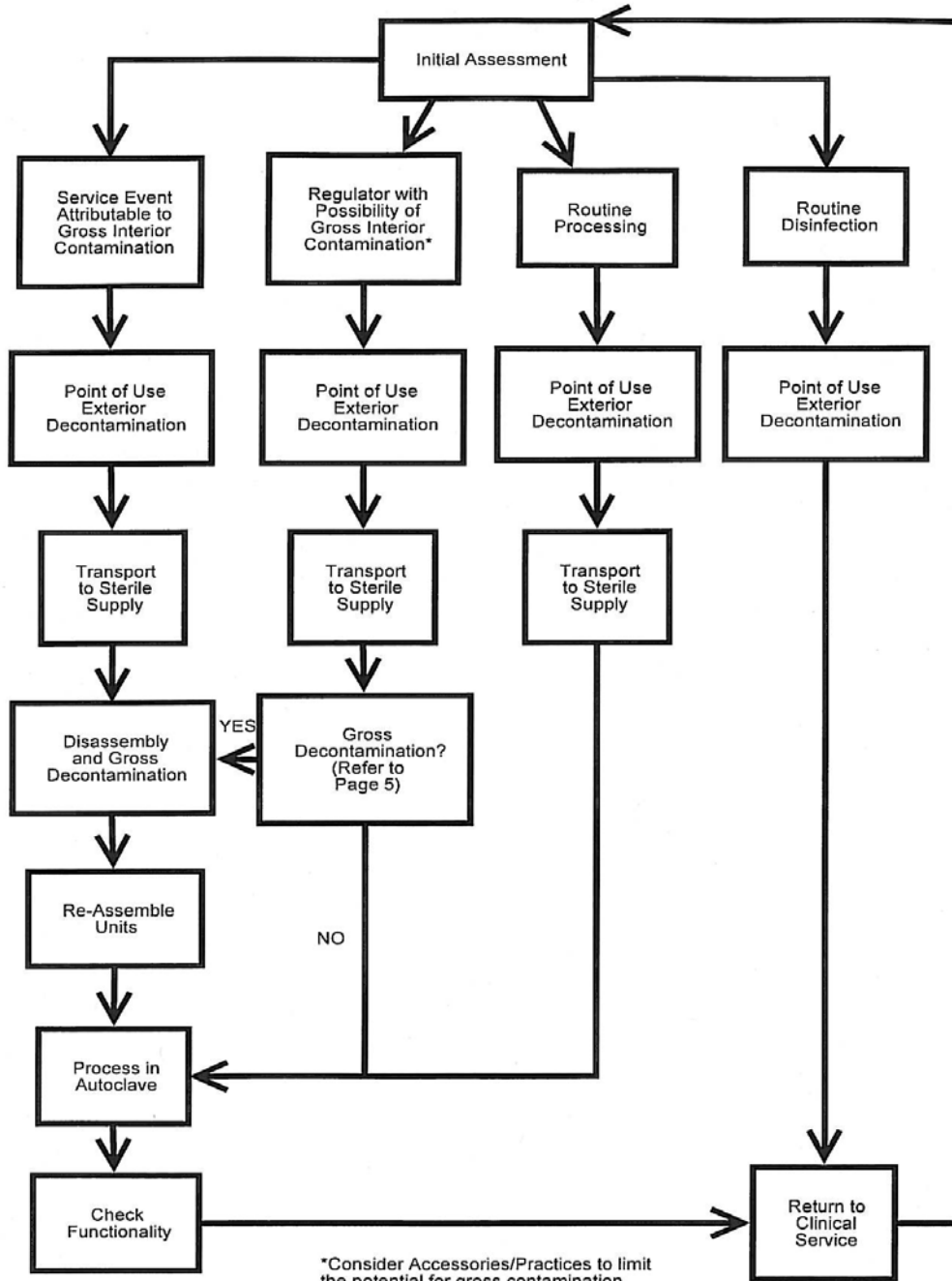
- o Once the unit has been disassembled, all components should be allowed to soak in an enzymatic cleaning solution such as LiquinoxTM for 20 minutes (note: do not submerge dial gauges). Some of the Boehringer components are factory mated and should be kept with the original device. Please refer to your products instructions for use for complete details.
- o All components with visible contamination should then be scrubbed with a soft-bristled nylon brush or some other appropriate cleaning device until all visible soil has been removed. Manual cleaning is preferred over automated wash cycles. Automated washers may be used provided they do not exceed 250°F and highly alkaline cleaners are not used.
- o The components should then be removed from the solution and rinsed with tap water for 3 minutes.
- o Components may additionally be placed in an ultrasonic cleaner, completely submerged (note: do not submerge dial gauges), for 10 minutes.
- o The parts should then be rinsed with purified water for 3 minutes ensuring that no contamination or cleaning solutions remain.
- o In the event that signs of contamination remain, repeat the steps above.
*Dial gauges can be externally decontaminated with the use of mild disinfectants (refer to the user manual for instructions).

PROCESSING

- Boehringer suction controls should be processed in a pre-vacuum autoclave at 250°F for 30 minutes.
 - o Suction regulators should be set to the “continuous” or “REG” positions during this process.
 - o Suction regulators with dial gauges must be oriented such that the gauge is vertical to prevent pooling of liquids in the gauge.
 - o Ensure the patient and supply ports of the device are open to allow the steam to access the interior of the device.
- Units may be allowed to air dry or be attached to a vacuum source for one minute to ensure internal drying. Heated drying cycles must not exceed 250°F.
- Ensure the device has thoroughly cooled to the touch before returning to clinical service.
- Boehringer suction controls are able to withstand several other common methods of sterilization (EtO, Sterrad, etc.) however validation of these methods is the responsibility of the facility.

It is the responsibility of the hospital to ensure that all suction controls returned to Boehringer have been appropriately disinfected or decontaminated.

APPENDIX A – Suction Control Processing Flow Chart



*Consider Accessories/Practices to limit the potential for gross contamination.
 -Permanently Installed Hydrophobic Filter (9100)
 -Gravity Trap (7791)



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