SubCutaneous Injection Site SimulatOR (SCISSOR) N3 Solution for Subcutaneous Formulations

The SCISSOR N3 advances the Pion Subcutaneous Injection Site Simulator *in vitro* model capability for investigating the release performance of subcutaneous formulations under simulated physiological conditions. It assesses the risk and performance of subcutaneously administered drugs including biologics, peptides and small molecules.

Simulating the stress conditions and environmental transitions that can lead to aggregation and precipitation of the API or poor *in vivo* release performance, it allows investigation of the API interaction with the extracellular matrix, monitors the pH change upon injection, and identifies optimal excipient conditions.

The SCISSOR N3 is the only commercially available solution that bridges the gap between standard dissolution and solubility results and *in vivo* Pharmacokinetics (PK) studies.

- Run up to 3 independent assays on a single SCISSOR N3, simultaneously, and up to 6 on a SCISSOR N6.
- Optional automated sample fraction collector for unattended operation, with programmable sampling volumes and times, 240 vial capacity, and media refill after sampling.
- Integrated camera and turbidity sensors for effective detection of turbidity and assessment of precipitation or dissolution of particles in suspension.
- Fiber Optic probe port for use with Rainbow R6 Concentration monitor to generate concentration profiles in real-time.
- Physiologically relevant temperatures and buffer environments maintained during assays.
- Monitors pH change upon injection in the extracellular matrix (ECM).
- Optimized extracellular matrix options provide accurate simulation of the extracellular matrix.

Product Configurations

The SCISSOR N3 Subcutaneous Injection Site Simulator is available in the following configurations.

- SCISSOR N3 Subcutaneous Injection Site Simulator The N3 can be configured with up to 3 chamber assemblies (60 mL or 300 mL) and requires the SCISSOR Camera Assembly to operate (one per chamber). The N3 instrument includes a temperature and pH control system for the assay chamber, sampling pump and flow through vials for aliquot collection and an external rack for manual sampling and electrode storage. Addition of a fraction collector and auto-injector is an optional extra.

- SCISSOR N3 Subcutaneous Injection Site Simulator with concentration monitor
  This adds a 3-Channel Rainbow R6 in-situ UV-vis system to the N3 system and uses fixed path length dip probes. Addition of a fraction collector and auto-injector is an optional extra.
- SCISSOR N6 Subcutaneous Injection Site Simulator
  The N6 system consists of two N3 instruments sharing a common SCISSOR software. It can be outfitted with up to 6 Chambers. Addition of a fraction collector and auto-injector is an optional extra.
- SCISSOR N6 Subcutaneous Injection Site Simulator with concentration monitor
  This adds a 6-Channel Rainbow R6 in-situ UV-vis system to the N6 system and uses fixed path length dip probes. Addition of a fraction collector and auto-injector is an optional extra.

REQUIRED ACCESSORIES

- Chamber Assemblies- The Chamber Assembly includes a 60 mL or 300 mL volume chamber, cartridge holder, LED light source and detectors, temperature probe, and pH electrodes for the cartridge and chamber. Each chamber assembly requires a video camera, which must be ordered separately.
- Cartridge Pack with Artificial Extracellular Matrix (ECM) and cartridges to allow for 5 experiments.
- SCISSOR Camera Assembly, one per chamber

TECHNICAL SPECIFICATIONS

- pH range: 4-10, +/- 0.05 pH over range
- Chamber temperature:
  - 34°C (typical); adjustable over 30 – 40°C
  - Stability +/- 1.0°C degrees over 24 hours
  - Temperature equilibration time, < 1 hour
- Camera image capture: 2 images/minute
- Pump flow rate: > 25 mL/minute
- Fluid transit time (chamber to sampling port): <30 seconds
- (4) selectable stirring speeds
- LED wavelength - 504 nm

CONSUMABLES

- Scissor Cartridge Packs with ECM
- Scissor Electrode Storage and pH buffer solutions
- Pipette tips for Auto-Injector

OPTIONAL ACCESSORIES

- SCISSOR Autoinjector
- Fraction Collector for SCISSOR N3/N6. The SCISSOR Fraction Collector is an automated system that samples up to 6 flow-through assay streams when used with SCISSOR instruments. It has an integral wash station built into the deck of the system that washes the sampling cannula after each aliquot is drawn and transferred to the HPLC vial. After wash it draws from a buffer reservoir and replenishes the buffer in the flow stream. It has a capacity of 40 vials per SCISSOR Chamber for up to 6 Chambers. The Fraction Collector requires a dedicated USB 2.0 port.

DIMENSIONS AND WEIGHT

	Height	Width	Depth	Weight
Scissor	34.7 cm (13.7 inches)	60.1 cm (23.7 inches)	45.1 cm (17.8 inches)	30 kg (65 lbs.)
Autosampler	63.8 cm (25.1 inches)	76 cm (29.9 inches)	53.3 cm (20.95 inches)	40 kg (88 lbs.)
Autosampler with enclosure	81.5 cm (32 inches)	102 cm (40 inches)	75.4 cm (29.7 inches)	Exclosure weight 40 kg (88 lbs.)
Rainbow R6	275 mm (10.9 inches)	177 mm (7 inches)	436 mm (17.2 inches)	15 kg (33 lbs.)

Pion

Pion stands behind the science

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