# Dissolution Systems Source Book

Dissolution testing and analysis

2020 - 2021







## Agilent Sites and Services





## For your dissolution workflow

Agilent Dissolution Systems Digital Source Book

www.nxtbook.com/nxtbooks/agilent/dissolution\_sourcebook/index.php



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https://community.agilent.com/community/technical/dissolution



Dissolution 1-on-1 Training

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Dissolution Hotline (Email Address)

dissolution.hotline@agilent.com



Dissolution Discussion Group (DDG)

www.dissolution.com

## Welcome

Agilent Technologies, Inc. is well known within the pharmaceutical community for its broad portfolio of instruments and supplies, and now offers a variety of dissolution and pharmaceutical testing equipment. Agilent's unique position as a leader in analytical instruments allows us to meet all your needs for equipment, software, and reporting packages, qualification documentation and services, training and postsale support – anywhere you operate around the globe.

The latest edition of the Dissolution Source Book provides a detailed view of this portfolio, including dissolution apparatus, automated systems, calibration and verification tools, dissolution software, analytical UV-Vis and HPLC integration and physical testing. Here you will find in-depth product descriptions, regulatory information, useful tips, specifications and ordering details for thousands of Agilent dissolution products.

There is also a digital version of the Dissolution Source Book. The Dissolution Systems Digital Source Book contains many videos as well as links to white papers, webinars, posters, and presentations. Access the digital version at

www.nxtbook.com/nxtbooks/agilent/dissolution\_sourcebook/index.php

Agilent chemists are always available to assist you with dissolution questions.

Contact our Dissolution Hotline at **dissolution.hotline@agilent.com**.

More information is available at **www.agilent.com/lifesciences/dissolution**or by contacting your local Agilent representative.

## Table of Content

1	Market Solutions and Industry Information	3	3	Dissolution Software	85
	Market Solutions	4		Dissolution Workstation Software	86
	Industry Information	8	_		
2	B: 1.: A	44	4	Qualification Tools	91
_	Dissolution Apparatus and Accessories	11		280-DS Mechanical Qualification System	92
	Apparatus 1,2,5,6 and Intrinsic – 708-DS Dissolution Apparatus	12	E	Automotod Biocolution Connelling Contour	
	dissoGUARD and dissoSHIFLD	22	5	Automated Dissolution Sampling Systems and Accessories	95
	708-DS Accessories	22		850-DS Dissolution Sampling Station	96
	Baskets, Paddles and Shafts	24		Firmware Capabilities	98
	Vessels for 708-DS	26			
	Accessories for 708-DS	30	6	Automated UV Dissolution Systems	101
	Dissolution Accessories	30		Cary 60 UV Dissolution System	102
		00		Cary 60 UV-Vis Spectrophotometer	108
	Baskets, Paddles, Shafts	33		Cary WinUV Dissolution Software	110
	Dissolution Vessels	40			
	Conversion Kits	43	7	Content Uniformity	117
	Capsule Wire Weights and Sinker Baskets	45		TRS100 Raman Spectrophotometer	118
	Sampling and Temperature Measurement	47	0		
	Filtration	50	8	HPLC Solutions and Software	123
	Captiva Premium Syringe Filters	52		Agilent InfinityLab LC Series	124
	GE Whatman Filter Plates	54		Agilent InfinityLab Poroshell 120 columns	126
	Evaporation Covers	56	0	Disintegration Apparatus	107
	Transdermal Delivery Systems –		9		127
	USP Apparatus 5,6, and 7	57		100 Automated Disintegration Apparatus	128
	Enhancer Cell (or Immersion Cell)	60	10	Accessories and Replacement Parts	
	Intrinsic Dissolution Apparatus	62	10	for Legacy Products	131
	Verification Tools	64			
	Water Baths and Heater/Circulators	65	11	Service and Qualification	155
	Apparatus 3 – BIO-DIS Reciprocating Cylinder	66			
	Apparatus 7 – Reciprocating Holder Apparatus 7	72	12	Educational Services and Industry Support	161
	400-DS Apparatus	79			

# Market Solutions and Industry Information



## **Market Solutions**

## Agilent solutions for the pharmaceutical industry

#### **About Agilent**

Agilent Technologies is the world's premier measurement company. Through the company's acquisition of Varian, Inc. in 2010, we expanded our already extensive product portfolio for the pharmaceutical industry. The former VanKel Technology Group, which Varian acquired in 2001, offered many instruments for testing and evaluating pharmaceutical dosage forms including dissolution and disintegration. These products and accessories are now fully integrated in the worldwide Agilent distribution network.

Agilent's history spans back to 1939 when Bill Hewlett and Dave Packard started HP and helped shape the technology industry from what is now Silicon Valley in California. Agilent began operating in 1999 as an independent company, but retained the historical HP commitment to innovation and contribution, uncompromising integrity, teamwork, trust and respect for the individual.

#### Practical solutions for pharmaceutical testing

With a rich history in supporting the pharmaceutical industry, Agilent offers solutions for drug discovery, development, and manufacturing. The addition of the dissolution business furthers Agilent's support of the pharmaceutical industry through a portfolio of leading dissolution instrumentation and services. Being part of a company that provides the leading UV-Vis and HPLC solutions to the pharmaceutical industry allows us to offer complete workflow solutions, from dissolution apparatus, sampling devices, analytical instruments and the software to control them.

We manufacture dissolution instrumentation to test nearly every dosage form produced. Our staff of application chemists can assist you in selecting the right apparatus and accessories for your method. Whether in R&D or QA/QC, when analyzing those samples, we offer industry leading UV-Vis technology through the Cary 60 spectrophotometer. We can help you automate your workflow with offline or online solutions. Should your methodology require HPLC analysis, we have you covered there as well. The Agilent InfinityLab LC Series, with its flexible, modular design, ensures configurations ideally suited to meet your application requirements.



#### Workflow enhancements

We strive to provide solutions for every type of dissolution user, from routine applications to early drug development. Our equipment is designed to be easy to use, flexible and modular in nature. As the workload increases, we offer greater degrees of automation, both in the dissolution test run and sample collection as well as the data analysis and reporting. Purchasing a dissolution system from Agilent ensures you have one vendor to turn to should you have questions or require assistance, resulting in less downtime and better utilization of your equipment.



#### Quality

At Agilent, we believe that our customers define quality. They do this every day with the products and services they purchase. Customers buy based on perceived value, that is, they measure the benefits against the costs and select the product and experience that provides superior value. We, therefore, define quality as customer-perceived value.

Agilent products are designed to meet or exceed current published pharmacopeia, as well as FDA and ASTM, requirements at the time of manufacture. Our goal is to supply you with the highest quality pharmaceutical testing solutions on the market. Agilent's quality management system provides you the assurance that our company has the requisite quality system in place to support your activities around the globe.

#### **Agilent quality policy**

Agilent will earn customer loyalty by providing products, services and interactions of the highest quality and greatest value. To achieve this result, we will:

- 1. Ensure that all of our products comply with applicable safety and regulatory requirements.
- 2. Ensure our products meet or exceed their published specifications.
- 3. Maintain and continually improve the effectiveness of our product and service business management systems to conform at a minimum to ISO 9001 Quality Management Standard or more stringent or legally required standards as dictated by specific markets.
- 4. Continually monitor and improve customers' total experience.
- 5. Establish quality requirements for suppliers, partners, and contractors and hold them accountable to comply.
- 6. Treat customers in accordance with Agilent's Standards of Business Conduct and Privacy policies.

## 1 Market Solutions and Industry Information

#### Conforming to ISO 9001:2015

Agilent is committed to maintaining our product and service Business Management Systems by conforming to the requirements of ISO 9001:2015. Agilent's product development, manufacturing, and service/support operations meet the applicable ISO requirements. In achieving ISO 9001 certification, Agilent has demonstrated to third-party auditors that we have certain processes in place and under control.

These processes involve activities including:

- Calibration
- Continuous process improvement
- Corrective action
- Customer satisfaction
- Document and record control
- Incoming quality control/In-process inspection/Final inspection
- Internal audits
- Inventory management
- Management review/Management involvement/Resource management
- Procurement control
- Statistical process control
- Training/Certification
- Organization structure/Organization change

Also, Agilent maintains a company-wide ISO 14001 certificate for our Environmental Management System. If you require a copy of an ISO certificate related to a particular Agilent product, please visit our Quality Policy & Resources webpage at www.agilent.com/quality/index.shtml

#### The Agilent service advantage - helping you focus on what you do best

Agilent brings a worldwide network of highly skilled, experienced professionals committed to your success. Our factory-trained field service engineers combine regulatory training along with product maintenance and support knowledge to properly install and qualify your dissolution apparatus. Whether it is Installation or Operational Qualification (IQ/OQ), Performance Verification Testing (PVT, or PQ), or Mechanical Qualification (MQ), we can assist you with initial installations or routine qualification services. We offer customized service agreements based on your specific needs and supported by one of our 65 global service centers.



## **Industry Information**

## Apparatus, pharmacopeia, and regulatory affairs overview

The design of dissolution apparatus is specified by the various pharmacopeias from around the world. In addition, both the FDA and ASTM, as well as other regulatory groups, have called for tighter mechanical specifications. The apparatus is routinely operated in facilities regulated by federal agencies, such as the US Food and Drug Administration, which require laboratories to operate under good manufacturing practices (GMPs).

Agilent's dissolution apparatus are developed to operate under GMP environments which require installation, operational, and ongoing performance or mechanical qualifications to verify that the systems are operating as intended. We also provide several software tools that simplify compliance in the dissolution lab. Agilent offers extensive documentation and services that provide full instrument qualifications, including the most recent guidance on mechanical qualification of dissolution apparatus.

We provide the instruments and accessories to test essentially all types of dosage forms, including tablets, capsules, semisolids, transdermal patches, microspheres, implants, etc. Our equipment is designed to easily work with immediate, modified, delayed, or extended release products. Our designs adhere to compendial guidelines. We also offer some noncompendial designs when the traditional methodologies are not suitable for some unique drug release characteristics.



The 708-DS Dissolution Apparatus and 850-DS Sampling Station are designed with compliance in mind.

#### Applications and testing capabilities of Agilent dissolution apparatus

Description	Common Products Types
	ally require the placement of
Shaft with attached mesh basket fabricated from stainless steel; the dosage form is contained within the basket, lowered into media and rotated typically at 50-100 rpm.	<ul> <li>Capsules</li> <li>Tablets</li> <li>Floating dosage forms</li> <li>Modified release products</li> <li>Beads</li> <li>Suppositories</li> </ul>
Paddle blade fixed to the bottom of a shaft fabricated from stainless steel or PTFE coating; the dosage form is introduced directly to the media and the shaft is rotated typically at 50-75 rpm.	<ul><li>Tablets</li><li>Capsules</li><li>Hydrogels</li><li>Powders</li><li>Suspensions</li><li>Microparticles</li></ul>
Rotating paddle apparatus with the addition of a transdermal system attached to a stainless steel screen and ring assembly; placed at the bottom of the vessel.	- Transdermal patches
Rotating dissolution apparatus that utilizes a rotating cylinder upon which a transdermal patch is placed; cylinder provides mixing by convection principles.	- Transdermal patches
Mimicking the pH changes of the GI tract, glass cylinders containing the dosage form between capped screens of varying mesh sizes reciprocate 10 cm within 300 mL vessels containing media for a designated time period before the dosage form is transported to another row of media (six rows are available, more with a change of trays).	<ul> <li>Capsules</li> <li>Beads</li> <li>Chewables</li> <li>Veterinary products</li> <li>Enteric coated products</li> <li>Extended, modified or sustained release formulations</li> </ul>
Holders designed for sustained or extended release, including small-volume or combination products, reciprocate through a distance of 2 cm in volumes ranging from 300 mL down to as little as 3 mL.	<ul> <li>Transdermal systems</li> <li>Osmotic pumps</li> <li>Implants</li> <li>Drug-eluting stents</li> <li>High-potency, low-dose systems</li> </ul>
oped to provide drug release information for the API and topical formulations.	
Stainless steel die containing a pellet of pure drug substance with a constant surface area to determine the intrinsic dissolution rate; used in early drug development for API characterization.	- Pure drug substances
Cells consists of a chamber containing dosage form with synthetic or natural membrane representing skin to test biorelevance using small-volume vessels and miniature paddles.	<ul><li>Ointments</li><li>Creams</li><li>Gels</li><li>Transdermal</li></ul>
The Peak Vessel contains an inverted peak in the base of the vessel to displace disintegrated particles in the unstirred zone, preventing cone formation.	<ul><li>Beads</li><li>Products exhibiting coning problems</li></ul>
	paratus are the most commonly used throughout the world. These methods traditions a vessels containing a fixed volume of fluid referred to as dissolution medium.  Shaft with attached mesh basket fabricated from stainless steel; the dosage form is contained within the basket, lowered into media and rotated typically at 50-100 rpm.  Paddle blade fixed to the bottom of a shaft fabricated from stainless steel or PTFE coating; the dosage form is introduced directly to the media and the shaft is rotated typically at 50-75 rpm.  Rotating paddle apparatus with the addition of a transdermal system attached to a stainless steel screen and ring assembly; placed at the bottom of the vessel.  Rotating dissolution apparatus that utilizes a rotating cylinder upon which a transdermal patch is placed; cylinder provides mixing by convection principles.  Thember through which media flows in alternating directions, or on/within numerous he cylinders or holders typically reciprocate in 300 mL vessels although both larger and so the media flows of the GI tract, glass cylinders containing the dosage form between capped screens of varying mesh sizes reciprocate 10 cm within 300 mL vessels containing media for a designated time period before the dosage form is transported to another row of media (six rows are available, more with a change of trays).  Holders designed for sustained or extended release, including small-volume or combination products, reciprocate through a distance of 2 cm in volumes ranging from 300 mL down to as little as 3 mL.  Stainless steel die containing a pellet of pure drug substance with a constant surface area to determine the intrinsic dissolution rate; used in early drug development for API characterization.  Cells consists of a chamber containing dosage form with synthetic or natural membrane representing skin to test biorelevance using small-volume vessels and miniature paddles.

# Dissolution Apparatus and Accessories



## USP Apparatus 1, 2, 5, 6 and Intrinsic

### Agilent 708-DS Dissolution Apparatus

The 708-DS Dissolution Apparatus solidifies our commitment to provide an ideal platform for laboratories to standardize their dissolution testing. This instrument is designed to deliver consistent performance and results while conforming to current internationally harmonized pharmacopeial specifications for basket, paddle, rotating cylinder, paddle over disk and intrinsic dissolution tests.

The instrument's versatile dissolution platform can be configured for your needs today as well as tomorrow. The intelligent design accommodates all requirements from basic manual testing to automated configurations for high-throughput sampling and online analysis. The 708-DS is designed to accommodate a variety of vessel sizes and accessories based on the dosage form being tested. The apparatus allows for advanced usage options including automated dosage delivery, in-vessel temperature monitoring, automated sampling and in situ fiber optic analysis. The 708-DS can be configured for either 6- or 8-position testing based on your application.



Interactive demo of 708-DS Dissolution Apparatus - experience at http://d-next.net/agilent/#/view2/1

Providing a new standard for reliability and reproducibility in dissolution testing, the rugged platform conforms to either the USP Performance Verification Test (PVT) or the most rigorous enhanced mechanical qualification (MQ) standards as recommended by the ASTM, US FDA, and many worldwide regulatory agencies. The advanced design serves to minimize or eliminate variability, allowing for monitoring subtle changes attributed to dosage forms, not the dissolution apparatus. In fact, particular attention was given to simplifying the measurement of critical parameters, allowing for optimal alignment while minimizing vibration.

- Flexible sampling options: easy access to all vessels ensures quick, simple manual sampling through the evaporation cover or the convenient manual sampling bracket. Alternatively, automate your sampling using the programmable, hands-free manifold and the 850-DS Dissolution Sampling Station
- Accurately measure and record individual vessel temperatures manually with the handheld temperature probe or automate this process with the AutoTemp feature
- Automate your dosage delivery with the Dosage Delivery Module (DDM), or introduce samples manually through the evaporation cover with helpful on-screen prompts. Using the DDM feature allows you to precisely drop samples simultaneously or sequentially at a predetermined interval
- Customize your instrument with interchangeable dissolution accessory components, including paddles, baskets, rotating cylinder, and small-volume options. The common upper shafts support interchangeable baskets and paddles, yet maintain the correct height to save time when switching configurations
- Easily navigate the touch screen panel to setup, store and operate up to 35 methods on the easy-to-read color display. The intuitive interface with screen-locking security features also offers multiple languages, including English, Spanish, Japanese, Chinese and more
- Hands-free evaporation cover suspension offers a simple way to add media to the vessels, place dosage forms in the vessel, manually sample and measure physical parameters. The evaporation covers automatically travel with the apparatus drive unit using either the alignment posts or DDM assemblies
- Ensure proper vessel alignment with the 708-DS TruAlign vessel. The incorporated collar allows for better centering and vessel verticality than traditional glass-lipped vessels. There is an indicator tab on the collar allowing for greater reproducibility to minimize variability between dissolution runs



Hands-free evaporation cover suspension supports easy media addition.

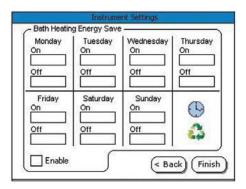
#### Did you know?

#### 708-DS standard features

- Programmable power-saving function to conserve energy
- Individual username and password access with configurable access levels
- Visual guidance for manual dosage introduction and sampling

#### 2 Dissolution Apparatus and Accessories

- Decrease cleaning time with the quick-connect fittings and angled water bath that supports complete draining
- The heater/circulator is freestanding to minimize vibration. The self-priming unit is quiet and designed to fit beneath the base plate to conserve valuable bench space
- Conserve energy by programming an automatic sleep schedule for the heater/ circulator when not in use
- Control access and prevent unwanted changes to instrument settings and methods with the different user levels provided by the 708-DS firmware
- Improve traceability to all system activity using the individual user name and password access feature
- Using easy-to-install conversion kits, the 708-DS is designed to accept 100 and 200 mL vessels, the 250 mL Chinese Pharmacopoeia vessel, and standard 1L vessels.
   The 2L model can incorporate 1 and 2L vessels as well as smaller volume vessels with conversion kits



Control the heater/circulator by programming the on/off cycles for energy efficiency.



The 708-DS is easily configured for USP Apparatus 1, 2, 5, and 6 as well as Intrinsic Dissolution or Enhancer (Immersion) Cell use.

#### Designed with compliance in mind

The recessed head with unobstructed access on the 708-DS makes setting and verifying physical parameters easier than ever, which is especially critical for Mechanical Qualification.

Agilent has not only raised the standard for dissolution instrumentation with the 708-DS, but the 280-DS Mechanical Qualification System simplifies the apparatus qualification procedure. Our solution also includes the traditional AIQ compliance services and electronic documentation consisting of IQ, OQ, PQ and/or MQ using Agilent's ACE software platform. In addition to these traditional offerings, Agilent provides training and familiarization, SOP templates and guidance, educational seminars, technical and application related support, and much more.

#### Online dissolution and analysis

Modular detection and automation components can easily be integrated to accomplish a UV analytical finish during dissolution testing. Agilent offers online UV Dissolution capabilities with the Cary 60 UV-Vis Spectrophotometers with either multicell or fiber optic configurations. See page 101 for more details.



Multicell UV Dissolution System, including the 708-DS Dissolution Apparatus, 850-DS Dissolution Sampling Station and Cary 60 UV-visible Spectrometer.

#### Did you know?

#### Is compliance important to you?

Agilent's Dissolution Workstation Software provides control of up to four dissolution apparatus from one PC. This software can operate any Agilent dissolution apparatus and sampling systems, as well as systems from Varian and VanKel.

See page 86 for more information about Dissolution Workstation Software.

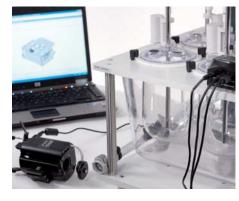
#### Standard 708-DS configuration

Because the 708-DS is designed for configurability, you have the ability to select the exact options you need for your instrument. A standard 708-DS includes:

- 708-DS Dissolution Apparatus
- Vessel plate level adjustment tools
- Receptor shafts with locking collars (6 or 8)
- Evaporation covers (6 or 8)
- Verified basket/paddle shafts and height setting devices
- USP 40-mesh baskets and molded 3-fin baskets (for pre-test mixing)
- Vessels (6 or 8)
- Level
- Heater/circulator
- Integrated hand-held temperature probe
- Safety manual and technical documentation CD

#### Optional enhancements

- Dosage Delivery Modules (DDM)
- AutoTemp In-vessel Temperature Monitoring
- Autosampling with automated manifold
- Bulk package of Full Flow Filters
- Low actinic red vessels
- Individually verified vessels and baskets
- VF molded vessels
- Built-in printer



Take physical parameter measurements of the 708-DS using the Agilent 280-DS Mechanical Qualification System. See pages 92 ff. to learn more about the

#### Did you know?

It is important to record the physical parameters of accessories (shafts, baskets and vessels) as well as the vessel position they are assigned to. All critical Agilent accessories are serialized for traceability.

#### 708-DS Dissolution Apparatus bundles

In order to simplify ordering, product numbers are available for the most common 708-DS configurations. Each bundle includes a 708-DS, 1L TruAlign clear glass vessels, interchangeable paddle and basket shafts, and baskets. Options to further customize each apparatus gives you the flexibility to support your specific testing needs.

Should you have any questions about configuring your apparatus, contact your local Agilent representative or contact us directly via the Dissolution Hotline at dissolution.hotline@agilent.com

#### 708-DS Dissolution Apparatus (6-position)

Description	Part No.
708-DS Dissolution Apparatus, 1L, 6-position	G7910A
Includes printer, handheld temperature probe, 1L vessels, interchangeable verified electropolished paddle and basket shafts, baskets, evaporation covers and complete accessories for 6 positions.	
Options for G7910A	
Dosage Delivery Modules (DDMs)	G7910A #101
DDMs and sampling manifold	G7910A #102
DDMs, sampling manifold and temperature monitoring	G7910A #103
Sampling manifold without temperature monitoring	G7910A #104
Sampling manifold with temperature monitoring	G7910A #105
Note: Only one (1) selection may be chosen from options #101-105 for G7910A (no	t a required selection).
Low actinic - red vessels	G7910A #110
Delete handheld temperature probe	G7910A #115
Delete basket shafts and baskets	G7910A #120
Delete paddle shafts	G7910A #125
PTFE-coated paddle shafts	G7910A #126
PEEK paddles	G7910A #127
Note: Only one (1) selection may be chosen from options #125-127 for G7910A (no	t a required selection).
VF molded vessels	G7910A #130
708-DS Dissolution Apparatus, 2L (includes 1L vessels)	G7910A #140
Verified accessories	G7910A #145
Non-slit evaporation cover	G7910A #146
Full Flow Filter, UHMWPE, 10 µm, 1,000/pk	G7910A #160
Full Flow Filter, UHMWPE, 35 µm, 1,000/pk	G7910A #161
Full Flow Filter, UHMWPE, 70 μm, 1,000/pk	G7910A #162
Full Flow Filter, PVDF, 10 μm, 1,000/pk	G7910A #163
Full Flow Filter, PVDF, 35 µm, 1,000/pk	G7910A #164
Delete 708-DS printer	G7910A #890
Add Installation Service	G7910A #44K
Add Familiarization Service	G7910A #44L

Note: For complete qualification services offering, see page 155.

#### Did you know?

#### **Dosage Delivery Modules**

USP <711> requires that dosage forms sink to the bottom of the vessel before rotation of the blade begins. Equip your 708-DS with DDM to simplify dropping your dosage form when using paddles. Methods can be programmed to automatically start simultaneously or sequentially. The DDM option saves analyst time and prevents costly timing errors. This feature is especially valuable when automated sampling systems are configured.

The 708-DS can be ordered to allow the use of 2L vessels. This configuration is typically used when greater volume is required to achieve sink conditions. If there is a chance you may need this capability, it must be ordered with this option; the 708-DS cannot be upgraded to the larger volume in the field. All of the automated features (DDM, AutoTemp and automated sampling) can be used on the 2L 708-DS. The 1L vessels as well as the other small-volume conversion kits can also be used.



2-Liter 708-DS Dissolution Apparatus equipped with DDM, Sampling and AutoTemp options.

#### Did you know?

#### **Documentation options**

When configuring a system, consider what other equipment it will be integrated with in your laboratory. If you plan to include an 850-DS, there is no need to duplicate a printer on both instruments. If the 708-DS will also be used for manual sampling, you may include G7913A #880 to add this option.

#### 708-DS Dissolution Apparatus (8-position)

Description	Part No.	
708-DS Dissolution Apparatus, 8-position	G7911A	
Includes printer, handheld temperature probe, 1L vessels, interchangeable verified electropolished paddle and basket shafts, baskets, evaporation covers and complete accessories for 8 positions.		
Options for G7911A		
Dosage Delivery Modules (DDMs)	G7911A #101	
DDMs and sampling manifold	G7911A #102	
DDMs, sampling manifold and temperature monitoring	G7911A #103	
Sampling manifold without temperature monitoring	G7911A #104	
Sampling manifold with temperature monitoring	G7911A #105	
Note: Only one (1) selection may be chosen from options #101-105 for G79	11A (not a required selection).	
Low actinic - red vessels	G7911A #110	
Delete handheld temperature probe	G7911A #115	
Delete basket shafts and baskets	G7911A #120	
Delete paddle shafts	G7911A #125	
PTFE-coated paddle shafts	G7911A #126	
PEEK paddles	G7911A #127	
Note: Only one (1) selection may be chosen from options #125-127 for G79	11A (not a required selection).	
VF molded vessels	G7911A #130	
708-DS Dissolution Apparatus, 2L, (includes 1L vessels)	G7911A #140	
Verified accessories	G7911A #145	
Non-slit evaporation cover	G7911A #146	
Full Flow Filter, UHMWPE, 10 μm, 1,000/pk	G7911A #160	
Full Flow Filter, UHMWPE, 35 μm, 1,000/pk	G7911A #161	
Full Flow Filter, UHMWPE, 70 μm, 1,000/pk	G7911A #162	
Full Flow Filter, PVDF, 10 µm, 1,000/pk	G7911A #163	
Full Flow Filter, PVDF, 35 μm, 1,000/pk	G7911A #164	
Delete 708-DS printer	G7911A #890	
Add Installation Service	G7911A #44k	
Add Familiarization Service	G7911A #44L	
Note: For complete qualification services offering, see page 155.		



Non-resident sampling cannulas in a TruAlign vessel on the 708-DS.

#### Did you know?

#### Hydrodynamic disturbances

Avoid hydrodynamic disturbances caused by resident dwelling probes. The sampling manifold only lowers the probes during sampling – lifting the probes between timepoints. By mimicking the manual procedure for sampling, the semi-automated system simplifies your method transfer and validation.

The 708-DS Dissolution Apparatus can pair with an 850-DS Sampling Station as well as one of Agilent's spectrophotometers to create an automated solution that best fits your needs. The 708-DS and 850-DS system provides an unattended, repeatable semi-automated solution for your laboratory. See page 101 for online UV dissolution system options.

#### 708-DS Dissolution Apparatus and 850-DS Sampling Station

Description	Part No.
Options for G7913A	
708-DS Dissolution Apparatus and 850-DS Sampling Station	G7913A
Includes 708-DS Dissolution Apparatus with DDMs, sampling manifold, vess accessories and 850-DS Sampling Station with 16x100 mm sample tray.	sels, paddles, baskets,
Add temperature monitoring to 708-DS	G7913A #105
Low actinic - red vessels	G7913A #110
Delete basket shafts and baskets	G7913A #120
Delete paddle shafts	G7913A #125
PTFE-coated paddle shafts	G7913A #126
PEEK paddles	G7913A #127
Note: Only one (1) selection may be chosen from options #125-127 for G7913A (not a re	quired selection).
VF Molded Vessels	G7913A #130
708-DS Dissolution Apparatus, 2L, (includes 1-Liter vessels)	G7913A #140
Verified accessories	G7913A #145
Non-slit evaporation cover	G7913A #146
Full Flow Filter, UHMWPE, 10 μm, 1,000/pk	G7913A #160
Full Flow Filter, UHMWPE, 35 μm, 1,000/pk	G7913A #161
Full Flow Filter, UHMWPE, 70 μm, 1,000/pk	G7913A #162
Full Flow Filter, PVDF, 10 µm, 1,000/pk	G7913A #163
Full Flow Filter, PVDF, 35 µm, 1,000/pk	G7913A #164
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7913A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7913A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7913A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7913A #213
Add Dissolution Workstation Software cable kit	G7913A #220
Note: Dissolution Workstation Software (G4974AA) or Software Bundle with PC (G4974. see page 86.	AA), ordered separately,
Add 708-DS printer	G7913A #880
Add printer to 850-DS	G7913A #881
Add Installation Service	G7913A #44K
Add Familiarization Service	G7913A #44L





Manual temperature measurement using 708-DS integrated hand-held temperature probe.

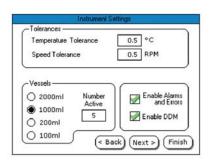
#### Did you know?

#### Temperature monitoring

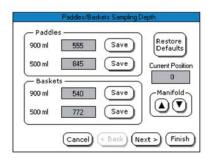
The USP requires that temperature be maintained during the test. Verify and monitor individual vessel temperatures prior to starting a test with the AutoTemp option, which records all the vessel temperatures at once, or via the integrated hand-held temperature probe to measure and record the vessel temperatures one at a time. When using the AutoTemp feature, once the set temperature is reached, the apparatus can begin the test automatically without analyst intervention.

#### 708-DS Dissolution Apparatus - Upgrade Options

Description	Part No.
708-DS Dissolution Apparatus – Printer Options	
Thermal printer assembly, for use with 708-DS	K1005-05226
708-DS Dissolution Apparatus – Options	
DDM assembly, for use with 708-DS	1005-1897
708-DS alignment post, for use in place of DDM with manifold	1005-1898
708-DS evaporation cover plug, white, for use in place of DDM	1200-1012
708-DS Dissolution Apparatus – Motorized Manifold Options	
708-DS manifold, sampling only, 8-position, 1L	G7910-68005
708-DS manifold, sampling only, 8-position, 2L	G7910-68006
708-DS manifold, sampling/temperature, 6-position, 1L	G7910-68011
708-DS manifold, sampling/temperature, 6-position, 2L	G7910-68012
708-DS manifold, sampling/temperature, 8-position, 1L	G7910-68013
708-DS manifold, sampling/temperature, 8-position, 2L	G7910-68014
Resident sampling kit, 6-position, 900 mL	K1001-01193
Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident sampling kit, 6-position, 500 mL	K1001-01195
Resident sampling kit, 8-position, 500 mL	K1001-01196
708-DS Dissolution Apparatus – Temperature Probe	
708-DS vessel temperature probe, handheld	K1005-01568
708-DS vessel temperature probe, single, 1L	5075-1050
708-DS vessel temperature probe, single, 2L	5075-1039
708-DS vessel temperature probe, 2x connect - dual, 1L	G7910-60019
708-DS vessel temperature probe, 2x connect - dual, 2L	G7910-60022
708-DS vessel temperature probe, 2x connect - single, 1L	G7910-60021
708-DS vessel temperature probe, 2x connect - single, 2L	G7910-60023



Specific settings and features within the 708-DS firmware such as tolerances, vessel volumes and alarms are easily adjusted to meet your laboratory's exact requirements.



The ability to specify an exact depth for the manifold means that each sample is withdrawn from the same USP location within the dissolution vessel. This adds to the reproducibility and consistency for every test performed - a critical consideration for dissolution testing.

#### Did you know?

#### Need an upgrade?

If you're looking to improve productivity and automate your 708-DS, an upgrade kit is available to add the necessary components. Contact your Agilent Service representative and reference part number K1002-02045 to add the internal and external components for DDM, sampling and temperature measurement.

## dissoGUARD Surveillance System

Merel, an Agilent dissolution partner, offers dissoGUARD, a powerful dissolution surveillance system that offers a real-time view of your dissolution vessels. A dedicated camera is located beneath each vessel location, and illumination is controlled via the software. The system gives you the ability to store videos, export pictures and archive videos for future analysis, track the position of dosage forms, timing and location of sampling cannulas, behavior of particles in-vessel and more. The PRO version enables users to evaluate physical parameters such as centering, wobble and paddle rotation speed. dissoGUARD can be retrofitted to any Agilent 708-DS.

Designed to support the Agilent 708-DS Dissolution Apparatus, dissoGUARD adds unmatched visibility into the dissolution vessel environment.

To learn more about this system, visit **www.dissoguard.com**, or contact your Agilent representative.



dissoGUARD Software.

#### dissoGUARD

Description	Part No.
dissoGUARD Surveillance System for Agilent 708-DS, includes 7 embedded cameras, 1 external camera, software and accessories.	G7988A
dissoGUARD PRO Software, provides monitoring of RPM, Wobble and Centering throughout the dissolution test.	G7988A#100
708-DS bath shield (for use with dissoGUARD)	G7988A#120
Add Installation Service	G7988A#44K
Add Familiarization Service	G7988A#44L

#### Did you know?

USP <1092> suggests that visual observations and recordings of dosage form behavior are helpful during the disintegration phase of the dissolution test to detect patterns that may indicate variability in the manufacturing process.



dissoGUARD System with 708-DS.



dissoGUARD System with amber lighting.

## dissoSHIELD

The dissoSHIELD option can be added to any 708-DS dissolution apparatus to protect light-sensitive products during the dissolution run and shield the bath from UV light by enclosing the area beneath the vessel plate. This allows the use of conventional clear glass - no need to purchase special vessels. The dissoSHIELD allows visibility to the vessels through three hinged doors on the front and sides and can be used with or without dissoSHIELD. When used with dissoGUARD, the special dynamic red lighting allows visibility of the vessels while protecting the light-sensitive products being tested.

#### dissoSHIELD

Description	Part No.
dissoSHIELD, 708-DS Bath Shield for light protection	G7988A#120
To be used when dissoGUARD is installed on a 708-DS.	



dissoSHIELD offers multiple viewing ports for visibility.

#### Did you know?

USP <1092> suggests that proper lighting, with appropriate consideration of photo-degradation, is needed for visual observations of the vessel contents during the dissolution test. Captured images of dosage form behavior may be especially helpful for formulators during product development and optimization stages.



dissoGUARD System with dissoSHIELD.

## 708-DS Accessories

#### Baskets, paddles and shafts

For Apparatus 1 (baskets) and Apparatus 2 (paddles) dissolution testing, Agilent's variety of quality accessories can support your laboratory needs while maintaining compliance with regulatory standards.

#### Two-piece interchangeable paddle/basket shafts

Switching between paddles and baskets is simple with Agilent's two-piece interchangeable paddle/basket shafts. Rather than resetting the height of the individual shafts when you change between paddles and baskets, the upper receptor shaft stays securely in place, while the lower interchangeable paddle or basket shaft can be switched for your specific testing needs. The paddle and basket shaft assemblies are designed with height offsets so that the proper height is maintained after the changeover.

These shafts are manufactured to meet or exceed the USP specifications. They are precisely engineered, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the media so there is less chance for contamination and corrosion. Each component is serialized for traceability and includes a Certificate of Conformance.

The 708-DS can also be used with single-piece basket and paddle shafts. The minimum shaft length required is 21 inches.



Two-piece interchangeable paddle/basket shafts with receptor shafts and 40-mesh baskets.



- A = 40-mesh basket (p/n 12-2100V)
- B = PTFE-coated basket (p/n 12-2110)
- C = Gold-plated basket (p/n 12-2105)
- D = 20-mesh basket (p/n 12-2120V)
- E = 10-mesh basket (p/n 12-2125)
- F = Suppository basket (p/n 12-2130)
- G = 3 fin basket (p/n 12-2115)
- H = Mini basket (p/n 12-2102)
- I = Bolus basket (p/n 12-2185).

#### Did you know?

Paddle and basket shafts from Agilent come as Verified Accessories with individual certificates of conformance (COCs) that document actual measured values of all critical dimensions, the measurement device used for certification and its traceability. Additionally, a wide variety of additional Verified Accessories are available, including various baskets, and vessels to meet your needs for Mechanical Qualification. For individual baskets and vessels, the verified accessories are denoted with a V at the end of the part number.

#### 708-DS Accessories - Paddles, Basket Shafts and Baskets

Description	Part No.	
Two-Piece Paddle/Basket Shafts with individual Certificate of Conformance		
Upper Receptor Shafts		
Upper receptor shaft, 21 in. (total length when assembled)	14-3613	
Lower Interchangeable Paddle and Basket Shafts		
Paddle, lower interchangeable, PTFE-coated	14-3602	
Paddle, lower interchangeable, electropolished stainless steel	14-3603	
Basket shaft, lower interchangeable, 3-clip, USP	14-3631	
Basket shaft, lower interchangeable, O-ring	13-3632	
Paddle, lower interchangeable, PTFE-coated, for 2L	14-3604	
Paddle, lower interchangeable, stainless steel, for 2L	14-3605	
Basket shaft, lower interchangeable, 3-clip, for 2L	14-3634	
Paddle, lower interchangeable, PEEK	14-3606	
Mini basket shaft, lower interchangeable, stainless steel, O-ring	14-3636	
Mini paddle, lower interchangeable, PTFE-coated	14-3607	
Mini paddle, lower interchangeable, stainless steel	14-3608	
Mini paddle, lower interchangeable, stainless steel, for 250 mL (CP)	14-1449	
Baskets		
Basket, USP, 40-mesh	12-2100	
Basket, USP, 40-mesh, includes individual CoC	12-2100V	
Basket, mini, 40-mesh	12-2102	
Locking Rings		
Shaft locking ring, for all models	12-2096	





Upper shaft receptor and lower paddle piece.



Paddles in storage case (included), 6/pk (p/n 16-3602). Six paddles are included in the kit, although the case will store eight.

#### Did you know?

#### An easy way to save

Replace your entire set of accessories with convenient 6-packs of select paddle, basket, and receptor shafts. Keep your system running smoothly by regularly refreshing key components.

Description	Part No.
Paddle, lower, PTFE-coated, 6/pk	16-3602
Paddle, lower, electropolished stainless steel, 6/pk	16-3603
Receptor, 21 in. total, 6/pk	16-3613
Basket, lower, 3-clip, 6/pk	16-3631

#### Vessels for 708-DS

Agilent's patented TruAlign vessels for the 708-DS precisely align the vessel every time. Each vessel is individually turned on a lathe to precisely locate the vessel center. Only TruAlign vessels have a collar incorporated onto the vessel around the ground glass groove, maintaining accurate centering and verticality alignment with the dissolution apparatus. An indicator tab on the collar provides reproducible vessel orientation while the serial number offers easy identification.

TruAlign vessels for the 708-DS are available in 100 mL and 200 mL, 1L and 2L sizes. They are available in clear or low actinic – red for light-sensitive products. TruAlign vessels are also available as Peak vessels to prevent cone formation. Individual Certificates of Conformance (CoC) can be obtained by ordering the verified versions of these vessels.



An individually serialized 1L TruAlign vessel (p/n 12-5149).

#### Did you know?

#### More than great products

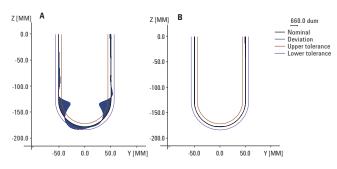
Quality equipment is just one component of your work. We believe education is critical to ensuring correct results. For this reason, we offer numerous educational programs geared to various functions within your company. See page 161 for more information.

#### VF molded vessels

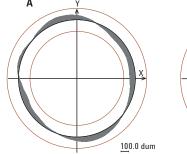
Agilent has also introduced molded TruAlign vessels which are vacuum formed (VF) and offer the tightest precision available to reduce position-to-position variability and improve uniformity. With specifications over 10 times more stringent than standard vessels, this option eliminates inconsistencies and removes vessel irregularity as a possible cause for failure. TruAlign VF vessels are offered as 1L clear glass only (available with or without an individual Certificate of Conformance).

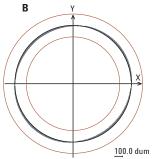
#### Did you know?

Learn more about Agilent's VF molded vessels at: www.agilent.com/lifesciences/vfvessels



Variation in vessel shape between standard vessels tested by Agilent (A) and Agilent VF molded vessels (B), which are well within USP vessel tolerances. The center of the three lines indicates the ideal shape of the cylinder and hemisphere. The two lines drawn on both sides represent ± 0.3 mm from the center line.





Variation in roundness between a standard vessel (A) and an Agilent VF molded vessel (B). The center of the three lines indicates the ideal shape of the cylinder and hemisphere. The two lines drawn on both sides represent ± 0.3 mm from the center line.

Note: the above drawings are not to scale. The shapes are exaggerated for illustration purposes.

#### Conversion kits

The 708-DS Dissolution Apparatus can also support small-volume dissolution. Each position will require a conversion kit to hold a 100 or 200 mL vessel in position. The conversion kits are designed to be used with either mini paddles, mini baskets, or Enhancer (Immersion) Cells (see pages 60 ff.).

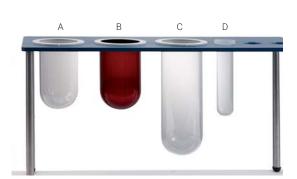
Special conversion kits, available in sets of 6 and 8, are also available for the Chinese Pharmacopeia (CP) 250 mL vessel. These kits include the 250 mL vessel designed according to CP specifications, vessel adapter ring, two-piece mini paddle, evaporation cover, height setting device and manifold conversion block (see page 29 for complete details).

#### 708 Accessories - Vessels and Conversion Kits

Description	Part No.
TruAlign Vessels for 708-DS Dissolution Apparatus	
TruAlign vessel, 100 mL	12-5145
TruAlign vessel, low actinic – red, 100 mL	12-5146
TruAlign vessel, 200 mL	12-5147
TruAlign vessel, low actinic – red, 200 mL	12-5148
TruAlign vessel, 1L	12-5149
TruAlign vessel, 1L, with certificate	12-5149V
TruAlign vessel, low actinic – red, 1L	12-5152
TruAlign vessel, low actinic – red, 1L, with certificate	12-5152V
TruAlign Peak vessel, 1L	12-5153
TruAlign Peak vessel, 1L, with certificate	12-5153V
TruAlign Peak vessel, low actinic – red, 1L	12-5154
TruAlign vessel, 2L	12-5157
TruAlign vessel, 2L, with certificate	12-5157V
TruAlign vessel, low actinic – red, 2L	12-5158
TruAlign vessel, low actinic – red, 2L, with certificate	12-5158V
TruAlign Peak vessel, 2L	12-5159
TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170

(Continued)

1L TruAlign Peak vessel (p/n 12-5153).



- A = 1L TruAlign vessel (p/n 12-5149)
- B = 1L low actinic red TruAlign vessel (p/n 12-5152)
- C = 2L TruAlign vessel (p/n 12-5157)
- D = 200 mL TruAlign vessel (p/n 12-5147)

#### Did you know?

Agilent offers you the convenience of ordering all your dissolution accessories online at www.chem.agilent.com/store

#### 708-DS Accessories - Vessels and Conversion Kits

Description	Part No.		
TruAlign VF Molded Vessels for 708-DS Dissolution Apparatus			
TruAlign VF molded vessel, clear, 1L	12-1501		
TruAlign VF molded vessel, clear, 1L with certificate	13-0010		
Small Volume TruAlign Vessel Conversion Kits for 708-DS			
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368		
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450		
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451		
Height gauge sphere, 15 mm, for small volume vessels	K4040-00495		



250 mL Vessel kit (CP) (p/n 12-1450).

#### Did you know?

A 708-DS Dissolution Apparatus can easily convert to a small-volume apparatus. For example, to convert a 6-position, 1L 708-DS for 200 mL testing with paddles, simply order the parts in the table on the right. Once installed, a simple adjustment to the sampling manifold is also necessary that requires no additional parts or service call.

#### Small-volume conversion ordering example

Quantity	Description	Part No.
6	TruAlign vessel, 200 mL	12-5147
6	TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
6	Mini paddle, lower interchangeable, stainless steel	14-3608

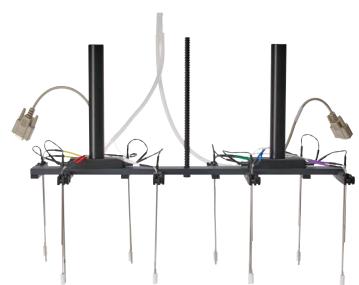
#### Accessories for 708-DS

In addition to vessels, paddles, baskets and shafts, Agilent offers a variety of accessories specific to the 708-DS platform.

#### 708-DS Accessories

Description	Part No.		
708-DS Upgrade Kit			
708-DS internal upgrade for DDM, sampling, temperature	K1002-02045		
Replacement Tubing Assemblies for 708-DS Manifold			
Tubing assembly, for 1L 708-DS, sample and return cannulas, 6-position	1005-1920		
Tubing assembly, for 1L 708-DS, sample and return cannulas, 8-position	1005-1921		
Tubing assembly, for 2L 708-DS, sample and return cannulas, 6-position	1005-1922		
Tubing assembly, for 2L 708-DS, sample and return cannulas, 8-position	1005-1923		
Sampling Manifolds for 708-DS			
708-DS manifold, sampling only, 8-position, 1L	G7910-68005		
708-DS manifold, sampling only, 8-position, 2L	G7910-68006		
708-DS manifold, sampling/temperature, 6-position, 1L	G7910-68011		
708-DS manifold, sampling/temperature, 6-position, 2L	G7910-68012		
708-DS manifold, sampling/temperature, 8-position, 1L	G7910-68013		
708-DS manifold, sampling/temperature, 8-position, 2L	G7910-68014		

(Continued)



708-DS Sampling Manifold.

#### Did you know?

Have your laboratory needs changed? Are you ready to upgrade to an automated sampling system? While it's strongly recommended to prepare for this situation when initially ordering your instrument, to add sampling capabilities to your 708-DS, choose the 708-DS upgrade kit and sampling manifold that best fits your needs based on features and vessel volume.

Contact your Agilent representative about scheduling installation of these items:

www.agilent.com/chem/contactus

#### 708-DS Accessories

Resident Probe Sampling Kits for 708-DS  Resident sampling kit, 6-position, 900 mL  Resident sampling kit, 8-position, 900 mL	K1001-01193 K1001-01194
Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident sampling kit, 6-position, 500 mL	K1001-01195
Resident sampling kit, 8-position, 500 mL	K1001-01196
Evaporation Covers	
708-DS evaporation cover, standard, for CP/USP sampling	K1005-05225
708-DS evaporation cover, non-slit, for CP/USP sampling	G7910-60030
708-DS evaporation cover, low loss for use with resident sampling probes	K1005-05218
708-DS alignment post, for use in place of DDM with manifold	1005-1898
708-DS evaporation cover plug, white, for use in place of DDM	1200-1012
708-DS evaporation cover plug, black, flat	12-6370
708-DS evaporation cover, for blank position	K1400-00210

(Continued)



The standard 708-DS evaporation cover (p/n K1005-05225) supports both the harmonized USP and CP sampling location. Opaque design allows use with light-sensitive products.

#### 708-DS Accessories

Miscellaneous Accessories for 708-DS		
Heater/circulator, 115/230V	G7986B	
Water bath temperature probe	67-0300	
708-DS vessel temperature probe, handheld	K1005-01568	
DDM assembly, for use with 708-DS	1005-1897	
Thermal printer assembly, for use with 708-DS	K1005-05226	
Thermal printer paper, for use with 708-DS, 10 rolls/pk	G7910-87002	
Cannula rinse cup, with shaft clip	17-1340	
Cannula rinse cup carrying tray	17-1345	
Acrylic rinse tray, for 708-DS	17-1351	
Storage rack for two-piece paddle/basket shafts	12-1352	
Sample tubing rinse kit	17-1341	
Storage rack for one-piece paddle/basket shafts	12-1350	
Manual sampling bracket, for use with manifold, 708-DS	17-3151	
Manual sampling bracket, resident probes, 708-DS	17-3152	
Molded baskets, 3-fin (for pretest mixing)	12-1049	

#### Did you know?

#### Manual sampling bracket

A manual sampling bracket option is available for the 708-DS Dissolution Apparatus. This bracket gives users the ability to sample manually from each vessel position in an efficient and repeatable manner. The bracket attaches to the front of the apparatus and is available with the option to use resident sampling probes (which reside in the evaporation cover) or a motorized manifold. The manifold option takes full advantage of the instrument's capability to achieve a reproducible sampling position at each timepoint. A photo of the manual sampling bracket is shown on page 49.



Two-piece interchangeable basket/paddle shaft storage rack (p/n 12-1352).



Heater/circulator (p/n G7986B).



Built-in printer for the 708-DS (p/n K1005-05226).

## **Dissolution Accessories**

#### Baskets, Paddles and Shafts

For Apparatus 1 (baskets) and Apparatus 2 (paddles) dissolution testing, Agilent's variety of quality accessories can support your laboratory's needs while maintaining compliance with regulatory standards. In keeping with the most current guidance for mechanical qualification, Agilent offers Verified Dissolution Accessories including baskets, paddles and shafts with certificates of conformity with actual component measurements for all critical dimensions using traceable devices.

#### **Basket shafts**

Whether you need electropolished stainless steel, PTFE-coated, gold-plated or mini basket shafts, Agilent provides these individually serialized accessories. Basket shaft options include 3-clip shafts to meet standard USP design, O-ring for automated systems, or conical to support air bubble dispersion. A range of basket shaft lengths to accommodate various models and volume configurations are available.

#### **Baskets**

From the standard USP 40-mesh stainless steel basket, to custom baskets with varying mesh sizes, to baskets specific to small or large dosage forms, Agilent supports your Apparatus 1 needs. Unless otherwise noted, all baskets fit the standard basket shafts.

#### Did you know?

#### Legacy products

Agilent continues to support customers with accessories for legacy products. See pages 131 ff. for a complete listing of accessories that are compatible with the 709-DS, 705-DS, 7000/7010 and 7025/7030 V-Series.

#### Ordering

Order Agilent parts and supplies for current as well as legacy instruments at www.chem.agilent.com/store



- A = Standard 3-clip shaft (p/n 14-3620)
- B = Conical 3-clip shaft (p/n 14-3624)
- C = Standard O-ring shaft (p/n 13-3621)
- D = Conical O-ring shaft (p/n 13-3623)
- E = PTFE-coated 3-clip shaft (p/n 13-3622)

#### **Paddles**

All paddles are serialized and designed to meet USP specifications for Apparatus 2. Each paddle includes an individual Certificate of Conformance as standard. Select from electropolished stainless steel, PTFE-coated or the biocompatible, chemically inert PEEK (polyetheretherketone) paddles in a range of sizes. Additionally, mini and mega paddles for small- and large-volume dissolution testing are available.

#### Two-piece interchangeable paddle/basket shafts

Switching between paddles and baskets is simple with Agilent's two-piece interchangeable paddle/basket shafts. Rather than resetting the height of the individual shafts when you change between paddles and baskets, the upper receptor shaft stays securely in place, while the lower interchangeable paddle or basket shaft can be switched for your specific testing needs. The paddle and basket shaft assemblies are designed with height offsets so that the proper height is maintained after the changeover.

These shafts are manufactured to meet or exceed the USP specifications and precisely engineered, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the media so there is less chance for contamination and corrosion. Further, each component is serialized for traceability.

The 708-DS can also be used with single-piece basket and paddle shafts. The minimum shaft length required is 21 inches.



A = Electropolished stainless steel paddle, 21 inch (p/n 14-3595)

B = PTFE-coated paddle, 21 inch (p/n 14-3594)

C = PEEK paddle, 24 inch (p/n 13-3598)

D = Electropolished mini paddle, 24 inch (p/n 14-3600)

E = PTFE-coated mini paddle, 24 inch (p/n 14-3599)

Also available in 2-piece design (receptor shaft with interchangeable lower assembly).



Upper shaft receptor and lower interchangeable paddle piece.

#### Did you know?

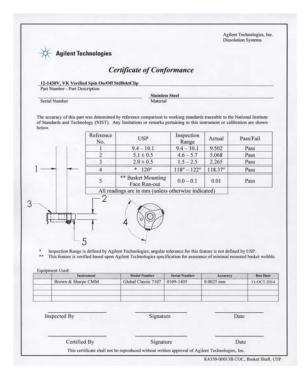
Analysts are required to ensure that the apparatus is properly adjusted prior to the start of each test. The Interchangeable shafts allow the switching of paddle and basket lower shafts without changing the height resetting.

## **Certificates of Conformity**

There is some confusion regarding what constitutes a Certificate of Conformance or Certificate of Analysis (CoC, CoA). Simply stating a component meets USP requirements is not sufficient. Each critical parameter for each individual accessory should be measured and documented. According to ASTM E2503: "3.1 Analyst Responsibilities: Verify the vessel, basket, and paddle dimensions on receipt through measurement or Certificate of Analysis (CoA) or Certificate of Conformance (CoC)"

- 4.3 Apparatus Setup: During apparatus installation or after replacement of parts or components, verify that the description and critical dimensions for each part meet the original description and dimension. After this statement, a more detailed description is given for vessels, paddles and basket/shaft dimensions.
- 4.3.3 Paddle Dimensions: In the absence of a CoA or CoC, an appropriate measuring device is used to measure the relevant dimensions of the paddle. Examples of dimensions to be determined on each paddle should include but are not limited to: shaft diameter, blade height, blade thickness, total blade length, length of flat portion on bottom of blade, radius of the angle on the top outer edge of the top of the blade, radius of the outside edge of the blade, difference between the distance from the midline of the shaft to the top outer edge for the two sides, and difference between the heights of both sides of the paddles at the outside top.

Verification in GMP applications means documentation. If you measure it, you document it. Without documentation (of the actual measurements) you cannot prove anything.



Certificate of Conformance for an Agilent basket shaft.

## Did you know?

Certificates of Conformance must contain actual measurements of the physical parameters contained in the harmonized USP for each serialized component to verify that it meets required specifications and tolerances. Documentation includes the traceability for individual calibrated tools and gauges used for each measurement of the physical dimensions.

## One-Piece Basket Shafts with Individual Certificate of Conformance

Description	Part No.
21 - 24 in. (53 - 61 cm) Basket Shafts for 7000/7010, 705/708/7	'09-DS
Basket shaft, USP 3-clip, 21 in.	14-3620
Basket shaft, O-ring, 21 in.	13-3621
Basket shaft, PTFE-coated, 21 in.	13-3622
Basket shaft, 3-clip, conical, 21 in.	14-3624
Basket shaft, USP 3-clip, 24 in.	13-3629
Basket shaft, for bolus basket, 24 in.	13-3630
Baskets	
Note: Baskets are not supplied with a certificate of conformance (CoC) unles	ss noted with a "V" in the part number.
Basket, USP, 40-mesh	12-2100
Basket, USP, 40-mesh, includes individual CoC	12-2100V
Basket, mini, 40-mesh	12-2102
Basket, gold-plated, 40-mesh	12-2105
Basket, PTFE-coated, 40-mesh	12-2110
Basket, 3-fin assembly, 40-mesh	12-2115
Basket, 20-mesh, 864 µm	12-2120
Basket, 20-mesh, with CoC	12-2120V
Basket, 10-mesh	12-2125
Basket, slotted, for suppository testing	12-2130
Basket, 450x2750-mesh, 1 µm	12-2140
Basket, 400x2800-mesh, 2 µm	12-2145

(Continued)

## Did you know?

## More than great products

Quality equipment is just one component of your work. We believe education is critical to ensuring correct results. For this reason, we offer numerous educational programs geared to various functions within your company. See page 161 for more information.



Close-up of standard 3-clip shaft (p/n 14-3620) and conical 3-clip shaft (p/n 14-3624).

## One-Piece Basket Shafts with Individual Certificate of Conformance

Description	Part No.
Baskets	
Basket, 325x2300-mesh, 5 µm	12-2146
Basket, 200x1400-mesh, 10 μm	12-2148
Basket, 165x800-mesh, 20 μm	12-2149
Basket, 325x325-mesh, 43 μm	12-2150
Basket, 270x270-mesh, 53 μm	12-2151
Basket, 150x150-mesh, 104 μm	12-2152
Basket, 100x100-mesh, 140 μm	12-2154
Basket, 50x50-mesh, 280 µm	12-2155
Bolus basket, 20x20-mesh, 864 µm	12-2180
Bolus basket, 40x40-mesh, 381 µm	12-2185
Basket, Metformin vertical sample holder, large	12-2165
Basket, Metformin vertical sample holder, small	12-2170
Additional Baskets and Sample Holders	
Stationary basket shaft (basket sold separately)	12-2065
Stationary basket, Felodipine quadrangular	12-2069
Float-A-Lyzer holder, for use with USP Apparatus 1	12-2066
Float-A-Lyzer holder, stationary, for use with USP Apparatus 2	12-2067
Float-A-Lyzer holder, for use with USP Apparatus 3	



Stationary basket (p/n 12-2069).



Stationary basket, Felodipine quadrangular (p/n 12-2069).



A = 40-mesh basket (p/n 12-2100V) B = PTFE-coated basket (p/n 12-2110)

C = Gold-plated basket (p/n 12-2105)



Float-A-Lyzer with holder and evaporation cover (p/n 12-2066).

## Two-piece Interchangeable Paddle/Basket Shafts

Description	Part No.
Two-piece Interchangeable Paddle/Basket Shafts with Individual Certif Conformance	icate of
Paddle, lower interchangeable, PTFE-coated	14-3602
Paddle, lower interchangeable, electropolished stainless steel	14-3603
Basket shaft, lower interchangeable, 3-clip, USP	14-3631
Basket shaft, lower interchangeable, O-ring	13-3632
Upper receptor shaft, for 15 in. total shaft length	14-3612
Upper receptor shaft, 21 in. (total length when assembled)	14-3613
Upper receptor shaft, 24 in.	13-3614
Paddle, lower interchangeable, PTFE-coated, for 2L	14-3604
Paddle, lower interchangeable, stainless steel, for 2L	14-3605
Basket shaft, lower interchangeable, 3-clip, for 2L	14-3634
Paddle, lower interchangeable, PEEK	14-3606
Mini basket shaft, lower interchangeable, stainless steel, O-ring	14-3636
Mini paddle, lower interchangeable, PTFE-coated	14-3607
Mini paddle, lower interchangeable, stainless steel	14-3608
Shaft Accessories	
Storage rack for one-piece paddle/basket shafts	12-1350
Storage rack for two-piece paddle/basket shafts	12-1352
Shaft locking ring, for all models	12-2096



Two-piece interchangeable basket/paddle shaft storage rack (p/n 12-1352).



Paddle (p/n 14-3603) and upper receptor shaft (p/n 14-3612).

## Did you know?

An easy way to save	Description	Part No.
Replace your entire set of accessories	Paddle, lower, PTFE-coated, 6/pk	16-3602
vith convenient 6-packs of select paddle,	Paddle, lower, electropolished stainless steel, 6/pk	16-3603
pasket, and receptor shafts. Keep your system running smoothly by regularly	Receptor, 21 in. total, 6/pk	16-3613
refreshing key components.	Basket, lower, 3-clip, 6/pk	16-3631

## Paddle Shafts with Individual Certificate of Conformance

Description	Part No.	
21 - 24 in. (53 - 61 cm) Paddle Shafts for use with 7000/7010E, 705/708/709-DS		
Paddle, PTFE-coated, 21 in.	14-3594	
Paddle, PTFE-coated, 24 in.	13-3596	
Paddle, electropolished, 21 in.	14-3595	
Paddle, electropolished, 24 in.	14-3597	
Paddle, PEEK, 24 in.	13-3598	
Mini paddle, PTFE-coated, 24 in.	14-3599	
Mini paddle, electropolished, 24 in.	14-3600	
Mega paddle, electropolished stainless steel, 24 in.	13-3601	



Storage rack for one-piece paddle/basket shafts (p/n 12-1350).

## Did you know?

## Ordering

Order Agilent parts and supplies for current as well as legacy instruments at

www.chem.agilent.com/store



Six paddles are included in the kit (p/n 16-3602), although the case will store eight.



Individual paddles and basket shafts are shipped in a single storage container.

## Dissolution Vessels

Agilent provides a variety of dissolution vessels for use with Agilent dissolution apparatus, as well as other equipment manufacturers. A wide variety of vessel types and volumes are available. Agilent's vessels are designed meet regulatory specifications, ensuring quality and consistency.

Inferior vessels are a frequent cause of qualification errors. Don't risk your results – use the original Agilent glassware.



 $TruAlign\ vessel\ for\ the\ 708-DS\ with\ Certificate\ of\ Conformance\ (CoC)\ (p/n\ 12-5149V).$ 

## TruAlign vessels

The 708-DS uses TruAlign vessels which are individually turned on a lathe to locate the precise center of the vessel. A ground groove is cut into the vessel rim to incorporate a collar onto the vessel to maintain accurate centering and verticality alignment with the dissolution apparatus. An indicator tab on the collar provides reproducible vessel orientation while the serial number offers easy identification.

TruAlign vessels for the 708-DS are available in 100 and 200 mL, and 1 and 2L sizes. Low actinic – red, Peak, and Verified versions are also available for select volumes.

#### VF molded vessels

Agilent also offers a molded vessel – in EaseAlign, TruCenter and TruAlign form – which are vacuum formed (VF) and provide the tightest precision available to reduce positionto-position variability and improve uniformity. With specifications over 10 times more stringent than standard vessels, this option eliminates inconsistencies and puts the focus on the dosage form. The VF vessels are offered as 1L clear glass only and are available with or without a Certificate of Conformance. For more information on VF vessels, take a look at our technical overview at www.agilent.com/lifesciences/vfvessels

## Did you know?

#### Verified dissolution accessories

Do you need vessels that are individually certified to meet with Mechanical Qualification guidelines? Agilent offers Verified Dissolution Accessories with a certificate of conformance that documents the actual measured values of all critical dimensions, the measurement device used for certification, and its traceability.



1L TruAlign VF molded vessel (p/n 13-0010).

## TruAlign Vessels for 708-DS

Description	Part No.
TruAlign vessel, 100 mL	12-5145
TruAlign vessel, low actinic – red, 100 mL	12-5146
TruAlign vessel, 200 mL	12-5147
TruAlign vessel, low actinic – red, 200 mL	12-5148
TruAlign vessel, 250 mL, for Chinese Pharmacopeia	12-1452
TruAlign vessel, 1L	12-5149
TruAlign vessel, 1L, with certificate	12-5149V
TruAlign vessel, low actinic – red, 1L	12-5152
TruAlign vessel, low actinic – red, 1L, with certificate	12-5152V
TruAlign Peak vessel, 1L	12-5153
TruAlign Peak vessel, 1L, with certificate	12-5153V
TruAlign Peak vessel, low actinic - red, 1L	12-5154
TruAlign vessel, 2L	12-5157
TruAlign vessel, 2L, with certificate	12-5157V
TruAlign vessel, low actinic – red, 2L	12-5158
TruAlign vessel, low actinic – red, 2L, with certificate	12-5158V
TruAlign Peak vessel, 2L	12-5159
TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170
TruAlign VF molded vessel, clear, 1L	12-1501
TruAlign VF molded vessel, clear, 1L with certificate	13-0010
Height gauge sphere, 15 mm, for small volume vessels	K4040-00495
Small-volume TruAlign Vessel Conversion Kit for 708-DS Dissolution Apparatus	:
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451

## Did you know?

The Peak vessel was introduced to solve coning problems. Some dosage forms form a cone in the bottom of the vessel. The result is the media only comes in contact with the outer layer, slowing the dissolution process. Typically results are lower than anticipated. The Peak vessel disperses the cone exposing greater surface area. While the Peak vessel is not presently included in the USP, multiple methods using this vessel have been accepted by the FDA. As with any non-compendial accessory, proper justification is required for use.



1L TruAlign Peak vessel (p/n 12-5153).

## Conversion Kits

#### Small-volume kits

Small-volume conversion kits are an excellent, cost-effective way to use your existing equipment for testing that requires a smaller volume of media. These kits allow the 708-DS to convert from the standard 1-Liter vessel to a smaller volume. Each position will require a conversion kit to hold the mini-vessel in position. These kits can also be used with Online UV dissolution systems when preparing standards for automated analyses. In this configuration, a single conversion kit is used in position 7 of the dissolution apparatus. The smaller volume allows you to prepare a smaller amount of standard, saving you money. The conversion kits are designed to be used with either mini paddles or mini baskets, which are sold separately.

100 and 200 mL conversion kits are available for the 708-DS, as well as the legacy 705-DS, 7000/7010, and 7025 Dissolution Apparatus. If you intend to use automated sampling options for these instruments with a small-volume conversion kit, you may need a modified or new sampling manifold to accommodate the change in vessel diameter and sampling position.

- Small-volume conversion kits, sold individually or in packages, typically require:
- Mini vessel
- Mini paddle or mini-basket and basket shaft
- Evaporation cover
- Centering ring assembly or adapter

Shaft lengths and diameters, as well as vessel types, are noted with the part number descriptions.



708-DS conversion kit (p/n 12-6368), 200 mL vessel with mini paddle.

## Did you know?

#### Sink condition requirements

In any dissolution test, it is imperative that there is sufficient media to meet sink requirements, which means that media volume at least three times beyond the point of saturation should be used. The dissolution rate should not be inhibited by saturation. At the same time you must consider the detection limits of your analytical technique. Vessel volume adjustments can help to meet the appropriate conditions for your dissolution method.

## Conversion Kits for 708-DS Dissolution Apparatus

Description	Part No.
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451

## Large-volume configuration

If you potentially need to test using a larger volume (e.g., 2L), you need to buy your new 708-DS with this configuration. A 2L system is able to support 1L vessels; only a vessel change is required. A standard 1L system cannot be converted to a 2L system after purchase.

708-DS Dissolution Apparatus: 8-position, 2L model with motorized lift.

## Legacy products

Did you know?

## Legacy products

Agilent continues to support customers with accessories for legacy products. See pages 131 ff. for a complete listing of accessories that work with the 709-DS, 705-DS, 7000/7010 and 7025/7030 V-Series.



2L TruAlign vessel (p/n 12-5157).

## Capsule Wire, Weights and Sinker Baskets

Capsule wire, weights and sinker baskets are used to retain a solid dosage form at the bottom of the vessel for testing when the dosage form is buoyant. Depending on your dosage form a variety of options are available.

The flexible capsule wire meets USP requirements and has a 0.032 in. diameter. The stainless steel wire is twisted around the dosage form to provide sufficient mass and to ensure the dosage form sinks to the bottom of the vessel.

Sinker baskets are offered in a variety of mesh sizes and made of stainless steel. The press-on caps use O-rings to seal the basket once the dosage form is inserted. The Japanese Pharmacopoeia (JP) sinker basket is also available as an alternative.

A three-prong capsule weight can be used to retain your capsule for testing. These weights fit traditional capsule sizes one through three, and are sold individually.



Capsule weight wire (top row), two versions of wire sinkers and a Japanese sinker (second row), mesh sinkers (third row) and 3-prong sinkers (fourth row).

## Capsule Wire, Weights and Sinker Baskets

Description	Part No.
Capsule weight wire, 316 stainless steel, 0.032 in. dia., 50 ft.	12-3000
Capsule weight, 3-prong	12-3050
Capsule weight, robotic type, with magnetic cap	12-3055
Capsule weight, robotic type, with magnetic inserts in legs	12-3056
Sinker basket, with cover, 10-mesh, 1905 μm	12-3060
Sinker basket, with cover, 8-mesh, 2591 µm	12-3062
Sinker basket, with cover, 20-mesh, 864 µm	12-3063
Sinker basket, with cover, 40-mesh, 381 µm	12-3064
Sinker basket, with cover, 100-mesh, 140 μm	12-3065
Sinker basket, with cover, 60-mesh, 229 µm	12-3066
Sinker basket, with cover, 150-mesh, 104 µm	12-3067
Sinker basket, with cover, 270-mesh, 53 μm	12-3068
Sinker basket, with cover, 325-mesh, 45 µm	12-3072
Sinker basket, Japanese Pharmacopoeia (JP)	12-3070

## Sinker Baskets Dimensions\*

Inside diameter	20.3 mm / 0.8 in.
Outside diameter (with cover)	25 mm / 0.98 in.
Inside height	11.7 mm / 0.46 in.
Outside height (without cover)	15 mm / 0.59 in.
Outside height (with cover)	20 mm / 0.79 in.

<sup>\*</sup>Excludes Japanese Pharmacopoeia sinker basket (p/n 12-3070).



Japanese Pharmacopeia sinker basket (p/n 12-3070).

## Did you know?

#### When to use a sinker

Sinkers are used during a dissolution test to sink a dosage form that would otherwise float. The USP specifies that a small piece of non-reactive material, such as not more than a few turns of steel wire, can be attached to the dosage form to prevent floating. Other validated sinkers may also be used for this purpose.

Weights and sinker baskets may also be used for sticky dosage forms, as well as powders contained in capsule shells.

# Sampling and Temperature Measurement

For a guick, manual sampling solution, the Agilent cannula luer lock assembly is comprised of a bent cannula and a sampling syringe that are best used with the Full Flow Filters. The sampling cannulas are available two in different lengths based on the volume of media, 500 or 900 mL, from which you will sample. An adjustable gauge can be included with this assembly to ensure repeatable positioning for each sample.

Resident sampling kits are available to pull samples through a resident-dwelling probe when there is no automated manifold. Probes left in the media during a dissolution run will alter the hydrodynamics and may affect the rate of release. Therefore, it is critical that resident probe methods are validated against manual sampling to ensure the integrity of the dissolution test is intact.

For automated sampling, the motorized manifold of the 708-DS will lower and raise sampling cannulas at each timepoint when used with the 850-DS Dissolution Sampling Station. The standard sampling manifolds withdraw samples from the proper USP sampling point, halfway between the top of the paddle/basket and the top of the media. Full Flow Filters are recommended for use to prevent undissolved particles from contaminating the sample lines.

A sampling bracket may also be installed on the dissolution apparatus to simplify and improve consistency when manually sampling. This bracket is able to utilize the automated manifold or a resident sampling kit - either way, repeatable sampling is achieved with less time and effort.

## Did you know?

USP requires the removal of sample aliquots at specific timepoints that must also be filtered within a ±2% window of when the dosage forms were introduced into the media. For example when a calibrated timer indicates its time to pull a sample, you have a 36-second window to pull a sample and filter it for a 30-minute time point. Additionally, you have only 18 seconds for a 15 minutes time point, and so on.



Manual sampling on the 708-DS.

The legacy 7025 and 7030 Dissolution Apparatus include individual sampling cannulas that may include temperature probes as well. The sampling depth of the cannulas is preset and stored in the firmware of the instrument based on the apparatus installed and volume. The cannulas are only submerged at the time of sampling to minimize hydrodynamic disturbance.

The 708-DS and legacy 709-DS also support an automated, non-resident manifold, which is included in those systems preconfigured for automated sampling. Any unit without the automated manifold can be retrofitted by our service organization. The exact depth of 64 different sampling locations is stored in the 708-DS firmware depending on vessel volume and USP apparatus installed.

Autosampling manifolds can also support the AutoTemp In-Vessel Temperature Sensing System to lower temperature probes at a specifically programmed time. Once the temperature is measured, the manifold removes the probes to avoid hydrodynamic disturbances. AutoTemp makes starting methods easy, particularly when combined with the Dosage Delivery Module (DDM) option. As soon as the desired temperature is reached, the values are recorded and the dosage forms are introduced. Like the Autosampling option, AutoTemp is available on new apparatus and may also be retrofitted to an existing instrument.



Resident cannula kit on the 708-DS. See table below for available kits

## **Resident Sampling Kits/Accessories**

DescriptionPart No.Resident sampling kit, 6-position, 900 mLK1001-01193Resident sampling kit, 8-position, 900 mLK1001-01194Resident sampling kit, 6-position, 500 mLK1001-01195Resident sampling kit, 8-position, 500 mLK1001-01196Resident probe sample cannula, 500 mL17-3330Resident probe sample cannula, 900 mL17-3335		
Resident sampling kit, 8-position, 900 mL  Resident sampling kit, 6-position, 500 mL  Resident sampling kit, 8-position, 500 mL  K1001-01195  Resident sampling kit, 8-position, 500 mL  K1001-01196  Resident probe sample cannula, 500 mL  17-3330	Description	Part No.
Resident sampling kit, 6-position, 500 mL K1001-01195  Resident sampling kit, 8-position, 500 mL K1001-01196  Resident probe sample cannula, 500 mL 17-3330	Resident sampling kit, 6-position, 900 mL	K1001-01193
Resident sampling kit, 8-position, 500 mL K1001-01196 Resident probe sample cannula, 500 mL 17-3330	Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident probe sample cannula, 500 mL 17-3330	Resident sampling kit, 6-position, 500 mL	K1001-01195
	Resident sampling kit, 8-position, 500 mL	K1001-01196
Resident probe sample cannula, 900 mL 17-3335	Resident probe sample cannula, 500 mL	17-3330
	Resident probe sample cannula, 900 mL	17-3335

Note: Resident sampling kits for the 7000/7010 or 705-DS must be used with the low-loss evaporation cover (p/n 12-6328).

## **Manual Sampling Accessories**

Description	Part No.
Bent cannula with Luer Lock, for sampling from 900 mL in 1L vessels, 4.75 in.	12-3200
Bent cannula with Luer Lock, for sampling from 500 mL in 1L vessels, 7.75 in.	12-3210
Bent cannula with adjustable gauge, 4.75 in. (900 mL), 708-DS	12-3221
Bent cannula with adjustable gauge, 7.75 in. (500 mL), 708-DS	12-3222
Adjustable gauge kit, 708-DS	12-3223
Cannula, PEEK, for low-volume sampling	12-3219
Filter holder, 25 mm	12-3220
Glass syringe, 20 cc	12-3230
Manual sampling bracket, for use with manifold, 7000/7010	17-3150
Manual sampling bracket, for use with manifold, 708-DS	17-3151
Manual sampling bracket, resident probes, 708-DS	17-3152
Captiva 20 mL Disposable plastic Syringes, 100/pk	5190-5103

## Did you know?

## For your sampling needs

Agilent offers a variety of height spacers to increase working space when performing manual sampling.

See page 64 for Verification Tools, including these spacers. Full Flow Filters are recommended for use with automated sampling options. See page 50 for details.



- A = Glass syringe, 20 cc (p/n 12-3230)
- B = Bent cannula with Luer Lock (p/n 12-3200)
- C = Bent cannula with adjustable gauge (p/n 12-3221)



Manual sampling bracket mounted on the 708-DS (p/n 17-3151 or 17-3152).

## Filtration

Dissolution continues until a sample is filtered, so it is critical to filter at the specified timepoint. When using manual or automated sampling cannulas, you have the option to use one of the Agilent Full Flow Filters or conventional filter tips to ensure the integrity of your dissolution sample.

#### **Full Flow Filters**

Made of either ultrahigh molecular weight polyethylene (UHMWPE) or the polyvinylidene fluoride (PVDF), the Full Flow Filter offers increased surface area to optimize filter life and prevent clogging. In those instances where chemical compatibility is an issue with UHMWPE, we offer PVDF filters. These are made of a low protein-binding material that can filter a wide variety of active drug substances. Both UHMWPE and PVDF filters can be used with 1/8 in. diameter cannulas and are available in packs of 100 or 1000. Full Flow Filters are color coded for easy identification. Certificates of analysis can be provided on request.

## Conventional filter tips

Standard conventional filter tips are made of polyethylene fluoride and can also be used with 1/8 in, diameter cannulas.

# Agent Incompany For the 2.7 de 10 Start Land For Table 1.7 d

Full Flow Filters, 10 µm, 35 µm, 70 µm.

## Did you know?

Filtration is critical to the dissolution test. Any small particles will continue to dissolve until the filtration step is completed. Agilent offers cannula filters as well in line filters to ensure that the dissolution process is complete at the time the sample is withdrawn.

## Filters and Filter Tips for Sampling Cannulas

Description	Part No.
Original Full Flow Filters	
Full Flow Filter, UHMWPE, 1 µm, 100/pk	17-4003
Full Flow Filter, UHMWPE, 4 µm, 100/pk	17-4004
Full Flow Filter, UHMWPE, blue, 10 µm, 100/pk	17-4000
Full Flow Filter, UHMWPE, blue, 10 µm, 1000/pk	17-4005
Full Flow Filter, UHMWPE, white, 35 µm, 100/pk	17-4010
Full Flow Filter, UHMWPE, white, 35 µm, 1000/pk	17-4015
Full Flow Filter, UHMWPE, red, 70 μm, 100/pk	17-4020
Full Flow Filter, UHMWPE, red, 70 µm, 1000/pk	17-4025
Full Flow Filter, PVDF, green, 10 µm, 100/pk	17-4040
Full Flow Filter, PVDF, green, 10 µm, 1000/pk	17-4045
Full Flow Filter, PVDF, yellow, 35 μm, 100/pk	17-4050
Full Flow Filter, PVDF, yellow, 35 μm, 1000/pk	17-4055
Filter Tips	
Filter tip, PE, 2 µm, 100/pk	17-4100
Filter tip, PE, 5 µm, 100/pk	17-4110
Filter tip, PE, 10 µm, 100/pk	17-4120
Inline Filtration	
Inline filter, luer lock, 5 µm (for use with BIO-DIS)	3081-0004
Apparatus 3/7 inline filter housing, PEEK (for use with FF filters)	K1200-00855

 $Note: PE = polyethylene, PVDF = polyvinylidene fluoride, UHMWPE = ultrahigh \, molecular \, weight \, polyethylene$ 

## Did you know?

## Cut costs and plan ahead

Save money by ordering our economical 1000 pack! Same high quality filters, just packaged in bulk.



# Captiva Premium Syringe Filters

Sample filtration prior to HPLC, UHPLC, GC, GC/MS, or LC/MS analysis is critical to achieving optimal system performance. Agilent Captiva Premium Syringe Filters make the process faster than ever with the industry's highest flow rates and loading capacities. In addition, Agilent sets the standard for LC/MS testing and certifying more syringe filters to be completely free of observed extractables than any other manufacturer. All Agilent Captiva Premium Syringe Filters are supplied with a HPLC or LC/MS Certificate. Choose from a variety of membrane types and pore sizes to suit your needs.

High-quality Agilent Captiva syringe filters arrive ready to use - and are tested and certified to be free of UV-absorbing substances So you can be confident that extractables or other contaminants will not damage the integrity of your samples.

## Premium Filters, 100/pk

Description	Diameter (mm)	Pore Size (µm)	Certification	Housing	Part No.
PTFE	4	0.2	LC	Polypropylene	5190-5082
	4	0.45	LC	Polypropylene	5190-5083
	15	0.2	LC	Polypropylene	5190-5084
	15	0.45	LC	Polypropylene	5190-5085
	25	0.2	LC	Polypropylene	5190-5086
	25	0.45	LC	Polypropylene	5190-5087
Nylon	15	0.2	LC	Polypropylene	5190-5088
	15	0.45	LC	Polypropylene	5190-5091
	25	0.2	LC	Polypropylene	5190-5092
	25	0.45	LC	Polypropylene	5190-5093
PES	4	0.45	LC/MS	Polypropylene	5190-5095
	4	0.2	LC/MS	Polypropylene	5190-5094
	15	0.2	LC/MS	Polypropylene	5190-5096
	15	0.45	LC	Polypropylene	5190-5097
	25	0.2	LC/MS	Polypropylene	5190-5098
	25	0.45	LC	Polypropylene	5190-5099
Regenerated	4	0.2	LC	Polypropylene	5190-5106
cellulose	4	0.45	LC	Polypropylene	5190-5107
	15	0.2	LC	Polypropylene	5190-5108
	15	0.45	LC	Polypropylene	5190-5109
	25	0.2	LC	Polypropylene	5190-5110
	25	0.45	LC	Polypropylene	5190-5111
Cellulose acetate	28	0.2	LC	MBS	5190-5116
	28	0.45	LC	MBS	5190-5117
Glass	15	n/a	LC/MS	Polypropylene	5190-5120
microfiber	28	n/a	LC	MBS	5190-5122



Captiva Premium Syringe Filters are available in different membrane and pore sizes.

## Econofilters, 1,000/pk

Description	Diameter (mm)	Pore Size (µm)	Housing	Part No.
PVDF	13	0.2	Polypropylene	5190-5261
	13	0.45	Polypropylene	5190-5262
	25	0.2	Polypropylene	5190-5263
	25	0.45	Polypropylene	5190-5264
PTFE	13	0.2	Polypropylene	5190-5265
	13	0.45	Polypropylene	5190-5266
	25	0.2	Polypropylene	5190-5267
	25	0.45	Polypropylene	5190-5268
Nylon	13	0.2	Polypropylene	5190-5269
	13	0.45	Polypropylene	5190-5270
	25	0.2	Polypropylene	5190-5271
	25	0.45	Polypropylene	5190-5272
PES	13	0.2	Polypropylene	5190-5273
	13	0.45	Polypropylene	5190-5274
	25	0.2	Polypropylene	5190-5275
	25	0.45	Polypropylene	5190-5276
Polypropylene	13	0.2	Polypropylene	5190-5277
	13	0.45	Polypropylene	5190-5278
	25	0.2	Polypropylene	5190-5279
	25	0.45	Polypropylene	5190-5280
Regenerated Cellulose	15	0.2	Polypropylene	5190-5310
(Premium Grade)	15	0.45	Polypropylene	5190-5308
	25	0.2	Polypropylene	5190-5309
	25	0.45	Polypropylene	5190-5307

Captiva Econofilters – High-quality Econofilters are shipped in large packs and are ideal for busy labs that need fast, efficient filtration at a reasonable price.

## Captiva Disposable Syringes, 100/pk

	• •
Volume	Part No.
5 mL	9301-6476
10 mL	9301-6474
20 mL	5190-5103

## GE Whatman Filter Plates

The filter plates are designed to group the filters in a single manageable plate for ease of use and automated exchange. Only the outer physical appearance was modified to a plate design – the internal product and contact components of the 25 mm disc filters remain unchanged.

Each filter plate consists of eight individual 25 mm filters configured for use with the Agilent 850-DS filter module option. Agilent recommends using each filter plate for a single timepoint to avoid clogging and potential carryover issues.

GE Whatman offers the 8-channel filter plates in  $0.2~\mu m$ ,  $0.45~\mu m$  and  $0.7~\mu m$  pore sizes. Analysis of dissolution samples is increasingly carried out by HPLC and UHPLC. To protect highly sensitive UHPLC columns from potential blockage with undissolved particles, Agilent and GE Whatman have collaborated to develop filter plates with this finer  $0.2~\mu m$  pore size.

Dissolution filter selection is dependent on the specific method and the drug formulation under test. The volumetric accuracy of the 850-DS is dependent on the membrane type, the pore size, and the cannula filter (Full Flow Filter) being used. The accuracy is also dependent on the drug product and its concentration, the excipient load, and the dissolution media; other factors that can impact the volume accuracy are the prime volume, pumping speed, and dwell time (all flexible parameters of the 850-DS). Due to high pressures encountered with the use of sub-micron filters, the accuracy specifications for the 850-DS are not guaranteed for all filter types and drug products under certain conditions.

GE Whatman filters and filter plates are supplied by authorized GE Healthcare representatives such as Fisher Scientific and VWR networks worldwide.

A useful guide for validating your choice of filters is available from Agilent at www.agilent.com/lifesciences/filter\_validation

For questions related to the use, options, or availability of these filter plates, please contact Agilent Technologies Dissolution Hotline at **dissolution.hotline@agilent.com** 

Agilent is happy to assist in resolving problems you may encounter with the 850-DS, the filter module, the filter plates, or any dissolution questions in general.



850-DS Dissolution Sampling System.

## Automated dissolution sample preparation for increased productivity

Save time and eliminate errors associated with manual sampling by implementing Whatman 850-DS 8-channel filter plates in your 850-DS Dissolution Sampling Station.

- Automated processing of up to 8 samples simultaneously
- Filter plates specially designed for Agilent equipment increase productivity by allowing reliable alignment of the liquid path and reducing the risk of jamming or leaks that may occur with other dissolution sample preparation systems

#### 850-DS 8-Channel Filter Plates

Description	Part No.
850-DS 8-Channel Filter plate, 0.45 μm, PTFE, 50/pk	7707-3000
850-DS 8-Channel Filter plate, 0.45 µm, nylon, 50/pk	7707-3100
850-DS 8-Channel Filter plate, 0.45 µm, PES, 50/pk	7707-3200
850-DS 8 Channel Filter plate, 0.7 µm, GMF, 50/pk	7707-3300
850-DS 8-Channel Filter plate, 0.2 µm, PTFE, 50/pk	7707-3400
850-DS 8-Channel Filter plate, 0.2 µm, nylon, 50/pk	7707-3500
850-DS 8-Channel Filter plate, 0.2 µm, PES, 50/pk	7707-3600
850-DS 8-Channel Filter plate, 0.2 µm, PVDF, 50/pk	7707-3700
850-DS 8-Channel Filter plate, 0.45 µm, PVDF, 50/pk	7707-3800
850-DS 8-Channel Filter plate, 1 µm, GMF, 50/pk	7707-3900

Note: These part numbers are NOT Agilent part numbers. They are the GE Whatman catalog numbers.



Filter plates for the 850-DS.

# **Evaporation Covers**

Evaporation covers maintain volumetric accuracy of the media used during dissolution testing by slowing the amount of media lost to evaporation. A variety of evaporation covers are available to fit your apparatus and vessels. Evaporation plugs are used to minimize evaporation by sealing unused ports in the evaporation covers.

## **Evaporation Covers and Accessories**

Description	Part No.
708-DS alignment post, for use in place of DDM with manifold	1005-1898
708-DS evaporation cover plug, white, for use in place of DDM	1200-1012
708-DS evaporation cover plug, black, flat	12-6370
708-DS evaporation cover, for blank position	K1400-00210
DDM assembly, for use with 708-DS	1005-1897
708-DS evaporation cover, low loss for use with resident sampling probes	K1005-05218
708-DS evaporation cover, standard, for CP/USP sampling	K1005-05225
708-DS evaporation cover, non-slit, for CP/USP sampling	G7910-60030



708-DS evaporation cover.



Standard evaporation cover for 708-DS. Switchable gasket accommodates sampling from USP and Chinese Pharmacopeia locations.



Standard evaporation cover for 708-DS (p/n K1005-05225).

## Did you know?

The standard evaporation cover on the 708-DS is designed to allow less than 1% evaporative loss over a 24-hour period under normal operating conditions. Agilent also offers other low loss covers that can reduce the loss even further.

and removal

# Transdermal Delivery Systems – USP Apparatus 5, 6, and 7

USP Apparatus 5 and 6 are commonly used for the testing of transdermal patches per USP General Chapter <724>.

## USP Apparatus 5 - Paddle Over Disk

The Paddle Over Disk assembly is used for the dissolution testing of transdermal patches, and is used with a standard dissolution apparatus, such as the 708-DS and paddles. The assembly is made of a stainless steel disk and PTFE locking ring that holds the removable, replaceable screens in place. Screens are provided with the ring assemblies but are also offered in a variety of other sizes that are sold separately.

Agilent also offers a "non-compendial" transdermal patch holder system as an alternative to the traditional Apparatus 5 assembly. Also made of stainless steel, the O-ring assembly eliminates the need for adhesives to hold the patch. The clam-shell design secures the patch in place and exposes only the active release area of patches with an inactive perimeter around the release area.

## USP Apparatus 6 – Rotating Cylinder

The Rotating Cylinder assembly uses a stainless steel cylinder and includes four slots at the top for improved media circulation within the dissolution vessel. Each Rotating Cylinder includes two sizes, one for smaller patches, the other for larger ones. No need to match an upper and lower assembly.

#### USP Apparatus 7 – Reciprocating Holder

Transdermal delivery systems may also be tested with Apparatus 7 using a variety of sample holders. For more information on the instrumentation and holders available from Agilent, see page 74.



USP Apparatus 5 Paddle Over Disk.

## Did you know?

The Agilent 708-DS can also support transdermal testing using USP Apparatus 5 and 6 accessories. This includes setup and storage of precise sampling manifold locations in the firmware based on vessel volume and the assembly installed. The 708-DS is easily converted to smaller volumes typically associated with transdermal testing as well.

See pages 43 ff. for more information about 708-DS volume conversion kits.

## Transdermal Delivery (Compatible with all Apparatus Models)

Description	Part No.
Paddle Over Disk	
Paddle Over Disk assembly, with 35 mm opening, 40-mesh screen	12-4200
Paddle Over Disk assembly, with 35 mm opening, 40-mesh screen, with certificate	12-4200V
Paddle Over Disk assembly, 125 µm, EP	12-4201
Replacement screens, 125 µm, EP, 100/pk	12-4209
Replacement screens, 35 mm openings, 40-mesh, 100/pk	12-4210
Disk disassembly kit, for 12-4200	12-4211
Paddle Over Disk assembly, with 56 mm opening, 120-mesh screen	12-4230
Replacement screens, 56 mm openings, 120-mesh, 100/pk	12-4231
Disk disassembly kit, for 12-4230	12-4232
Transdermal Patch Holders	
Transdermal patch holder, 2.5 cm <sup>2</sup>	12-4300
Transdermal patch holder, 5.0 cm <sup>2</sup>	12-4310
Transdermal patch holder, 7.0 cm <sup>2</sup>	12-4320
Transdermal patch holder, 10.0 cm <sup>2</sup>	12-4330
Watch glass screen, polypropylene, 6/pk	12-4400
Watch glass screen, stainless steel, 6/pk	12-4410



Rotating Cylinder, large and small rotating cylinder is included with each order. No need to mate and match upper and lower assemblies.



(Left to right) Paddle Over Disk assemblies, transdermal patch holders.

## **Rotating Cylinder and Accessories**

Description	Part No.
Rotating Cylinder set. Includes large and small rotating cylinders to accommodate various transdermal patch sizes	14-1371
Height gauge, Rotating Cylinder, USP	12-7335

## PTFE suspension cups

For "viscous" suspensions, the PTFE suspension cup is a weighted holder with a hemispheric bottom designed to sit at the bottom of a standard 1L vessel to control the exposed surface area. The suspension is weighed in the center cup prior to analysis in order to correlate the release rate.

## **Suspension Cups**

Description	Part No.
Weighted holder, 5.72 cm outside dia., 0.52 cm inside dia.	12-4050
Insert cup, 17.5x8.2 mm, use with 12-4050	12-4055
Insert cup, 20x8.2 mm, use with 12-4050	12-4060



PTFE suspension cup (p/n 12-4050).

## Did you know?

## Preparing suspension cups

- 1. Weigh empty suspension cup (removable center cup only).
- 2. Add desired amount of suspension to removable center cup.
- 3. Re-weigh suspension cup to obtain amount of suspension.
- 4. Insert center cup into outer piece.
- 5. Carefully insert the assembly into the dissolution vessel.
- 6. Add media to vessel by carefully pouring down the side wall.
- 7. Begin dissolution test.

# Enhancer Cell (or Immersion Cell)

# Designed for release rate dissolution testing of ointments, creams, gels and topicals

Used in research, quality control and product development laboratories, the Enhancer Cell provides release rate data for topicals using your standard Apparatus 1 or 2 with either the 200 mL Enhancer Cell vessel and mini-paddle or the USP 1-Liter vessel and paddle. Also referred to as Immersion Cell, the Enhancer Cell is a PTFE cell with adjustable volume and retaining cap to eliminate air pockets trapped against the skin or artificial membrane that provide the diffusion barrier. It is a cost-effective alternative to investing in the fragile and more labor-intensive Vertical Diffusion, or Franz Cells.

- Ideal for testing ointments, creams and gels
- Available in several surface areas, including 0.5, 2.0 and 4.0 cm<sup>2</sup>
- Used with traditional dissolution apparatus and a 200 mL flat bottom vessel or 1L vessel
- Meets SUPAC-Semisolid Guidance
- An alignment tool, available in various sizes to match membrane surface area size, is
  used to hold the membrane in place while eliminating air pockets with the universal
  adjustment tool. Alignment tools specific to the surface area are sold individually

Take a look at Agilent's tutorial video on the Enhancer Cell at

www.agilent.com/chem/enhancercell

## Did you know?

The Enhancer Cell also known as Immersion Cell is now included in the new USP General Chapter <1724> Semisolid Drug Products - Performance Tests.



Enhancer Cell (p/n 12-4000) and accessories.

## **Enhancer Cells and Accessories**

Description	Part No.
Enhancer Cell, 4 cm² surface area membrane (one per position)	12-4000
Enhancer Cell, 2 cm <sup>2</sup> surface area membrane (one per position)	12-4001
Enhancer Cell, 0.5 cm <sup>2</sup> surface area membrane (one per position)	12-4002
Height spacer (1 cm)/alignment tool, for 4 cm <sup>2</sup> Enhancer Cell (one required)	12-4020
Height spacer (1 cm)/alignment tool, for 2 cm <sup>2</sup> Enhancer Cell (one required)	12-4021
Height spacer (1 cm)/alignment tool, for 0.5 cm <sup>2</sup> Enhancer Cell (one required)	12-4022
Adjustment tool, for all Enhancer Cell sizes (one required)	12-4015
Cuprophan membrane, 126x345 mm, 10 sheets/pk	12-1370

## Did you know?

The Enhancer Cell conforms with the Immersion Cell Model A in USP chapter <1724>. Please see our video on how to test ointments, creams and gels with the Enhancer Cell; visit http://read.nxtbook. com/agilent/source\_book/dissolution\_ systems\_2017\_2018/enhancer\_cell.html

## **Enhancer Cell ordering example**

To add Enhancer Cell components to an existing 708-DS, refer to the following list:

Quantity	Description	Part No
6	Enhancer Cell, 4 cm <sup>2</sup> surface area membrane (one per position)	12-4000
1	Height spacer (1 cm)/alignment tool, for 4 cm <sup>2</sup> Enhancer Cell (one required)	12-4020
1	Adjustment tool, for all Enhancer Cell sizes (one required)	12-4015
6	Mini paddle, lower interchangeable, stainless steel	13-3608
6	TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170
6	TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368

# Intrinsic Dissolution Apparatus

The Intrinsic Dissolution Apparatus provides the dissolution rate of a pure active pharmaceutical ingredient (API) by exposing the API to a constant surface area of dissolution medium. The intrinsic rate is determined by rotating the apparatus in a dissolution vessel containing 37 °C media and pulling samples until at least 10% of the API has dissolved. The rate is then calculated by plotting the cumulative amount of API dissolved from the exposed surface area with respect to time.

Based on the modified Woods Apparatus as described in USP <1087>, the design includes threaded rings on the inside of the die cavity to prevent the compacted API from falling out of the die cavity during analysis. The apparatus includes a punch used to compress the API into a pellet with the aid of a laboratory press (not provided by Agilent). The Intrinsic Apparatus includes:

- Stainless steel die cavity with either a 0.5 or 0.125 cm<sup>2</sup> surface area
- Punch
- Shaft with holder
- Gasket ring

The surface plate, used in conjunction with the punch and a laboratory press, is sold separately. Only one surface plate is required and may be used with multiple apparatus.

Intrinsic dissolution is expressed in terms of  $mg/time/cm^2$ , and is useful in studying the solubility characteristics of a pure drug substance.

## Did you know?

The intrinsic device conforms with the Rotating Disk method in USP Chapter <1087> Apparent Intrinsic Dissolution.



Intrinsic Dissolution Apparatus (p/n 12-4101) and accessories.

## **Intrinsic Dissolution Apparatus**

Description	Part No.
Intrinsic Dissolution Apparatus, 0.5 cm <sup>2</sup> exposed surface area, with punch, shaft and holder, for 7000E/7010, 708-DS, 705-DS	12-4101
Intrinsic Dissolution Apparatus, 0.125 cm² exposed surface area (18 in. shaft)	12-4110
Intrinsic die, 0.5 cm <sup>2</sup> exposed surface area	12-4120
Punch	12-4140
Shaft and die holder only, for intrinsic dissolution (18 in. shaft)	12-4150
Surface plate, for intrinsic dissolution	12-4130

Note: Surface plate sold separately. Only one plate required for testing.

## Did you know?

Take a look at the video of the Agilent Intrinsic Apparatus at:

www.agilent.com/lifesciences/ intrinsic-video

## Intrinsic dissolution apparatus example

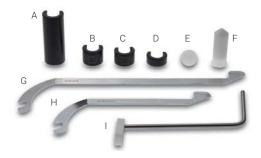
In addition to the standard dissolution apparatus, to configure a 708-DS for intrinsic dissolution use, see the following example:

uantity	Description	Part No.
6	Intrinsic Dissolution Apparatus, 0.5 cm <sup>2</sup> exposed surface area, with punch, shaft and holder, for 7000E/7010, 708-DS, 705-DS	12-4101
I	Surface plate, for intrinsic dissolution	12-4130

# **Verification Tools**

#### **Verification Tools**

Description	Part No.
Height Spacers for USP Apparatus 1 and 2	
Height spacer, paddles, ball without retrieval string, 25 mm	12-7240
Height spacer, paddles, ball with retrieval string, 25 mm	12-7250
Height spacer, paddles, ball with retrieval string, 25 mm, with certificate	12-7250V
Height spacer, intrinsic apparatus, ball with retrieval string, 38 mm	12-7260
Height spacer intrinsic apparatus, ball with retrieval string, 38 mm, with certificate	12-7260V
Height spacer, for attachment to paddles, 25 mm above bottom of vessel	12-7270
Height spacer, for attachment to paddles, 25 mm above bottom of vessel, with certificate	12-7270V
Height spacer, for attachment to basket shaft, 25 mm above bottom of vessel	12-7280
Height spacer, for attachment to basket shaft, 25 mm above bottom of vessel, with certificate	12-7280V
Height gauge, Rotating Cylinder, USP Sets height to 25 mm above bottom of vessel	12-7335
Height and Centering Tools for USP Apparatus 1 and 2	
Height tool, stainless steel, sets height of basket and paddles, 25 mm	12-7300
Height tool, stainless steel, sets height of basket and paddles, 25 mm, with certificate	12-7300V
Height tool, stainless steel, sets height of basket and paddles, for 2L vessels, 25 mm	12-7301
Height tool, stainless steel, sets height of basket and paddles, for 2L vessels, 25 mm, with certificate	12-7301V
Height tool, stainless steel, sets height of basket and paddles, used for testing antibiotics, 45 mm	12-7330
Height tool, stainless steel, sets height of basket and paddles, used for testing antibiotics, 45 mm, with certificate	12-7330V
Height tool, stainless steel and Delrin, for Peak vessels 9.73 mm spacer above the top of the peak	12-7230
Bubble level, for horizontal centering	12-7325



- A = Height spacer (p/n 12-0321) 3.25 inch for use with 100/200 mL vessels
- B = Height spacer for baskets (p/n 12-7210)
- C = Height spacer for paddles (p/n 12-7200)
- D = Height spacer for Peak vessels (p/n 12-7220)
- E = Spacer ball for paddles (p/n 12-7240)
- F = Height gauge for attachment to basket shaft (p/n 12-7280)
- G = Height tool for 2L vessels (p/n 12-7301)
- H = Height tool for 1L vessels (p/n 12-7301)
- I = Height tool for PEAK vessels (p/n 12-7230)

## Water Baths and Heater/Circulators

Agilent offers a number of water baths and replacement parts for the water baths, including fittings, adapters, tubing and clamps, as well as heater/circulators.

- Acrylic fabricated water baths for disintegration testers and BIO-DIS apparatus are made of a three-piece construction with solvent-welded seams
- The molded high-performance polymer PETG design, utilized on most Agilent dissolution apparatus, provides better chemical and heat stability than standard acrylic baths and the rounded corners make cleaning easier
- The 708-DS (as well as the Apparatus 3 and Apparatus 7) utilizes a universal voltage heater/circulator. It is designed specifically to fit beneath the apparatus housing and minimize vibration



708-DS heater/circulator.

## Water Baths, Heater/Circulators and Accessories

Description	Part No.
Water Baths and Replacement Parts	
Water bath, for 100 Automated Disintegration Tester, with fittings	60-2120
Water-bath assembly (includes fittings and tubing), used with 708-DS	1005-1808
Water bath, for BIO-DIS, 22.56x20.68x7.5 in.	60-2400
Drain valve for molded bath	62-9000
Bulkhead bath fitting	62-9010
Bath flow deflector	62-9020
Barbed angle adapter	62-9025
PVC tubing with 3/4 in. outer dia., 1/2 in. inner dia., 50 ft.	62-9030
Bath tubing clamps, stainless steel, 4/pk	62-9040
Heater/circulator cable, for use with 7000/7010/BIO-DIS/Apparatus 7	K5075-00871
Heater/circulator cable, for use with 708-DS	5075-0057
Heaters/Circulators	
Dissolution Heater/circulator, 115/230V	G7986B
Note: The heater/circulator can be used with 708-DS, as well as legacy 7000/7010, 7020, 7 apparatus, and the BIO-DIS and Apparatus 7.	025 and 705-DS dissolution
Options for G7986B	
Cable for use with 7000/7010/BIO-DIS/Apparatus 7	G7986B #100
Cable for use with 708-DS	G7986B #101

# Apparatus 3

# BIO-DIS Reciprocating Cylinder Apparatus and Accessories

# Extended release-rate dissolution testing that meets requirements of USP Apparatus 3 and EP Reciprocating Cylinder specifications

The Agilent BIO-DIS Reciprocating Cylinder Apparatus is ideal for automatic dissolution testing of dosage forms that require different types of media. Typically used for imitating the pH changes that occur in the body, this instrument is perfectly suited for extended and sustained release dosage forms.

The BIO-DIS can automatically perform a complete media change, simulating the pH change that occurs in the digestive tract. Due to the reciprocating action and the change in pH, the instrument may be used for a variety of applications. Capable of running unattended for extended periods of time, the BIO-DIS can store up to 15 programs and provide direct control over timepoints, agitation rate, sampling rate, movement between vessel rows, hold dip time, and drain time.

#### Did you know?

The BIO-DIS stands for Biorelevant Dissolution. Originally designed for extended release formulations, the apparatus allows detailed in vitro release of drug as it varies pH, agitation rate and residence time and simulating the exposure of the drug to various conditions within the GI tract.



BIO-DIS Reciprocating Cylinder Apparatus.

#### Features include:

- Simulate gastrointestinal conditions with simple programming that allows in vitro dissolution pH profiling with biorelevant media agitation rates and retention times
- Useful for release-rate testing of floating dosage forms, beads and chewables
- Use one instrument to test and transport a variety of samples, saving valuable bench space. Samples are automatically transported from one medium to the next without operator intervention
- Be confident knowing the BIO-DIS is compliant with the reciprocating cylinder apparatus, USP Apparatus 3 and EP harmonized specifications
- Select a standard volumetric reciprocating cylinder option or small and large volume configuration to meet testing needs for low dose or poorly soluble formulations. Other options include a double row instrument for increased testing throughput

The standard seven-position system includes the following items:

- Three outer media tube vessel carriers, 14 positions each
- Seven inner sample tubes with upper and lower caps
- One sample kit of polypropylene and stainless steel screens
- 42 outer media tubes, 300 mL (USP)
- One external heater/circulator



BIO-DIS accessories.

## Inline filter housing

Filtration is a necessary step to stop the dissolution process. Inline Full Flow Filter housings are ideal for use with the BIO-DIS Reciprocating Cylinder Apparatus (USP Apparatus 3) and the Reciprocating Holder (USP Apparatus 7) when either of these instruments are used with automated sampling like the 850-DS. This housing allows the use of the standard Full Flow Filters (for more details see pages 50 ff.). Constructed of PEEK material the housing is inert to most chemicals. The Full Flow Filter is inserted onto the receptor and the housing is screwed closed. One housing is used for each sample line

## **BIO-DIS Reciprocating Cylinder Apparatus**

Description	Part No.
BIO-DIS Reciprocating Cylinder Apparatus, 300 mL, 7 samples x 6 rows	G7970A
Options for G7970	
100 mL, 7 samples x 6 rows	G7970A #100
1L, 3 samples x 3 rows	G7970A #105
Double row dip, 300 mL, 14 samples x 3 rows	G7970A #110
Double row dip, 1L, 6 samples x 1 row	G7970A #115
Note: The standard BIO-DIS is configured as a 300 mL system. Select from one of the abovolume or configuration is desired.	ove options if an alternative
Add Installation Service	G7970A #44K
Add Familiarization Service	G7970A #44L

## Note: For complete qualification services offering, see page 155.

## Conversion/Retrofit Kits

Description	Part No.
Conversion kit, 100 mL	27-6100
Conversion kit, 1L	27-6105

## Did you know?

## Automated sampling for BIO-DIS

Easily automate the sample collection process for Apparatus 3 using the Agilent 850-DS Dissolution Sampling Station. See pages 96 ff. for more details.

#### Filtration options

Accomplish manual inline filtration using the conventional Full Flow Filters with an inline filter housing. These inline filters should be used for systems configured with an 850-DS Sampling Station (option #150). Or use the 850-DS with optional filter module to automate filtration with innovative Whatman filter plates from GE Healthcare that sample down to 0.2  $\mu$ m, 0.45  $\mu$ m pore size. See pages 54 ff. for more details.



In-line filter housing (PEEK) (p/n K1200-00855), shown on optional mounting bracket.

## BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station

Description	Part No.
BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station	G7977A
Options for G7977A	
100 mL, 7 samples x 6 rows	G7977A #100
1L, 3 samples x 3 rows	G7977A #105
Double row dip, 300 mL, 14 samples x 3 rows	G7977A #110
Double row dip, 1L, 6 samples x 1 row	G7977A #115
Note: The standard BIO-DIS is configured as a 300 mL system. Select from one of the above volume or configuration is desired.	e options if an alternative
Inline filter housing option	G7977A #150
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7977A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7977A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7977A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7977A #213
Add Dissolution Workstation Software cable kit (software ordered separately)	G7977A #220
Add printer to 850-DS	G7977A #880
Add Installation Service	G7977A #44K
Add Familiarization Service	G7977A #44L

Note: For complete qualification services offering, see page 155.

## **BIO-DIS Dimensions**

Height	Width	Depth	Weight
73.66 cm / 29 in.	68.58 cm / 27 in.	69.85 cm/ 27.5 in.	43.1 kg / 95 lbs, dry without vessels

## Did you know?

Dissolution Workstation Software (G4974AA) can be used to control up to four systems with the BIO-DIS, a pump, and the 850-DS Dissolution Sampling Station. In fact, the software allows for additional programming capabilities. For example, it allows multiple samples to be taken at different time points from the same row as well as additional media changes to be programmed by exchanging the media racks.

## **BIO-DIS Reciprocating Cylinder Acessories**

Description	Part No.
Inner Sample Tubes (with threaded glass ends)	
Standard inner sample glass tube for 300 mL outer media tube	27-5000
BIO-DIS Tube for 300mL outer media with caps, USP (contains p/n 27-5000, 27-1000 & 27-1020)	27-5005
BIO-DIS Tube for 100mL outer media with caps, USP (contains p/n 27-5010, 27-1030 & 27-1010)	27-5006
Inner sample glass tube for 100 mL outer media tube	27-5010
Outer Media Tubes	
Outer media tube, USP, 300 mL	27-5100
Outer media tube, 100 mL	27-5110
Outer media tube, flat bottom, 1000 mL	27-5120
Upper and Lower Caps	
Standard upper cap, USP, 300 mL, for use with P/N 27-5000	27-1000
Upper cap, 100 mL, for use with P/N 27-5010	27-1010
Standard lower cap, USP, 300 mL, for use with P/N 27-5000	27-1020
Lower cap, 100 mL, for use with P/N 27-5010	27-1030
Lower cap, wider diameter for improved mixing, for use with P/N 27-5000	27-1050
Replacement Cannulas and Tubing	
Replacement tubing kit, App 3/7, (for use with inline luer fittings)	27-0126
Replacement tubing kit, App 3/7 (for use with 1/4-28 inline fittings)	27-0127
Evaporation Caps	
Evaporation cap, USP, for 300 mL tube	27-1500
Evaporation cap, for 100 mL tube	27-1510
Evaporation cap, USP, tinted, for 300 mL tube	27-1520
Vessel Carrier for Outer Media Tubes	
Vessel carrier, for 300 mL tube, 7x2 layout, set of 3	27-6000
Vessel carrier, for 100 mL tube, 7x2 layout, set of 3	27-6005
Vessel carrier, for 50 mL tubes. 7x2 layout, set of 3	27-6050
Vessel carrier, 1L vessel, 1x3 layout, set of 3	27-6010

## Did you know?

Apparatus 3 may also be used for disintegrating dosage forms by using a non-compendial lower cap with a wider diameter which creates improved mixing for particulates that may pass through the lower screen.



Vessel carrier rack for Apparatus 7 (p/n 27-6050).

(Continued)

### **BIO-DIS Reciprocating Cylinder Acessories**

Description	Part No.
Replacement Screens for Inner Sample Tubes	
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 20-mesh, 840 m	27-2000
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 40-mesh, 405 m	27-2005
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 56-mesh, 250 m	27-2007
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 78-mesh, 177 m	27-2010
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 100-mesh, 150 m	27-2015
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 20-mesh, 840 m	27-2200
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 40-mesh, 405 m	27-2205
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 78-mesh, 177 m	27-2210
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 100-mesh, 150 m	27-2215
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 10-mesh, 1905 m	27-2099
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 20-mesh, 864 m	27-2100
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 30-mesh, 533 m	27-2103
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 40-mesh, 381 m	27-2105
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 100-mesh, 140 m	27-2110
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 200-mesh, 74 m	27-2115
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 300-mesh, 46 m	27-2120
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 400-mesh, 38 m	27-2125
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 8-mesh, 2591 m	27-2300
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 10-mesh, 1905 m	27-2305
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 20-mesh, 864 m	27-2310
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 40-mesh, 381 m	27-2315
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 60-mesh, 229 m	27-2320
Basket Adapters	
Basket adapter, O-ring, for BIO-DIS	27-2400
Basket adapter, 3-clip, for BIO-DIS	27-2401
-	











BIO-DIS screens.

p/n 27-2105

p/n 27-2100

p/n 27-2015

p/n 27-2205

# Apparatus 7

### Reciprocating Holder Apparatus 7 and Accessories

The Agilent Reciprocating Holder Apparatus 7 is ideal for automatic dissolution testing of dosage forms that require a change of media, a smaller volume or more vigorous agitation. Initially developed for testing transdermal patches, this apparatus now includes many different dosage form holders. The reciprocating holder has a stroke length of 20 mm and can be programmed to dip between 5 and 40 dips per minute. At the end of a designated time period, the dosage form is automatically transported from one row to the next. Typical products tested include extended release tablets, transdermals, osmotic pumps and arterial stents.

The standard apparatus has seven sample positions with six rows and is available with 100 or 300 mL outer tubes. The firmware can be preprogrammed to automatically move to a fresh row of media for as many as six media changes. For smaller volumes, the instrument is available with 50 mL vessels in a 7-row configuration. Dissolution Workstation Software can also be used to control and log events of an Apparatus 7 with an 850-DS Sampling Station. After incorporating PC control, additional media changes can be accommodated by exchanging the vessel racks with fresh media.



50 mL Reciprocating Holder Apparatus 7, shown in 6x7 automated configuration.

#### The Reciprocating Holder Apparatus 7:

- Simulates the biorelevant conditions for the skin, gastrointestinal tract and tissue required for transdermal, oral drugs and implants with biorelevant temperature agitation rates and retention times
- Tests and transports a variety of samples, saving valuable bench space. Samples are automatically transported from one medium to the next without operator intervention, and can run unattended for up to six days
- Stores up to 15 programs and maintains direct control over timepoints, agitation rate, sampling rate, and movement between vessel rows, hold dip time, and drain time
- Accommodates a variety of dosage form holders including cylinders, reciprocating disks, angled disks, spring holders, stent holders, and pointed rods
- Supports typical volume configurations of 20, 50, 100 and 300 mL. Additional conversion kits are available that can transition the instrument to support different volumes

#### A standard Apparatus 7 includes the following items:

- Outer media tube vessel carriers
- Outer media tubes
- One external heater/circulator
- Built-in printer

### Did you know?

#### Dosage holder options

Agilent offers a variety of standard and customizable holder options to meet your application needs. These include reciprocating disks, angled disks, and cylinders for transdermal patches. For traditional oral dosage forms, acrylic pointed rods, stent holders

### Integration options for sampling and filtration

The 7-position Apparatus 7 (100 or 300 mL) systems can be integrated with the 850-DS Dissolution Sampling Station, with optional built-in filter module to automate filtration down to 0.2 µm,  $0.45\,\mu m$  pore size. Inline filtration is also possible.

### Reciprocating Holder Apparatus 7

Description	Part No.	
USP Apparatus 7 Reciprocating Holder	G7972A	
Options for G7972A		
6-row, 7-sample, 300 mL configuration	G7972A #100	
6-row, 7-sample, 100 mL configuration	G7972A #105	
12-row, 12-sample, 50 mL configuration Note: Only manual sampling is available for G7972A#110.	G7972A #110	
Note: Apparatus 7 Row/Sample Configuration – One (1) selection is required.		
Acrylic pointed rod assembly	G7972A #120	
Transdermal holder kit	G7972A #121	
Reciprocating disk, 2.5 cm <sup>2</sup>	G7972A #123	
Reciprocating disk, 5.0 cm <sup>2</sup>	G7972A #124	
Reciprocating disk, 7.0 cm <sup>2</sup>	G7972A #125	
Reciprocating disk, 10.0 cm <sup>2</sup>	G7972A #126	
Angled disk holder, 1.98 in.	G7972A #127	
Angled disk holder, 1.42 in.	G7972A #128	
Mini basket assembly, 40-mesh	G7972A #129	
Mini basket assembly, 50-mesh	G7972A #130	
Spring holder, 1.45"L x .58"ID x .031" wire ID	G7972A #131	
Spring holder, 1.40"L x .31"ID x .040" wire ID	G7972A #132	
Spring holder, 0.96"L x .33"ID x .031" wire ID	G7972A #133	
Spring holder, 0.60"L x .25"ID x .031" wire ID	G7972A #134	
Note: Sample Holder Type – One (1) selection is required.		
Add Installation Service	G7972A #44K	
Add Familiarization Service	G7972A #44L	
Note: For complete qualification corvings offering age page 155		

Note: For complete qualification services offering, see page 155.

### Reciprocating Holder Apparatus 7 and 850-DS Sampling System

Description	Part No.
Reciprocating Holder Apparatus 7 and 850-DS Sampling Station	G7978A
Options for G7978A	
6-row, 7-sample, 300 mL configuration	G7978A #100
6-row, 7-sample, 100 mL configuration	G7978A #105
6-row, 7-sample, 50 mL configuration	G7978A #110
Note: Apparatus 7 Row/Sample Configuration – One (1) selection is required.	
Acrylic pointed rod assembly	G7973A #120
Transdermal holder kit	G7978A #121
Reciprocating disk, 1.6 cm <sup>2</sup>	G7978A #122
Reciprocating disk, 2.5 cm <sup>2</sup>	G7978A #123
Reciprocating disk, 5.0 cm <sup>2</sup>	G7978A #124
Reciprocating disk, 7.0 cm <sup>2</sup>	G7978A #125
Reciprocating disk, 10.0 cm <sup>2</sup>	G7978A #126
Angled disk holder, 1.98 in.	G7978A #127
Angled disk holder, 1.42 in.	G7978A #128
Mini basket assembly, 40-mesh	G7978A #129
Mini basket assembly, 50-mesh	G7978A #130
Spring holder, 1.45 in. L x .58 in. D x 0.031 in. wire ID	G7978A #131
Spring holder, 1.40 in. L x .31 in. ID x 0.040 in.wire ID	G7978A #132
Spring holder, 0.96 in. L x .33 in ID x 0.031 wire ID	G7978A #133
Spring holder, 0.60 in. L x .25 in. ID x 0.031 in. wire ID	G7978A #134
Note: Sample Holder Type (options #120-134) – One (1) selection is required. Please specify	y quantity.
Inline filter housing option	G7978A #150
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7978A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7978A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7978A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7978A #213
Add Dissolution Workstation Software cable kit (software ordered separately)	G7978A #220
Add printer to 850-DS	G7978A #880
Add Installation Service	G7978A #44K



850-DS Dissolution Sampling Station.

Note: For complete qualification services offering, see page 155.

### Reciprocating Holder Apparatus 7 Accessories

Description	Part No.
Pointed acrylic rod kit	27-3000
Transdermal patch holder kit	27-3001
Replacement acrylic rod kit	27-3002
1.6 cm² reciprocating disk	27-8005
2.5 cm <sup>2</sup> reciprocating disk	27-8010
5.0 cm <sup>2</sup> reciprocating disk	27-8015
7.0 cm <sup>2</sup> reciprocating disk	27-8020
10.0 cm <sup>2</sup> reciprocating disk	27-8025
Angled disk, 1.98 in.	27-8035
Angled disk, 1.42 in.	27-8036
Basket shaft, mini	27-8600
Basket, mini, 40-mesh	27-8620
Basket, mini, 50-mesh	27-8621
Basket assembly, titanium	27-8622
Spring holder, Alza, 1.45 in. L x 0.58 in. ID x 0.031 in. wire ID, spring offset	27-0100
Spring holder, Alza, 1.40 in. L x 0.31 in. ID x 0.040 in. wire ID, spring offset	27-0101
Spring holder, Alza, 0.96 in. L x 0.33 in. ID x 0.031 in. wire ID, spring offset	27-0102
Spring holder, Alza, 0.60 in. L x 0.25 in. ID x 0.031 in. wire ID, spring offset	27-0103
Spring holder, Alza, 1.00 in. L x 0.50 in. ID x 0.031 in. wire ID, spring offset	27-0104
Spring holder, Alza, 1.45 in. L x 0.58 in. ID x 0.031 in. wire ID, spring centered	27-0105
Spring holder, Alza, 1.40 in. L x 0.31 in. ID x 0.040 in. wire ID, spring centered	27-0106
Spring holder, Alza, 0.96 in. L x 0.33 in. ID x 0.031 in. wire ID, spring centered	27-0107
Spring holder, Alza, 0.60 in. L x 0.25 in. ID x 0.031 in. wire ID, spring centered	27-0108
Spring holder, Alza, 1.00 in. L x 0.50 in. ID x 0.031 in. wire ID, spring centered	27-0109

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### Reciprocating Holder Apparatus 7 Accessories

Description	Part No
Replacement tubing kit, App 3/7, (for use with inline luer fittings)	27-0126
Replacement tubing kit, App 3/7 (for use with 1/4-28 inline fittings)	27-0127
Outer tube, 50 mL	27-5130
Outer tube, calibrated, 50 mL, class B	27-5135
Outer tube, 50 mL, low actinic – red	27-5160



BIO-DIS Reciprocating Cylinder and Reciprocating Holder Apparatus 7 Compatibility Table

		Apparatus 7 – Outer Tube			
Part No.	Holder	50 mL	100 mL	300 mL (USP)	1000 mL
27-5000	Inner tube (300 mL)	-	-	<b>*</b>	•
27-5010	Inner tube (100 mL)	-	•	•	•
27-2400	Durafit basket adapter	-	NR	•	•
27-2401	Basket adapter with clip assembly	-	NR	<b>*</b>	•
27-8620	Basket, mini, 40-mesh	*	NR	•	•
27-8621	Basket, mini, 50-mesh	•	•	•	*
27-8600	Basket shaft, mini	*	•	•	•
27-8622	Basket assembly, titanium	•	•	•	•
27-3000	Pointed acrylic rod	•	•	•	•
27-3002	Replacement acrylic rod kit	•	•	•	•
27-3001	Transdermal patch holder kit	-	-	•	•
27-8005	1.6 cm <sup>2</sup> reciprocating disk	-	•	•	•
27-8010	2.5 cm <sup>2</sup> reciprocating disk	-	-	•	*
27-8015	5.0 cm <sup>2</sup> reciprocating disk	-	-	•	•
27-8020	7.0 cm <sup>2</sup> reciprocating disk	-	-	•	•
27-8025	10.0 cm <sup>2</sup> reciprocating disk	NR	NR	•	•
27-6540	Replacement stent holder	•	•	•	•
27-6541	Stent holder, 8 mm (horizontal)	•	•	<b>*</b>	•
27-6542	Stent holder, 18 mm (vertical)	•	•	•	•
27-6543	Stent holder, 30 mm (vertical)	•	•	•	•
27-0101	Spring holder, 1.40 in. L x 0.31 in. inner dia. x 0.040 in. wire inner dia.	<b>*</b> *	<b>*</b> *	<b>*</b> *	•
27-0102	Spring holder, 0.96 in. L x 0.33 in. inner dia. x 0.031 in. wire inner dia.	<b>*</b> *	<b>*</b> *	<b>*</b> *	*
27-0103	Spring holder, 0.60 in. L x 0.25 in. inner dia. x 0.040 in. wire inner dia.	<b>*</b> *	<b>*</b> *	<b>*</b> *	*
27-0104	Spring holder, 1 in. L x 0.50 in. inner dia. x 0.031 in. wire inner dia	•	•	•	•
27-8035	Angled disk, 1.98 in.	-	-	-	•
27-8036	Angled disk, 1.42 in.	-	-	-	•

Diamond image (ullet) = Compatible, Shaded box = Not compatible, NR = Not Recommended, Asterisk (\*) = based on dimension measurements only

### Did you know?

The compatibility table on the left provides details on holders and outer tube volumes for your specific testing needs.

# 400-DS Apparatus 7

### The first compendial small-volume dissolution testing apparatus for novel dosage forms

The 400-DS sets the performance standard for small-volume drug-release testing of medical devices or combination products such as drug eluting stents (DES) or medicated contact lenses that release small amounts of active pharmaceutical ingredients (API) during a long period of time. The apparatus offers bathless heating, custom sample holders, integrated autosampling, media replacement and liquid handling capabilities.

Systems are available in sample cell sizes of 5 or 10 mL. Dissolution can be performed in volumes as low as 3 mL, providing significant gains in sample concentration for UV or LC analysis while virtually eliminating evaporation even when used with organic solvents. Utilization of the media replacement capabilities and sampling capacity, up to 36 timepoints, or 360 mL of media, per sample cell, can be used per test.

Controlled by a customized version of Dissolution Workstation Software, the 400-DS is capable of storing the operating parameters and method data required for a 21 CFR Part 11 environment. A relational database is used for system, method and test result storage, archival and retrieval. A single PC and software can control up to four systems. Each PC on a common network can then store all data in a centralized database.





400-DS Dissolution Apparatus.

### The 400-DS:

- Saves time by simultaneously testing up to 13 samples, or 12 samples and a control or standard, while providing users direct visibility of each dissolution cell
- Maintains temperature control through internal temperature probes and external heating jackets; no water bath is required
- Minimizes evaporation through the fully closed system and the integrated syringe pump and autosampler save valuable bench space
- Offers automated media addition/removal through a port on the bottom of the cell
- Enables sample holder reciprocation through an externally controlled magnetic plate and supports between 1 and 35 dips per minute (DPM) to best match your requirements
- Includes a built-in autosampler that accommodates 12 individual sample rows with either 2 or 4 mL HPLC vials
- Permits up to 36 timepoints and five different media types per method including the use of solvents at high concentrations
- Automates full or partial media replacement via a built-in fluidics module at every timepoint for each vessel
- Can be safely used with 100% ethanol and methanol

Items included with a standard 400-DS (software ordered separately):

- 400-DS base unit with built-in syringe pump
- 13 sample cells (5 or 10 mL)
- 13 heater jackets for sample cells
- Sample tray (13 individual rows)
- Sample vials (2 and 4 mL) for volume calibration
- Bottle caps and tubing for dissolution media/waste
- Modified temperature probe (for temperature calibration)
- Sample extraction tool
- Communication/power cables

### Did you know?

### 400-DS sample cells

Please consider the volume of media your method will require. It is not possible to switch between 5 and 10 mL cells on the same instrument. Keep in mind that the total volume of media the dosage form is exposed to is cumulative. Example: a method using 10 mL of media that has five timepoints and includes a complete media change at each time-point would have a total volume of 50 mL.

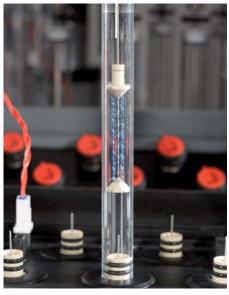
### Dissolution cell design

- A glass tube, open at both ends, is placed on top of the fluidics module, and a heating jacket surrounds each tube (no water bath is required). The bottom end is capped by the sampling port, while the top end is sealed after the sample holder is inserted
- All sampling and media replacement is performed from the sampling port at the bottom of the dissolution cell
- Temperature is recorded and independently controlled using an integrated temperature probe at the bottom of each cell
- The 400-DS supports the USP-specified stroke length of 20  $\pm$  1.0 mm required for Apparatus 7
- 5 or 10 mL sample cells are available but not interchangeable on the same instrument



Description	Part No.
400-DS Automated Apparatus 7	G7975A
400-DS, 5 mL sample cell	G7975A #105
400-DS, 10 mL sample cell	G7975A #110
Note: 400-DS sample cell size – One (1) selection is required. Sample cells are r	not interchangeable.
5 mL stent holder assembly	G7975A #120
10 mL stent holder assembly	G7975A #121
Basket assembly, PEEK	G7975A #122
Pacemaker lead holder, 1.7 mm	G7975A #123
Basket, 50-mesh, 10 mL	G7975A #124
Basket, mesh end, 20 m	G7975A #125
Punctal plug, 5 mL	G7975A #126
Contact lens holder, 5 mL	G7975A #127
Flat blank holder, 10 mL	G7975A #128
Contact lens holder, 16 mm, 5 mL	G7975A #129
Basket, 50-mesh, 5 mL	G7975A #130
Contact lens holder, 16 mm, 10 mL	G7975A #131
Add Installation Service	G7975A #44K
Add Familiarization Service	G7975A #44L
Note: 400-DS Workstation Software (G4973AA) not included.	

Note: For complete qualification services offering, see page 155.



400-DS sample cell with stent holder.



Internal view of cell holders.

### 400-DS Software and Accessories

Description	Part No.
400-DS Workstation Software	G4973AA
400-DS Workstation Software Bundle, with PC, printer and monitor	G9263AA
400-DS, with PC, printer, software, 5 mL cell	33-0105
400-DS, with PC, printer, software, 10 mL cell	33-0505
Dissolution cell, 10 mL	33-9000
Dissolution cell, 5 mL	33-9005
Heater element with cable assembly, 10 mL	33-9001
Heater element with cable assembly, 5 mL	33-9006
Vial tray row, single, 1.5 mL	33-9013
Vial tray row, single, 4 mL	33-9002
Extraction tool	33-9007
Vial, pre-crimped 12x32, 100/pk	33-9010
Stent holder assembly, 5 mL	33-9009
Glass vial, clear, with PTFE/silicone cap, 15x45, 100/pk	17-5030

(Continued)



400-DS pacemaker lead holder (p/n 33-9025) and stent holders (p/n 33-9012).

### 400-DS Software and Accessories

Description	Part No.
400-DS Sample Holder	
Stent holder assembly, 10 mL	33-9012
PEEK basket assembly	33-9022
Pacemaker lead holder, 1.7 mm, requires stent holder assembly	33-9025
50-mesh basket, 10 mL	33-9029
50-mesh basket assembly, 10 mL	33-9041
PEEK basket	33-9042
Basket, mesh end, 20 m	33-9046
Punctal plug holder, 5 mL	33-9047
Contact lens holder, 5 mL	33-9048
Flat blank holder, 5 mL	33-9049
Contact lens holder, 16 mm, 5 mL	33-9050
50-mesh basket, 5 mL	33-9051
50-mesh basket assembly, 5 mL	33-9052
Contact lens holder, 16 mm, 10 mL	33-9053

### Did you know?

Agilent offers a variety of standard holders for stents, pacemaker leads, medicated contact lens, wound care products, and more. Contact your Agilent representative for information on custom-designed holders specifically for your testing needs.



### 400-DS Specifications

Reciprocation Length	20.0 ± 1.0 mm
Dip Rate	1-35 ± 5% DPM
Temperature Ambient	+ 5 to 55 ± 0.2 °C
Volume (Media)	3-5 (5 mL cell) or 8-12 (10 mL cell) ± 1%
Volume (Sample)	2 or 4 mL tray ± 1%
Timepoint (Samples)	Specified as HHH:MM:SS ± 2%
Number of Timepoints	Up to 36 (with tray change)
Input Voltage	115V / 230V AC; 50 / 60 Hz
Types of Media (per test)	Up to 5
Evaporation	0.2% or less over 24 hours

### **400-DS Dimensions**

Height	Width	Depth	Weight
58.42 cm / 23 in.	53.34 cm / 21 in.	59.69 cm / 23.5 in.	58.97 kg / 130 lb.



# 3 Dissolution Software



# Agilent Dissolution Workstation Software

# Complete, integrated control of multiple dissolution systems from a single computer

Dissolution Workstation Software integrates Agilent's dissolution apparatus and automated sampling components, allowing you to simultaneously control up to four systems of any configuration from a desktop PC. The software provides a mechanism for the user to build, edit, search, retrieve, and archive all dissolution methods and test reports from a single interface.

- Get Organized Combine system, method, and test information in one database for easy maintenance and data review.
- Increase Efficiency Eliminate manual documentation of each step of the dissolution testing process, improve data management, and reduce errors.
- Be Compliant Meet electronic records and signature requirements for 21 CFR Part 11 compliance with built-in features.
- Rest Assured Integrate data security with features designed to simplify data export and LIMS integration.

Method parameters, instrument and accessory information, and test data are captured and recorded with the software. View test status information in real time as the software progresses through the timepoints for each dissolution system. As part of 21 CFR Part 11 regulations, user changes to methods and system configurations can be easily tracked and documented.

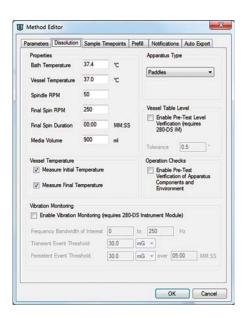
### Did you know?

### Supported apparatus

Agilent's complete line of dissolution equipment is available for use with Dissolution Workstation Software.

#### This includes:

- 708-DS and legacy models
   (USP Apparatus 1 and 2)
- BIO-DIS Reciprocating Cylinder and Reciprocating Holder (USP Apparatus 3 and 7)
- 850-DS and legacy 8000 Dissolution
   Sampling Station and pumps



Dissolution Workstation Method Editor.

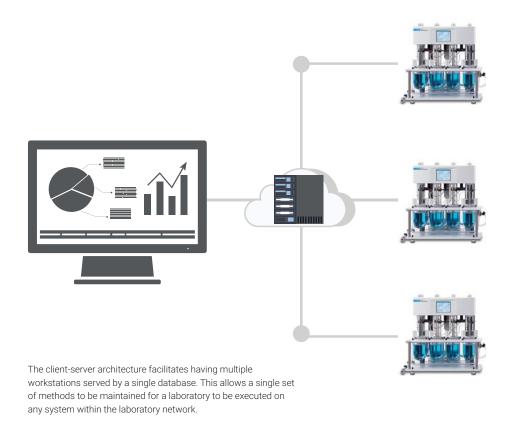
Dissolution Workstation Software maintains a complete history for all executed tests, which can be digitally verified and electronically signed. Print, preview or export PDF documented results generated by a dissolution run in the protected database created locally or on a network. The client-server architecture offers the potential to integrate or export the data to a laboratory information management system (LIMS).



Dissolution Workstation Software provides the compliance and data security required for your regulated environment.

### Did you know?

With Agilent Dissolution Workstation Software, you can configure an environment that fits the needs of your lab. The remote-control capabilities of Dissolution Workstation Software and the 708-DS Dissolution Apparatus allows you to remotely begin tests and view system status from any networked workstation. A simple ethernet connection even allows you to start dissolution tests remotely, and remove the PC from the dissolution environment.



### **Dissolution Workstation Software**

- Contains several different user groups to assign proper rights and privileges to individual users
- Includes an audit trail feature that creates test reports highlighting differences between versions of methods or system configurations
- Can support dissolution methods that include a media change
- Does not have restrictions on the different combinations of equipment with any of four systems that may be configured
- Offers an ideal solution to eliminating manual transcription errors, and improving efficiency and data integrity

### Did you know?

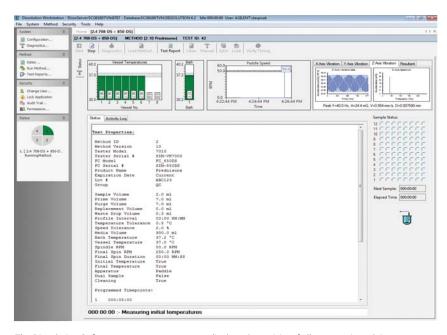
Dissolution Workstation Software, in conjunction with the 280-DS instrument module, provides the ability to monitor vibration throughout the entire dissolution test. Any event recorded above your preset threshold both transient and persistent - is documented in the final report to aid in potential failure investigations.

### **Dissolution Workstation Software**

Description	Part No.
Dissolution Workstation Software (PC not included)	G4974AA
Dissolution Workstation Software Bundle (includes PC/printer/monitor)	G9264AA
280-DS Instrument Module Kit	12-0595

### **Dissolution Workstation Software enhancements**

- Consolidate and maintain data in one paperless location, with options of exporting information into your laboratory information management system (LIMS) or Microsoft Excel.
- Add and document an automated system cleaning cycle to the end of each method, extending the life of your dissolution equipment. Auto-cleaning can even be an unattended operation when using the 850-DS Sampling Station.
- Comply with current enhanced mechanical qualification (MQ) guidelines, including verifying and documenting the condition of accessories prior to each test.
- Improve failure investigations related to environmental impacts by monitoring the dissolution apparatus and environment for vibration using the Instrument Module (IM) of the 280-DS Mechanical Qualification System.



The Dissolution Software system status screen displays the activity of all systems in real time.

# Exclusive 280-DS Instrument Module (IM) monitoring provides important insights related to vibration

The importance of adding vibration and environmental impact monitoring to Dissolution Workstation Software cannot be overstated as this feature provides the user with important information that is not available elsewhere. It has been known for many years that vibration can dramatically impact dissolution results. Regulatory bodies suggest companies monitor and control the level of vibration – you now have a tool to do just this. The lack of an industry-wide norm demonstrates how internal and external vibrations may affect each product and individual environments differently. With baseline values for vibration on the x-, y- and z-axes, dissolution systems as well as their environments can consistently be monitored in real time.

This added benefit may be used during early research to develop internal tolerances for specific methods, as part of a quality control initiative for well-established methods – or to watch for wear and tear to prevent instrument failure. If failure should occur, this feature speeds problem solving and helps to get instruments back online faster.



When used with Dissolution Workstation Software the 280-DS Instrument Module provides valuable insight into real-time environmental test conditions. Read more about the 280-DS Mechanical Qualification System on pages 92 ff.

# 4 Qualification Tools



# Agilent 280-DS Mechanical Qualification System

### Redefine Dissolution Qualification

Easily perform measurements required for enhanced Mechanical Qualification (MQ) or the physical parameter documentation for the USP Performance Verification Test (PVT) in as little as 30 minutes for both paddles and baskets! The Agilent 280-DS Mechanical Qualification System (MQS) allows you to measure all critical physical parameters of the dissolution apparatus with increased reliability and precision. The 280-DS works with any dissolution apparatus with open space between the drive unit and vessel plate to obtain accurate, repeatable measurements virtually hands-free. Simply place either the Instrument or Vessel Modules to take measurements without the use of separate tools or added steps that increase time in the qualification process. Coupled with software ideal for a 21 CFR Part 11-compliant environment, the system has the ability to maximize analyst efficiency, reduce instrument downtime and improve dissolution failure investigations.

The Instrument Module (IM) and Vessel Module (VM) electronically capture all the necessary measurements for the 280-DS. These durable modules replace the need for individual measuring gauges with an all-in-one system that accurately verifies physical parameters without the guesswork associated with manual gauges.



280-DS MQS with modified arm extension allows compatibility with various brands of dissolution apparatus.

### Did you know?

### 280-DS MQS recalibration

Depending on usage conditions and frequency, the 280-DS should be periodically recalibrated. Agilent offers this service at multiple locations worldwide. Contact Agilent Service to initiate recalibration of your 280-DS.

www.agilent.com/lifesciences/ dissolutionrepair

### Instrument Module measurements include:

- Vessel plate level
- Triaxal vibration
- Temperature

### Vessel Module measurements include:

- Rotational speed (RPM)
- Shaft wobble
- Basket wobble
- Vessel centering
- Vessel verticality
- Shaft verticality
- Basket and paddle height



280-DS Mechanical Qualification System and Workstation Software.

### Reliable, secure data recording and storage

280-DS Workstation Software incorporates an intuitive, user-friendly interface built on a familiar and compliant software platform. It includes preloaded regulatory methods – such as ASTM E2503 – for quick setup and execution. Previously stored data files are categorized and easily retrieved from a secure database. The software also contains enhanced capabilities, such as data trending, that can improve failure investigations and increase apparatus integrity.

### 280-DS Mechanical Qualification System

Description	Part No.
280-DS Mechanical Qualification System, with 280-DS Workstation Software	G7980AA
Cable kit for Agilent/Varian/VanKel Dissolution Apparatus connection	G7980AA #100
Spacer kit for 280-DS VM (for use with shorter vessels)	G7980AA #105
HP ProBook laptop for use with 280-DS	G7980AA #650
Add Familiarization Service	G7980AA #44L
Add Installation Service	G7980AA #44K
Note: For complete qualification services offering, see page 155.	
280-DS Replacement Parts	
280-DS Instrument Module Kit	12-0595
Magnetic Clip, RPM, 280-DS	K1005-02019
Temperature Probe, 280-DS	K1005-02024
Cable to connect PC to Agilent/Varian/VanKel Dissolution Apparatus	5075-0252



The 280-DS transforms the process of gathering mechanical qualification data.

### Did you know?

When using the 280-DS with an Agilent dissolution apparatus, the user achieves an additional advantage. A simple RS232 connection from the instrument to the PC allows the software to initiate spindle rotation when necessary. This is especially useful when measuring RPM, wobble and vibration, and provides even greater time savings and efficiency! This connectivity can be achieved by adding option #100 when ordering.

# Automated Dissolution Sampling Systems



# Agilent 850-DS Dissolution Sampling Station

### Centralize Dissolution Workflow

The Agilent 850-DS Dissolution Sampling Station can be incorporated seamlessly into your existing workflow to provide an unattended sampling and cleaning solution that increases productivity and eliminates variability. Supporting a range of dissolution methods, the 850-DS works with USP dissolution apparatus 1, 2, 3, 5, 6 and 7 for precise and repeatable results using conventional test tubes, HPLC vials and even 96-well plates.

- Create and store custom dissolution methods
- Control precise and repeatable sampling
- Document critical instrument data
- Prepare samples for subsequent UV-Vis or HPLC analysis
- Automate cleaning of the instrument to prepare for your next test



850-DS Dissolution Sampling Station with optional built-in filtration module.

### Built-in syringe pump and optional filter changer module

Conserve bench space using the integrated syringe pump with variable speeds for shorter timepoint intervals. The 850-DS handles different types of media – including those containing surfactants – for superior autosampling performance. Media replacement is a standard feature and can be used with or without the optional filter module. Should you require filtration down to 0.2  $\mu m,$  0.45  $\mu m,$  this is possible with the exclusive Whatman 850-DS 8-channel filter plates from GE Healthcare that simplifies the need for replacement between timepoints.

Visit www.gelifesciences.com/distributors for contact information regarding filter plate ordering.



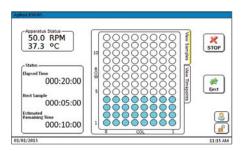
The 850-DS optional filter module uses eight 25 mm disc filters in a novel plate design.

## Firmware Capabilities

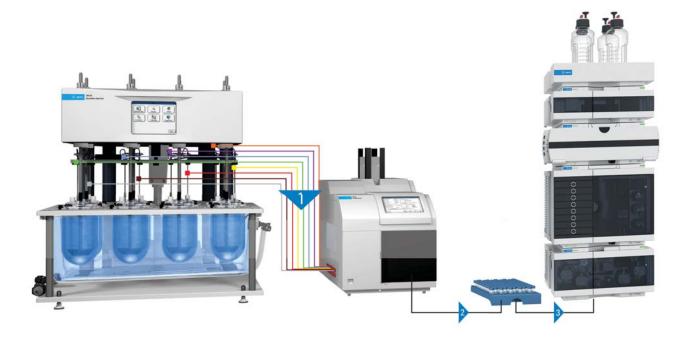
The 850-DS firmware supports a variety of languages including English, German, Japanese, Portuguese, Chinese and Spanish. Easily display real-time status of instrument conditions, including the sample tray format installed, as well as calculate time for minimum sampling interval during method setup, preventing timing errors.

#### The firmware also:

- Differentiates between full and partial media change for accurate timing
- Can prevent unauthorized instrument with individual usernames and password changes
- Accepts methods with up to 36 timepoints
- Automatically calculates minimum sampling intervals
- Supports data-export functionality via RS232, SD card, or optional built-in printer
- Synchronized start enables performance of two dissolution tests in parallel



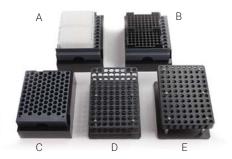
The 850-DS firmware displays real-time status of method progression.



Samples collected by the 850-DS into an Agilent HPLC sample tray can be placed directly into the HPLC autosampler, avoiding the need to manually transfer individual vials to a separate tray.

### 850-DS Dissolution Sampling Station

Description	Part No.
850-DS Dissolution Sampling Station	
850-DS Dissolution Sampling Station	G7930A
850-DS Dissolution Sampling Options	
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7930A #210
Sample tray kit, 108-position, 2 mL, includes tray and needle block assembly	G7930A #211
Sample tray kit, 100-position, 2 mL, includes tray and needle block assembly	G7930A #212
Sample tray kit, 96-well plate, includes tray and needle block assembly	G7930A #213
Add Dissolution Workstation Software cable kit (software ordered separately)	G7930A #220
Add printer to 850-DS	G7930A #880
Add Installation Service	G7930A #44K
Add Familiarization Service	G7930A #44L
Note: For complete qualification services offering, see page 155.	
850-DS Filtration Module	G7931A
96-position (12 x 8), 14 mL sample tray (for use with test tubes)	K1005-02066
850-DS Dissolution Sampling Station Option and Replacement Parts	
Sample tray, 96-position, 12 x 8, 2 mL, for use with HPLC vials	K1005-05212
Sample tray kit, 108-position, 2 mL, requires needle block conversion	K1001-01202
Sample tray, 54-position, 9 x 6, for 2 mL vials, for use with K1001-01202	5022-6502
Sample tray kit, 100-position, 2 mL, requires needle block conversion	K1001-01203
100 position tray for 2 mL vials	G1313-44510
Sample tray kit 96-well plate, requires needle block conversion	K1001-01204
Glass tubes, 16x100 mm, 250/pk	17-5001
Glass vials, 12x32 mm, w/ cap (PTFE/silicone), 100/pk	17-5020
850-DS Printer Kit (includes side panel)	K1005-05221



- A = 96-well plate sample tray (p/n K1001-01204) for use with two (2) 96-position well plates
- B = 108-position HPLC vial sample tray (p/n 5022-6502) - for use with two (2) 54-position HPLC sample trays
- C = 100-position HPLC vial sample tray (zigzag) (p/n G1313-44510) - for use with 100-position HPLC sample tray
- D = 96-position test tube sample tray (p/n K1005-02066) - for use with 16 x 100 mm
- E = 96-position HPLC vial sample tray (p/n K1005-05212) - for use with 12 x 32 mm HPLC vials.

The 850-DS Dissolution Sampling Station is also part of the following system bundles:

### 850-DS Dissolution System Bundles

Description	Part No.
850-DS Dissolution System Bundles	
708-DS Dissolution Apparatus and 850-DS Sampling Station	G7913A
708-DS and Cary 60 Online UV Dissolution System – Multicell	G7926A
BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station	
Reciprocating Holder Apparatus 7 and 850-DS Sampling Station	G7978A

### 850-DS Dissolution Sampling Station

Dimensions	
Height	40.0 cm
Height with filter module	60.0 cm
Width	39.0 cm
Width with filter waste bin	48.0 cm
Depth	60.0 cm
Weight	27.0 kg
Specifications	
Sampling accuracy	10 mL ± 2.5%
Sample volume per vial/tube	0.1-14 mL (up to 28 mL with dual sample)
Sample frequency	Method specific with minimum of 2 minutes
Number of samples per test	Up to 36 with manual tray exchange
Pump speed	Variable (6, 8, 10, or 12 mL/min)

Note: For the complete 850-DS specifications, visit

www.agilent.com/en-us/products/dissolution/automated-sampling-systems/850-ds-dissolution-sampling-station



# Cary 60 UV Dissolution System

### Ultimate flexibility in UV dissolution measurement

Agilent offers UV Dissolution systems with the Agilent Cary 60 UV-visible spectrophotometer. Whether you want an online or offline system, multicell-based or in situ measurement via fiber optics, we have just the configuration to suit your needs.

### Cary 60 UV-visible spectrophotometer

- Multicell UV Dissolution: Utilizes a multicell changer that allows for the integration of up to two dissolution apparatus with one UV spectrophotometer. In a single- or dual-apparatus configuration, each vessel has a dedicated flow cell. Samples are taken simultaneously and read sequentially.
- Cary WinUV Software: Supports the 850-DS Dissolution Sampling Station in line with the Cary 60, offering sample archival or offline collection for HPLC analysis.
- Fiber Optic UV Dissolution: May be configured for use with a fiber optic multiplexer, and integrated with either one or two apparatus. The fiber optic probes are mounted on the moveable manifold and are precisely positioned in the media only during measurements.

If you need assistance with selecting the system most suitable for your laboratory, please contact your Agilent representative or the Dissolution Hotline at dissolution.hotline@agilent.com

The 708-DS is fully compatible with this online UV-Dissolution system. In addition, you can retrofit many older Varian and VanKel apparatus with this system.



Cary 60 UV-visible spectrophotometer.

## UV dissolution details - Cary 60 UV-visible spectrophotometer

### **General Information**

Software Package	Cary WinUV
Number of Apparatus	1 to 2
Multicomponent Analysis	No
Fiber Optic System Availability	Yes

### **Online Sampling System Details**

Closed Loop Sampling	Yes (Multicell)
Path Lengths (mm)	0.2, 0.5, 1, 2, 5, 10 (Multicell) 1, 2, 5, 10, 20 (Fiber Optic)
Automated Dosage Delivery and Sampling	Yes
Temperature Monitoring	Yes
Simultaneous Sampling	Yes (Multicell)
Sequential Sampling	Yes (Fiber Optic)
Sample Filtration (minimum pore size m)	0.2 or 0.45 µm with 850-DS Dissolution Sampling Station and filter module
Sample Archival	Yes (Multicell with 850-DS Dissolution Sampling Station)

### Cary 60 Spectrophotometer Details

Wavelength Range	190-1100 nm
Slit Width	1.5 nm
Lamp Type	Xenon Flash
Instrument Design	Scanning
Wavelength Accuracy	< ± 0.5 nm
Wavelength Reproducibility	± 0.1 nm
Photometric Accuracy	± 0.005 Abs (NIST 930D)
Photometric Noise	± 0.0001 Abs
Baseline Flatness	< 0.001 Abs
Stray Light	< 1.0% (198 nm) < 0.05% (220 nm) ≤ 0.05% (370 nm)

### **Cary WinUV Software Details**

Real-time Data Visible	Yes
Independent Methods	Yes
Offline Analysis	Yes
Tablet Weight Normalization	Yes
Medium Volume Changes	Yes
Customizable Reports	Yes
21 CFR Part 11 Package	Yes
Electronic Signatures	Yes

### Online UV Dissolution - Multicell

Precise and accurate determination of dissolution concentrations is achieved with UV-Vis dissolution methods. These remain among one of the most common analytical techniques for dissolution sample analysis. The Agilent Online UV Dissolution System with the Cary 60 UV-visible Spectrophotometer integrates dissolution testing with online UV analysis to provide a single source, automated performance testing solution.

Available in either single or dual apparatus configurations, the system supports individual flow cells for a range of path lengths. The multicell changer accommodates eight flow cells per dissolution apparatus, allowing for a blank, standard and six samples. The system can take both blank and standard readings during each timepoint. Additionally, each vessel position is configured with its own flow cell and tubing, eliminating cross-contamination.

### Did you know?

### Cary 60 integrates easily with singleor dual-apparatus operation for increased throughput and automation

- Long-lasting, no warm-up time Xenon lamp flashes only when taking a measurement
- No degradation of photosensitive active drug components associated with continually burning lamps
- Virtual immunity to room light, reducing noise and allowing for a linear absorbance range up to 3.5 AU
- Configurable with Agilent 850-DS for collecting and archiving samples for LC analysis (multicell only).



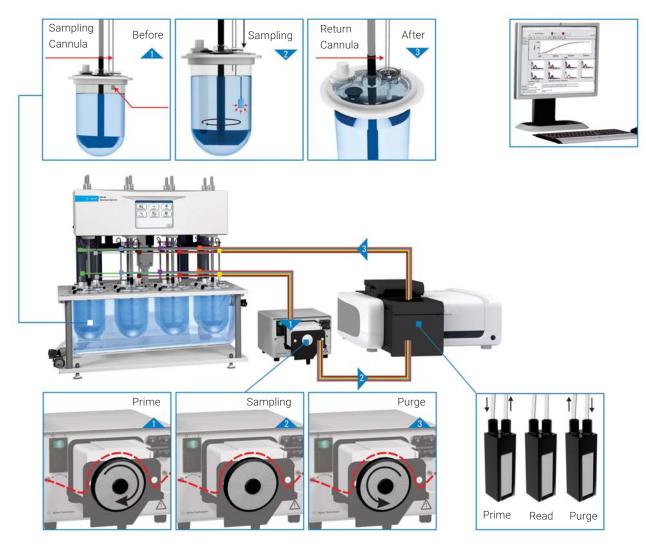
708-DS, 850-DS Dissolution Sampling Station and Cary 60 Multicell UV Dissolution System.

### Cary 60 UV Dissolution System: Single Apparatus with Peristaltic Pump

The Cary 60 can be configured with a peristaltic pump to transfer the sample to the flow cell. Cells are analyzed and the sample is returned to the vessel maintaining vessel volume and eliminating the need for media replacement.

### Flow configuration (as shown below)

- 1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the peristaltic pump simultaneously.
- 2. The pump then moves the sample into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
- After the samples are measured, the pump reverses flow and returns all sample volume to the dissolution vessels. No volume is lost in this closed-loop system. The sample lines are then purged and remain empty until the next timepoint.



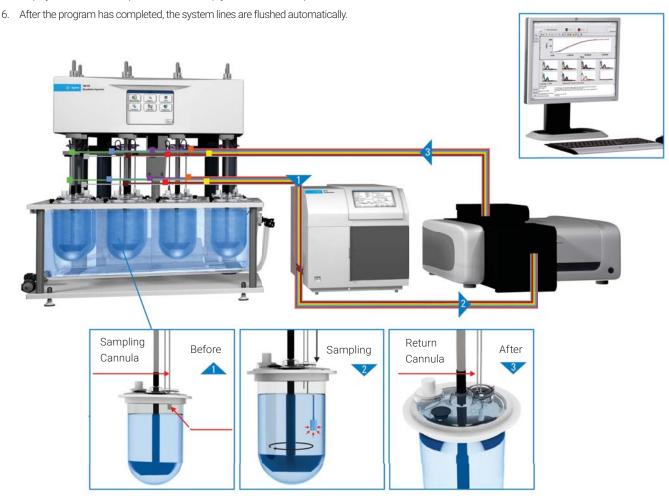
Cary 60 UV Dissolution System - Single Apparatus setup with peristaltic pump.

### Cary 60 UV Dissolution System: Single Apparatus with 850-DS Sampling Station

The multicell system is ideal for providing repeatable results, especially when additional filtration or sample archival is required, via the 850-DS Dissolution Sampling Station with filter module. Integrating the 850-DS Dissolution Sampling Station with the Cary 60 allows you the flexibility of online UV analysis and offline collection for methods requiring an LC finish.

### Flow configuration (as shown below)

- 1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the built-in 850-DS syringe pump simultaneously.
- 2. The 850-DS pumps and moves the samples through the filters on the integrated filter module (if the method calls for additional filtration, otherwise this step can be bypassed).
- 3. Samples are then collected for archival in the 850-DS sample trays. If there is no need for archival, this step is bypassed.
- 4. The volume continues on into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
- 5. After the samples are measured, the sample lines are purged with air and all volume is returned to the dissolution vessels. No volume is lost in this closed-loop system and the sample lines remain empty until the next timepoint.



Cary 60 UV Dissolution System - Single Apparatus setup with 850-DS Dissolution Sampling Station.

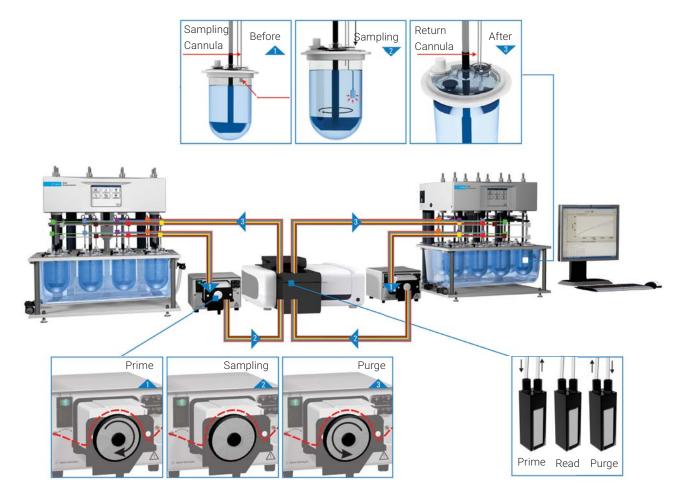
### Cary 60 UV Dissolution System: Dual Apparatus with Peristaltic Pumps

For maximum efficiency, up to two dissolution apparatus can be used with a single Cary 60. A dual apparatus system will incorporate two peristaltic pumps or 850-DS Dissolution Sampling Stations to allow independent methods to be run on the two systems.

### Flow configuration (as shown below)

- 1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the respective peristaltic pumps simultaneously.
- 2. The pump then moves the sample into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
- 3. After the samples are measured, the pump reverses flow and returns all sample volume to the dissolution vessels. No volume is lost in this closed-loop system. The sample lines are then purged and remain empty until the next timepoint.
- 4. After the programs have completed, the system lines are flushed automatically.

The flow configuration is identical for each apparatus in a dual-system setup. Independent methods can be executed concurrently. The cell changer of the Cary 60 supports two sets of dedicated flow cells, eliminating the chance of cross-contamination or carryover.



Cary 60 UV Dissolution System - Dual Apparatus setup with peristaltic pumps.

# Agilent Cary 60 UV-Vis Spectrophotometer

### Online UV Dissolution - Fiber Optic

The Fiber Optic Online UV Dissolution System offers versatility and flexibility while delivering the highest level of automation and data integration for your UV dissolution needs. The Cary 60 UV-visible spectrophotometer offers excellent optical transmission and reproducibility capabilities, and the extended linear photometric range is ideally suited for superior fiber optic analysis.

The fiber optic multiplexer ensures precise and rapid position-to-position movement to decrease time needed between sample timepoints. The system's probes use silica fibers for optimal performance, and interchangeable tips make cleaning and replacement cost-efficient and easy. Tip pathlengths from 1 to 20 mm are available to accommodate a wide variety of sample concentrations.

### Advantages of fiber optic UV dissolution

- Ideal for rapid timepoint requirements with the ability to take readings as often as every 45 seconds
- Samples are read directly in the dissolution vessel, which eliminates contamination, carryover and dilution of samples
- Compensates for samples with excipient and background interferences
- Cleaning is simple, requiring only rinsing and wiping of the fiber optic probes and tips
- Fewer moving parts and consumables (for example, filters, sample tubing) reduce cost of ownership

### Did you know?

### Why choose fiber optic UV dissolution?

Save time with real-time sample analysis and reporting of dissolution data using in situ fiber optic probes. Also, no pumps or moving media/samples means no system flush is required. This greatly improves turnaround time and maximizes efficiency - simply rinse some key accessories and you're ready to begin the next test.



Cary 60 UV-visible spectrophotometer with multiplexer for fiber optic UV dissolution.

The system is based on the Cary 60 UV-visible Spectrophotometer, with Xenon flash lamp technology for fiber optic utilization. Because the system is based on a standard spectrophotometer, parts and service are readily available worldwide.

The fiber optic system utilizes a 12-position multiplexer, to read samples sequentially. A single spectrophotometer can be used with two dissolution apparatus.

The fiber optic probes can be mounted on a movable manifold that lowers the probe to the correct sampling height in the vessel. The sample is read and the probe is raised either entirely out of the media or held in the upper level of the media to minimize bubble formation and prevent drying on the tip surface.

### Cary 60 UV-Vis Spectrophotometer Dimensions

Height	Width	Depth	Weight
19.6 cm / 8 in.	47.7 cm / 19 in.	56.7 cm/ 23 in.	18 kg / 40 lbs

### Cary 60 UV-Vis Spectrophotometer Specifications

Wavelength	Wavelength	Wavelength	Photometric	UV-Vis Limiting
Range	Accuracy	Reproducibility	Range	Resolution
190 - 1100 nm	+/- 0.5 at 541.94 nm	+/- 0.1 nm	+/- 3.5 Abs	- 1.5 nm</td



708-DS Dissolution Apparatus and Cary 60 Fiber Optic UV Dissolution system.

### Agilent Cary WinUV Dissolution Software

Agilent Cary WinUV Dissolution Software supports both the Agilent Multicell and Fiber Optic Online UV Dissolution Systems. The software generates accurate and robust data and accommodates a wide variety of dissolution samples and methods. Analysts can easily customize final reports with a complete summary of the data acquisition using comparison and statistical evaluation tools, data tables and dissolution profiles.

### Agilent Cary 60 UV-visable spectrophotometer

The Cary 60 utilizes a Xenon flash lamp that only turns on when acquiring a data point, minimizing photo-bleaching of samples. The Cary 60 acquires data at a rate of 80 Hz with a maximum scan rate of 24,000 nm/min applying a dual-detector approach to measure sample and source simultaneously.

This rugged instrument is easy to operate and economical to own. Because the lamp only illuminates when taking a reading, not only do you save energy, but there are significant lamp savings versus conventional deuterium-lamp systems.

### Did you know?

### Testing in a regulated environment?

Cary WinUV Dissolution Software includes an optional Compliance Manager package that allows your laboratory to install and configure proper 21 CFR Part 11 controls.

### Maximize Cary WinUV software

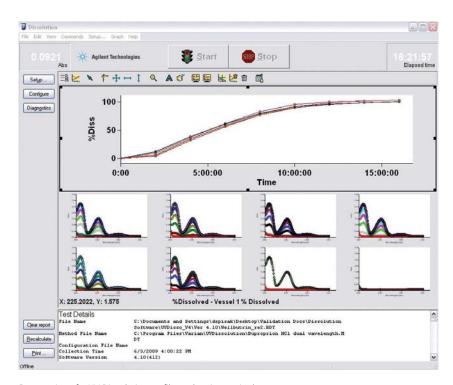
When the Cary 60 is not being used for an online Dissolution test, there is an entire suite of applications available in Cary WinUV software to maximize its value as a standalone spectrophotometer. These include Advanced Reads, Scan, Concentration, Kinetics, and more.



Cary 60 UV-visable spectrophotometer with 18-cell changer.

### Cary WinUV dissolution software

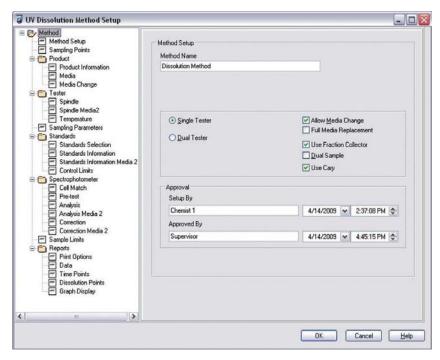
- Can integrate a peristaltic pump or 850-DS Dissolution Sampling Station with optional filter module for accurate preparation of samples and archival
- Controls apparatus features such as dosage delivery, automated sampling and vessel temperature monitoring
- Creates data processing and reports for samples taken offline using the UV dissolution
- Accommodates media change methods, capsule shell corrections and infinity spins required for various methods
- Includes advanced UV capabilities, such as second derivative analysis, baseline correction and more, to work with challenging spectra
- Easily integrated into a 21 CFR Part 11 compliant environment



Progression of a UV Dissolution profile as data is acquired.

### Key software functionalities

- Advanced UV-Vis analysis options include single wavelength, scan, and single and scan options
- Allows two independent methods to be run simultaneously when using a dualapparatus configuration
- Online or offline testing of standards for percentage (%) and milligrams (mg) dissolved calculations
- Built-in PreTest Scan feature to confirm analysis wavelength prior to dosage introduction
- Immediate notification of out-of-specification results
- Supports media change or media addition methods
- Hardware configuration files and method files stored separately for quick retrieval and reduced turnaround times
- Dissolution profiles and customizable reports are visible in real time
- Manual data entry and recalculation provides flexibility by allowing you to obtain validated calculations and reports for samples taken on other offline systems
- Diagnostics module allows for easy troubleshooting and cleaning



A comprehensive Method Setup utility is at the core of Cary WinUV Dissolution Software.

### Did you know?

### Flexible standard measurement and calculation options

The UV Dissolution application incorporates several online standard options including Post Cycle Standard (for bracketed analysis), Bridged Mean, and Running Mean. Each method stores how results are calculated depending on your specific preferences.

# Superior linear range (> 3 Abs) of the Cary 60 UV-visible spectrophotometer

The linear range of a spectrophoto-meter defines the absorbance range in which measurements are accurate. The linear range of the Cary 60 permits the analysis of a wide range of sample concentrations, reduces the need for dilution or smaller path length cells, and measures highly turbid solutions (for fiber optics).

The Agilent UV dissolution systems are scalable to your needs. In the ordering tables, you will find all components forming a complete dissolution testing system with UV-Visible analysis.

### Automated UV Systems - Cary 60 Dissolution Software and Accessories

Description	Part No.
Cary 60 Software - UV Dissolution Multicell Packages	
708-DS and Cary 60 Online UV Dissolution System – Multicell	G7926A
Note: Software and PC ordered separately (G4971AA or G9261AA).	
Options for G7926A	
Add AutoTemp, for 708-DS	G7926A #105
Add low actinic - red accessories	G7926A #110
Delete basket shafts and baskets	G7926A #120
Delete paddles	G7926A #125
PTFE-coated paddles	G7926A #126
PEEK paddles	G7926A #127
Note: Only one selection may be chosen from options #125-127 for G7926A (not required).	
2L 708-DS Dissolution Apparatus	G7926A #140
Verified accessories	G7926A #145
Non-slit evaporation cover	G7926A #146
Full Flow Filter, UHMWPE, 10 µm, 1,000/pk	G7926A #160
Full Flow Filter, UHMWPE, 35 µm, 1,000/pk	G7926A #161
Full Flow Filter, UHMWPE, 70 µm, 1,000/pk	G7926A #162
Full Flow Filter, PVDF, 10 μm, 1,000/pk	G7926A #163
Full Flow Filter, PVDF, 35 µm, 1,000/pk	G7926A #164
Peristaltic pump	G7926A #200
Add 850-DS Dissolution Sampling Station, with built-in syringe pump	G7926A #205
Note: One selection is required from pump options #200 or #205 for G7926A.	
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7926A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7926A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7926A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7926A #213
Cary 50/60 flow cell, 0.2 mm, 8/pk	G7926A #300
Cary 50/60 flow cell, 0.5 mm, 8/pk	G7926A #301
Cary 50/60 flow cell, 1 mm, 8/pk	G7926A #302
Cary 50/60 flow cell, 2 mm, 8/pk	G7926A #303
Cary 50/60 flow cell, 5 mm, 8/pk	G7926A #304
Cary 50/60 flow cell, 10 mm, 8/pk	G7926A #305

Note: One selection is required from options #300 - 305 for G7926A.

(Continued)

### Did you know?

### Dual-cell tubing kit

The Cary 60 makes it easy to interconnect two different cells within the multicell transport. This allows you to switch between two sets of cells, typically with different path lengths, with no disassembling or reassembling of the tubing lines. Switching between methods requiring cells of different path lengths is as easy as selecting the cells to be read using Cary WinUV Dissolution Software. Only one dissolution apparatus can be used when the dual cell tubing is in place (p/n 11-1320).

### Automated UV Systems - Cary 60 Dissolution Software and Accessories

Description	Part No.
Add printer, for 708-DS	G7926A #880
Add printer to 850-DS	G7926A #881
Delete 708-DS Dissolution Apparatus	G7926A #900
Dual system 708-DS	G7926A #920
Add Installation Service	G7926A #44K
Add Familiarization Service	G7926A #44L
Note: For complete qualification services offering, see page 155.	
UV Dissolution Software, multicell (PC not included)	G4971AA
UV Dissolution Software bundle, multicell, with PC, printer, monitor	G9261AA
Flow cell for use with Cary 50/60, 10 mm	11-1300
Flow cell for use with Cary 50/60, 0.2 mm	11-1301
Flow cell for use with Cary 50/60, 0.5 mm	11-1302
Flow cell for use with Cary 50/60, 5 mm	11-1305
Flow cell for use with Cary 50/60, 2 mm	11-1310
Flow cell for use with Cary 50/60, 1 mm	11-1315
Cary 50/60 18-cell holder	G6867A
Tubing kit, dual path length, for Cary UV Dissolution System	11-1320
Flow cell tubing replacement kit, for Cary UV Dissolution System	11-1226

### Cary WinUV Software - UV Dissolution Fiber Optic Packages and Software

Description	Part No.
Options for G7927A	
708-DS and Cary 60 Fiber Optic Online UV Dissolution System	G7927A
Note: Software and PC ordered separately (G4972AA or G9262AA)	
Add AutoTemp, for 708-DS	G7927A #105
Add low actinic - red, accessories	G7927A #110
Delete basket shafts and baskets	G7927A #120
Delete paddles	G7927A #125
PTFE-coated paddles	G7927A #126
PEEK paddles	G7927A #127
708-DS Dissolution Apparatus, 2L	G7927A #140
Verified accessories	G7927A #145
Non-slit evaporation cover	G7927A #146
Fiber optic removable tip, 1 mm, 6/pk	G7927A #300
Fiber optic removable tip, 2 mm, 6/pk	G7927A #301
Fiber optic removable tip, 5 mm, 6/pk	G7927A #302
Fiber optic removable tip, 10 mm, 6/pk	G7927A #303
Fiber optic removable tip, 20 mm, 6/pk	G7927A #304
Note: One (1) selection is required from options #300-304 for G7927A.	
Add printer, for 708	G7927A #880
Delete 708-DS Dissolution Apparatus	G7927A #900
Dual system 708-DS	G7927A #920
UV Dissolution Software, fiber optic, without PC	G4972AA
UV Dissolution Software Bundle, fiber optic, with PC, printer, monitor	G9262AA
Add Installation Service	G7927A #44K
Add Familiarization Service	G7927A #44L

Note: For complete qualification services offering, see page 155.

### Did you know?

### Upgrade your Cary 50/60

Increase productivity as laboratory needs change by using your dissolution apparatus and spectrophotometer with an online UV dissolution system. Add the necessary software, cell changer or multiplexer, and other accessories to maximize the efficiency of your instrumentation and streamline analysis. Fiber optic probes/tips and flow cells must be ordered separately depending on the desired pathlength.

### Cary WinUV Software - UV Dissolution Fiber Optic Accessories

Description	Part No.
Benchtop table for UV dissolution system, with keyboard tray	11-1125
4-port USB-to-serial converter	11-1011
External cuvette holder, 1 cm, for FO	11-1012
External cuvette holder cover, 1 cm	11-1014
Fiber optic patchcord, 20 in.	11-1424
Fiber optic probe, 2 m, no tip, for 7000, 7010, 708-DS, 709-DS	11-1425
Fiber optic probe, 2 m, no tip, for 7025/7030	11-1426
Fiber optic removable tip, 1 mm	11-1429
Fiber optic removable tip, 2 mm	11-1430
Fiber optic removable tip, 5 mm	11-1435
Fiber optic removable tip, 10 mm	11-1440
Fiber optic removable tip, 20 mm	11-1445
Fiber optic probe holder, for Distek evaporation cover	12-0592
Cary 60 Upgrade Options	
Cary 60 fiber optic upgrade, includes Cary WinUV software for fiber optic UV dissolution and multiplexer, for 708-DS (probes/tips ordered separately)	11-1141



Fiber optic probe with tips.

# 7 Content Uniformity



# Content Uniformity

# High throughput testing using the Agilent TRS100 Raman spectrophotometer

The Agilent TRS100 Raman system performs fast analysis of intact tablets, capsules, and other dosage forms for the quantification of API(s), polymorphs and crystalline content. Transmission Raman technology from Agilent enables simple method-development and is easy to implement in analytical laboratories and production areas. TRS methods have had regulatory approvals for content uniformity (CU), assay, and identification (ID) applications.

- High throughput
- Nondestructive
- Quantification of low-dose drug products
- Capsules and coatings
- No sample preparation
- Limits of detection/Quantification (LOD/LOQ) approx. 0.1-1% w/w

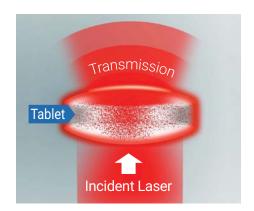


TRS100 Raman spectrophotometer.

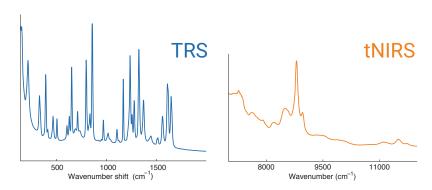
### What is TRS?

Transmission Raman spectroscopy (TRS) is a Raman spectroscopy technique where the detection of the Raman emission is measured on the opposite side of the sample from the incidence beam. This ensures a more representative sample measurement when compared to traditional backscatter sampling.

TRS100 measurements take seconds per sample and produce spectrally-rich information, with high chemical specificity for accurate quantitative or qualitative analysis of intact samples. Routine applications include release testing, formulation development, and in-process control monitoring. Transmission Raman spectroscopy (TRS) is highly chemically specific and sensitive to low concentrations of APIs and excipients.



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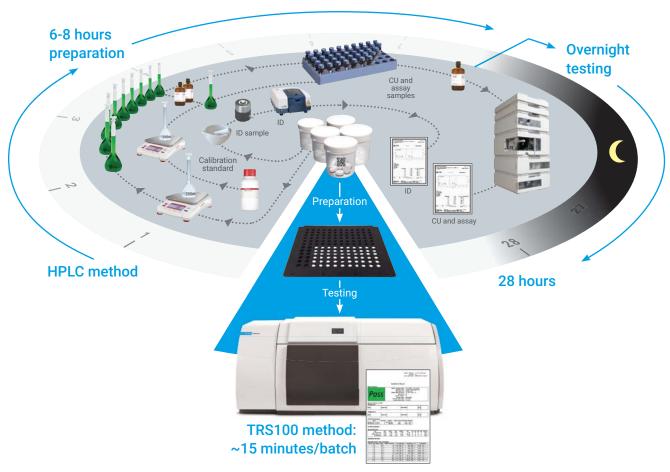
TRS spectrum with discrete API and excipient features, compared with transmission near-infrared spectroscopy (tNIRS) for the same three-API product.

### **Content uniformity**

Content Uniformity (CU) testing, also known as Dose Uniformity testing, is performed on each batch of dosage forms to verify that the amount of API contained within the dosage forms is consistent throughout the batch. Tablets, capsules and other solid dosage forms are sampled from across the batch and are randomly selected for testing by the either the content uniformity method or the weight variation method. These procedures are harmonized between the USP, EP and JP and the method of uniformity testing is based on the amount or ratio of API to the weight of each dose.

For CU determinations, ten dosage units are individually prepared in volumetric solutions designed to completely extract and dissolve the API, usually assisted with hydro-organic solvents and aggressive mixing.

Samples are generally analyzed by HPLC or UV depending on the number of active components or other components of the dosage form. The testing is usually conducted using a large amount of laboratory space due to the amount of volumetric glassware required, as well as the shaking and ultrasonication equipment used to dissolve the samples.



The client-server architecture facilitates having multiple workstations served by a single database. This allows a single set of methods to be maintained for a laboratory to be executed on any system within the laboratory network.

Group testing is often employed where several batches of ten tablets are prepared and run consecutively in HPLC systems. This means the testing is resource intensive for analyst time, solvents and waste and that results are often generated overnight, adding an additional day to the release time.

Transmission Raman Spectroscopy (TRS) is a proven alternative to wet-chemistry analytical methods. The TRS100 Raman system enables fast analysis of solid dosage forms for API content without sample preparation, consumables or solvents. Content uniformity analysis is reduced to minutes per batch, speeding up your QC workflow, saving significant lab costs. and reducing resource usage by avoiding sample-preparation.

### High throughput testing - QC during manufacture

The TRS100 sample-handling system is flexible and customizable using trays that can hold up to 300 single or mixed dosage forms. This enables high-throughput automated quantitative testing in the laboratory or at the point of manufacture, whether effective in-process control monitoring or real-time release testing (RtRT).

- High volume dose testing
- PC monitoring
- Process validation
- Real-time release testing



Example of tray designs.

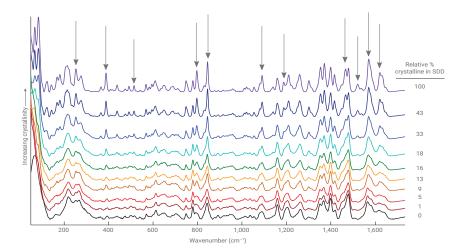
### Solid-State analysis

During drug product development the API form, form change and the compatibility of the API with the formulation excipients is crucial for the product performance and stability. As the TRS100 is highly sensitive to APIs (LOD/LOQ 0.1 to 1% w/w) it can be utilized for the assessment of polymorphs, crystallinity and excipient compatibility during drug development and stability. The flexible and customizable sample-handling trays can accommodate most sample holders (e.g. well plates, vials, cuvettes, bags).

### Residual polymorphs/crystallinity in intact tablets

Most means of residual polymorph/crystallinity analysis quantification are destructive, slow, and expensive. Raman is generally ideal for this kind of analysis but TRS brings additional benefits.

- Low-energy "phonon mode" region measures crystalline vibrational modes directly
- TRS has high sensitivity to polymorphs down to 0.1 to 1% comparable with solidstate nuclear magnetic resonance (ssNMR) - in a fraction of the time
- Recrystallization may occur in hotspots throughout the tablet TRS quantifies the intact dosage form, sampling the entire tablet volume, including any hotspots
- No sample preparation or risk of form conversion
- Low cost per test



TRS spectra collected on an TRS100 Raman system. Nine powder mixtures of varying crystallinity from  $0-9.4\ \%\ w/w\ absolute\ crystallinity.\ Visualization\ of\ the\ spectra\ indicates\ distinctive\ regions\ (marked),$ which correspond to changes in crystallinity.

Method* (w/w)	LOQ	Time per sample
Powder X-ray diffraction (pXRD)	2.5 to 10%	About 1 hour
Solid-state nuclear magnetic resonance (ssNMR)	<1%	Greater than 24 hours
TRS100 Raman system	<1%	About 10 seconds

Solid state techniques compared.

For more information on the TRS100, including technical specifications, visit www.agilent.com/chem/trs100

### Did you know?

### TRS100 compliance and regulatory requirements

TRS100 is used to release drug products for content uniformity, assay and ID, meeting the requirements from regulatory authorities as an alternative to HPLC or UV techniques.

Designed exclusively for quality control, analysis, and testing in pharmaceutical manufacturing, working to the industry's strict regulatory requirements. Integrated sample-handling for minimal operator interaction. Automatic calibration using NIST and ASTM-approved standards. Meets relevant USP, EP, and 21 CFR Part 11 requirements.

# HPLC Solutions



### Agilent InfinityLab LC Series

### Efficient LC solutions for any application and budget

From routine analysis to cutting-edge research, the Agilent InfinityLab LC Series offers the broadest portfolio of liquid chromatography solutions, helping you to achieve highest operational efficiency while keeping within your budget.

### Agilent 1290 Infinity II LC System – The benchmark in efficiency

The Agilent 1290 Infinity II LC embodies the next generation of LC, giving you the ultra-high performance to achieve maximum efficiency.

- Unmatched separation and detection performance deliver analysis data of the highest quality with up to 1300 bar / 2 mL - for ultimate confidence in your results
- Highest sample capacity and fastest injection cycles combine with new levels of usability – for highest throughput for any application
- Seamless integration in current infrastructure and smooth method transfer from legacy equipment – for non-disruptive transition to highest productivity



1290 Infinity II LC System.

### Agilent 1260 Infinity II Prime LC System – Highest confidence and accuracy in your everyday analysis

The Agilent 1260 Infinity II Prime LC delivers the highest quaternary UHPLC performance, facilitating seamless method transfer and automated buffer blending.

- UHPLC power range up to 800 bar and 5 mL/min opens the door to the world of ultrahigh LC performance
- Performance comparable to high-pressure mixing makes this system the perfect front end for mass spectrometry
- ISET cutting-edge technology from 1290 Infinity II platform facilitates seamless method transfer
- Easy-to-use BlendAssist tool for accurate buffer and additive blending saves time and lowers costs
- 1260 Infinity II Prime LC delivers UHPLC productivity with HPLC ownership costs



1260 Infinity II Prime LC System.

### Agilent 1260 Infinity II LC System -Everyday efficiency in every way

The Agilent 1260 Infinity II LC is the trusted platform with the broadest instrument choice, taking you to the next level of efficiency.

- A broad range of reliable instrumentation matches with the latest column technologies to guarantee robust separation and detection performance with up to 600 bar / 5 mL - for highest confidence in your results
- Easy column handling and superior sample logistics from sample submission to data analysis - for highest instrument utilization and fast turnaround.
- Designed for method transferability and stepwise upgrade capability now and in the future – for risk and care-free integration in current infrastructure matching your budget



1260 Infinity II LC System.

### Agilent 1220 Infinity II LC System -Affordable efficiency

The Agilent 1220 Infinity II LC is an affordable, high-quality integrated LC system, putting you on the fast track to efficiency.

- A factory-configured and tested system that allows you to start analyzing your samples right after arrival - for daily productivity
- Robust and highly reliable LC quality with up to 600 bar / 5 mL compatible with all InfinityLab LC Series detectors – for easy-upgrade to meet future demands



1220 Infinity II LC System.

### Agilent InfinityLab Poroshell 120 columns

More than 15 years ago, Agilent introduced the industry's first superficially porous column technology with Poroshell 300 for large molecules, followed by Poroshell 120 for small molecules. Today, the Agilent InfinityLab Poroshell 120 family has grown to include 18 chemistries – including new phases for chiral and HILIC separations.

Whether you use traditional HPLC systems or newer UHPLC systems, you will experience exceptional separation efficiency, and significantly boost performance and throughput from every LC in your lab.

- A scalable family of particles: 1.9  $\mu m$ , 2.7  $\mu m$ , and 4  $\mu m$  superficially porous particles enable you to get the best from your methods and all of your instruments
- Superior peak shape: High-purity silica and advanced bonding chemistries reduce peak tailing and give you faster, more accurate results
- Fast method development: Up to 18 chemistries maximize selectivity so you can find the optimal separation for your sample
- Long column life: Robust Poroshell particles and chemistries are stable at required pressures
- Proprietary, single-step porous shell process dramatically reduces tiny differences between lots and columns



Agilent InfinityLab Poroshell 120 columns in 3 scalable particle sizes: 1.9 µm, 2.7 µm and 4 µm.



# Agilent 100 Automated Disintegration Apparatus

# Integrated disintegration testing that conforms to harmonized regulatory requirements

An integral prerequisite for dissolution, dosage forms must be tested for disintegration to ensure maximum active pharmaceutical ingredient (API) contact with media and subsequent bioavailability. The disintegration test is an important quality control process that helps ensure the proper manufacturing controls are in place. The fully programmable Agilent 100 Automated Disintegration Apparatus provides a reliable, compliant approach to disintegration testing. The reciprocating drive system, water bath, and heater/circulator are incorporated into a single instrument offering a compact design to save valuable bench space. The three-basket apparatus comes complete with accessories required to perform the standard USP disintegration test.

The easy-to-use numeric keypad includes program, temperature, and printer control options. Simply enter the time duration of the test and the baskets will be lifted from the beaker at the end of the run. The basket is held above the media until you return to inspect the results. Individual digital time displays for each basket, and tests can be run simultaneously or sequentially, maximizing laboratory efficiency. The optional printer can be added to document critical test information.

The standard 100 Automated Disintegration Apparatus comes with:

- Three (3) 6-tube basket(s), 10-mesh / 1905 m (USP)
- Fluted disks USP
- Three (3) disintegration beakers USP
- Disintegration spacer gauge 25 mm

### Did you know?

#### Instant status reporting

By outfitting the 100 Automated Disintegration Apparatus with the optional printer, you have the ability to record instrument status at a predefined interval as well as at any time during the test by pressing Print on the instrument panel.



100 Automated Disintegration Apparatus.

### **Disintegration Testing**

Description	Part No.
100 Automated Disintegration Apparatus, 3-basket	G7962A
6-tube, 10-mesh, 1905 μm, USP, verified	G7962A #110
6-tube, 20-mesh, 864 μm	G7962A #111
6-tube, 10-mesh, 1905 μm, nylon, with stainless screen	G7962A #112
3-tube, 10-mesh, 1905 µm, 38 mm, outer diameter	G7962A #113
3-tube, 10-mesh, 1905 μm, 38 mm, outer diameter, verified	G7962A #114
1-tube, 10-mesh, 1905 µm, 44 mm, outer diameter	G7962A #115
6-tube, 40-mesh, 381 μm, with screened cover	G7962A #116
Note: #110-116 Disintegration basket types – multiple selections possible, not required.	
Add printer	G7962A #880

### 100 Automated Disintegration Apparatus Baskets

Description	Part No.
Basket, 6-tube, 10-mesh, 1905 μm (USP)	37-3001
Basket, 6-tube, 10-mesh, 1905 μm (USP), verified with certificate	37-3001V
Basket, 6-tube, 20-mesh, 864 µm	37-3010
Basket, 6-tube, 10-mesh, 1905 μm, nylon, stainless steel screen	37-3020
Basket, 3-tube, 10-mesh, 1905 mm, 38 mm outer dia.	37-3030
Basket, 3-tube, 10-mesh, 1905 μm, 38 mm outer dia., verified with certificate	37-3030V
Basket, 1-tube, 10-mesh, 1905 mm, 44 mm outer dia.	37-3040
Basket, 6-tube, 40-mesh, 381 μm, with screened cover	37-3050

100 Automated Disintegration Apparatus accessories.

### Did you know?

### Verified disintegration accessories

Many standard disintegration accessories, such as basket rack assemblies, can be ordered with individual certificates that verify conformance of critical dimensions. The certificates include the measurements, measuring device information, and its traceability. Any part number that ends in V indicates a Verified component.

- A = 6-tube standard basket (p/n 37-3001)
- B =10-mesh basket, 3-tube, (p/n 37-3030)
- C =10-mesh basket, 1-tube, (p/n 37-3040)
- D =10-mesh basket, 6-tube, 40-mesh basket, (p/n 37-3050)
- E = Standard cover (p/n 37-2100) with fluted disks (p/n 37-4000)
- F = 3-tube cover (p/n 37-2105)
- G = Plunger (no p/n, example only)
- H = 6-tube cover (p/n 37-2110)

### 100 Automated Disintegration Apparatus Accessories

Description	Part No.
Suspension rod dia. for holding 1-basket rack	37-1040
Cover, for 6-tube, 10-mesh, 1905 m basket	37-2100
Cover, for 3-tube, 10-mesh, 1905 m basket	37-2105
Cover, for 6-tube, 40-mesh, 381 m basket	37-2110
Screen, 10-mesh, 1905 µm, stainless steel, for 6-tube basket, set of 6	37-2200
Screen, 20-mesh, 864 µm, stainless steel, for 6-tube basket, set of 6	37-2205
Screen, 40-mesh, 381 µm, stainless steel, for 6-tube basket, set of 6	37-2210
6 USP fluted disks, for Agilent 100 and Standard Disintegration Apparatus	37-4000
3 Plastic disks, for Agilent 100 Disintegration Apparatus	37-4010
1 Plastic disk, for Agilent 100 Disintegration Apparatus	37-4020
6-tube plunger assembly	37-4100
3-tube plunger assembly	37-4110
6-tube plunger assembly, for use in Canada	37-4120
Replacement tubes, 6-tube basket, 25 mm, set of 6	37-5000
Replacement tubes, 6-tube basket, 25 mm, set of 6, verified with certificate	37-5000V
Replacement tubes, 3-tube basket, 38 mm, set of 3	37-5005
Replacement tube, 1-tube basket, 44 mm	37-5010
Disintegration beaker, for Standard Disintegration Apparatus	37-5200
Disintegration beaker, USP for Disintegration Apparatus	37-5305
Disintegration beaker, USP for Disintegration Apparatus, verified with certificate	37-5305V
Disintegration gauge, 2.5 cm, from vessel bottom	37-9000
Printer option for Agilent 100, 115/230V	37-0200
Water bath temperature probe	67-0300



1L disintegration beaker (p/n 37-5305).

### 100 Automated Disintegration Apparatus Dimensions

Height	Width	Depth	Weight
74.93 cm / 29.5 in.	55.88 cm / 22 in.	52.07 cm / 20.5 in.	29.7 kg / 65.5 lbs, dry with 3 baskets

### 100 Automated Disintegration Apparatus Specifications

Dip Speed	Stroke Length	Temperature	Temperature	Test Duration
(DPM)	(cm)	Range (°C)	Accuracy (°C)	(hh:mm:ss)
30 ± 1	5.5 ± 0.1	Ambient + 5 to 55	± 0.2	Up to 99:59:59

# 10 Accessories and Replacement Parts for Legacy Instruments



# Accessories for Legacy Instruments

Agilent offers a complete line of dissolution and physical testing accessories to support legacy instruments that are still under service support.

Accessories for the following legacy instruments can be found in this section:

- 705-DS, 709-DS, 7000, 7010, 7025 V-Series and 7030 V-Series Dissolution Apparatus\*
- Cary 8454 UV-Vis Spectrophotometer
- Calibration and Verification Tools\*
- QAII C Station and 5010 Calibration and Verification Tools\*
- 8000 Dissolution Sampling Station
- 806 Syringe Pump
- 810 Peristaltic Pump
- Rotating Bottle Apparatus\*
- 200 Tablet Hardness Tester\*
- 250 Friability Tester\*
- 350 Tapped Density Tester\*

### Did you know?

All instruments marked with an "\*" in the list have reached their End of Guaranteed Support date(s). Agilent will continue to maintain several key accessories for these products, but cannot guarantee their availability. Contact your Agilent representative to plan a smooth transition to your next generation dissolution instrumentation!



Legacy 709-DS Dissolution Apparatus.

### **Basket Shafts/Assemblies**

Description	Part No.
14.5 in. (37 cm) Basket Shafts for 7025/7030	
Basket shaft, USP, for 7025/7030	13-3615
21 - 24 in. (53 - 61 cm) Basket Shafts and Assemblies for 705-DS	S, 7000/7010E, 705/708/709-DS
Basket shaft, USP 3-clip, 21 in.	14-3620
Basket shaft, O-ring, 21 in.	13-3621
Basket shaft, PTFE-coated, 21 in.	13-3622
Basket shaft, 3-clip, conical, 21 in.	14-3624
Basket shaft, USP 3-clip, 24 in.	13-3629
Basket shaft, for bolus basket, 24 in.	13-3630

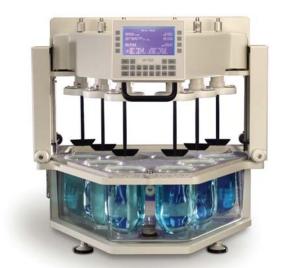
### Did you know?

### Questions about availability, compatibility, or anything else?

You can contact Agilent's dissolution experts directly at

### dissolution.hotline@agilent.com

Simply let us know what you are looking for or what type of problem you need to solve – we're always here to help.



Legacy 7025 V-Series Dissolution Apparatus.

### Paddle Shafts and Accessories

Description	Part No.
14.5 in. (37 cm) Paddle Shafts for 7025/7030	
Paddle, PTFE-coated, for 7025/7030	13-3589
Paddle, electropolished, for 7025/7030	14-3590
Paddle, PEEK, for 7025/7030	14-3591
21 - 24 in. (53 - 61 cm) Paddle Shafts for use with 7000/7010E, 705/708/709-E	os
Paddle, PTFE-coated, 21 in.	14-3594
Paddle, PTFE-coated, 24 in.	13-3596
Paddle, electropolished, 21 in.	14-3595
Paddle, electropolished, 24 in.	14-3597
Paddle, PEEK, 24 in.	13-3598
Mini paddle, PTFE-coated, 24 in.	14-3599
Mini paddle, electropolished, 24 in.	14-3600
Shaft Accessories	
Collet, for 3/8 in. dia. shafts, for 7000/7010	12-1320
Collet, for 1/4 in. dia. shafts, for 7000/7010	12-1330
Shaft locking ring, for all models	12-2096
Basket and paddle shaft locking rings, 6/pk	12-2099



Electropolished stainless steel paddle, 21 inch (p/n 14-3595).

### EaseAlign vessels

EaseAlign vessels are designed to be used on the legacy 705-DS, 7000 and 7010 dissolution apparatus, and are compatible with many other manufacturer instruments as well. The EaseAlign vessel is held in place by a centering ring and is available in various types and sizes.

### EaseAlign Vessels for 705-DS and 7000/7010 Dissolution Apparatus

Description	Part No.
EaseAlign vessel, 1L	12-5000
EaseAlign vessel, 1L, with certificate	12-5000V
EaseAlign vessel, low actinic - red, 1L	12-5010
EaseAlign vessel, low actinic - red, 1L, with certificate	12-5010V
EaseAlign vessel, 100 mL	12-5040
EaseAlign vessel, low actinic - red, 100 mL	12-5041
EaseAlign vessel, 200 mL	12-5050
EaseAlign vessel, low actinic - red, 200 mL	12-5051
EaseAlign vessel, flat bottom for Enhancer Cell, 200 mL	12-5055
EaseAlign vessel, 2L	12-5070
EaseAlign vessel, 2L, with certificate	12-5070V
EaseAlign vessel, low actinic - red, 2L	12-5075
EaseAlign vessel, 4L	12-5080
EaseAlign vessel, clear plastic, 1L	12-5200
EaseAlign vessel, clear plastic, 1L, with certificate	12-5200V
EaseAlign Peak vessel, 1L	12-5500
EaseAlign Peak vessel, 1L, with certificate	12-5500V
EaseAlign Peak vessel, low actinic - red, 1L	12-5505



200 mL glass vessel (p/n 12-5050) used in conversion kits.

### TruCenter vessels

Used with the 7025 and 7030 Dissolution Apparatus, TruCenter vessels offer superior centering and vessel verticality and are turned on a lathe during manufacture to find the exact center. The vessels incorporate a groove and synthetic flange with magnetic collar to align on the vessel plate. The magnetic closure on the vessel plate makes inserting or removing a vessel simple.

In addition to not floating when empty, an added benefit of the TruCenter vessel is the plastic collar that decreases the chance of breakage compared to traditional glass collared vessels.

Conversion kits are available to upgrade your 705-DS and 7000/7010 models to TruCenter vessels (see following table).



1L TruCenter vessel (p/n 12-5035).

### TruCenter Vessels for 7025, 7030 and 709-DS Dissolution Apparatus

Description	Part No.
TruCenter Vessels for 7025 Dissolution Apparatus	
TruCenter vessel, without adapter, 200 mL	12-5033
TruCenter vessel, with adapter, 200 mL	12-5034
TruCenter vessel, with collar, 1L	12-5035
TruCenter vessel, with collar, 1L, with certificate	12-5035V
TruCenter vessel, low actinic - red, with collar, 1L	12-5120
TruCenter Peak vessel, with collar, 1L	12-5125
TruCenter Peak vessel, low actinic - red, with collar, 1L	12-5130

### **TruCenter conversion**

TruCenter vessels, standard on the 7025 Dissolution Apparatus, offer superior centering and vessel verticality compared to EaseAlign vessels. Conversion kits are available to  $upgrade\ your\ 705\text{-}DS\ and\ 7000/7010\ models\ to\ TruCenter\ vessels.\ The\ TruCenter\ kit$ includes:

- 1L TruCenter vessel
- Adapter ring
- Evaporation cover

### Vessel Conversion Kits and Accessories for 705-DS and 7000/7010 **Dissolution Apparatus**

Description	Part No.
1L Conversion Kits	
Conversion kit, TruCenter, with ground groove, 1L	12-6100
Conversion kit, TruCenter, with ground groove, 1L, with certificate	12-6100V
200 mL Conversion Kits	
Conversion kit, EaseAlign, with 24 in. paddle, flat bottom vessel, 200 mL (for use with Enhancer Cells)	12-0301
Conversion kit, EaseAlign, 24 in. paddle, 200 mL vessel	12-0318
1L Conversion Kits	
Height spacer paddle, 100/200 mL, 15 mm, for 7000/7010	12-0320
Height spacer, 100/200 mL, 3.25 in., for 7000/7010	12-0321
Evaporation cover, EaseAlign, for use with 100/200 mL vessel	12-6315



The 200 mL EaseAlign conversion kit (p/n 12-0318) contains a vessel adapter, mini-paddle, and 200 mL vessel for small volume dissolution testing.

### Conversion Kits and Accessories for 7025 Dissolution Apparatus

Description	Part No.
100 mL Conversion Kit	
TruCenter conversion kit, with paddle, 100 mL	12-0308
TruCenter conversion kit, with paddle and temperature monitoring, 100 mL	12-0315
200 mL Conversion Kit	
TruCenter conversion kit, with paddle and temperature monitoring, 200 mL	12-0314
Conversion Kits Accessories	
TruCenter vessel, with adapter, 200 mL	12-5034
TruCenter vessel, without adapter, 200 mL	12-5033

### Manual Sampling Accessories for 7000/7010

Description	Part No.
Bent cannula with adjustable gauge, 4.75 in. (900 mL)	12-3215
Bent cannula with adjustable gauge, 7.75 in. (900 mL)	12-3216
Adjustable gauge kit (cannulas not included)	12-3217
Manual sampling bracket, for use with manifold, 7000/7010	17-3150

### Sampling Cannulas and Accessories

Description	Part No.
Sampling cannula, 4.5 in., 900 mL (for 7000/7010 manifold)	17-3300
Sampling cannula, 6.5 in., 500 mL (for 7000/7010 manifold)	17-3305
Cannula extension kit, 500 mL (for use with one 4.5 in. cannula)	17-3306
Sampling cannula, 8.12 in., for 2L vessel (for 7000/7010 manifold)	17-3307
Sampling cannula, 10 in., for 4L vessel (for 7000/7010 manifold)	17-3309
Manual sampling cannula assembly, 500 mL	17-3311
Manual sampling cannula assembly, 900 mL	17-3312
Sampling cannula (for 7025/7030)	17-3313
Return cannula (for 7025/7030)	17-3314
Manual sampling cannula (for 7025/7030)	17-3317
Return cannula, 2 1/4 in. (for 7000/7010 manifold)	17-3320
Sampling cannula, 4.5 in., 900 mL (for 7000/7010 manifold)	17-3300
Printer paper, 10 rolls/pk	12-9995
Printer paper, 100 rolls/pk	12-9996
Ribbon cartridge, 5/pk	12-9997

### Replacement Sampling Accessories for Legacy Dissolution Apparatus

Description	Part No.
Internal Motor Drive and Sample Manifolds for 7000/7010	
Internal motor drive, for 3x3 configuration	12-0200
Internal motor drive, for 4x2, 4x3, 4x4 configurations	12-0205
Sample manifold, for use with 3x3 configuration, 1L	17-3100
Sample manifold, for use with 4x2 configuration, 1L	17-3102
Sample manifold, for use with 4x4 configuration, 1L	17-3107
Sample manifold, for use with 4x4 configuration, 200 mL	17-3116
Replacement Sample Manifold Tubing for 7000/7010	
Sample manifold tubing/cannulas, sampling, 1L, 3x3 configuration	1005-1687
Sample manifold tubing/cannulas, return, 1L, 3x3 configuration	1005-1688
Sample manifold tubing/cannulas, sampling, 2L, 3x3 configuration	1005-1782
Sample manifold tubing/cannulas, return, 2L, 3x3 configuration	1005-1783
Sample manifold tubing/cannulas, sampling, 1L, 4x2 configuration	1005-1692
Sample manifold tubing/cannulas, return, 1L, 4x2 configuration	1005-1693
Sample manifold tubing/cannulas, sampling, 2L, 4x2 configuration	1005-1778
Sample manifold tubing/cannulas, return, 2L, 4x2 configuration	1005-1779
Sample manifold tubing/cannulas, sampling, 1L, 4x4 configuration	1005-1670
Sample manifold tubing/cannulas, return, 1L, 4x4 configuration	1005-1671
Sample manifold tubing/cannulas, sampling, 2L, 4x4 configuration	1005-1780
Sample manifold tubing/cannulas, return, 2L, 4x4 configuration	1005-1784
Sample manifold tubing/cannulas, return, online UV, 4x4 configuration	1005-1785

(Continued)

### Replacement Sampling Accessories for Legacy Dissolution Apparatus

Description	Part No.
Replacement Sample Cannula Tubing for 7020/7025/7030	
Sample tubing/cannulas, sampling/return, 6-position, V-Series	1005-1787
Sample tubing/cannulas, sampling/return, 8-position, V-Series	1005-1786
Replacement Sample Tubing for 8000 Sampling Station and Pumps	
Sample tubing, syringe pump to filter changer, 6-position	1005-1722
Sample tubing, syringe pump to filter changer, 8-position	1005-1729
Sample tubing, syringe pump or filter changer to 8000, 6-position	1005-1696
Sample tubing, syringe pump or filter changer to 8000, 8-position	1005-1674
Sample tubing, from 8000 valves, 6-position	1005-1694
Sample tubing, from 8000 valves, 8-position	1005-1672
Sample tubing, to 8000 valves, 6-position	1005-1695
Sample tubing, to 8000 valves, 8-position	1005-1673
Tubing connector, barbed fitting for peristaltic pump (female)	3090-0159
Tubing connector, union fitting (male)	3090-0160

### **Centering Rings and Accessories**

Description	Part No.
Centering ring, EaseAlign, for 705-DS and 7000/7010	12-6050
Centering ring, EaseAlign, retrofit, 6-position, includes pins and evaporation covers	12-6060
Centering ring, EaseAlign, retrofit, 8-position, includes pins and evaporation covers	12-6062
Locating pins, EaseAlign, 12/pk	12-6065
Conversion kit, EaseAlign, for Hanson vessels, 6/pk	12-6070
Alignment plate, TruCenter	12-6115

### **Evaporation Covers and Accessories**

Description	Part No.
Evaporation cover, low-loss split hinge design	12-6327
Evaporation cover, low-loss hinged, for EaseAlign centering rings	12-6328
Evaporation cover, low-loss hinged, for use with resident probes	12-6329
Evaporation cover, low actinic - red, with DDM opening, EaseAlign	12-6311
Evaporation cover, for use with 4L vessels	12-6326
Evaporation cover, EaseAlign	12-6300
Evaporation cover, EaseAlign, for DDM	12-6310
Evaporation cover, EaseAlign, for use with 100/200 mL vessel	12-6315
Evaporation cover, EaseAlign, low actinic - red	12-6320
Evaporation cover, for use with EaseAlign, solid cover for non-vessel positions	12-6330
Evaporation cover, manual sampling, opening for Japanese sinkers, for 7025/7030	12-6352
Evaporation cover, dual sampling, for 7025/7030	12-6353
Evaporation cover, for three openings for basket and two sampling ports	12-0463
Evaporation plugs, 36/pk	12-6350
Evaporation hole plug, for 7025/7030	12-6358



EaseAlign Centering Ring (p/n 12-6050) and Evaporation Cover (p/n 12-6300).

### **Rotating Cylinder and Accessories**

Description	Part No.
Rotating Cylinder, 4.45 cm outside dia.	12-1360

### **Intrinsic Dissolution Apparatus**

Description	Part No.
Intrinsic Dissolution Apparatus, $0.5~\rm cm^2$ exposed surface area, with punch, shaft and holder, for 7000/7010	12-4100

Note: Surface plate sold separately. Only one plate required for testing.

### **Water Baths**

Description	Part No.
Water Baths and Replacement Parts	
Water bath, molded, for use with 4x4 configuration	60-1500
Water bath, for 7025 and 7030	60-2110
Water bath, for Rotating Bottle, 24x12x12 in.	60-2200

### Heater/Circulators

Description	Part No.
Heater/circulator, 115/230V	G7986B
Note: The heater/circulator can be used with 708-DS, as well as legacy dissolution apparatus, and the BIO-DIS and Apparatus 7.	
Options for G7986B	
Cable for use with 7000/7010/BIO-DIS/Apparatus 7	G7986B #100

# Cary 8454 UV-Vis Spectrophotometer

The Cary 8454 UV-visible spectrophotometer is no longer sold for use with online dissolution systems. Accessories are still available.

### Cary 8454 Sampling Systems

Description	Part No.
Multicell Transport Sampling System	G1127A
Valve Sampling System	G1128A
Multi-apparatus sampling system for two dissolution apparatus	G1129A
Additional sampling system for one dissolution apparatus	G1130A
Automated Sipper System for the Cary 8454/8453	89068D
Flow cell, for use with 8453/8454, 1 mm	5061-3396
Flow cell, for use with 8453/8454, 2 mm	5061-3397
Flow cell, for use with 8453/8454, 5 mm	5065-9918
Flow cell, for use with 8453/8454, 10 mm	5061-3398



Cary 8454 UV-visible spectrophotometer.



# Calibration and Verification Tools

## **QAII C Mechanical Qualification Station Replacement Parts**

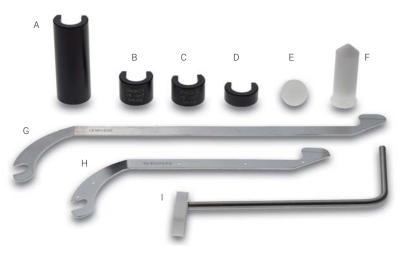
Description	Part No.
Adapter, universal for QAII and QAII C	12-9005
Calibration shaft, with certification	12-9010
Reflective RPM sensor clip, black	12-9015
Reflective RPM sensor clip, white	12-9020
Magnetic RPM sensor clip, for 1/4 dia. shaft	12-9021
Magnetic RPM sensor clip, for 3/8 dia. shaft	12-9025
Printer paper, 10 rolls/pk	12-9995
Printer paper, 100 rolls/pk	12-9996
Ribbon cartridge, 5/pk	12-9997



QAII C Mechanical Qualification Station.

### **Verification Tools**

Description	Part No.
Height and Centering Tools for USP Apparatus 1 and 2	
Vessel centering tool, pass/fail gauge, EaseAlign centering rings	12-7310
Vessel centering tool, pass/fail gauge, EaseAlign centering rings, with certificate	12-7310V
Height Spacers for USP Apparatus 1 and 2	
Height spacer, 100/200 mL, 3.25 in., for 7000/7010	12-0321
Height spacer, baskets, for 7000/7010	12-7210
Height spacer, paddles, for 7000/7010	12-7200
Height spacer paddle, 100/200 mL, 15 mm, for 7000/7010	12-0320
Height spacer paddle, 100/200 mL, 15 mm, for 7000/7010	12-0320
Height spacer, for Peak vessels	12-7220



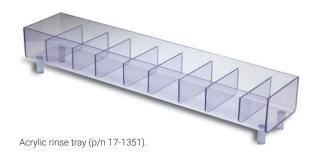
- A = Height spacer (p/n 12-0321) 3.25 inch for use with 100/200 mL vessels
- B = Height spacer for baskets (p/n 12-7210)
- C = Height spacer for paddles (p/n 12-7200)
- D = Height spacer for PEAK vessels (p/n 12-7220)
- E = Spacer ball for paddles (p/n 12-7240)
- F = Height gauge for attachment to basket shaft (p/n 12-7280)
- G = Height tool for 2L vessels (p/n 12-7301)
- H = Height tool for 1L vessels (p/n 12-7301)
- I = Height tool for PEAK vessels (p/n 12-7230)

Description	Part No.
Accessories for 8000 Dissolution Sampling Station	
Media replacement option, internal (specify printer type)	17-0110
Media/rinse chamber	17-1200
Printer, retrofit kit	17-1400
Stacking rack, for 8000	17-1500
Autocalibration fixture	17-5100
Adapters, to connect PTFE to 810 Peristaltic Pump tubing, 24/pk	17-6050
Nut and ferrule, 1/4-28, for 1/16 in. inner dia. tubing	17-6070
Printer paper, 10 rolls/pk	12-9995
Printer paper, 100 rolls/pk	12-9996
Ribbon cartridge, 5/pk	12-9997
Trays for 8000 Dissolution Sampling Station	
Sampling tray, open tube, 16x100 mm	17-1000
Sampling tray, HPLC, 12x32 mm	17-1050
Acrylic rinse tray, 6 vessels, 3x3, for 7000/7010	17-1300
Acrylic rinse tray, 7-8 vessels, for 7000/7010	17-1310
Sample tubing rinse kit	17-1341
Acrylic rinse tray, for 708-DS	17-1351



Sampling trays with HPLC septum-capped vials, top (p/n 17-1000) and glass tubes, bottom (p/n 17-1050).

(Continued)



Description	Part No.
Tubes, Vials and Needles for 8000 Dissolution Sampling Station	
Glass tubes, 16x100 mm, 250/pk	17-5001
EaseAlign vessel, low actinic – red, 1L	12-5010
Glass vials, 12x32 mm, w/ cap (PTFE/silicone), 100/pk	17-5020
Glass vial, clear, with PTFE/silicone cap, 15x45, 100/pk	17-5030
Calibration tubes, 10 mL, 8/pk	17-5040
Replacement needle kit, 8/pk (4 long, 4 short)	K1002-00477
Replacement valve kit, long needle	17-6200
Replacement valve kit, short needle	17-6210
Replacement Tubing for 810 Peristaltic Pump	
Purple/white Marprene replacement tubing, 8/pk	17-6000
Purple/white Viton replacement tubing, 8/pk	17-6005
White silicone replacement tubing, 8/pk	17-6010



HPLC septum-capped vials, left (p/n 17-5020) and glass tubes, right (p/n 17-5001).

Description	Part No.
Color-coded Clear Tubing for 8000 Dissolution Sampling Station	
Sample manifold tubing/cannulas, sampling, 1L, 4x4 configuration	1005-1670
Sample manifold tubing/cannulas, return, 1L, 4x4 configuration	1005-1671
Sample tubing, from 8000 valves, 8-position	1005-1672
Sample tubing, to 8000 valves, 8-position	1005-1673
Sample tubing, syringe pump or filter changer to 8000, 8-position	1005-1674
Sample manifold tubing/cannulas, sampling, 1L, 3x3 configuration	1005-1687
Sample manifold tubing/cannulas, return, 1L, 3x3 configuration	1005-1688
Sample manifold tubing/cannulas, sampling, 1L, 4x2 configuration	1005-1692
Sample manifold tubing/cannulas, return, 1L, 4x2 configuration	1005-1693
Sample tubing, from 8000 valves, 6-position	1005-1694
Sample tubing, to 8000 valves, 6-position	1005-1695
Sample tubing, syringe pump or filter changer to 8000, 6-position	1005-1696
Sample tubing, syringe pump to filter changer, 6-position	1005-1722
Sample tubing, syringe pump to filter changer, 8-position	1005-1729
Sample manifold tubing/cannulas, sampling, 2L, 4x2 configuration	1005-1778
Sample manifold tubing/cannulas, return, 2L, 4x2 configuration	1005-1779
Sample manifold tubing/cannulas, sampling, 2L, 4x4 configuration	1005-1780
Sample manifold tubing/cannulas, return, 2L, 4x4 configuration	1005-1784
Sample manifold tubing/cannulas, return, online UV, 4x4 configuration	1005-1785
Sample tubing/cannulas, sampling/return, 8-position, V-Series	1005-1786
Sample tubing/cannulas, sampling/return, 6-position, V-Series	1005-1787
Tubing assembly, male lure for 810 Peristaltic Pump, 12x12, for BIO-DIS	1005-1791
Tubing assembly, barbed fitting, 12x12, for BIO-DIS	1005-1793

(Continued)

Description	Part No.
Replacement Tubing for 8000 Dissolution Sampling Station	
Tubing assembly, 8 flared, male to female, 72 in.	1005-1891
Tubing assembly, 6 flared, male to female, 72 in.	1005-1892
Tubing assembly, 8 double flared, male to male, 72 in.	1005-1893
Tubing assembly, 6 double flared, male to male, 72 in.	1005-1894
Tubing assembly, for 1L 708-DS, sample and return cannulas, 6-position	1005-1920
Tubing assembly, for 1L 708-DS, sample and return cannulas, 8-position	1005-1921
Tubing assembly, for 2L 708-DS, sample and return cannulas, 6-position	1005-1922
Tubing assembly, for 2L 708-DS, sample and return cannulas, 8-position	1005-1923
Tubing assembly, female/lure to sample cannula, 8-valve, for BIO-DIS	1005-1952
Tubing assembly, male/lure to male ¼-28, 8-valve, for BIO-DIS	1005-1953
Tubing assembly, female 1/4-28 to return cannula, 8-valve, for BIO-DIS	1005-1954

## 806 Syringe Pump Accessories

Description	Part No.
Replacement syringe, for 806 Syringe Pump	K1002-00437

## 810 Peristaltic Pump Accessories

Description	Part No.
Peristaltic Replacement Tubing	
Purple/white Marprene replacement tubing, 8/pk	17-6000
Purple/white Viton replacement tubing, 8/pk	17-6005
White silicone replacement tubing, 8/pk	17-6010

# Agilent Rotating Bottle Apparatus

## **Rotating Bottle Accessories**

Description	Part No.
Bottle Caps	
Cap, with Viton liner, for 100 mL	32-1101
Cap, with Viton liner, for 200 mL	32-1105
Decanting cap, with 40-mesh screen, for 200 mL	32-1125
Screens and Liners	
Viton liner, for 200 mL	32-1205
Replacement screen, for decanting cap, 40-mesh, for 200 mL	32-1225
Clips	
Bottle clips, for 16x100 mm tubes	32-1301
Bottle clips, for 28x98 mm (40 mL) tubes	32-1302
Bottle clips, for 200 mL	32-1305
Bottles	
Bottle, with cap, 100 mL	32-5001
Bottle, with cap, low actinic - red, 200 mL	32-5030
Bottle only, low actinic - red, 100 mL	32-5521
Bottle only, 100 mL	32-5530



Rotating Bottle Apparatus.

# Agilent 200 Hardness Tester

### 200 Tablet Hardness Tester and Accessories

Description	Part No.
Hardness/fragment safety shield	42-2010
Hardness/fragment brush	42-2030
Tablet thickness gauge, handheld, dial gauge, 0-10 mm	42-6105
Tablet thickness gauge, handheld, digital gauge, 0-10 mm	42-6110
RS232 serial port, retrofit	42-0250
Thickness gauge option	42-0300
Battery for Mitutoyo gauge	42-0355
Printer, 115V/230V	42-0120
Jaw plate, 1/16 radius	42-1015
Jaw plate, 1/4 radius	42-1020
Jaw plate, 1/8 radius	42-1025
Jaw plate, bolus type	42-1030
Jaw plate, 3/16 radius	42-1035
Jaw plate, flat face	42-1040
Jaw plate, adjustable	42-1050
Printer paper, 10 rolls/pk	12-9995
Printer paper, 100 rolls/pk	12-9996
Ribbon cartridge, dot matrix, black	12-9993
Ribbon cartridge, dot matrix, purple	12-9998



Agilent 200 Tablet Hardness Tester.

### 200 Tablet Hardness Tester Calibration Tools

Description	Part No.
Calibration fixture	42-2000
Trim pot tool	42-2005
Hardness/calibration weight hanger	42-2020
Calibration weight, 200 gm, with certificate	42-1200
Calibration weight, 500 gm, with certificate	42-1205
Calibration weight, 1kg, with certificate	42-1210
Calibration weight, 2 kg, with certificate	42-1215
Calibration weight, 5 kg, with certificate	42-1220
Calibration weight, 10 kg, with certificate	42-1225
Calibration weight, 20 kg, with certificate	42-1230

### 200 Tablet Hardness Tester Jaw Plates

Description	Part No.
Jaw plate, standard	42-1000
Jaw plate, shelf type	42-1005
Jaw plate, 1/8 x 60 degree	42-1010
Jaw plate, 1/16 radius	42-1015
Jaw plate, 1/4 radius	42-1020
Jaw plate, 1/8 radius	42-1025
Jaw plate, bolus type	42-1030
Jaw plate, 3/16 radius	42-1035
Jaw plate, flat face	42-1040
Jaw plate, adjustable	42-1050



Jaw plates:

A = Standard (p/n 42-1000)

 $B = 1/8 \times 60 \text{ degree (p/n 42-1010)}$ 

C = 1/8 radius (p/n 42-1025)

D = Flat face (p/n 42-1040)

E = Shelf (p/n 42-1005)

F = 1/16 radius (p/n 42-1015)

G = Bolus (p/n 42-1030)

H = Adjustable (p/n 42-1050)

# Agilent 250 Friability Tester

## 250 Friability Tester Accessories

Description	Part No.
Dual-chamber drum, clockwise rotation	47-1000
Dual-chamber drum, clockwise rotation, with certificate	47-1000V
Dual-chamber drum, counterclockwise rotation	47-1005
Dual-chamber drum, counterclockwise rotation, with certificate	47-1005V
Single-chamber drum, clockwise rotation	47-1010
Single-chamber drum, clockwise rotation, with certificate	47-1010V
Single-chamber drum, counterclockwise rotation	47-1015
Single-chamber drum, counterclockwise rotation, with certificate	47-1015V
Abrasion drum	47-1020
10-degree lift (wedge)	47-1030
Printer, 115V/230V, retrofit	47-0153



250 Friability Tester with two dual-chamber drums.

# Agilent 350 Tapped Density Tester

## 350 Tapped Density Tester Accessories

Description	Part No.
Tapped Density Platforms	
Platform, 10 mL, 14 mm drop, USP	52-1000
Platform, 25 and 50 mL, 14 mm drop, USP	52-1010
Platform, 100 mL, 14 mm drop, USP	52-1020
Platform, 250 mL, 14 mm drop, USP	52-1030
Platform, 500 mL, 14 mm drop, USP	52-1040
Platform, 10 mL, 3 mm drop, USP or ASTM	52-1050
Platform, 25 and 50 mL, 3 mm drop, USP or ASTM	52-1060
Platform, 100 mL, 3 mm drop, USP or ASTM	52-1070
Platform, 250 mL, 3 mm drop, USP or ASTM	52-1080
Graduated Cylinders	
Graduated cylinder, funnel top, hexagonal base, 10 mL	52-5000
Graduated cylinder, funnel top, hexagonal base, 100 mL	52-5010
Graduated cylinder, funnel top, hexagonal base, 250 mL	52-5020
Graduated cylinder, standard top, hexagonal base, 25 mL	52-5040
Graduated cylinder, standard top, hexagonal base, 50 mL	52-5050
Graduated cylinder, standard top, hexagonal base, 500 mL	52-5060
Acoustic Cabinet	
Acoustic cabinet	52-2010
Printer	
Printer, retrofit, 115V/230V	52-0153



350 Tapped Density Tester, dual-platform in the specially designed acoustic cabinet.

# 11 Service and Qualification



# Service and Qualification

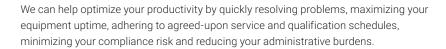
# Agilent services and support – your laboratory partner

Agilent offers you a variety of comprehensive qualification and service options for your dissolution apparatus and analytical instruments. Focus on what you do best and let Agilent provide you with installation and familiarization, hardware and software training, and complete qualification services.

Our service organization has the experience, education and training to ensure your dissolution equipment is properly installed and qualified, not only at the time of purchase, but throughout the life of the instrument. Our engineers and chemists are cGMP-trained and receive extensive ongoing training to ensure they have the requisite knowledge.

We can work with you to develop a service offering that meets your specific needs for:

- Instrument maintenance and repair
- Regulatory compliance
- Software and data systems
- Training and educational services







### Preventive maintenance and repair service

Keeping your dissolution apparatus in top condition is critical to meeting current USP Performance Verification Test (PVT) requirements, as well as the recent enhanced Mechanical Qualification (MQ) specifications put forth by the FDA and ASTM. It is even more important that your apparatus are routinely serviced.

We offer a number of repair contract options that cover maintenance, repair and qualification services. For Agilent's Service Center Repair information, visit www.agilent.com/lifesciences/dissolutionrepair



### Qualification documentation

Maintaining the proper instrument and qualification documentation is essential. To ensure you meet the cGMP requirements, Agilent provides qualification services and documentation for all our dissolution instrumentation. Our qualification protocols include installation qualification (IQ), operational qualification (OQ), and in the case of Apparatus 1 and 2, a performance qualification (PQ) based on the USP Performance Verification Test (PVT). A mechanical qualification (MQ) procedure is also available. Our PQ procedure contains current USP practices for qualification with current acceptance criteria. Similarly, the MQ protocol accurately reflects the current specifications and tolerances for physical parameters contained in, for example, the ASTM process. Our dedicated compliance group strives to ensure this documentation remains current according to the ever-changing industry regulations.



### Compliance services

Our laboratory services group provides a cost-effective alternative to performing these qualification services. You can be assured the job will be performed correctly. In fact, Agilent is ranked #1 in compliance by lab professionals worldwide.

Our service group is trained to perform the PQ for Apparatus 1 and 2. We offer these services for our own equipment, as well as for all other brands of dissolution apparatus. We will work with you or your metrology department to establish a schedule to ensure your equipment remains qualified. When performing a PQ, our services include a verification of the critical physical parameters and the chemical qualification using your USP prednisone tablets with either the single- or two-stage procedure for paddles and/or baskets.

For customers who choose to perform the MQ procedure, we provide this service as well. Our engineers are equipped with our electronic qualification tools to measure all the relevant physical parameters. Our protocols include the specifications as outlined in the USP, as well as the FDA and ASTM recommendations.

### Training and educational services

Agilent offers training on the proper operation of all its equipment. This service can be ordered at the time of instrument purchase. We also offer a variety of other educational programs that can be delivered in a wide range of methods to best suit your needs.

Contact your Agilent representative for more information or to set up a time to discuss your specific requirements.

## Enterprise Edition (EE) Compliance Services (IQ/OQ/PQ/MQ)

Description	Part No.
708-DS Dissolution Apparatus	
EE IQ Service for 708-DS	SYS-DI-708 R26N091
EE OQ Service for 708-DS	SYS-DI-708 R26J091
EE PQ Service for 708-DS	SYS-DI-708 R26P091
EE MQ Service for 708-DS	SYS-DI-708 R26M091
EE IQ/OQ Service for 708-DS	SYS-DI-708 R26H091
EE IQ/OQ/MQ Service for 708-DS	SYS-DI-708 R26T091
EE IQ/OQ/PQ Service for 708-DS	SYS-DI-708 R26U091
BIO-DIS Reciprocating Cylinder Apparatus	
EE IQ Service for BIO-DIS Apparatus 3 Reciprocating Cylinder	SYS-DI-BIO R26N091
EE OQ Service for BIO-DIS Apparatus 3 Reciprocating Cylinder	SYS-DI-BIO R26J091
Reciprocating Holder Apparatus 7	
EE IQ Service for Apparatus 7 Reciprocating Holder	SYS-DI-APP7 R26N091
EE OQ Service for Apparatus 7 Reciprocating Holder	SYS-DI-APP7 R26J091
400-DS Apparatus 7	
IQ Service for 400-DS (Small Volume Apparatus 7)	SYS-DI-400 R26N091
OQ Service for 400-DS (Small Volume Apparatus 7)	SYS-DI-400 R26J091
IQ/OQ Service for 400-DS (Small Volume Apparatus 7)	SYS-DI-400 R26H091
100 Automated Disintegration Apparatus	
IQ Service for 100 Automated Disintegration	SYS-ZZ-OTHER2
OQ Service for 100 Automated Disintegration	SYS-ZZ-OTHER2
850-DS Dissolution Sampling Station	
850-DS Dissolution Sampling Station IQ* (for use with 708-DS, BIO-DIS, Apparatus 7)	Add "-E" to SYS-DI-XXX
850-DS Dissolution Sampling Station OQ* (for use with 708-DS, BIO-DIS, Apparatus 7)	Add "-E" to SYS-DI-XXX

(Continued)

# Did you know?

A wide variety of preventive maintenance and service agreements are available for all of Agilent's dissolution and physical testing instruments. Contact your local Agilent representative to find the solution that best fits your laboratory's needs.

## Enterprise Edition (EE) Compliance Services (IQ/OQ/PQ/MQ)

Description	Part No.
UV Dissolution Hardware and Software	
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ	SYS-UV-60 R26N091
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ/OQ	SYS-UV-60 R26J091
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ/OQ	SYS-UV-60 R26H091
UV Dissolution Software, Cary 60 or 8454, IQ	SYS-SW-CS-E R26N091
UV Dissolution Software, Cary 60 or 8454, OQ	SYS-SW-CS-E R26J091
Workstation Software	
IQ Service for Dissolution Workstation Software	SYS-SW-CS R26N091
OQ Service for Dissolution Workstation Software	SYS-SW-CS R26J091
280-DS Mechanical Qualification System	
IQ/OQ Service for 280-DS Mechanical Qualification System	SYS-ZZ-OTHER2

# 12 Educational and Industry Support



# Dissolution Seminar Series

# Broaden your dissolution horizon

Are you new to dissolution? Or could you do with a refresher on the latest regulatory developments? The Agilent dissolution team offers a unique series of seminars tailored to your needs. We provide the latest in theory, techniques, and hands-on training for those involved with dissolution testing.

Our instructors include Agilent employees with close links to industry, as well as prominent scientists from academia and the dissolution industry.

The courses are not disguised sales presentations. All course materials are vendor-neutral and designed to provide a solid base of knowledge. Also, course materials are relevant to a GMP environment. Our chemists understand the latest regulations and what it takes to comply.

These courses are offered at various locations around the world and can also be scheduled at your facility.

For more information on dates or to request a seminar, please contact the Dissolution Hotline: dissolution.hotline@agilent.com



# Dissolution seminar topics

Description	Duration
General	
Fundamentals of Dissolution	4 hours
Dissolution Aberrant Data Investigation	60 minutes
Overview of In Vitro Dissolution	20 minutes
The Dissolution Procedure	60 minutes
The Benefits of Dissolution Automation in Your Laboratory	45 minutes
Trends in Small Volume Dissolution Testing	60 minutes
Agilent Dissolution Product Portfolio	20 minutes
Applications of USP Apparatus 3: Reciprocating Cylinder	25 minutes
Concepts of Qualifying Non-Compendial Apparatus	40 minutes
Dissolution SOPs: Do What You Say and Say What You Do	45 minutes
Breaking Bad Dissolution Habits	60 minutes
Dissolution and the Analytical Method Transfer	45 minutes
USP Apparatus 7: Reciprocating Holder Apparatus	20 minutes
Compendial	
USP <1058> Analytical Instrument Qualification (Revision) and Its Impact on Dissolution Apparatus Qualification	30 minutes
USP <1724> Semisolid Drug Products Performance Tests	25 minutes
USP <1092> The Dissolution Procedure: Development and Validation	25 minutes
USP <1087> Apparent Intrinsic Dissolution	20 minutes
USP <1711> Dissolution Procedures for Oral Solid Dosage Forms	30 minutes
USP <1236> Solubility Measurements	15 minutes
USP <711> Dissolution and <1094> Capsules: Dissolution Testing, Crosslinking, and Related Quality Attributes	25 minutes
USP <724> Drug Release Testing and Analysis of Transdermal Systems	30 minutes
Regulatory	
PFDA Guidance: Dissolution Testing and Acceptance Criteria for IR Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances	20 minutes
FDA Guidance: Dissolution Testing of Chewable Tablets	25 minutes
PIC-S Pharmaceutical Inspection Cooperation Scheme	15 minutes
Enhanced Mechanical Qualification of the Dissolution Apparatus	60 minutes

# Did you know?

The courses are offered at various locations around the world and can also be scheduled at your facility.

Contact the Dissolution Hotline: dissolution.hotline@agilent.com

# Dissolution 1-on-1

# Standardize your laboratory training with Agilent's self-paced course

To make it easier for analysts to get up-to-date dissolution training, Agilent recently launched a newly updated version of Dissolution 1-on-1, its industry-leading, self-paced training course on the Dissolution Exchange. This comprehensive online course is free and can serve as a training resource for new analysts or as a refresher for experienced dissolution chemists, technicians, reviewers, and metrologists.

Agilent has partnered with CoAcS, Ltd. to produce a comprehensive assessment package that you can purchase to test analysts on the course material. This testing package allows you to identify managers by site or department that can in turn identify those that need training and assessment. The training package offers up to three opportunities for successful completion, at which time the user and associated manager receive confirmation of satisfactory completion. Training packages are managed and tracked online for your convenience.

### Did you know?

#### Dissolution 1-on-1

Available in English, Chinese, and Spanish. http://dissolution.chem.agilent.com/learn/dissolution-1-on-1/

#### Dissolution 1-on-1

Dissolution 1-on-1 includes the latest industry changes regarding dissolution apparatus qualification, plus an introduction to dissolution testing.

The course covers:

- The Dissolution Apparatus Anatomy
- Critical Physical Parameters
- Performing the Dissolution Test
- Dissolution Apparatus Qualification
- Dissolution and Automation



Dissolution 1-on1 Self-paced Training Course.

# Video Training

## Labcast:

# Live from the Agilent global broadcast studio

### What is Labcast?

In simple terms, Labcast is a way for Agilent to communicate through video directly to your PC, tablet or phone. Video broadcasting from our studios in Cary, NC allows instantaneous conferencing, training and services to all points around the globe. Agilent trainers can televisit you and your employees to explore the latest methods and techniques for effective dissolution testing. Keep your lab personnel updated on new practices with ongoing education programs and even link with other locations for standardized training sessions. All this without leaving home. Contact our team at dissolution.hotline@agilent.com to learn more!



# Dissolution apparatus qualification: PVT versus MQ - what is right for your laboratory

#### 60-minute module

Agilent's Laboratory Services has prepared a one-hour seminar on the qualification of USP Apparatus 1 and 2. Significant changes have occurred in dissolution apparatus qualification during the last several years. The USP Performance Verification Test (PVT) migrated from a range test to a much more definitive test which focuses greatly on accuracy and variability of the dissolution apparatus through new acceptance criteria highlighting the geometric mean and %CV. Likewise, the alternative approach towards apparatus qualification, enhanced Mechanical Qualification (MQ) will also be highlighted and discussed in detail.

The module addresses the following topics:

- Overview of the Dissolution Performance Verification Test
- Background of Performance Qualification (PQ) and Analytical Instrument Qualification (AIQ)
- Dissolution Mechanical Qualification (MQ) standards, requirements, specifications and tolerances
- PVT and MQ: finding the right test for your laboratory
- Evaluation of why laboratories are using the MQ test

# Dissolution aberrant data investigation

#### 60-minute module

Lack of proper failure investigation and documentation generally leads the list of problems in FDA observations of analytical laboratories. Many standard operating procedures for handling out-of-specification data do not properly deal with dissolution data. Join our chemists for a live seminar on the proper procedures for investigating and documenting out-of-specification dissolution test results in your lab.

The module addresses the following topics:

- Detailed procedures for properly investigating and documenting out-of-specification results
- Ideas about how rudimentary investigations may uncover calculation or standard preparation errors proceeding to additional testing
- Discussion on how proper investigation and reporting can limit the possibility that an analyst will repeat an error in a second test
- Review of actual FDA observations



# Apparatus 3

### 60-minute module

The reciprocating cylinder, or Apparatus 3, became an official method in the USP XXII, Fifth Supplement. Given the increasing introduction of modified and extended release products, this valuable tool is growing in usage. This one-hour presentation covers the historical development as well as the principles of the operation and is designed for anyone interested in learning how the instrument operates.

The module addresses the following topics:

- Evolution of Apparatus 3 from previous dissolution apparatus
- Principles of operation
- Demonstration of Apparatus 3
- When to consider Apparatus 3 in method development
- Calibration requirements
- Automation of the sampling process
- Options / accessories for unique dosage forms

# Dissolution Discussion Group

# Tap into the knowledge-base from dissolution users around the world!

The Agilent-sponsored DDG is a vendor-neutral online forum designed to host discussions on industry research, best practices, regulatory issues, R&D challenges and more, all in an open environment that is free from regulatory oversight. Search the database of questions and answers going back to 1999. Discussions are anonymous and supported by fellow analysts and chemists in QC, R&D, stability and academia. Free to join, free to use!

www.dissolution.com



# Practical Solutions Newsletter

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# **Agilent Community**

Now dissolution users have a great resource to locate information, discuss best practices, and, most importantly, find trusted answers. Visit the Agilent Dissolution community and take advantage of this great opportunity to connect with application and product experts.

https://community.agilent.com/community/technical/dissolution



# Dissolution Hotline

Agilent's dissolution chemists are always available to assist with questions about finding the instrument that best supports your laboratory, method development and regulatory support.

Contact our team at dissolution.hotline@agilent.com



# **Agilent Practical Solutions Newsletter**

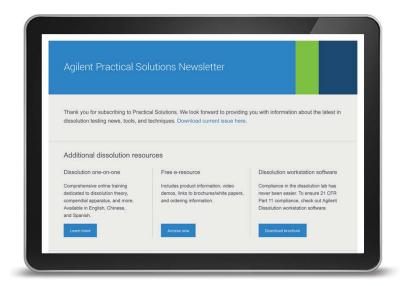




# Regulatory updates, workflow innovations, and practical advice

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