Disi AutoSense™



AUTOMATED INTELLIGENT DISINTEGRATION TESTING



DISI AUTOSENSE™ DISINTEGRATION TESTER

Automated Intelligent Disintegration Testing

The Disi AutoSense[™] from Teledyne Hanson Research delivers fully automated disintegration testing in compliance with USP <701> and <2040> and their harmonized EP and JP methods. Designed for precision, productivity, and ease-of-use, the Disi AutoSense provides a fast, lowmaintenance solution for disintegration labs conducting tests in new product development and batch/lot manufacturing facilities. Each tester position is able to be programmed and operated independently, allowing up to four different products to be tested simultaneously in the four-position model. Controlled by sophisticated software, the system measures and stores test data while displaying in-process disintegration values graphically in real time. 21 CFR Part 11 compliance is enhanced by secure audit



trails, data security, and advanced user permissions settings. Every Disi AutoSense system is fully supported by Teledyne Hanson's world-renowned installation, qualification, and maintenance support services.



Disi Autosense[™] System Components

4-position model shown; also available in 1-position or 2-position.

AUTOMATED INTELLIGENT DISINTEGRATION TESTING

Real Time Profiling of Disintegration Results

Highly sophisticated Disi AutoSense technology automatically detects the disintegration profile of each individual tablet. Using the principle of magnetic induction, copper wire rings built into the acrylic disks placed above each tablet enable instantaneous electromagnetic tracking of very small changes in tablet thickness during each stroke of the test. A special sensor built into the base of the SmartBasket assembly continuously measures temperature of the disintegration medium. At 100% disintegration the system senses the completion of the test and automatically lifts the basket out of the beaker. Precise temperature and percent disintegration readings are displayed on the computer screen in real time while being automatically stored in the AutoSense database for later retrieval and reporting in table and graphical formats.



Self-Aligning Quick-Connect Smartbasket™ System



The electronically intelligent SmartBasket assemblies for the Disi AutoSense tester are ordered separately. Chooses from 6-tube USP Apparatus A for standard dosage forms, or 3-tube USP Apparatus B for dosage forms over 18 mm in length. Designed for accuracy, intelligent automation and high productivity, the basket assembly connects and disconnects instantly by means of a reliable magnetic coupling that also aligns itself automatically to the center line of each beaker. The system requires no tools and no manual adjustment of the basket position. The highly sophisticated electronics built into the SmartBasket assembly are protected by a watertight, corrosion-resistant construction that allows for fast, easy cleaning and low maintenance.

Intelligent Support for 21 CFR Part 11 Compliance

Each Disi AutoSense system is controlled by a Windows-based client/server software operating system. An important feature is the complete audit trail automatically generated by the system to assist in complying with 21 CFR Part 11 requirements, without the need for special training or manual intervention. The regulatory compliance feature is built into every Disi AutoSense system. Each tablet tested can be traced back via its batch ID number at any time. User permissions and security settings are highly configurable and are recorded by the software. Standard tablets, capsules, and special products with multi-stage disintegration are accurately monitored and fully documented. The "residual height" trigger in the monitoring system is user-defined to accommodate any non-disintegration phase that often occurs with



certain capsules. Teledyne Hanson's precision disintegration beakers, manufactured to tightly controlled tolerances, are optimized for reduced variability and ease of compliance with the liquid levels required by USP guidelines.

DISI AUTOSENSE™ DISINTEGRATION TESTER



ORDERING INFORMATION

DISI AUTOSENSE™ DISINTEGRATION TESTER

40-207-001 Disintegration Tester, 1-Position*

- **40-207-002** Disintegration Tester, 2-Position*
- 40-207-004 Disintegration Tester, 4-Position*

* Supply kit included with each system contains beakers, communications cable, cleaning brush, siphon tube, and digital thermometer. Order software, SmartBaskets, power cords, and heater/circulator separately.

SOFTWARE LICENSE WITH WIBUKEY

- 40-207-102 Software Package for Disi AutoSense-1
- 40-207-103 Software Package for Disi AutoSense-2
- 40-207-104 Software Package for Disi AutoSense-4

SMARTBASKET™ ASSEMBLIES

40-207-106 SmartBasket Assembly, 6-Tube (USP App A)

Includes magnetic quick-connect basket/shaft assembly, six glass tubes, six auto-detection disks, and six screens.

40-207-108 SmartBasket Assembly, 3-Tube (USP App B)

Includes magnetic quick-connect basket/shaft assembly, three glass tubes, three auto-detection disks, and three screens.

POWER CORDS, MAIN INSTRUMENT

40-207-178	Power Cord, Main Instrument, Central Europe
40-207-179	Power Cord, Main Instrument, United Kingdom
40-207-180	Power Cord, Main Instrument, North America
40-207-181	Power Cord, Main Instrument, Switzerland

HEATER/CIRCULATOR WITH POWER CORD

40-207-030	Heater/Circulator, 230V/50Hz, Central Europe
40-207-031	Heater/Circulator, 230V/50Hz, China
40-207-032	Heater/Circulator, 230V/50Hz, United Kingdom
40-207-033	Heater/Circulator, 230V/60Hz, Central Europe
40-207-034	Heater/Circulator, 115V/60Hz, United States
40-207-035	Heater/Circulator, 100V/50Hz, United States

Q-PAK[™] QUALIFICATION GUIDELINES

40-208-004 Q-Pak for Disi AutoSense-1
40-208-005 Q-Pak for Disi AutoSense-2
40-208-006 Q-Pak for Disi AutoSense-4

For further information, please contact your local Teledyne Hanson Research representative or email us at hansonsales@teledyne.com



9810 Variel Avenue Chatsworth, CA 91311 USA Phone: +1 818.882.7266 www.teledynehanson.com

 \odot Teledyne Hanson Research, a division of Teledyne Instruments, Inc. \mid 99-310-066 Rev. 06 September 2019