

AUTO INFUSION SETS FLOW RATE TESTER



Auto Infusion Sets Flow Rate Tester - ToronMed™ ISFRT-Auto

ToronMed™ ISFRT-Auto is an automatic infusion set flow rate tester developed for medical device manufacturers, quality-control laboratories, and third-party testing facilities that require accurate, reproducible verification of single-use infusion set performance. The system simulates gravity-fed clinical infusion conditions by applying a controlled 1-meter hydrostatic head to the test set, then measuring the volume of sodium chloride solution delivered within the time limits specified by ISO 8536-4. Automated level control, integrated temperature management, and a built-in timer reduce operator involvement and eliminate the manual sources of variance that affect simpler hydrostatic column setups. The ToronMed™ ISFRT-Auto accommodates both standard 20 drops/mL and finer 60 drops/mL dropper configurations, making it suitable for the full range of commercial infusion set types.

The instrument maintains a constant liquid level at 1000 ± 10 mm throughout each test run using an independently developed hydrostatic pressure device, rather than relying on an open reservoir that falls as fluid exits. A puncture-plug interface at the base of the constant-level assembly allows the spike of the infusion set under test to be inserted directly, replicating the physical connection made to an infusion bottle in clinical use. A height-adjustable column mechanism allows operators to vary the water column above or below the standard 1-meter reference height, supporting extended test programs that evaluate set performance across a range of hydrostatic pressures. Model code ToronMed™ ISFRT-Auto identifies this automated variant within the ToronMed™ medical device testing line.

The ToronMed™ ISFRT-Auto includes a thermostatically controlled water tank that circulates test fluid at 23°C, meeting the temperature conditioning requirement of ISO 8536-4 without the need for a separate bath. A countdown timer automates test duration and signals the end of each collection period. A balance station provides a stable, level platform beside the instrument for placing a calibrated analytical balance or graduated measuring cylinder, so collected effluent can be measured by weight or volume without additional setup.

APPLICATIONS

Auto Infusion Sets Flow Rate Tester - ToronMed™ ISFRT-Auto Applications

The ToronMed™ ISFRT-Auto supports flow rate qualification across the full range of single-use, gravity-fed medical delivery sets covered by ISO 8536-4 and related international standards.

- Infusion Set Production QC: verifying that single-use gravity-fed infusion sets deliver the minimum specified volume of NaCl solution within the time limits set by ISO 8536-4, for line-end and incoming-inspection testing in manufacturing environments
- Donor Set and Transfusion Set Testing: evaluating blood donor and transfusion set flow rates under standard hydrostatic conditions per ISO 1135-4, confirming that set geometry and lumen sizing support safe blood administration flow rates
- Medical Device Design Validation: supporting V&V testing of new infusion set configurations, drip chamber geometries, and tube dimensions before regulatory submission, with documented test results traceable to ISO 8536-4 conditions
- Third-Party Compliance Testing Laboratories: providing a standardized, reproducible test platform for ISO 8536-4 flow rate testing conducted on behalf of medical device clients, with controlled temperature and pressure conditions that satisfy auditor requirements
- Regulatory Submission Data Generation: producing documented flow rate test data for CE marking technical files, FDA 510(k) submissions, and other regulatory approval processes that require ISO 8536-4 test evidence
- Process Development and Formulation Studies: evaluating the effect of set design changes on deliverable flow rate under controlled conditions, including variations in dropper calibration, tubing inner diameter, and flow regulator design



Standards

The ToronMed™ ISFRT-Auto is designed and built to align with the testing requirements of internationally recognized medical device performance standards covering infusion and transfusion equipment.

- ISO 8536-4 – Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
- ISO 1135-4 – Transfusion equipment for medical use – Part 4: Transfusion sets for single use, gravity feed
- EN 1618 – Flow characteristics for non-intravascular catheters

FEATURES

Auto Infusion Sets Flow Rate Tester - ToronMed™ ISFRT-Auto Key Features

The ToronMed™ ISFRT-Auto integrates active level control, thermostatically managed temperature, and automated timing to deliver consistent, auditable infusion set flow rate measurements with minimal operator input.



- Puncture-Plug Constant-Level Interface: the base of the hydrostatic reservoir accepts the infusion set spike directly through a puncture plug, replicating the connection to a clinical infusion bottle and keeping the test configuration close to real-world use conditions
- Active Hydrostatic Head Control: a proprietary level-stabilization device replenishes the reservoir continuously to hold the water column at 1000 ± 10 mm throughout the full test duration, preventing the head-drop artifact that affects open-reservoir test methods
- Adjustable Flow Rate Setting: the target flow rate can be configured before each test run, allowing a single instrument to cover multiple set types and dropper calibrations within the same test session
- Thermostatically Controlled Water Tank: circulates test fluid at 23°C to meet the temperature conditioning requirements of ISO 8536-4, replacing the need for a standalone temperature bath and ensuring stable fluid viscosity throughout the test
- Integrated Countdown Timer: automates test duration control and signals collection-period end without requiring the operator to observe a separate timepiece, reducing the risk of timing errors in high-throughput testing

- Height-Adjustable Column Mechanism: raises or lowers the reservoir assembly along a vertical lifting column, allowing the operator to vary the effective hydrostatic head above or below the standard 1-meter reference point for extended test programs
- Dedicated Balance Station: provides a stable, level platform at the instrument base for placing an analytical balance or measuring cylinder beneath the set outlet, enabling gravimetric or volumetric collection of effluent without separate bench arrangements

THEORY & METHOD

Theory and Method

Flow rate testing for gravity-fed infusion sets rests on Torricelli's principle: the velocity of fluid exiting a reservoir under gravity is proportional to the square root of the fluid column height above the outlet. ISO 8536-4 operationalizes this by specifying a 1-meter hydrostatic head (1000 mm of fluid) with a sodium chloride solution at 9 g/L, which matches the osmolarity and physical properties of normal saline as used in clinical IV therapy. The standard quantifies performance as the total volume delivered over a fixed time window rather than an instantaneous flow rate, because clinical relevance depends on the cumulative delivery within a dosing period.

Two dropper calibration categories define the pass/fail thresholds. A set calibrated to deliver 20 drops per milliliter must pass at least 1000 mL of NaCl solution through to the outlet within 10 minutes under the 1-meter head. A finer-drop set calibrated at 60 drops per milliliter must achieve the same minimum volume within 40 minutes. These criteria confirm that lumen diameter, drip chamber design, and flow regulator resistance collectively permit adequate gravity-driven delivery for the intended clinical use. A set that fails these thresholds would restrict fluid delivery to a rate clinically insufficient for routine infusion therapy.

Maintaining a constant reservoir level throughout the test is necessary because a falling fluid level reduces the hydrostatic head and decreases the driving pressure, which would cause measured flow rate to drop below the true set resistance and produce an artificially low result. The ToronMed™ ISFRT-Auto addresses this with an active constant-level reservoir that

replenishes fluid to hold the head at 1000 ± 10 mm regardless of outflow. Fluid temperature is controlled at 23°C because kinematic viscosity of aqueous solutions varies with temperature; standardizing to 23°C removes this variable and ensures that results from one test setup are comparable to results from another, as required for valid inter-laboratory data.

TECHNICAL SPECIFICATIONS

Auto Infusion Sets Flow Rate Tester - ToronMed™ ISFRT-Auto Technical Specifications

Instrument Parameters

Parameter	Specification
Hydrostatic Head	1000 ± 10 mm
Test Fluid Temperature	23°C (thermostatically controlled)
Flow Rate Setting	Adjustable
Height Adjustment	Variable via up/down lifting column mechanism

Physical Dimensions

Component	Dimensions (L × W × H)
Test Device	280 × 420 × 1660 mm
Constant Temperature Water Tank	420 × 3809 × 755 mm

Standard Configuration

Item	Description
Instrument	Main test unit with vertical lifting column, balance station, and hydrostatic head assembly
Hydrostatic Head	Constant-level reservoir with puncture-plug base for direct spike insertion
Height Adjustment Device	Column lifting mechanism for setting variable hydrostatic pressure conditions
Constant Temperature Water Tank	Thermostatically controlled fluid reservoir maintaining 23°C test temperature
Measuring Cup	Graduated volumetric collection vessel for effluent volume measurement
PU Pipe	Polyurethane fluid interconnection tubing



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