

MRI SUCTION REGULATOR



BOEHRINGER

®

Boehringer Laboratories, LLC
300 Thoms Dr.
Phoenixville, PA 19460
800-642-4945

***MRI Suction
Regulator Model:***

3708

Congratulations on your purchase of a Boehringer Suction Regulator. We consider our Suction Regulators to be the best in the world. We are confident it will provide you with reliable, trouble-free, safe patient care and low cost of operation. This product is intended for use by individuals properly trained in suctioning procedures by or on the order of a physician. Please read these instructions carefully.

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Definition of Terms and Symbology

VACUUM	Air or other gases at a sub atmospheric pressure typically expressed as mmHg or cmH ₂ O.
SUCTION	A use of vacuum that causes a fluid or solid to be drawn into an interior space or to adhere to a surface because of the difference between the external and internal pressures.
	Alerts the user to the presence important operating and maintenance instructions in the literature accompanying the device.
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 <u>or</u> may result in substandard performance of the device or system.
IMPORTANT	Indicates an action that is emphasized to ensure proper operation of equipment.
OFF	Supply suction is off and patient circuit is vented to atmospheric pressure.
REG	Supply suction is on and regulated output is controlled to prescribed setting.
LINE	Supply suction is on and regulation is bypassed to deliver maximum suction to collection circuit.
CONTIN	Intermitting regulator setting that provides continuous regulated suction to the collection circuit.
INT	Intermitting regulator setting that allows periodic, automatic application & venting of the collection circuit.
	Lo Spike: Accuracy of regulation depends primarily on the ability to provide a consistent level of vacuum under changing flow conditions. Involuntary pneumatic biopsy, or tissue damage, can occur when high levels of vacuum are applied to delicate tissue. With a Boehringer regulator, you can depend on very low “spike” compared to our competitor’s models. “Spike” is the variation in indicated suction as flow in the collection circuit changes from an a free flowing condition to an occluded condition. We measure spike as the change in indicated suction from full flow to a no flow condition using a typical collection circuit with a 14 French catheter. To test, set the regulator to 100 mm flowing, and then allow occlude the 14Fr catheter. The change in the indicated suction level is “Spike”. Boehringer regulators are checked on the assembly line to meet a specification of less than 10% of the indicated setting, for example 10mmHg spike at a 100 mmHg setting. An evaluation of a regulator’s spike allows one to determine whether the device is truly “regulating”. A safe and reliable regulator should regulate to its set position regardless of variable flow conditions.
PARALLAX	Inaccuracy caused by observational position of an indicating element (pointer) to a reference element (scale).

Safety Information

WARNING!

- This product is intended for use by or on the order of a physician. It is to be used by individuals who are properly trained in medical suctioning procedures. Please read these instructions carefully.
- Suction regulators must only be attached to vacuum systems. Do not attach to compressed air, nitrogen, or oxygen sources.
- ***Suction catheters, collection canisters and suction tubing must be carefully evaluated and selected to ensure adequate function for the specific clinical environment and intended field of use.***
- Do not use Boehringer suction regulators in the presence of flammable anesthetics.
- Do not use conductive tubing in an MRI environment. To avoid inductive heating, do not loop collection tubing.
- There have been reports of increased intracranial pressures associated with endotracheal suctioning procedures. "Persistent, increased ICP has been associated with neurological damage and fatalities". (ECRI, Healthcare Product Comparison System (US). Regulators, Suction. Plymouth Meeting (PA), 1999.).



Always verify regulator operation (Droop, see page 4 for details) before use on a patient. Verify operation by establishing the desired vacuum level with the collection circuit and suction catheter attached to the regulator. Occlude the suction catheter and note that the indicated vacuum does not rise by more than 10% of the original setting.

- ***Intermitting Regulators: The automatic return of the patient circuit to atmosphere may not eliminate the need for catheter tip irrigation. As with any automatic system, it is important to monitor the results to be sure that drainage is occurring in a safe efficient manner. The fact that the intermitter is cycling is not an indication that effective drainage is occurring.***
- ***The Model 3708 Boehringer MRI Suction Regulator is the only MR conditional regulator with FDA 510K approval.***
- ***The high air flow of the models 3740 and 3840 contraindicate their use with a Vacuum Assisted Delivery (VAD).***

CAUTION!

- Collection canisters are mandatory for all suction procedures. We strongly recommend the use of an overflow protection device (filter or trap bottle) at all times between the regulator and collection canister. See Accessories at the end of this manual.

CLINICAL USE

The **3700 Series Continuous Suction Regulators** are designed to provide accurate control of wall suction for use in suction therapy procedures in the operating, recovery, intensive care unit, labor and delivery, neonatal, pediatrics, patient bedside, and emergency room.

The **3700 Series Intermittent Suction Regulators** are designed to provide an intermittent suction source for gastrointestinal drainage procedures. They may also be used in procedures needing continuous suction.

Installation

All Boehringer MRI Conditional suction regulators are supplied with fittings specified at the time of purchase. These fittings are not to be removed or replaced by anyone other than Boehringer Laboratories personnel. Removal or replacement of any MRI Conditional suction regulator fitting by other than Boehringer Laboratory personnel could create a safety hazard, and will void any and all warranties.

Operation –

Model 3708 MRI Regulator incorporates a 3-way control valve with OFF, REG, and LINE.

OFF: With control valve in the OFF position, suction is off and the collection circuit is returned to atmospheric pressure by an internal vent port, a special feature of the Boehringer design.

REG: With control valve in the REG position, wall suction may be controlled to a specific level by turning the large adjusting knob in the direction indicated. A spring opposed diaphragm assembly precisely controls the level of suction provided at the lower port of the Regulator within the range of the gauge. This assembly "senses" changes in the patient collection circuit and makes appropriate adjustments to maintain the suction level that has been selected. Regulated settings are verified by the large, easy to read gauge.

LINE: With control valve in the LINE position, the regulating mechanism is bypassed. Full wall suction is applied to the patient collection system through the lower port of the Regulator. The LINE suction mode is engaged by depressing the safety spring release and rotating the control valve to the line position. LINE setting is verified by the exposure of the "LINE" warning at the bottom of the gauge label.

CAUTION: Full line suction may cause damage to sensitive tissue.

Maintenance - All Models

Boehringer medical suction regulators do not require manufacturer-prescribed planned or preventive maintenance to maintain their intended safety or performance when used in accordance with these Instructions for Use.

- ANSI/AAMI EQ56 and ANSI/AAMI EQ89 describe maintenance approaches used in medical equipment management programs, including planned maintenance and preventive maintenance. Planned maintenance generally refers to maintenance activities performed before a device experiences a loss of function. Preventive maintenance generally refers to routine replacement, overhaul, or refurbishment of components without regard to their current condition.
- Boehringer does not prescribe a planned or preventive maintenance interval for these regulators. If a health care organization classifies a suction regulator as critical equipment, or otherwise includes the regulator in a scheduled inspection or maintenance program, the organization should determine the appropriate inspection, testing, or maintenance strategy for that use environment in accordance with its

equipment management program, applicable regulatory or accreditation requirements, and its own risk assessment.

- Before each use, users must verify proper regulator operation as described in the Safety Information section. Any regulator exhibiting damage, abnormal operation, or malfunction should be removed from service and evaluated before further use.

Cleaning & Disinfection

Please refer to Boehringer document 7700.192, **Boehringer Suction Regulator Recommendations for Decontamination and Autoclaving** for guidance. This information is available online at www.boehringerlabs.com, or toll-free at 1-800-642-4945.

DISASSEMBLY

Regulator:

1. Back out lock screw (8) on housing assembly (7) with 1/16 hex wrench.
2. Unscrew diaphragm housing (7) from regulator body (12).
3. Remove valve retaining screw (9) and washer (10) with 5/32 hex wrench. Pull out control valve (15).
4. In the unlikely event suctioned material should enter the regulator diaphragm housing, it will be necessary to disassemble and scrub the unit as follows:
 - a. Remove quad ring (5), lens cap retaining ring (1) and lens cap (2).
 - b. Push out diaphragm (3) by pressing on piston/stem assembly (4).
 - c. Remove piston/stem assembly (4) and spring (6).

Gauge:

5. Remove the retaining ring (17) using retaining ring pliers.
6. From the front of the gauge, use thumb to rotate and loosen view tube (19). Then remove view tube-piston-diaphragm assembly (19-20-21).
7. Remove the lower lip of the diaphragm from outside of the view tube, and slide out the diaphragm-piston assembly.
8. Remove the upper diaphragm lip from the top of piston, and slide diaphragm off piston.
9. Remove spring (22).

NOTE: *It is not necessary to remove the gauge body (24) from the regulator body (12) prior to cleaning.*

IMPORTANT: *Always clean the unit prior to assembly. See the Cleaning and Disinfection section above for details.*

Assembly and Lubrication –

After disassembling and cleaning the instrument, assemble and lubricate as follows. Parts are available from Boehringer Labs and may be ordered by part number (P/N). Part numbers are found in figure 1 at the end of this manual.

1. Lubricate control valve (15) over entire mating surface with synthetic lubricant (P/N 1895).
2. Rotate valve as you insert it into the body. Remove the valve and inspect for dry areas. The valve must have a thin layer of lubricant over its entire diameter without excess in the cross ports.
3. Lubricate the threaded sleeve in diaphragm housing (7) and U-cup (11) with a light coat of synthetic lubricant (P/N 1895).
4. Assemble diaphragm housing in reverse order of disassembly.
5. Inspect quad ring seal (5) for cuts or wear. Replace if needed.
6. Assemble unit in reverse order of disassembly.

Gauge:

7. Slide large end of diaphragm (20) over piston (21) until top ring snaps into groove in piston. Be certain the top bead of the diaphragm is completely engaged into the groove of the piston.

CAUTION: *If the diaphragm is not seated properly it will rub against the view tube and may lead to premature failure of the gauge.*

8. Slide view tube over diaphragm-piston assembly.
9. Roll edge of diaphragm around bottom of view tube and into groove. Make sure there are no folds or twists and that diaphragm is smooth. Ref. 3700.051 for detailed assembly instructions.
10. Insert spring (22) into piston/view tube subassembly.
11. Slide piston subassembly with spring up (gauge body facing down) into gauge body (24).
12. Press until view tube assembly rests on shoulder in gauge body.
13. Assemble retaining ring (17) into groove in gauge body.

Regulator:

14. Place spring (6) on piston/stem assembly (4) and then insert through diaphragm housing assembly (7).
15. Cover piston/stem assembly (4) with lens cover (2) and snap lens cap retaining ring (1) into groove.
16. Assemble quad ring (5) to stem (4), then screw housing into body (12).
17. Tighten lock screw (8) to retain diaphragm housing on regulator body groove.
18. Insert the control valve (15), and position the valve retaining washer (10) before securing it with the valve retaining screw (9)

IMPORTANT: *Always test the reassembled unit after each maintenance procedure. See the Test section below for exact test procedure.*

Test –

1. With the control valve in the REG or CONTIN position and a collection system attached with a 14 Fr. catheter, regulator should control vacuum from 10-100% of full scale.
2. With the control valve in the REG or CONTIN position and housing turned all the way off, with suction port occluded, gauge should read zero.

3. With the control valve in the REG or CONTIN, adjust regulator to the middle of the scale and occlude the catheter. Gauge movement should be less than 5% of the full scale of the regulator. This measurement is called droop.
4. The gauge should be accurate to $\pm 5\%$ of FS for any measurement within the range of the scale. If this is not the case, please return the gauge to the manufacturer for repair/replacement.

CAUTION: *Inaccurate gauge calibration may lead to a high suction condition applied to the patient.*

5. With the control valve in the OFF position, suction should be at atmospheric and gauge should read zero. With suction port occluded, gauge should read zero.
6. With the control valve in the REG or CONTIN position, set the Regulator to the middle of the scale and turn control valve to OFF, then back to REG or CONTIN. Gauge indicator should not travel more than 20% past the set point before settling at the desired level.
7. A final, important step in instrument maintenance is the identification of the instrument. This confirms that a qualified individual performed service to accepted procedures and approved master gauges. An ID tag should accompany the instrument, which indicates (as a minimum): date of service, individual performing the service and the date of next service.

CAUTION: *Have the regulator factory serviced if not performing to specifications. See Warranty and Repair on p.12 for details on getting your instrument factory serviced.*

MRI Safety Testing Summary

The Boehringer MRI Regulators were evaluated for compatibility in an MRI environment. The static magnetic field strength was 3.0 Tesla, passively shielded.

The regulator was placed in the bore of the magnet, and no effect on the operation of the regulator was detected.

A full test report is contained available by request (Boehringer Document Number 3708.019).

Troubleshooting- All Models

Boehringer Suction Regulators have been designed for years of trouble-free service. Should you experience difficulty that is not the result of damage to the instrument, the most likely cause is aspiration of dirt and/or fluids into the Regulator.

Complete Technical Manuals and Service Bulletins can be found at
<http://www.boehringerlabs.com/support/suction-regulator-technical-manuals.php>

Video Tips and Techniques for use and repair can be found at:
<http://www.boehringerlabs.com/support/video/product-videos.php>
<http://www.youtube.com/boehringerlabsllc>

Symptom	Probable Cause	Solution
Instrument fails to provide suction at the patient port.	The supply or patient fittings are clogged	Replace or clean the fittings
Gauge doesn't respond to changes in suction (via control valve or adjustment knob)	Gauge diaphragm is improperly sealed on the gauge piston and/or view tube	Disassemble gauge and check the position of the gauge diaphragm.
Gauge piston is discolored	Material has entered the inside of the gauge	Instrument is contaminated. Disassemble and clean the instrument.
Gauge responds slowly to changes in suction	The small hole in the top of the View Tube may be plugged.	Using a small diameter probe, pierce the hole to clear the obstruction.
Instrument will not shut off or exhibits high droop	Dried fluids may have cut the quad ring seal.	Replace the quad ring (5) and Test the unit as per above procedure.
Instrument fails to regulate suction	Piston/Stem surface is binding with foreign matter	Disassemble and clean the instrument.
Erratic gauge movement resulting from regulator adjustment	Gauge is not sealed	Make sure retaining ring (17) is seated in groove on the gauge body and there is no end play in the view tube (19).

IMPORTANT: Always test the reassembled unit after each maintenance procedure. See the Test section above for exact test procedure.

Warranty and Repair

Boehringer Laboratories, LLC guarantees all 3700 Series LONG LIFE Suction Regulators for TWELVE years. Boehringer Laboratories, LLC will also warrant all fittings purchased from and installed by Boehringer Laboratories, LLC for the same warranty period as the suction regulator on which they were originally installed.

Boehringer Laboratories, LLC warrants to the original purchaser, new suction regulators purchased directly from Boehringer Laboratories, LLC or from an authorized dealer or representative. This warranty guarantees the suction regulators to be free from functional defects in materials and workmanship. We also guarantee that our suction regulators will meet our published specifications.

All regulators returned for repair shall be clean and free from contamination prior to shipment to Boehringer Laboratories. This requirement is for the safety of our employees as well as to comply with Federal Law prohibiting the shipment of unmarked biohazard materials. If units are returned contaminated, a cleaning charge may result.

A service charge may be assessed on any unit returned that shows evidence of gross abuse.

Boehringer Laboratories, LLC is the only authorized warranty service center for our suction regulators. Any repair service requesting a return authorization for repair will be asked to provide the name and location of the original equipment purchaser. If this information cannot be provided, the repair is not covered under warranty and will be a chargeable repair.

This warranty excludes acts of God, fire, flood and acts of war, terror or insurrection.

This warranty is not transferable from the original purchaser.

Boehringer Laboratories' sole and exclusive remedy under this warranty is limited to repairing and/or replacing the suction regulator. There are no other express or implied warranties beyond these warranties set forth above.

At Boehringer Laboratories, we are committed to lowering your suction regulator costs of operation!



All repairs will be shipped back within five days of receipt of purchase order authorization.

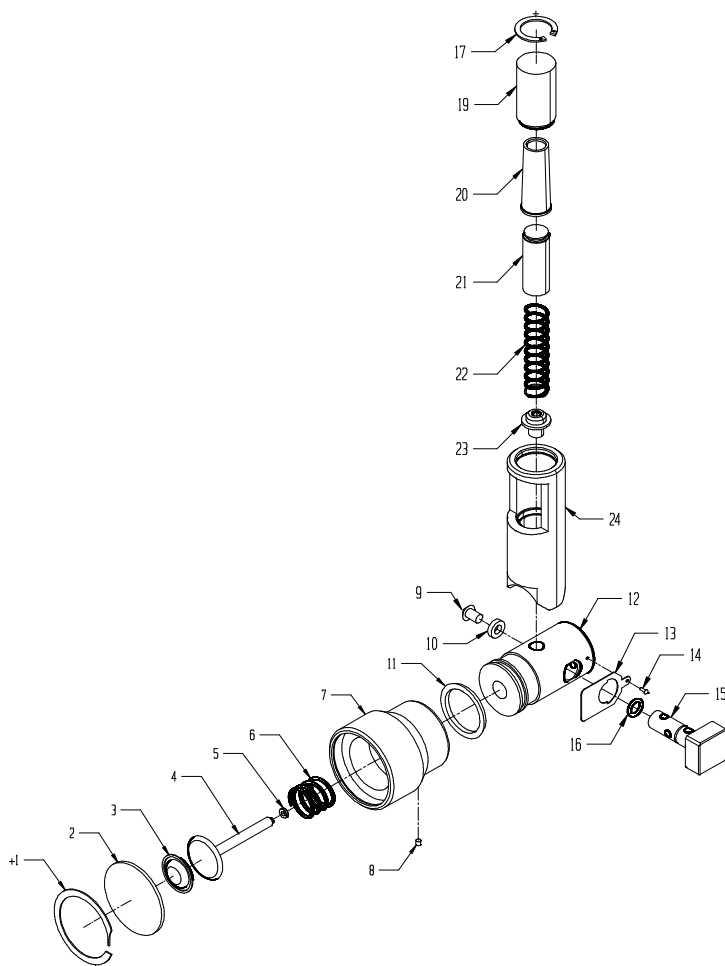
For quality factory service, call 800-642-4945 or 610-278-0900 for your return authorization. Ship returns to:

**Boehringer Laboratories, LLC
Repair Department
300 Thoms Dr.
Phoenixville, PA 19460**

New Products

We are continually striving to reach higher and higher standards of quality. We value your comments and input on our suction regulators. If you are pleased with this instrument, please find out more about Boehringer Laboratories' complete line of suction controls.

FIGURE 1 – Models 3708, 3718, 3748



<u>No.</u>	<u>P/N</u>	<u>Description</u>	<u>No.</u>	<u>P/N</u>	<u>Description</u>
1	33408	Lens Cap Retaining Ring, MRI	12	1458HC	Reg Body ¹ , Models 3708
2	33916	Lens Cap Disc, Model 3708	13	1462	Thumb Spring
2	33909	Lens Cap Backing, Model 3708	14	1480	Thumb Spring Retaining Screw
3	1466	Regulating Diaphragm	15	1453HC	Control Valve ¹
4	33411	Piston/Stem Assembly, MRI	16	353	Control Valve O-Ring
5	1461	Quad Ring	17	33409	Gauge Retaining Ring, MRI
6	33403	Spring, 200 mm Hg, MRI	18		Not Used
7	1871	Diaphragm Housing Ass'y	19	33040	Gauge View Tube ²
8	1479	Lock Screw	20	33042	Gauge Diaphragm
9	1468	Control Valve Retaining Screw	21	33036HS	Gauge Piston
10	1454	Control Valve Retaining Washer	22	33406	Gauge Spring, 200 mm Hg, MRI
11	1484	U-cup	23	33043	Fastener
			24	33035AN	Gauge Body with Label, 200 mm Hg

1. The Reg Body and Control Valve are factory matched. Please call for details on replacement.

2. For lot numbers before 01G, only the View Tube is needed to replace an earlier View Tube and View Tube

ACCESSORIES



Integral Trap Bottle – Model 9100

This device will protect your regulators and suction system from fluid overflow. The bottle provides a 60 ml backup overflow volume with shut-off capability provided by a precision float mechanism.

Specifications – All Models

- Inlet and outlet fittings: 1/8 NPT
- Gauge accuracy $\pm 5\%$ FSO
- Regulation Accuracy: $\pm 10\%$ F.S. from full flow to zero flow with 14 FR catheter attached.
- Leak rate in OFF position: less than 1 cc/min
- Free Air Flow: Greater than 38 LPM with regulator set to 100 mmHg at standard JCAHO supply (305mmHg @ 180 SCFH) and a typical collection circuit with a 14 Fr. catheter.
- Materials: polycarbonate, hard-anodized aluminum, stainless steel, Buna rubber, silicone, acetal copolymer, Phosphor Bronze.

Model	Regulation Range	User Selectable Modes	Wt. (lb)*	H x W x D (in)
3708	20-200 mm Hg	Off, Regulated Control, Line (source vacuum)	1.35	5 $\frac{3}{4}$ x 2 $\frac{1}{2}$ x 4

*Regulator weights are without fittings.

Operating and Storage Limits – All Models

We recommend that Boehringer Suction regulators be operated and stored at controlled conditions that typically reflect the medical facility environment.



**SETTING THE STANDARD
FOR RELIABILITY**

Boehringer Laboratories, LLC • 300 Thoms Dr. • Phoenixville, PA 19460
800-642-4945 or 610-278-0900

fax: 610-278-0907

www.boehringerlabs.com or www.autovac.com

email: info@boehringerlabs.com

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CC-252 - Updated maintenance requirements to reflect AAMI/ANSI EQ56 and EQ89 standards on page 5

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