

Hospital Suction Regulator and Inlet Performance Assessment

Services provided by

BOEHRINGER LABORATORIES, LLC
300 Thoms Drive, Phoenixville, PA 19460

Boehringer Suction Capability Assessment

Factory-trained professionals will be sent to your hospital to:

- Assess the compliance of your wall suction inlets to the NFPA 99 standard and recommend needed service.
- Determine the basic functional operation of your medical suction equipment. Many clinicians incorrectly assume that just because suction can be felt or heard the equipment is fully operational.* Twenty eight adverse events, including patient deaths, have been directly attributable to suction equipment failure.**
- Recommend appropriate clinical deployment of suction equipment in keeping with current professional practice guidelines to maximize your capital investment.
- Deliver multiple final report copies for dissemination to key stakeholders.

* Review of the FDA MAUDE (Manufacturer and User Facility Device Experience Database) from 1992 through 2011.

** "Setting safe and effective suction pressure: the effect of using a manometer in the suction circuit" Intensive Care Med (2000) 26: 15-19

Hospital Suction Regulator Performance Assessment For



Performed by:

Lauren Bentley MSBME
Boehringer Laboratories, LLC

(610) 278-0900

February 13-15, 2011

Purpose

This survey is designed to provide a detailed assessment by department of vacuum outlet and suction regulator performance. The assessment will highlight areas that fall short of performance specifications. The goal of such an assessment is to provide a blueprint for improvement in order to ensure that there is clinically appropriate equipment in each patient care area.

Executive Summary

In the [REDACTED] Medical Center, 612 of 725 suction regulators were tested for function and accuracy. Also, wall outlets in each department were evaluated for adequate static pressure and flow. At the conclusion of testing, 239 suction regulators were found to fall below stated performance criteria. Additionally, 47 wall outlets should be inspected either because of poor flow or potential obstruction. A summary of the regulator performance as well as the replacement recommendations are outlined below for each department. The regulators that are broken or tested outside specification are marked with an * in the attached spreadsheet.

Performance Criteria

Wall Outlet (*NFPA 99 Standard-NFPA 99 5.1.12.3.10.4*)

- Minimal Static Pressure is 20 inHg
- Minimal Flow requirement is 60% of code flow = 51 L/M

Suction Regulator

- Gauge accuracy must be $\pm 10\%$ of set point (100mmHg) (*ISO 10079-3:1999 6.6.6*)
- Flow must be greater than or equal to 20 L/M (*ISO 10079-3:1999 8.4.1*)
- There was no Pass/Fail mark for suction regulator spike.
 - Boehringer Laboratories cites their spike tolerance at + 10mmHg (*Boehringer 3800 Series IFU*)
 - Ohio Medical references +30mmHg as an acceptable level (*RT Magazine, February 2008 Issue, Article: Enhancing the Safety of Medical Suction through Innovative Technology. Patricia Carroll, RN, BC, CEN, RRT. MS*)
 - According to the AACN and AARC guidelines, 150mmHg is the highest level of suction that can be applied to an adult patient; therefore, when a spike test is performed at 100mmHg, a spike of 50mmHg would be the highest allowable by AACN/AARC standards for an adult regulator. In each department summary the number of regulators that exceeded each referenced performance standard are listed. (*AARC Clinical Practice Guideline. Nasotracheal Suctioning-2004 Revision & Update*)

Department Test Summary

Operating Room

Number of Rooms: 21

Number of rooms inspected: 21

Number of regulators identified: 9

Number of regulators tested: 6

Assessment Results:

- 2 intermittent suction regulators were found in the OR. These types of regulators are not needed in this patient care area.
- 1 surgical regulator was broken and would not turn on.
- Most vacuum outlets were directly connected to suction canisters. It is not a requirement to have a suction regulator on each outlet; however, there is a potential for suction canister implosion if static pressure >600mmHg is applied. If canister implosions are occurring, surgical hi-flow regulators (Model 3840) should be considered for this care area.
- Not all anesthesia workstations were inspected but at least one continuous suction regulator is required for airway maintenance on each cart.
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 3 units
 - >50mmHg 0 units

Total Regulators Needed:

- 2 Model 3800
- 1 Model 3840

Cystoscopy

Number of Rooms: 2

Number of rooms inspected: 2

Number of regulators identified: 0

Number of regulators tested: 0

Assessment Results: No regulators found

- There were no outlets that did not meet specification

Total Regulators Needed: See OR assessment results above to determine if there is a need for regulators

Interventional Radiology

Number of Rooms: 5

Number of rooms inspected: 5

Number of regulators identified: 7

Number of regulators tested: 7

Assessment Results:

- 4 regulators were broken or tested out of specification
- There were no outlets that did not meet specification

- Observed spike
 - 10mmHg-30mmHg 3 units
 - 30mmHg-50mmHg 1 units
 - >50mmHg 1 units

Total Regulators Needed: It is recommended to have at least one continuous suction regulator per patient bed.

- 4 Model 3800

Pre-Op

Number of Rooms: 20

Number of rooms inspected: 4

Number of regulators identified: 12

Number of regulators tested: 12

Assessment Results:

- 4 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 6 units
 - >50mmHg 3 units

Total Regulators Needed: It is recommended to have at least one continuous suction regulator per patient bed.

- No additional regulators are needed at this time.

PACU

Number of Rooms: 25

Number of rooms inspected: 9

Number of regulators identified: 24

Number of regulators tested: 24

Assessment Results:

- 5 regulator were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 11 units
 - >50mmHg 8 units

Total Regulators Needed: It is recommended to have one continuous and one continuous / intermittent regulator per patient bed.

- No additional regulators need to be acquired at this time.

Tower Operating Room

Number of Rooms: 10

Number of rooms inspected: 10

Number of regulators identified: 1

Number of regulators tested: 1

Assessment Results:

- One suction regulator was broken and would only deliver full Line vacuum.
- There were 32 outlets that had leaks. These outlets need to be inspected, cleaner or replaced if necessary.
- Most vacuum outlets were directly connected to suction canisters. It is not a requirement to have a suction regulator on each outlet; however, there is a potential for suction canister implosion if static pressure >600mmHg is applied. If canister implosions are occurring, surgical hi-flow regulators (Model 3840) should be considered for this care area.
- Not all anesthesia workstations were inspected but at least one continuous suction regulator is required for airway maintenance on each cart.

Total Regulators Needed:

- 1 model 3800

██████████ *Tower PACU*

Number of Rooms: 11

Number of rooms inspected: 11

Number of regulators identified: 22

Number of regulators tested: 22

Assessment Results:

- 10 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 7 units
 - 30mmHg-50mmHg 5 units
 - >50mmHg 4 units

Total Regulators Needed: Two continuous regulators are recommended per patient bed.

- 10 model 3800

██████████ *Tower Isolation*

Number of Rooms: 2

Number of rooms inspected: 2

Number of regulators identified: 4

Number of regulators tested: 4

Assessment Results:

- 1 regulator was broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 1 units
 - 30mmHg-50mmHg 2 units
 - >50mmHg 0 units

Total Regulators Needed: It is recommended to have two continuous regulators per patient bed.

- 1 model 3800

Tower Pre-Op

Number of Rooms: 8

Number of rooms inspected: 8

Number of regulators identified: 11

Number of regulators tested: 11

Assessment Results:

- 5 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 3 units
 - >50mmHg 3 units

Total Regulators Needed: It is recommended to have at least one continuous suction regulator per patient bed.

- 2 model 3800

Tower 6 West

Number of Rooms: 37

Number of rooms inspected: 18

Number of regulators identified: 28

Number of regulators tested: 25

Assessment Results:

- 14 regulators were broken or tested out of specification. There was a bin of broken regulators located in a supply closet. These regulators should be removed from service.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 3 units
 - 30mmHg-50mmHg 8 units
 - >50mmHg 12 units

Total Regulators Needed: It is recommended to have at least one continuous / intermittent suction regulator per patient bed.

- 26 model 3804

-Peds

Number of Rooms: 9

Number of rooms inspected: 7

Number of regulators identified: 7

Number of regulators tested: 3

Assessment Results:

- 1 regulator was broken or tested out of specification. There were 5 adult suction regulators found in this department.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 0 units
 - 30mmHg-50mmHg 1 unit
 - >50mmHg 2 units

Total Regulators Needed: It is recommended to have at least one continuous / intermittent suction regulator per patient bed. This department should be reviewed to see if pediatric regulators should be in place.

- 1 model 3804 or 3814 (depending on if a pediatric regulator is warranted)

██████ -Peds

Number of Rooms: 19

Number of rooms inspected: 12

Number of regulators identified: 18

Number of regulators tested: 10

Assessment Results:

- 2 regulators were broken or tested out of specification.
- 2 regulators were broken and being stored in a utility room. These should be removed from service.
- One outlet had no flow. This outlet should be inspected and replaced if necessary.
 - 10mmHg-30mmHg 3 units
 - 30mmHg-50mmHg 2 units
 - >50mmHg 3 units

Total Regulators Needed: It is recommended to have at least one continuous / intermittent suction regulator per patient bed. This department should be reviewed to see if pediatric regulators should be in place

- 2 model 3804 or 3814 (depending on if a pediatric regulator is warranted)

██████████ Tower AICU

Number of Rooms: 6

Number of rooms inspected: 5

Number of regulators identified: 11

Number of regulators tested: 10

Assessment Results:

- 5 regulators were broken or tested out of specification.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 0 units
 - 30mmHg-50mmHg 3 units
 - >50mmHg 5 units

Total Regulators Needed: It is recommended to have 1 continuous / intermittent and 2 continuous suction regulator per patient bed.

- 5 model 3800

██████████ Tower 5 West

Number of Rooms: 45

Number of rooms inspected: 23

Number of regulators identified: 38

Number of regulators tested: 34

Assessment Results:

- 14 regulators were broken or tested out of specification.
- 9 outlets in the department were at or below the minimally acceptable level. These outlets and perhaps the vacuum system for this department should be checked.
- Observed spike
 - 10mmHg-30mmHg 10 units
 - 30mmHg-50mmHg 9 units
 - >50mmHg 9 units

Total Regulators Needed: It is recommended to have at least one continuous and one continuous / intermittent suction regulator per patient bed.

- 18 model 3804
- 41 model 3800

██████████ Tower Oncology/Hematology Special Care Unit

Number of Rooms: 30

Number of rooms inspected: 27

Number of regulators identified: 49

Number of regulators tested: 48

Assessment Results:

- 21 regulators were broken or tested out of specification.
- 1 outlet had a leak and should be checked or replaced if necessary.
- Observed spike
 - 10mmHg-30mmHg 6 units
 - 30mmHg-50mmHg 18 units
 - >50mmHg 15 units

Total Regulators Needed: It is recommended to have at least one continuous and one continuous / intermittent suction regulator per patient bed.

- 7 model 3804
- 27 model 3800

██████████ Tower LDRP

Number of Rooms: 8+nursery

Number of rooms inspected: 8 + nursery

Number of regulators identified: 15

Number of regulators tested: 15

Assessment Results:

- 3 regulators were broken or tested out of specification.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 6 units
 - 30mmHg-50mmHg 4 units
 - >50mmHg 4 units

Total Regulators Needed: It is recommended to have at least one continuous suction regulator per patient bed and one pediatric continuous regulator on each warming table if not already equipped.

4 West

Number of Rooms: 21

Number of rooms inspected: 21

Number of regulators identified: 18

Number of regulators tested: 18

Assessment Results:

- 3 regulators were broken or tested out of specification.
- 3 outlets tested below specification or were broken.
- There were 7 rooms without regulators
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 5 units
 - >50mmHg 6 units

Total Regulators Needed: It is recommended to have at least one continuous/intermittent suction regulator per patient bed.

- 10 model 3800

Patient Care Center

Number of Rooms: 23

Number of rooms inspected: 18

Number of regulators identified: 9

Number of regulators tested: 8

Assessment Results:

- One regulator was broken or tested out of specification.
- One outlet showed no flow and should be checked and replaced if necessary.
- 10 rooms did not have a suction regulator
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 2 units
 - >50mmHg 3 units

Total Regulators Needed: It is recommended to have 1 continuous / intermittent suction regulator per patient bed.

- If regulators are replaced in other, more critical, departments within the hospital, then those replacements can be put in this department.

Endoscopy Procedure

Number of Rooms: 4

Number of rooms inspected: 4

Number of regulators identified: 8

Number of regulators tested: 8

Assessment Results:

- 7 regulators were broken or tested out of specification.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 0 units
 - 30mmHg-50mmHg 1 unit
 - >50mmHg 0 units

Total Regulators Needed: It is recommended to have one continuous and one high vacuum continuous suction regulator per patient bed.

- 3 model 3800
- 4 model 3840

Endoscopy Recovery

Number of Rooms: 12

Number of rooms inspected: 11

Number of regulators identified: 8

Number of regulators tested: 8

Assessment Results:

- 3 regulators were broken or tested out of specification.
- 3 rooms did not have any regulators
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 7 units
 - 30mmHg-50mmHg 1 unit
 - >50mmHg 0 units

Total Regulators Needed: It is recommended to have one continuous suction regulator per patient bed.

- 6 model 3800

NICU

Number of rooms: 36

Number of rooms inspected: 27

Number of regulators identified: 46

Number of regulators tested: 40

Assessment Results:

- 11 regulators were broken or tested out of specification
- There were no neonatal regulators in this department. There is a potential to oversuction neonates with the currently installed equipment. (Ref. AARC and AACN Guidelines)
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 19 units
 - 30mmHg-50mmHg 5 units
 - >50mmHg 10 units

Total Regulators Needed: It is recommended to have 2 continuous and 1 continuous / intermittent suction regulators per patient bed.

- 72 model 3810
- 36 model 3814

Cardiac Progressive Care Unit

Number of rooms: 49

Number of rooms inspected: 45

Number of regulators identified: 45

Number of regulators tested: 36

Assessment Results:

- 11 regulators were broken or tested out of specification
- 8 rooms did not have a suction regulator
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 7 units
 - 30mmHg-50mmHg 6 units
 - >50mmHg 22 units

Total Regulators Needed: It is recommended to have 1 continuous and 1 continuous / intermittent suction regulator per patient bed.

- 15 model 3804
- 49 model 3800

Emergency Room

Number of rooms: 47

Number of rooms inspected: 42

Number of regulators identified: 44

Number of regulators tested: 42

Assessment Results:

- 11 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 6 units
 - 30mmHg-50mmHg 16 units

- >50mmHg 15 units

Total Regulators Needed: It is recommended to have one continuous suction regulator per patient bed.

- 4 model 3810
- 11 model 3800

North

Number of rooms: 40

Number of rooms inspected: 32

Number of regulators identified: 34

Number of regulators tested: 32

Assessment Results:

- 14 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 9 units
 - 30mmHg-50mmHg 11 units
 - >50mmHg 6 units

Total Regulators Needed: It is recommended to have one continuous / intermittent suction regulator per patient bed.

- 22 model 3804

Neuro

Number of rooms: 48

Number of rooms inspected: 47

Number of regulators identified: 58

Number of regulators tested: 47

Assessment Results:

- 20 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 15 units
 - 30mmHg-50mmHg 15 units
 - >50mmHg 15 units

Total Regulators Needed: It is recommended to have one continuous and one continuous / intermittent suction regulator per patient bed.

- 14 model 3804
- 48 model 3800

Burn Unit

Number of rooms: 8

Number of rooms inspected: 3

Number of regulators identified: 6

Number of regulators tested: 6

Assessment Results:

- 3 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 0 units
 - 30mmHg-50mmHg 3 units
 - 50mmHg 2 units

Total Regulators Needed: It is recommended to have one continuous and one continuous / intermittent suction regulator per patient bed.

- 3 model 3800

Hyperbaric Oxygen

Number of rooms: 4

Number of rooms inspected: 2

Number of regulators identified: 4

Number of regulators tested: 4

Assessment Results:

- 3 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 2 units
 - 30mmHg-50mmHg 1 units
 - >50mmHg 1 units

Total Regulators Needed: It is recommended to have one continuous / intermittent suction regulator per patient bed.

- 3 model 3804

ICU

Number of rooms: 24

Number of rooms inspected: 22

Number of regulators identified: 50

Number of regulators tested: 37

Assessment Results:

- 26 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 14 units
 - 30mmHg-50mmHg 9 units
 - >50mmHg 10 units

Total Regulators Needed: It is recommended to have one continuous / intermittent and two continuous suction regulators per patient bed.

- 48 model 3800

Telemetry

Number of rooms: 32

Number of rooms inspected: 22

Number of regulators identified: 77

Number of regulators tested: 54

Assessment Results:

- 15 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 8 units
 - 30mmHg-50mmHg 29 units
 - >50mmHg 8 units

Total Regulators Needed: It is recommended to have one continuous / intermittent and one continuous suction regulator per patient bed.

- No additional regulators are needed at this time

Labor and Delivery

Number of rooms: 13+nursery

Number of rooms inspected: 13 + nursery

Number of regulators identified: 15

Number of regulators tested: 15

Assessment Results:

- 4 regulators were broken or tested out of specification
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 3 units
 - 30mmHg-30mmHg 4 units
 - >50mmHg 6 units

Total Regulators Needed: It is recommended to have at least one continuous suction regulator per patient bed and one pediatric continuous regulator on each warming table if not already equipped.

Cath Lab

Number of rooms: 4

Number of rooms inspected: 2

Number of regulators identified: 3

Number of regulators tested: 3

Assessment Results:

- 2 regulators were broken or tested out of specification.

- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 1 unit
 - 30mmHg-50mmHg 1 unit
 - >50mmHg 1 unit

Total Regulators Needed: It is recommended to have two continuous suction regulators per patient bed.

- 8 model 3800

Solid Organ Transplant Unit

Number of rooms: 48

Number of rooms inspected: 40

Number of regulators identified: 33

Number of regulators tested: 31

Assessment Results:

- 16 regulators were broken or tested out of specification.
- There were no outlets that did not meet specification
- Observed spike
 - 10mmHg-30mmHg 18 units
 - 30mmHg-50mmHg 5 units
 - >50mmHg 3 units

Total Regulators Needed: It is recommended to have one continuous and one continuous / intermittent suction regulator per patient bed.

- 48 model 3800
- 20 model 3804

Recommendations Summary

This survey of suction regulator performance for [REDACTED] Medical Center indicates that there is a potential for improvement with the current class of regulators in the facility. Based upon the sampling of the current equipment and the overall regulator census, a replacement recommendation was made for each department. The current need for suction regulators is summarized below.

Adult Continuous Suction Regulator Model 3800: 327 units

Adult Continuous / Intermittent Suction Regulator Model 3804: 128 units

Neonatal Continuous Suction Regulator Model 3810: 76 units

Neonatal Continuous / Intermittent Suction Regulator Model 3814: 36 units

High Vacuum Surgical Suction Regulator Model 3840: 5 units

Additionally, wall outlets were assessed for flow and static pressure. Based upon the sampled outlets, it appears that the [REDACTED] OR and 5th Floor West should be inspected for flow and possible occlusion.

BOEHRINGER®

Boehringer Laboratories, LLC

300 Thoms Drive ■ Phoenixville, PA 19460 ■ 800.642.4945 ■ www.boehringerlabs.com