Technical Information Report

AAMI TIR101: 2021

Fluid delivery performance testing for infusion pumps

AAMI
Advancing Safety in Health Technology

Fluid delivery performance testing for infusion pumps

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AAMI

Abstract: This document defines fluid delivery performance test methods that cover the full range of use conditions of an infusion pump in order to provide clinically relevant data of how the pump will perform in use. This document is applicable to syringe pumps, container pumps, and volumetric infusion pumps for all indicated delivery modes including enteral, patient controlled analgesia (PCA), or epidural and prescribed infusate sources (e.g., volumetric infusion pump drawing from a syringe). This document does not establish criteria for the clinical acceptability of infusion pump performance, provide guidance for test method validation, or address uncertainty of measurement.

Keywords: fluid delivery, infusion pumps, performance testing

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. A TIR must be acted on and the action formally approved usually every three years.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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NOTE Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR101, *Fluid delivery performance testing for infusion pumps* (AAMI TIR101:2021), but it does provide important information about the development and intended use of the document.

Introduction

In order to fulfill their mission, the fluid delivery elements of infusion pumps must behave as designed and as anticipated by clinicians, clinical and biomedical engineers, and other technical personnel. Since the creation of IEC 60601-2-24 [3] infusion pumps have markedly increased in complexity and sophistication of clinical usage.

The present edition of the IEC 60601-2-24 [3] standard was updated in 2012. Some of its methods of performance testing and reporting fail to offer 'clinically relevant and actionable' information in several aspects. This technical information report (TIR) seeks to correct, augment, and strengthen the standard providing designers and users with more complete and usable characterization of device behavior under a range of 'real world' clinical conditions.

The motivation behind the TIR has three primary elements: expanded test conditions, translated measurements into clinically-relevant metrics, and standardized testing and disclosure.

Present and prior editions of IEC 60601-2-24 [3] focus primarily on testing under nominal laboratory conditions, with small deviations around flow rates and outlet pressures. This TIR broadens the scope of testing to include additional test cases spanning the operational range of the device. For example, flow accuracy testing now includes both maximum and minimum selectable rates for the device in addition to the intermediate rates. Likewise, variation is included for ambient temperature and pressure, as well as fluid viscosity. This expanded test matrix more completely characterizes how the device will perform across the full spectrum of clinical use.

IEC 60601-2-24 [3] also has limitations in ability to relate measured performance to clinically-relevant metrics. So-called "Startup" and "Trumpet Curve" plots provide qualitative visual indication of startup time and short-term flow variability but fail to translate to quantitative metrics that clinicians can use to select appropriate equipment or adapt clinical practice to yield the best outcomes. This TIR introduces a quantitative measure for startup time delay. It also introduces a measure of short-term variability that relates back to medication half-lives, enabling clinicians to understand how the pump performance can impact patient outcomes based on the pharmacokinetics of the drugs they intend to deliver. Refer to Annex C for more details in comparing the Trumpet Curve approach with the pharmacokinetic filtering response.

Lastly, the TIR aims to provide a standardized approach to testing and labeling. A shared approach to test methods, conditions and disclosure enables for more straightforward comparison between similar products. This is a benefit to regulators, clinicians, and industry as each is looking to compare and contrast performance of different products or technologies. Further, this TIR suggests the addition of confidence and reliability indicators on top of typical results so that variability of performance can be understood.

Key elements of this TIR include methods for evaluating flow rate and bolus delivery accuracy under realistic excursions of intake and outlet pressure, environmental conditions, flow rates, measurement, and presentation of short-term flow variability in the critical flow rate ranges where short half-life medications are delivered and quantifying delay of flow stabilization. Testing and analysis apply statistical methodology to enhance the reliability as well as usability of reported values.

Fluid delivery performance testing for infusion pumps

1 Scope

This document defines fluid delivery performance test methods that are intended to accurately and efficiently align with the intended use of an infusion pump in order to provide clinically relevant presentation of test results. This document is applicable to syringe pumps, container pumps, and volumetric infusion pumps for all indicated delivery modes including enteral, patient controlled analgesia (PCA), or epidural and prescribed infusate sources (e.g., volumetric infusion pump drawing from a syringe). This document does not establish criteria for the clinical acceptability of infusion pump performance, provide guidance for test method validation, or address uncertainty of measurement.

The tests included in this document are:

- start-up delay time;
- short and long-term flow-rate accuracy over the entire period of intended use;
- environmental and pressure effects on long-term flow-rate accuracy;
- bolus dose accuracy.

NOTE 1 This document is not meant to be all inclusive of performance testing, and methods therein, that might be relevant and/or necessary to establish the performance data that is specifically relevant to a particular infusion pump's intended use and risk profile. Manufacturers should consider additional testing and/or scientific evidence if the infusion system is intended to deliver complex or non-Newtonian fluids.

NOTE 2 On-body delivery systems are not specifically addressed within this document; however, particular test methods within this report might be relevant to on-body delivery systems based on the intended use and risk profile of the system. Elements of the ISO 11608-1 [7] suite of standards might also be relevant for these types of delivery systems.

NOTE 3 Although the performance testing described in this document might be transferrable to implantable infusion pumps, this document is not intended to cover the testing necessary for implantable infusion pumps. See ISO 14708-4 [8] for information regarding implantable infusion pumps.

NOTE 4 It is the responsibility of the manufacturer to identify applicable environmental conditions. If there are additional environmental conditions that could impact product performance, those should be included in addition to the environmental conditions called out in Table 4. Respective standards including IEC 60601-1-11 [1] for the home healthcare environment and IEC 60601-1-12 [2] for medical emergency services should be considered as appropriate based on the labeling of the product. TIR101 test methods are generally limited in environments with mechanical vibration or shock by the test apparatus such as through the required precision of balances. If the environmental stressors are not compatible with the test methods defined in TIR101 (e.g., vibration is not compatible with use of balances), the manufacturer should identify alternative or additional test methods as appropriate such as including a subset of TIR test methods as pre- or post-tests if dictated by the intended use and/or risk management.

NOTE 5 The test methods of TIR101 characterize the delivery performance of the infusion pump at the time of test. It is the responsibility of the manufacturer to ensure appropriate characterization of the expected delivery performance over the use life of the infusion pump. This should include degradation of performance such as from wear out of the pumping mechanism. If performance degrades with depletion or aging of batteries, this should be considered, and a risk-based strategy should be adopted to inform clinicians to replace the battery. For batteries near their end of their manufacturer recommended service life, if flow rate accuracy is affected then an end of battery life alarm and/or near end of battery life alarm may be appropriate. If a battery with a low state of charge affects fluid delivery performance, then the manufacturer should establish the triggering points of their low battery alarms appropriately (e.g., low battery and battery depletion alarms). Manufacturers should include the flow rate accuracy testing and risk migration strategy for depleted or batteries near end of use life in their safety assurance case and disclose in operator's manual if the deviation causes the performance to exceed the stated accuracy specification (e.g., greater than 5 %).

