

## Invited Editorial

# Impact of Device Standards on Perfusion Practice

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Most of us are busy doing the noble deeds of patient care and some of us can barely catch enough sleep to worry about device standards. When we put together all the components and make it into a system, we take it for granted that they will work efficiently, effectively, and safely for the duration of use for which it is intended. This fact is pretty amazing considering that various components in your system likely came from different manufacturers and have never been tested as a system. Only recently, the Association for Advancement of Medical Instrumentation (AAMI) and the International Organization for Standards (ISO) have started to make inroads to established system standards.

So why should a clinician be concerned about standards? More important, how would standards affect a clinician's application and practice? There are rhetorical questions a clinician should ask such as, "Do the manufacturers live up to their claims? Do their claims live up to the user's expectations? Do their claims live up to the safety standards intended to deliver quality care to the cardiac patient?" Also, "Do the testing methods described in device standards provide information pertinent to clinical practice?"

This communication focuses on the latter question.

AAMI and ISO are two major standards organizations responsible for authoring testing standards, quality management, sterilization, and labeling appropriately to assure safe use and optimal performance of the products used for the cardiac patient. AAMI is a national member of ISO. ISO writes international standards for the world. Both standards are referenced by the US Food and Drug Administration, and ISO standards are referenced by respective regulatory agencies around the world such as the German Institute for Standardization (DIN) and the

Korea Agency for Technology and Standards (KATS). In reality, most documents on perfusion devices were generated by working group four (WG-4) in AAMI and promoted and supported by ISO around the world. ISO and the US Food and Drug Administration (FDA) have taken more active roles recently. Representation of the organizations is well supported by AmSECT since 1980. A period of representation hiatus occurred from 1990 to 1995.

Because of the amount of resources required to reach consensus around the world, many of the standards are just scratching the surface of what is adequate for the practicing perfusionist. For example, the standard for an oxygenator designated as a "blood gas exchanger" is AAMI/ISO document 7199.

An important document that accompanies an oxygenator is the Directions for Use (DFU). Very important information provided for the user is the oxygenation performance at 2, 4, or 6 L flow per minute expressed in a graph format indicating total oxygen transfer. The test conditions in vitro (bench) are  $12 \pm 2$  g/dl of hemoglobin  $37^\circ\text{C}$  and venous oxygen saturation of  $65\% \pm 5\%$ . These are the AAMI/ISO-specified testing conditions. It is interesting that manufacturers compare the gas exchange performances of their oxygenators against competitors citing the data were collected under AAMI/ISO testing conditions. All oxygenators would have the same transfer performances if AAMI/ISO standards were strictly controlled. All oxygenators must be able to oxygenate desaturated blood (same inlet conditions) to 99% or 100% on a single pass at  $37^\circ\text{C}$ . Manufacturers reference the testing method in the AAMI/ISO 7199 document when submitting their data to the FDA for approval of a product.

However, there are differences in gas exchange performances of oxygenators. Maximum oxygen transfer varies from 400 cc per minute to >600 mL per minute relative to brands. If the inlet condition (venous saturation) is lower, differences in performance will be evident from brand to brand and even within the same brand.

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In the clinical world, other factors such as anesthesia level, hypothermia, hemoglobin, blood flow, and venous oxygen saturation will affect oxygenator performance and gas transfer. When the patient is stressed with low venous oxygen saturations in combination with marginal anesthesia, at the onset, oxygenators with higher performance capabilities will be able to maintain adequate  $pO_2$  levels without or little adjustment in the  $FiO_2$ . Compensation for a lower performance oxygenator is hypothermia with left-shifted P50 causing an increase in the venous oxygen saturation. In routine cases, the lower performance oxygenation capability will not be detected. Ultimately, the clinician should be looking at the maximum oxygen transfer of a device. For example, a low  $pO_2$  is not always an indication of device failure. If a device is rated at 400 cc of oxygen transfer per minute and a total transfer of 450 mL of oxygen is calculated, the arterial  $pO_2$  may be lower even at an  $FiO_2$  of 1.0. Other clinical factors such as anesthesia

level, hemoglobin pathology, etc, should be considered. Therefore, the maximum performance of a brand oxygenator would be important information to the clinician.

The AAMI/ISO standard for a “blood gas exchanger” was one of the first perfusion devices ever to have a written standard. Because of many reasons beyond the scope of this communication, some important clinically relevant information is not currently addressed in the testing methods.

It is required that every 5 years all standards undergo mandatory review. The importance of the practicing perfusionist’s input into standards is paramount. This feedback could result in the modification of standards that will include more relevant performance information for clinical applications. AmSECT, probably the largest perfusion organization (currently the Chinese may have 2000 members) in the world, has the resources and definitely the policy to support such an endeavor.

Editor’s Note: Richard Chan is AmSECT’s representative to the Association for Advancement of Medical Instrumentation (AAMI) and the International Organization for Standards (ISO). In response to the request of AAMI and ISO for clinician feedback, AmSECT will conduct clinician opinion polls on the Society’s web site as a vehicle to effectively convey input to AAMI/ISO. AmSECT members will receive update e-mail notification when clinician polling is initiated on the AmSECT web site.