AMERICAN SOCIETY OF ANESTHESIOLOGISTS
GUIDELINES FOR DETERMINING ANESTHESIA MACHINE OBSOLESCENCE

*This document has been developed by the ASA Committee on Equipment and Facilities, and has not been reviewed or approved as a practice parameter or policy statement by the ASA House of Delegates.**

The following guidelines have been developed to assist anesthesia providers and other healthcare personnel, administrators and regulatory bodies in determining when an anesthesia machine is obsolete. Anesthesia equipment can become obsolete if essential components wear out and cannot be replaced. It may also become obsolete as a result of changes in medical practices, changes in the training and experience of anesthesia providers and/or development of new safety features.

An anesthesia machine should not be considered obsolete solely because it has reached an arbitrary age. Furthermore, a machine should not be expected to meet all of the performance and safety requirements specified in United States or international equipment standards published after the machine was manufactured. It is the responsibility of the anesthesia provider to determine if a machine's failure to meet newer standards represents a sufficient threat to patient safety to render the machine obsolete.

The ASA Standards for Basic Anesthetic Monitoring (1) apply to all anesthesia care. The equipment necessary to accomplish this monitoring may be integral to the anesthesia machine or separate from it. The criteria for defining obsolescence that are described in this document relate only to the gas and vapor delivery portion of the machine. Integral monitors (e.g., electrocardiograph, oxygen monitor, blood pressure monitor, pulse oximeter, carbon dioxide monitor) should be considered separately and are not addressed in these guidelines.

These guidelines apply only to existing machines and are not intended to unduly restrict the design of machines in the future. It is recognized that future machines may incorporate different safety mechanisms than those in use today to accomplish the same goals.

Absolute Criteria

An anesthesia machine shall be considered to be obsolete if any of the following criteria apply.

I. Lack of essential safety features

A. Minimum oxygen ratio device (O_2/N_2O proportioning system) on a machine that can deliver nitrous oxide

Rationale: Hypoxia has been a major cause of patient death or severe brain injury during anesthesia. An anesthesia machine that cannot deliver oxygen must automatically be rendered incapable of delivering nitrous oxide as well.

B. Oxygen failure safety ("fail-safe") device

Rationale: One of the most serious mishaps that occurred with anesthesia machines in the past was depletion of the oxygen supply (usually from an exhausted cylinder) without the user being aware. The result was delivery of a hypoxic mixture. This mishap can occur even with piped gas supplies. An oxygen failure safety device prevents this hazard by stopping the flow of nitrous oxide when there is a loss of oxygen supply pressure.

C. Oxygen supply pressure failure alarm

Rationale: While the supply of oxygen from a pipeline system or cylinders is usually very reliable, interruptions in that supply can occur. Given the critical nature of oxygen delivery, the operator of an anesthesia machine should be made aware immediately of the failure of the central oxygen supply so that appropriate remedial measures (e.g., opening a cylinder, reducing the use of oxygen, obtaining additional cylinders) can be taken.

D. Vaporizer interlock device

Note 1: This does not apply to an anesthesia machine that allows only one vaporizer to be mounted at a time.

Note 2: It may be possible to add a vaporizer interlock device to a machine.

Rationale: Turning on two vaporizers at the same time can result in dangerously high anesthetic vapor concentrations being delivered and contamination of the downstream vaporizer.

E. Pin Index Safety System

Rationale: This system is needed to prevent mounting a cylinder on an incorrect yoke.

F. Non-interchangeable, gas-specific (e.g., Diameter Index Safety System (DISS)) connectors on the gas pipeline inlets

Rationale: These connectors are needed to prevent attachment of an incorrect gas delivery hose to the machine.

II. Presence of unacceptable features

A. Measured flow (flowmeter-controlled) vaporizers (e.g., Copper Kettle, Vernitrol)

Rationale: These vaporizers have not been manufactured for some time and servicing for them is no longer available. Many anesthesia providers are not sufficiently familiar with them to use them correctly, which may result in delivery of inadequately low or dangerously high anesthetic vapor concentrations. Some of these vaporizers lack the side-fill feature needed to prevent accidental overfilling and spilling of liquid anesthetic into the breathing system.

B. More than one flow control knob for a single gas delivered to the common gas outlet of the machine

Note: This does not include the flow control knob for an auxiliary oxygen flowmeter.

Rationale: Having more than one flow control knob for a gas may result in an unintended high or low flow of gas being delivered. Parallel flowmeters may cause ambiguity since on all recently manufactured machines flowmeters are in series with one flow control knob for each gas delivered to the machine's common gas outlet.

C. Vaporizer with rotary concentration dial such that the anesthetic vapor concentration increases when the dial is turned clockwise.

Note: It may be possible to replace an unacceptable vaporizer without replacing the entire machine.

Rationale: All vaporizers manufactured in recent years are designed to deliver increased vapor concentration when the dial is turned counterclockwise. Uniformity in vaporizer controls will prevent errors and increase safety.

D. Connection(s) in scavenging system of the same (i.e., 15-mm or 22-mm) diameter as a breathing system connection

Note: It may be possible to replace an unacceptable scavenging connection without replacing the entire machine.

Rationale: Having 15- or 22-mm diameter connections in the scavenging system can result in incorrect connections between the breathing system and the scavenging system, potentially resulting in negative or high pressure in the breathing system. Current standards mandate 30-mm (preferred) or 19-mm connections in the scavenging system.

III. Adequate maintenance no longer possible

The manufacturer or certified service personnel will not or cannot service the machine with acceptable replacement parts so that it performs within the tolerances to which it was originally designed.

> Note 1: Although a manufacturer may declare that its own subsidiaries will no longer service, support or certify a particular machine, the essential core components of the machine may still be serviceable.
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> Note 2: Obtaining acceptable replacement parts can be a problem. In some cases it may be possible to obtain the parts from the party who supplied them to the machine manufacturer. Alternatively, such parts may be obtained from machines that have already been taken out of service.
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> Note 3: When a manufacturer declares that it will no longer provide support for a machine, responsibility is typically transferred to the user (healthcare facility) and/or the third party who services the machine.
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> Rationale: A machine that cannot be serviced or for which replacement parts are not available cannot be maintained according to the standards and specifications to which it was originally designed and is dangerous.

<u>Relative Criteria</u>

Consideration should be given to replacing an anesthesia machine if any of the following apply:

1. Lack of certain safety features

> A. Means to isolate the APL (adjustable pressure-limiting) valve during mechanical ventilation
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> Note: Isolation of the APL valve can be done in a number of ways (e.g., mechanically, electronically).
>
> Rationale: The APL valve is designed for use with manual, not mechanical, ventilation. If an APL valve is left open and is not isolated from the breathing system during mechanical ventilation, a portion of the inspired tidal volume may be lost.
>
> B. Oxygen flow control knob that is fluted and larger than the other flow control knobs

Rationale: Current standards mandate that the oxygen flow control knob be larger than other flow control knobs and fluted. Alterations to gas flows may be performed during low light conditions or when the anesthesia provider is not looking directly at the machine. Tactile identification of the oxygen flow control knob should reduce errors.

C. Oxygen flush control protected from accidental activation

Note: Protection can be either by placement or design of the control.

Rationale: Accidental activation of the oxygen flush can result in barotrauma.

D. Main On/Off switch for electrical power to integral monitors and alarms

Rationale: Current standards mandate that the main power switch, when turned on, enables integral monitors and alarms. Operators unfamiliar with older anesthesia machines may not appreciate that monitors and alarms are not automatically enabled and may neglect to turn on one or several of them if they are not activated by a single switch.

E. Anti-disconnection device at the fresh gas outlet

Rationale: Disconnection of the fresh gas inflow to the breathing system might lead to undesirable anesthetic or oxygen concentrations delivered to the patient, or create a significant leak in the breathing system with rapid loss of gas. Depending on the mode of ventilation (spontaneous or controlled) disconnection of the fresh gas hose may not be immediately apparent.

F. Airway pressure alarm (for detecting sustained positive pressure, negative pressure and high peak pressure)

Note: An alarm for detecting disconnections (low pressure alarm) is a criterion of the ASA Standards for Basic Anesthetic Monitoring.

Rationale: These pressure conditions represent an immediate threat to patient safety and need to be brought to the immediate attention of the anesthesia provider.

II. Problems with maintenance

The maintenance history indicates that problems with the machine (e.g., increasing frequency of service calls, machine frequently not available for use) are impacting clinical service in a manner that is unacceptable to the institution or which threatens patient safety.

Note: Maintenance records or logs should be kept for all anesthesia machines in clinical use and problems documented. These records should be reviewed regularly to determine what type of problems are occurring with each machine, how often they occur and their effect on the anesthesia practice.

III. Potential for human error

Differences between older and newer machines can be a source of confusion and error if certain features (e.g., automatic activation of monitors and alarms by a main On/Off Switch) are present on some machines but not on others or are in different locations on the machines.

Rationale: Having certain machine features in different locations on different machines can create confusion and increase the likelihood of operator error. Anesthesia providers more familiar with anesthesia machines manufactured recently may mistakenly expect that certain features are present on older machines and it may not be readily apparent that they are different. Standardization of anesthesia machines throughout an institution should be considered.

IV. Inability to meet practice needs

Examples:

A. The machine cannot accept vaporizers for newer potent inhaled volatile agents
Note: A vaporizer should never be placed downstream of the common gas outlet. This is a dangerous practice.

B. The machine cannot deliver fresh gas flows that are low enough for current anesthetic techniques.

C. The integral anesthesia ventilator is incapable of safely and effectively ventilating the lungs of the target patient population.

Rationale: New agents, techniques and/or ventilators may not be compatible with older anesthesia machines. If their use is considered to be necessary for optimal patient management, a new anesthesia machine should be obtained.

When it has been determined that a machine is obsolete it should not be placed somewhere in the facility where it might be used clinically (for example as an oxygen delivery device). A machine that has been determined to be obsolete should either be destroyed or donated to a worthy party (e.g., a developing country, zoo or laboratory). If the latter course is followed, it would be prudent to obtain legal advice about potential liability relating to the donation. Also it is prudent to ensure that the recipient possesses

the infrastructure (e.g., electrical power, medical gases), access to drugs and supplies (e.g., volatile anesthetics, circuits, replacement parts), technical expertise and training to safely use the machine.

> Rationale: Placing an obsolete machine where it might be used would involve many hazards. Many of the hazards noted above are related to the possible misuse of an older anesthesia machine by personnel unfamiliar with its idiosyncrasies and deviations from more modern machines. Placement of an obsolete anesthesia machine in a location where it would be used only infrequently during high-acuity situations, possibly by personnel without anesthesia training, can only magnify these risks. User expectations - that it is a "modern" machine with "modern" safety features - will still be present. The presence of an anesthesia machine in an atypical location may tempt personnel unfamiliar with the machine to modify it. Non-anesthesia personnel may avoid using it because they are not familiar with it.

The need to provide positive-pressure ventilation with oxygen in remote locations can be met by using an oxygen cylinder or flowmeter connected to a pipeline outlet and a non-rebreathing bag. This is inexpensive, easy to use and can easily be made available in remote locations.

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(1) Standards for Basic Anesthetic Monitoring Approved by House of Delegates and last amended on October 21, 1998. Available from the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge IL 60068-2573, www.ASAhq.org

** Variances from the recommendations contained in this document may be acceptable based on the judgment of the responsible anesthesiologist. The recommendations are designed to encourage quality patient care and safety in the workplace, but cannot guarantee a specific outcome. They are subject to revision from time to time as warranted by the evolution of technology and practice.*

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