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SERVICE DOCUMENT FOR RESEARCH INSTITUTIONS 12-1-16

Thank you very much for contacting me with respect to your need to have your inhalant anesthesia system serviced. I sincerely appreciate your interest in our products and services.

There is always some confusion with respect to what needs to be done—or what is done—at a “service” of inhalant anesthesia systems; and what the time interval between servicing should be. In Human Medicine, there are strict rules governing the “service” of inhalant anesthesia systems. However, in Veterinary Medicine, there is no regulatory body, nor agency which oversees and/or makes written recommendations with respect to servicing inhalant anesthesia systems--having said that, we do get some verbal recommendations from AAALAC. In most institutions we service, the AAALAC inspection team generally recommends that the inhalant anesthesia systems be “serviced” once a year. The IACUC group at most facilities we service usually follows the AAALAC verbal recommendations. Therefore, we are on campus once a year at most facilities to do the servicing. In addition, the ACVA (American College of Veterinary Anesthesiologists) is rather vague in their recommendations as well. From the ACVA website I will quote:

1. “Appropriate checkout methods and routine maintenance for such equipment should be standard operating procedures for veterinary facilities that use inhalant anesthetics.”
2. “The routine maintenance procedures for anesthetic equipment are usually explained in the operations manuals. Many anesthesia textbooks include guidelines for checkout of machines, breathing systems, ventilators, and scavenging systems. The specifics of these evaluations are too extensive for this report. However, each piece of equipment involved in the delivery of inhalant anesthetics should be evaluated regularly to assure its function and integrity.”

Our recommendation for a time interval, since we manufacture inhalant anesthesia systems, is once a year. But please understand that there are issues which may impact the time interval—especially the servicing of the anesthetic vaporizers.

What is even more confusing, is that most of the veterinary “service” companies seem to have different notions as to what a thorough service of the system is. We see everything from an agency doing the 10 second test and calling it “good,” to what we try to accomplish—which is a very thorough inspection of not only the components of the anesthesia machine, but ancillary systems as well. For example, in addition to the basic machine, we include the inspection of the carrier gas system, appliances used to deliver the inhalant anesthetic (non-rebreathing systems, induction chambers, etc.), and the waste gas management system.

Our basic service of the inhalant anesthesia system includes the following:

1. Visual inspection of vaporizer for defects

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- A. Broken Dial Stop
 - B. Loose drain / drain seal
 - C. Loose cap / cap seal
 - D. Cleaning of main bearing plates if required
 - E. "Feel" of vaporizer
2. Leak test of vaporizer
 - A. 100 mmHg in closed position
 - B. 200 mmHg in open position

PLEASE NOTE THAT THE BASIC SERVICE OF THE INHALANT ANESTHESIA SYSTEM DOES NOT INCLUDED PROFESSIONAL CLEANING AND CALIBRATION OF THE VAPORIZER (SEE BELOW)

3. Output test of vaporizer
 - A. Tested with Riken Analyzer to see if at each dial setting the output is within manufacturer's allowed tolerances.
4. Visual inspection of all components of system including induction chambers, non-rebreathing systems, rebreathing systems, flowmeters, tubing, oxygen flush, appliances such as Universal Control Arms, ventilators, gaskets seals, etc.
5. Leak test High Pressure System
6. Leak test Low Pressure System
7. Replace silicone conductive tubing (if necessary)
8. Service stickers installed on the machine and the vaporizer indicating that the devices are operating within manufacturer's tolerances
9. Written reports with respect to the status of the devices, including a Vaporizer Efficacy Report

The cost for the basic service varies, but is approximately \$200.00 plus parts (if any) and trip charge to the facility.

And, there are really two main components to the inhalant anesthesia system: 1) the vaporizer, and, 2) everything else. This may appear as an oversimplification, but is meant to show that vaporizers have special issues independent of the rest of the system.

The vaporizer is the heart of the device. In recent years, it has been demonstrated that the Isoflurane vaporizers do not need to be "Professionally Cleaned and Calibrated" every year. There are many reasons for this, but the primary reason is because Isoflurane is a relatively "clean" inhalant anesthetic, and it does not "gum up" vaporizers like some of the earlier inhalant anesthetics.

The Professional Cleaning and Calibration of vaporizers is not done in the field. The process requires sophisticated instrumentation; and must be performed under strict temperature and humidity conditions. The vaporizer is completely disassembled, wicks and seals are replaced, and the internal components are cleaned with a special solvent. The vaporizer is then partially reassembled, calibrated, and tested for proper operation. After complete assembly, the vaporizer is leak tested. The cost to have this done is

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approximately \$450.00 (It depends upon the style of vaporizer and if any ancillary parts need to be replaced).

The old recommendation for Professional Cleaning and Calibration of anesthetic vaporizers used to be at 1 year intervals. However, many of the current manufacturers of anesthetic vaporizers are recommending 3 years and beyond. Even in human medicine, some manufacturers are recommending a longer time interval than 1 year for Isoflurane vaporizers. However, most of the Service Centers for anesthetic vaporizers are stuck in the once a year mode. When I asked one of the national service centers why their recommendation was still one year, the reply was that they were in the business of servicing vaporizers—why should they turn away business? I have a gut feeling that the reason that most service centers still have their service stickers at one year intervals is because of previously stated reason; and, perhaps, liability issues (which originally stem from human medicine).

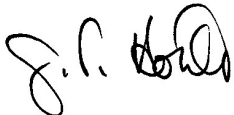
Regardless, our recommendation (unless the facility is involved in GLP studies) for Professional Cleaning and Calibration of Isoflurane and Sevoflurane vaporizers is within a 3 year window. (We guarantee all our new and reconditioned vaporizers for 3 years—parts and labor). With Halothane, because of the preservative Thymol which gums up the vaporizers, we still recommend yearly cleaning and calibration.

At our once a year service when we do our leak test and output test of the vaporizer, and if both tests are “good,” depending upon how long it has been since the last Professional Cleaning and Calibration, we will make our recommendation to you. To restate, if we find that the vaporizer is operating properly, we are comfortable with a Professional Cleaning and Calibration somewhere within a 3 year window. But we often rely on the comfort level of our customers.

Also, if you would like to schedule service, please let me know.

I hope that this has helped to answer the questions of service of inhalant anesthesia systems. Please let me know if you have any additional questions and/or concerns.

Best regards,



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