

# AAMI FOUNDATION

## CONTRIBUTION FORM

**I am pleased to support the Small-bore Connectors Testing Program through a contribution of the following amount to the AAMI Foundation:**

\$1,000    \$2,000    \$3,000    \$5,000    \$10,000    other: \$ \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

By making this contribution, I acknowledge that I have received, read and understood the Disclaimer that accompanies this Contribution Form.

Please select payment method:

A check made payable to AAMI Foundation for the full amount of my contribution is enclosed (mail to AAMI Foundation, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633).

Please charge my credit card:    American Express    Visa    Master Card

Card number \_\_\_\_\_ Exp. Date \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

If you have a question about making a contribution toward the Small-bore Connector Testing Program please contact Colleen Elliott at [celliot@aami.org](mailto:celliot@aami.org) or (703) 253-8261.

*The AAMI Foundation is a 501(c)(3) organization and donations are tax deductible to the extent provided by law.*

## Small-bore Connectors Testing Program

Contributions are requested from members of AAMI/CN, Small-bore Connectors Committee for small-bore connectors testing to be facilitated by the AAMI Foundation. Work on Part 1 of the proposal is ready to begin. This work will be performed by Cedic SRL.

The overall goal of this project is to provide validation of the specifications in the ISO 80369 series of standards for small-bore connectors. Specific goals are:

Part 1:

- To complete functional performance testing for each part of the series as specified in 80369-20, *Common test methods*.

Part 2:

- To complete a validation of the CAD analysis tool.

Part 3:

- To complete usability studies for those parts of the series that still require it (NOTE: usability testing has already been completed by a consortium of manufacturers for 80369-3; usability testing requirements for 80369-5 and 80369-7 have been fulfilled through history of use over decades)

The completion of this testing is essential to validate the specifications in the 80369 series of standards and to gain international acceptance for these documents. Once the documents are approved, published and implemented, it is hoped that the following outcomes will be achieved:

- Reduction of the number of patient injuries and deaths caused by tubing misconnections
- Lower costs
- Broader access to device choices that integrate
- Greater consistency across providers for increasingly mobile patient populations
- Less likelihood of therapy interruption due to connector incompatibility or unavailability

Cedic SRL has provided a statement of work for testing the connectors for each part of the series: 80369-3, 80369-5, 80369-6 and 80369-7.

Estimated Timeline and Budget for Part 1:

Phase I. Functional performance tests for 80369-3

TIME: Three weeks

BUDGET: \$11,200 + 12% overhead = \$12,544

Phase II. Functional performance tests for 80369-7

TIME: Three weeks

BUDGET: \$11,200 + 12% overhead = \$12,544

Phase III. Functional performance tests for 80369-5

TIME: Three weeks

BUDGET: \$11,200 + 12% overhead = \$12,544

Phase IV. Functional performance tests for 80369-6

TIME: Three weeks

BUDGET: \$11,200 + 12% overhead = \$12,544

Phase V. Functional performance tests for 80369-2

TIME: Three weeks

BUDGET: \$11,200 + 12% overhead = \$12,544

**TOTAL TIME: 15 weeks**

**TOTAL BUDGET: \$62,720**

All funds received will be used by the AAMI Foundation towards small-bore connectors testing (Parts 1-3) or other small-bore connectors projects. No refunds will be issued. Please read the accompanying Disclaimer. The accompanying contribution form must be completed and accompany all contributions.

If you have any questions, please contact Colleen Elliott, AAMI, Secretary to ISO/TC 210/JWG4, 703-253-8261, [celliot@aami.org](mailto:celliot@aami.org).

## **DISCLAIMER**

The standards of the Association for the Advancement of Medical Instrumentation (AAMI), including the standards on small-bore connectors (AAMI/ISO 80369 series), are developed through a voluntary consensus standards development process approved by the American National Standards Institute. This process brings together volunteers and seeks out the views of persons who have an interest in the subject of the standard(s), in this case small-bore connectors, in order to achieve consensus on the topic and related health and safety issues. AAMI administers the process and establishes rules to promote fairness in the development of consensus. The AAMI Foundation is helping to fund the costs of testing for the proposed standards on small-bore connectors by an independent organization. AAMI and the AAMI Foundation will not write the standards on small-bore connectors and will not independently test, evaluate, or verify the accuracy or completeness of any information or the soundness of any judgments contained in any draft or final standards on small-bore connectors.

AAMI and the AAMI Foundation disclaim liability for any personal injury, property, or other damages of any nature whatsoever, whether special, indirect, consequential, or compensatory, directly or indirectly resulting from the publication, use of, application, or reliance on any draft or final standard on small-bore connectors. Further, AAMI and the AAMI Foundation disclaim and make no guaranty or warranty, expressed or implied, as to the accuracy or completeness of any information published in the draft or final standards on small-bore connectors, and disclaim and make no warranty that the information in the draft or final standards will fulfill any of your particular purposes or needs or those of your company or association. AAMI and the AAMI Foundation do not undertake to guarantee the performance of any individual manufacturer or seller's products or services by virtue of this standard.

In publishing and making any draft or final standard on small-bore connectors available, AAMI and the AAMI Foundation are not undertaking to render professional or other services for or on behalf of any person or entity, nor are AAMI and the AAMI Foundation undertaking to perform any duty owed by any person or entity to someone else. Anyone using the standards should rely on his or her own independent judgment or, as appropriate, seek the advice of a competent professional in determining the exercise of reasonable care in any given circumstances. Information on the topic of small-bore connectors may be available from other sources, which the user may wish to consult for additional views or information not covered by the draft or final standards.

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