

ORCHESTATM
INFUSION

patents pending



Automate Your InfusionSM

**INSTECH
SOLOMON**

Major Features

- ◆ FDA 510(k) pump
- ◆ GLP and Part 11 compatible
- ◆ Wireless network up to 300 pumps
- ◆ Full service and support
- ◆ Validation portfolio available

Orchestra™ is a transformative technology to automate preclinical GLP toxicology infusion studies. The benefits of automation are reduced labor costs and improved study data quality.

The system comprises a human-use pump (made in U.S.) which has an FDA 510(k), wireless hardware, and software designed specifically for large infusion studies (up to 300 pumps). The software is GLP and Part 11 compatible.

Orchestra™ has been extensively tested for reliable data recording, system and data persistence in the event of catastrophic events, and robust wireless networking.

For a full demonstration of the system's capabilities, contact Instech Solomon.

Programming

Automated programming and other features should reduce infusion study labor costs by more than 50%.

By utilizing the software to program the pumps based on each animal's weight and dose group, tens or hundreds of thousands of flow rate calculations and pump keystrokes are avoided thereby reducing the risk of human error.

All pump programming for all dose groups for the entire study duration is done in less than ten minutes on the Orchestra™ software. Users do not need to calculate and enter settings directly into the pump. Flow rates are updated automatically by importing new weight tables from your LIMS into the Orchestra™ software.

Monitoring

All pumps in the study are displayed real-time on a single PC monitor for easy status recognition. Pumps with serious alarms are displayed in red. Pumps with less critical alerts are displayed in yellow. At a glance, users can identify any problem pumps as well as the cause for each pump alarm. Also, users may view detailed parameters of individual pumps.

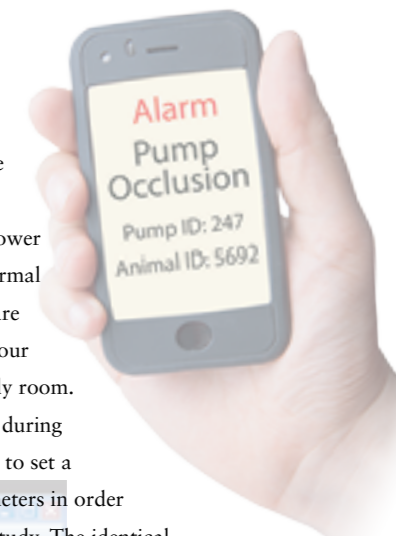
Documentation & Reporting

Electronic documentation replaces all handwritten paper documentation. The software is compatible with FDA requirements 21 CFR Part 58 (GLP's) and Part 11 (electronic records and signatures). All pump actions are automatically documented by the Orchestra™ software with time/date stamp and user ID stamp. This automation assures total data capture without the risks of missing events, indecipherable handwritten documentation, lost documentation, non-compliant documentation, and other human error.

Final reporting is prepared by Orchestra™ and includes tabulation of all test article dosing by animal ID, a complete log of all pumps events and parameters, and complete date/time and user ID stamping.

Alerts via Mobile Phone

Alarms and alerts at each pump are automatically and quickly sent to one or more mobile phones. This remote notification facilitates reduced manpower in the infusion study room during normal working hours and off-hours. Staff are freed to perform tasks elsewhere in your facility and are not bound to the study room. On-call staff need not remain on-site during off-hours. The software allows users to set a number of remote notification parameters in order to fine tune this feature to suit each study. The identical alarms and alerts may be sent to designated emails as well.



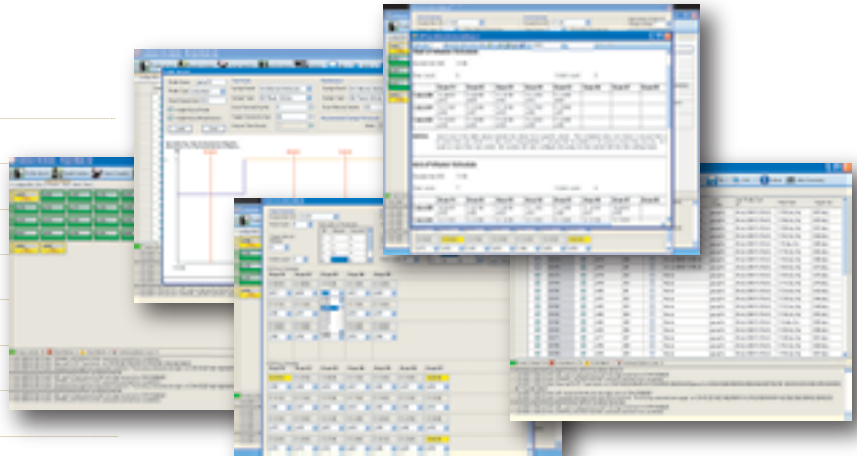
PK/TK Scheduling

Orchestra™ provides a solution to PK/TK scheduling using Start of Infusion and End of Infusion settings for either individual animals or cohorts. Blood sampling time points are compiled and a schedule of all bleed times is prepared to allow for proper staff scheduling. The pump follows the schedule and helps to streamline what traditionally is a tedious, demanding procedure.

Specifications

SOFTWARE

- Microsoft Windows XP
- Manage up to 300 pumps per study
- GLP and Part 11 compatible
- All events are time/date and user stamped
- Multiple dose groups
- Data persist in case of catastrophic event
- Users are required to enter ID code



WIRELESS NETWORK

- IEEE 802.15.4
- 16 channels available
- Tested in labs worldwide
- Range = 30m approx.



SYRINGE PUMP

- FDA 510(k) hospital syringe pump
- Syringe : 1 - 140 mL glass or plastic
- Flow rate : 0.01 - 3,000 mL/hr
- Backup battery : 12 hours approx.
- Dimensions : 24 x 10 x 15 cm
- Weight : 2.2 kg
- Cast metal housing
- Occlusion, battery, and standard alarms



**INSTECH
SOLOMON**

San Antonio, TX USA
Plymouth Meeting, PA USA
Almere, The Netherlands

TL +1 210-692-9908
FX +1 210-646-9314
www.solosci.com

patents pending

