

**ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION
PUBLIC/INVITED REVIEWER FORM**

INSTRUCTIONS: Please complete all 4 parts of the form on this page as well as providing your comments on the form that begins on the next page. Note in particular that:

Comments must be received by the comment deadline on the cover of the public review draft. Late comments may be deferred to the next revision of the document (usually five years from final approval date).

Failure to provide a rationale and suggested alternative text for a comment may result in the committee finding the comment non-persuasive.

When developing the US consensus position on international approval of an ISO or IEC draft, the committee is only required to consider comments from individuals or companies that are domiciled in the United States. (Individuals and companies domiciled outside of the US should contact their official member body to ISO or IEC to determine opportunities for commenting.)

When developing consensus on AAMI standards and recommended practices, the committee will consider comments from all interested and affected parties.

1. DOCUMENT: (Enter designation and title from cover page of draft)

2. YOUR INTEREST CATEGORY:

User Producer/Industry Government/Regulatory General Interest

3. NAME/DATE/SIGNATURE:

Name (print/type)

Date

Signature (required if returning ballot by surface mail or by fax)

4. CONTACT INFORMATION:

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RETURN TO: Standards Department

Email standards@aami.org

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General instructions on voting/commenting are available at the AAMI website at:

<http://www.aami.org/standards/downloadables/balinstr.pdf>

If you have more than 4 comments, copy blank page as needed. Please TYPE.

Name:			
Clause¹	Item²	Comment Type³	Comment⁴
			Comment/Objection: Rationale: Alternative Text:
			Comment/Objection: Rationale: Alternative Text:

¹ **Clause:** Enter clause numbers only in this field, eg, 3.4.5 or A3.4.5. Use the "Item" column for unnumbered sections (eg, Introduction). To specify an item within a numbered clause such as a table, paragraph, etc., fill in both the clause and item columns.

² **Item:** Enter non-numeric section headings (eg, Introduction) or items within a numbered clause (eg, paragraph 1; line 3; Table 2; Figure 5; or item c).

³ **Comment Type:** Enter "T" for Technical, "E" for Editorial, or "G" for General (including reason for abstaining on ballot)

⁴ **Comment:** Comments consist of up to three elements.

Comment/Objection: Try to state your comment or objection briefly and clearly, using the other sections for additional explanation and to provide alternate text. Avoid writing comments in the form of a question.

Rationale: Provide a detailed statement in support of your comment. Hints: Include references to published data (if any) that support your position. Refute the document's rationale (if any) in your statement. Skip for editorial comments.

Alternative Text: Enter suggested text for the draft that, if included, will resolve your comment.