ERWEKA
a VERDER company

PRODUCT BROCHURE

DISSOLUTION GUIDE

OUR BROAD RANGE OF DISSOLUTION TESTERS

OUR DISSOLUTION PROGRAM USP 1-7

ERWEKA offers dissolution testers for every single harmonized USP/EP/JP dissolution method – starting from USP 1 up to USP 7.

USP METHODS 1, 2, 5 AND 6

We offer a broad range of dissolution testers - from manual testing with the DT 126/128 Light up to the high-volume tester DT 9510 Series.

DISSOLUTION SYSTEMS

Our semi-automated dissolution systems are available as Offline, Online and On-/Offline Systems for UV-Vis and HPLC analytic.

PUMPS

Every dissolution system needs a pump – we offer several options suited to different needs.

FULLY AUTOMATED DISSOLUTION SYSTEM ROBODIS II+

The productivity booster for fully automated, 24/7 non-stop dissolution testing with up to 40 batches.

DISSO.NET 4 SOFTWARE

Our advanced dissolution software solution Disso.NET 4 controls all our dissolution systems.

MEDIA PREPARATION

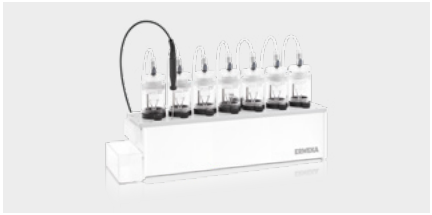
We offer the perfect companions to your dissolution tester for fast media preparation and filling of vessels.

CHEWING GUM TESTER DRT

Our dissolution tester for testing of in vitro release of substances into surrounding liquid medium.

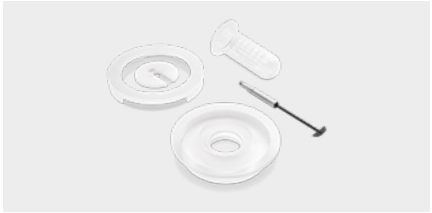
USP METHODS 3/7

The RRT 10 BioDis for automatic dissolution testing of different extended and sustained release dosage forms.



USP 4

USP method 4 is supported by our Flow-Through Cell DFZ II, available as standalone or as a system.



DISSOLUTION OPTIONS

ERWEKA offers a broad range of options for all of its dissolution testers and systems.

USP METHODS OVERVIEW

USP METHOD 1
Basket

Application
- Immediate / Extended and delayed release forms
- Tablets
- Capsules
- Beads
- Floating dosage forms
- Agitation method: Rotating Stirrer

Advantages
- Lots of experience (oldest method, more than 200 monographs in USP)
- No sinker necessary
- pH change possible

USP METHOD 2
Paddle

Application
- Tablets
- Capsules
- Beads
- Immediate / extended and delayed release forms
- Agitation method: Rotating Stirrer

Advantages
- Lots of experience
- Easy to use and robust
- pH change possible

USP METHOD 3
Reciprocating Cylinder

Application
- Low solubility drugs
- Tablets / Capsules
- Implants
- Granulates & Powders
- Suppositories
- Stents
- Cremes / Dialysis
- Agitation method: Fluid Movement

Advantages
- Easy pH change
- Hydrodynamic can be influenced by varying dip and rate

USP METHOD 4
Flow-Through Cell

Application
- Low solubility drugs
- Tablets / Capsules
- Implants
- Granulates & Powders
- Suppositories
- Stents
- Cremes / Dialysis
- Agitation method: Fluid Movement

Advantages
- Laminar flow possible
- Easy media change
- pH profile possible
- 2 system setups:
  - open system (permanent fresh media)
  - closed system (long-term tests over many days)

USP METHOD 5

Paddle over Disk

Application

- Transdermal patches
- Floating dosage forms
- Ointments
- Emulsions
- Agitation method: Rotating Stirrer

Advantages

- Standard equipment (USP 2 - paddle can be used)

USP METHOD 6

Rotating Cylinder

Application

- Transdermal patches
- Agitation method: Rotating Stirrer

Advantages

- Standard equipment can be used
- Variable volumes
- Big patches useable

USP METHOD 7

Reciprocating Holder

Application

- Transdermal patches
- Extended release dosage forms
- pH profiles
- Agitation method: Reciprocation

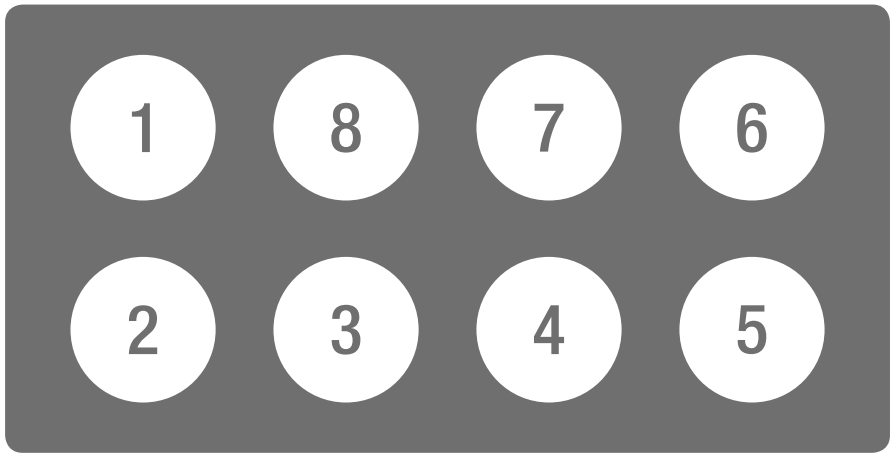
Advantages

- Small volumes possible
- Holder can be varied
- Easy pH change

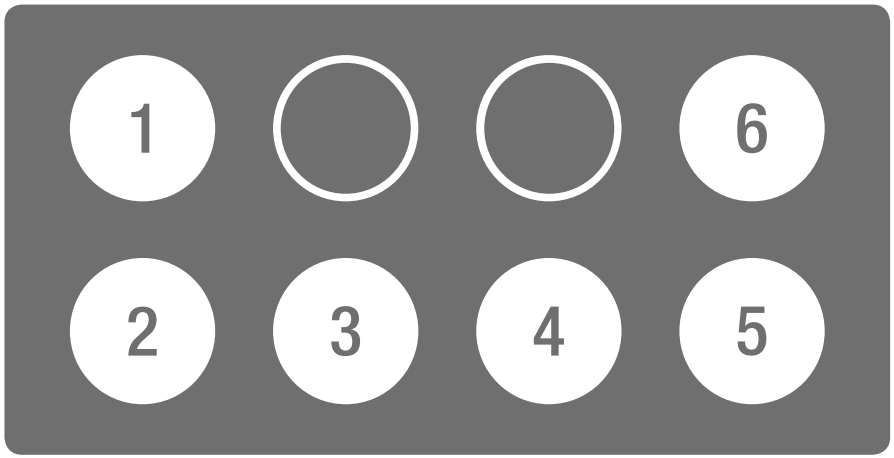
Different holder types

- Acrylic Rod: Extended release tablets
- Angled Disk: Transdermal system
- Fluoropolymer cylinder: Transdermal system
- Spring holder: Extended release tablets
- Reciprocating holder: Transdermal system

TEST STATION POSITIONS



Schematic view of ERWEKA test stations



Vessel configuration example DT 956

ERWEKA's dissolution tester can be equipped with 6 or 8 (12 or 14) test stations. Even though all of the testers are offered with a different number of stations, they differ from product line to product line.

The dissolution tester DT 126 light comes with a fixed number of 6 test stations, its bigger sibling, the DT 128 light comes with 8.

The dissolution testers of the DT 950 series always come with inlets for 8 vessels, which are covered with blinds, if a DT with 6 test stations is ordered.

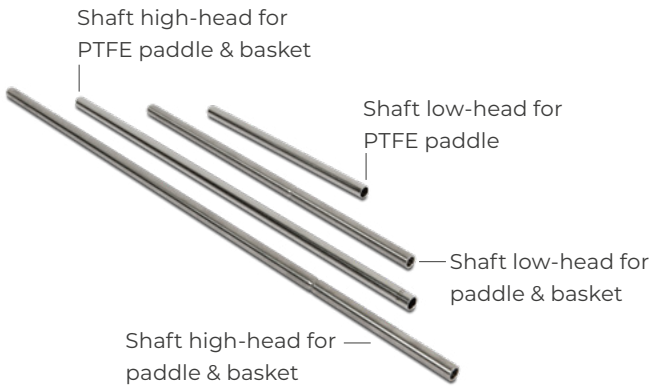
Dissolution testers with less then 8 stations can be upgraded by ERWEKA service.

Positions one through six are usually used for the samples. Position seven and eight are used for reference and blank samples, which are for example required for UV-Vis measurement.

LOW-HEAD, HIGH-HEAD & CLEANING POSITION

LOW-HEAD OPERATING MODE (LH)

The low-head mode on DT 950 is the standard mode and usually comes in conjunction with a system configuration with automated sampling station (ASS-9). Benefits are the closed vessels and therefore low evaporation.



HIGH-HEAD OPERATING MODE (HH)

The high-head mode is best used for manual testing and manual sampling on DT 950. To reduce evaporation, vessels are covered with a cover. Manual sampling is easier in high-head mode. Longer shafts have to be selected on purchasing for high-head mode. In addition, the high-head mode is the only mode of the DT light devices with a fixed head position.

CLEANING POSITION

The cleaning position is the highest position of the dissolution testers' head. It makes cleaning effortless and easy on DT 950.

KEY FACTS

ERWEKA's dissolution tester DT 950 offer two different operating modes which differ by the position of the head, and a third position for cleaning.

KEY FACTS

- 100 % USP/EP/JP compliant
- Compact design saving lab space
- High-head mode for easy acces to the vessels
- Universal shafts with attach-ments for Method 1, 2 (paddles included), 5 and 6 available
- Easy cleaning of the water bath and the set-up area
- External flow through heater reduces influence of external vibrations and ensures constant temperature
- Simple control using symbol keypad with LED display for wa-terbath temperature, RPM (speed per minute) and runtime
- Manual sampling using height adjustable holder for USP sam-pling points

ERWEKA light

MANUAL DISSOLUTION TESTING, SIMPLE AND COMPACT

DT LIGHT SERIES

The ERWEKA DT light Series delivers the proven ERWEKA quality in a comprehensive package for a budget for simple dissolution testing with USP method 1, 5 and 6. The DTs are equipped with 6 or 8 test stations and a fixed drive head (high-head), allowing easy access to each 1000 ml vessel.

The shafts can be replaced easily and the unique water bath of moulded PET is equipped with the time-proven ERWEKA water outlet for easy clea-ning. The external flow through heater reduces the influence of external vibrations and ensures a constant temperature. Every accessory that comes into contact with the dissolution sample is installed in Germany. Therefore our DT light Series has the ERWEKA made in Germany quality.

All these features make sure that the ERWEKA DT light Series is the perfect entry-level device for the world of dissolution testing.

Conical evaporation vessel covers are included

Art. No.	Dissolution Tester DT 126/128 Light incl. vessels, paddles, shafts
19996	DT 126 Light Dissolution Tester, USP method 2 paddle with 6 test stations
20412	DT 128 Light Dissolution Tester, USP method 2 paddle with 8 test stations

DT 126 light - Specifications

- High-head with 6 test stations
- Dimensions (width / depth / height): 510 mm / 450 mm / 660 mm
- Weight: 30 kg

DT 128 light - Specifications

- High-head with 8 test stations
- Dimensions (width / depth / height): 642 mm / 482 mm / 680 mm
- Weight: 38 kg

LED display and symbol keypad for easy control

100%
100% USP/EP/JP compliant

Manual testing

DIGITAL DISSOLUTION TESTING

DT 950 SERIES

The ERWEKA DT 950 is an advanced digital dissolution tester, designed to meet today's demanding standards while being adaptable for future challenges. Equipped with cutting-edge embedded PC technology, it ensures full compliance with USP, EP, and JP methods 1, 2, 5, and 6, offering reliable and precise dissolution testing. Its 7" touch display provides an intuitive user interface, and the intelligent TestAssist guides users step by step through the setup and testing process, eliminating errors and ensuring only valid parameters are used. This user-friendly approach makes test configurations straightforward, without the need for extensive training.

The DT 950, coming with ERWEKA's clean white design is designed for future upgrades, allowing users to expand from 6 to 8 test stations or from a manual dissolution tester to a semi-automatic Offline-, Online- or On-/Offline system.

It is possible to add features like automatic tablet drop or temperature sensors for each vessel. It also supports easy setup change between low-head and high-head modes, and software updates provide new features to be added over time.

For enhanced accuracy, the DT 950 separates the heater from the main device to minimize vibration. Data export to FTP servers e.g. for LIMS connection is supported, and the system includes enhanced IT security features to safeguard data.

With Audit Trail, method management and user management the DT 950 delivers a powerful, adaptable, and future-proof solution for dissolution testing, combining advanced technology with ease of use.

Art. No.	Dissolution Tester DT 950 Series
27380	DT 956 (LH/HH) 1000 ml Dissolution Tester with 6 test stations
27542	DT 957 (LH/HH) 1000 ml Dissolution Tester with 7 test stations
27543	DT 958 (LH/HH) 1000 ml Dissolution Tester with 8 test stations
27646	DT 956 (LH/HH) 2000 ml Dissolution Tester with 6 test stations
27647	DT 957 (LH/HH) 2000 ml Dissolution Tester with 7 test stations
27648	DT 958 (LH/HH) 2000 ml Dissolution Tester with 8 test stations

Advanced embedded technology

The DT 950 & DT 9510 Series feature an in-house developed embedded PC with Linux-based ERWEKA OS, combining ease of use with ERWEKA's dissolution testing expertise. The embedded digital technology offers all the benefits and the adaptability of a modern software, with regular updates that add new functions to meet evolving industry needs - making the DT Series a reliable, future-ready solution.

Modern user interface with TestAssist

The modern user interface of the DT 950 focuses the user on the most important function of the DT 950 - dissolution testing.

- TestAssist, the intelligent guide for dissolution testing
- DirectHelp, instant on-screen support with the tap of a question mark button
- Multilanguage operation in English, French, Spanish, Italian and German
- Method management: Create and edit methods for later use in TestAssist
- User management: Control user access and rights

Option: Automatic tablet drop

- Automatic drop of formulation for low-head & paddle
- Improved tablet drop to reduce moisture on formulations

Automated sampling station ASS-9

- Move up/down of sampling probes
- Repeatable, USP conform withdrawal position
- Prefiltration with poroplast tip filter (1, 4, 10 & 20 µm)
- Optional temperature sensors to record medium temperatures in all vessel (8 sensors)

KEY FACTS

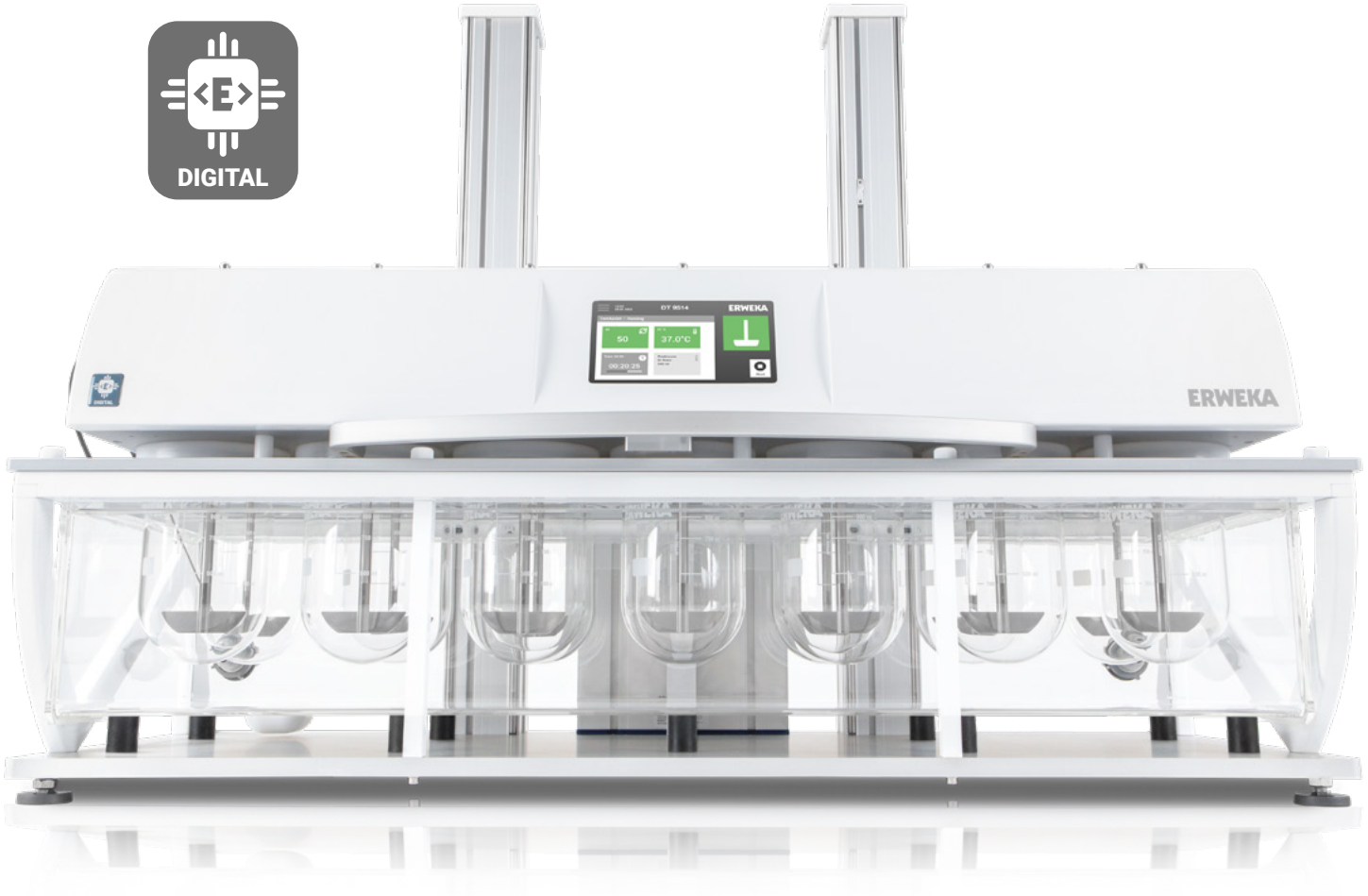
- USP methods 1, 2, 5 and 6
- Intuitive touch interface
- User & method management
- Audit Trail - full 21 CFR Part 11 compliance
- 100% USP/EP/JP compliant
- Upgradeable at any time
- Temperature measurement per vessel
- FTP data export (e.g. for LIMS)

HIGH VOLUME DIGITAL DISSOLUTION TESTING

DT 9510 SERIES

KEY FACTS

- USP methods 1, 2, 5 and 6
- Intuitive touch interface
- User & method management
- Audit Trail - full 21 CFR Part 11 compliance
- 100% USP/EP/JP compliant
- Upgradeable at any time
- Temperature measurement per vessel
- FTP data export (e.g. for LIMS)



OVERVIEW

DT 9510 SERIES

The ERWEKA DT 9510 Series is the extended-vessel version of the digital DT 950 Series dissolution tester.

Controlled by the embedded PC, every component of the DT 9510 is focused on reliable, high volume digital dissolution testing: The test stations (up to 14) are driven by a single, powerful motor and the big waterbath holds the temperature stable due to the thermal inertia of water. This ensures that parallel testing of two batches of samples can be done at precisely the same conditions, making comparsion between the two as reliable as possible and 100% compliant with the requirements by USP/EP/JP.

With the optional AirLift system, the dissolution head of the DT 9510 can be simply raised and lowered with the push of two buttons. Furthermore, DT 9510 Series has the same features as it's smaller model - digital dissolution testing is done with the help of the latest version of TestAssist and samples can be automatically dropped into the vessel by the optional tablet drop.

Option: Automatic tablet drop

- Automatic drop of formulation for low-head & paddle
- Improved tablet drop to reduce moisture on formulations

Automated sampling station ASS-18

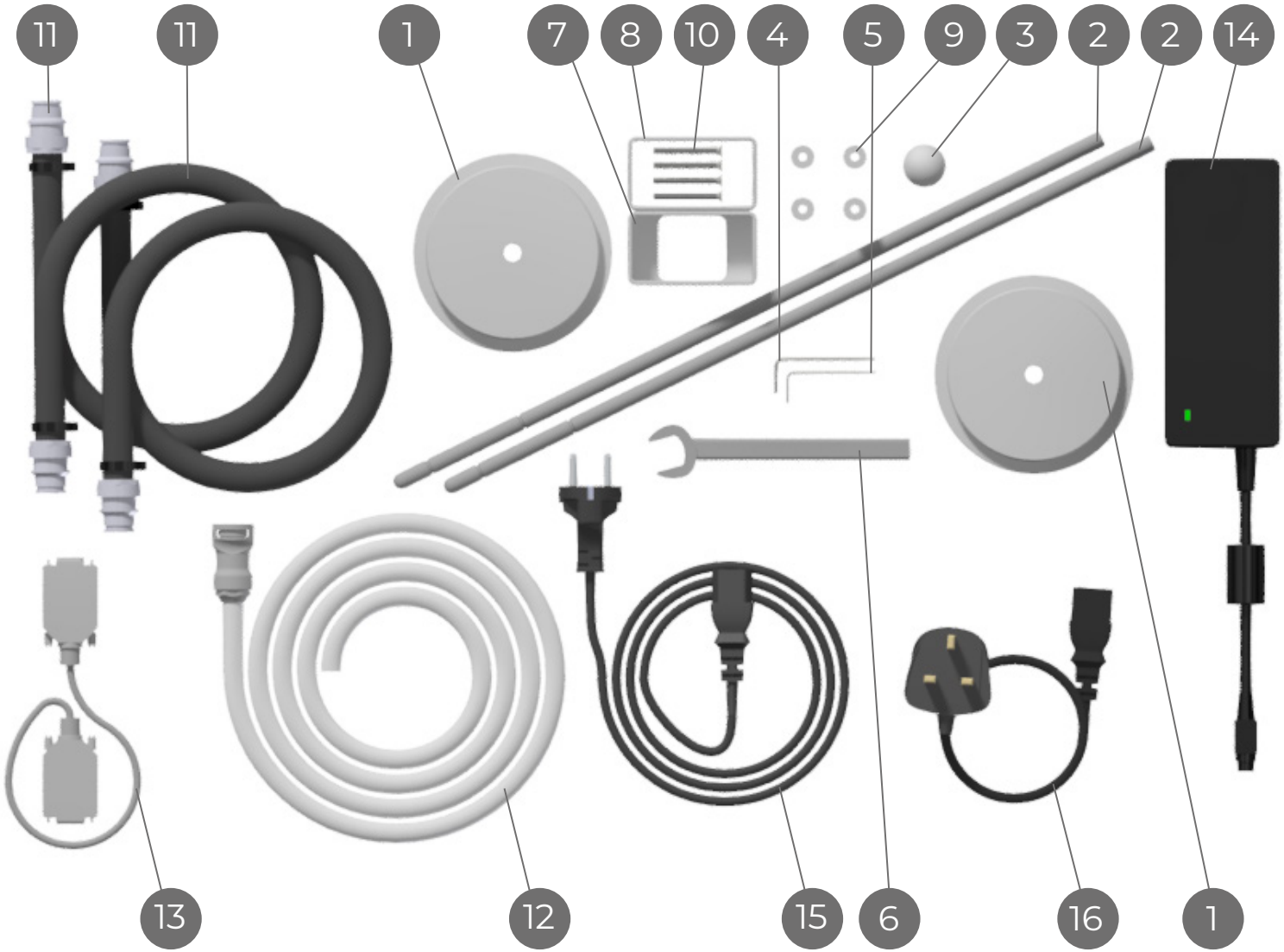
- Move up/down of sampling probes
- Repeatable, USP conform withdrawal position
- Prefiltration with poroplast tip filter (1, 4, 10 & 20 µm)
- Optional temperature sensors to record medium temperatures in all vessel (14 sensors)

Option: AirLift System - Easy to use and safe!

The AirLift system makes raising and lowering of the dissolution tester head as easy and safe as never before! The operator simply pulls the safety lever at the front of the DT 9510, and then pushes a button for either upward or downward movement. Whenever either of the two buttons is released, movement stops immediately, making the AirLift system and handling of the dissolution head as safe as possible. AirLift is an option of the DT 9510 Series dissolution tester and can also be upgraded after purchase.

Art. No.	Dissolution Tester DT 9510 Series
28312	DT 9512 (LH/HH) 1000 ml Dissolution Tester
28389	DT 9513 (LH/HH) 1000 ml Dissolution Tester
28390	DT 9514 (LH/HH) 1000 ml Dissolution Tester

DT 950 & 9510 ACCESSORY KIT



WHAT IS INSIDE? OVERVIEW

Nr.	Name	Purpose
1	Centring disc	Adjustment of the vessels
2	Measuring shaft	Adjustment of the vessels
3	POM-Plastic ball, d=25mm	Adjustment for height of paddles and baskets
4	Hexagon-wrench, SW2	Assembly shaft
5	Hexagon-wrench, SW2,5	Assembly power supply holder
6	Open-end wrench size 17	Leveling of the device
7	Power adapter holder part 1	Attachment power supply to DT
8	Power adapter holder part 2	Attachment power supply to DT
9	Power adapter holder cylinder	Attachment power supply to DT
10	Power adapter holder screws	Attachment power supply to DT
11	Heating tubes	Water supply between DT and heater
12	Drain hose with quick coupling	Emptying the water bath
13	RS-232-Connection cable	Communication between DT and heater
14	Power adapter 120W-24V-5A	Power supply
15	Power cord type F	Power supply European plug
16	Power cord type G	Power supply British plug

WHAT IS INSIDE?

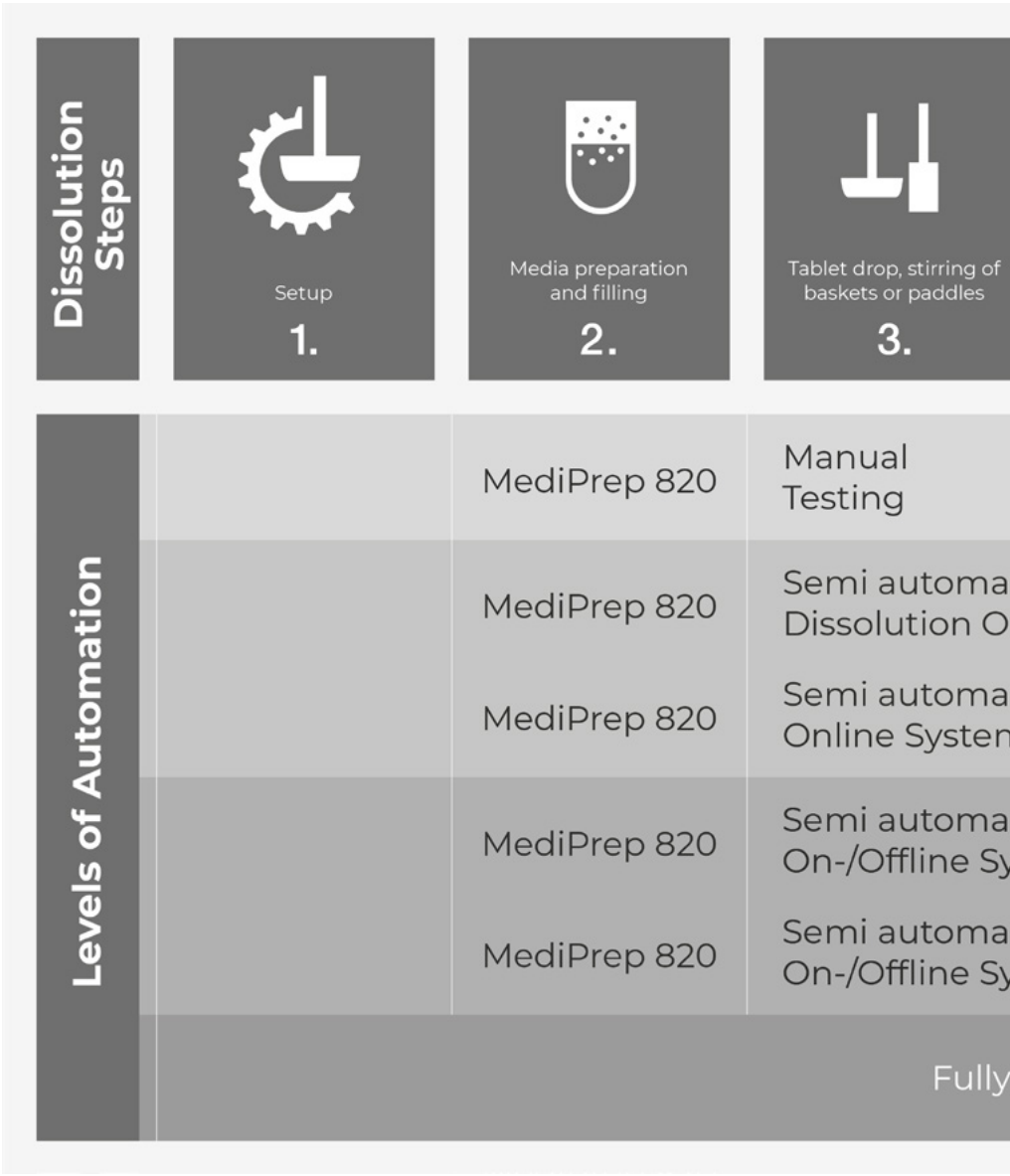
The ERWEKA accessory kit is equipped with 16 different accessories designed for use and set-up tasks on your device of the DT 950 & DT 9510 series. The following overview helps to discover the individual parts and to immediately see their benefits.

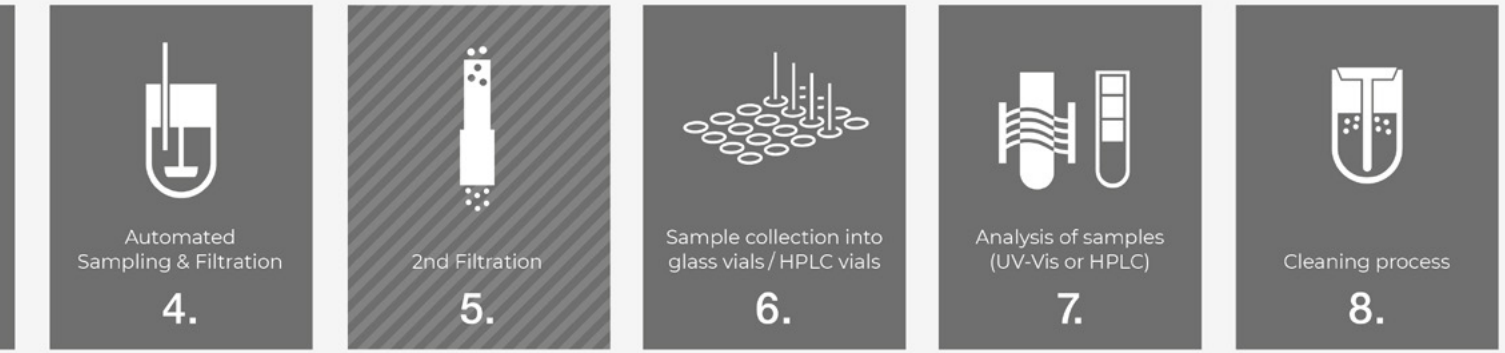
CONTACT OUR SERVICE TEAM

The accessory kit is designed so that all components are easy to find and use. However, if you have any questions, our ERWEKA service team will be happy to assist you at any time. Please just send us an e-mail to service@erweka.com.

LEVELS OF AUTOMATION

ERWEKA offers several products for different types of automation levels. The semi-automated Dissolution Offline System for automation of three steps of the dissolution process or a semi-automated Dissolution Online System are perfect entry-level systems into the world of 100% USP/EP/JP, automated testing. Our Dissolution On-/Offline System with UV-Vis or HPLC analysis automates five steps of the dissolution process. In addition with a MediPrep the media preparation can also be automated.





ted ffline System	optional	Sample collector	
ted Dissolution n with UV-Vis	optional	UV-Vis	
ted Dissolution ystem with UV-Vis	optional	UV-Vis Sample collector	
ted Dissolution ystem with HPLC	optional	Sample collector HPLC	
automated Dissolution System RoboDis II+			

FULL AUTOMATION

For fully automated 24/7 testing and 100%-reproducibility of all tests, we offer the RoboDis II+ - a real productivity booster with fully automated dissolution testing of up to 40 batches including setup, media preparation and cleaning automation.

DIGITAL TODAY.
FOR THE CHALLENGES OF THE FUTURE.

THE DIGITAL OFFLINE SYSTEM

The Digital Offline System for the DT 950 & 9510 Series is the next step in expanding the capabilities in the field of digital dissolution testing. It makes use of the advanced technology from the DT 950 & 9510 Series for the first step of dissolution automation: Fully automated sample withdrawal and sample storage for subsequent sample analysis.

With the updated TestAssist, the user can easily configure and start dissolution tests with automated sampling on our 7“ touch display. The user is guided through the dissolution test in few simple steps, enabling 100% USP/EP/JP compliant dissolution testing without distraction and errors and ensuring constantly valid parameters.

But there is more - with the clearly organised user management, easy handling of the complete digital offline system is only a button-tap away. Users can be easily configured with individual rights, making it easy to restrict functions only to authorized users - for example administrators and operators. Of course, the offline system includes all the other software features of the DT 950 platform, including Audit Trail, method management, sampling station with temperature sensors in each vessel, USB update and FTP data export (e.g. for LIMS).

The Digital Offline System is our most advanced dissolution system, offering an easy-to-use first step into dissolution automation.

Full control of connected hardware

The digital embedded PC technology in the digital dissolution tester DT 950 and DT 9510 take full control of the connected system hardware: The pump, the automated sampling station ASS-9/-18 and the sample collector. An external computer is not required, saving space, energy and maintenance.

DIGITAL

TestAssist functions & setup sampling via FRL

- Easy sample time-point configuration
- Advanced offline system settings
- Updated test interface for more test run information and transparency
- Setup sampling via FRL:
  - Min. 5 min intervals
  - Up to 7 days runtime
  - 25 ml tubes: 18x8 samples (DT 950)/ 9x14 samples (DT 9510)
  - 1.8, 4 & 10 ml tubes: 26x8 samples (DT 950)/ 13x14 samples (DT 9510)

Offline system cleaning

The system comes with a programmed cleaning routine for cleaning & emptying of tubing.

Art. No.	Dissolution Offline System
29017	Offline Dissolution System with IPC 8 and FRL 654 for DT 956
29018	Offline Dissolution System with IPC 8 and FRL 754 for DT 957
29019	Offline Dissolution System with IPC 8 and FRL 854 for DT 958
29024	Offline Dissolution System with IPC 16 and FRL 654-2 for DT 9512
29025	Offline Dissolution System with IPC 16 and FRL 754-2 for DT 9514
29551	Offline Dissolution System with PVP 620 and FRL 654 for DT 956
29552	Offline Dissolution System with PVP 720 and FRL 754 for DT 957
29553	Offline Dissolution System with PVP 820 and FRL 854 for DT 958
29554	Offline Dissolution System with PVP 1220 and FRL 654-2 for DT 9512
29555	Offline Dissolution System with PVP 1420 and FRL 754-2 for DT 9514

KEY FACTS

- USP methods 1, 2, 5 and 6
- Full stand-alone control of connected hardware
- User & method management
- Audit Trail - full 21 CFR Part 11 compliance
- 100% USP/EP/JP compliant
- Upgradeable at any time
- Temperature measurement per vessel
- FTP data export (e.g. for LIMS)

DISSOLUTION ONLINE SYSTEM UV-VIS

HIGHLIGHTS

The ERWEKA Dissolution Online Systems are the perfect, semi-automatic solution for dissolution testing with integrated UV-Vis online analysis.

The DT 950 series with integrated, automatic Sampling station ASS-9 transports freshly taken samples directly to the UV-Vis analysis. The samples are analyzed directly and the data is evaluated and saved using our advanced Disso.NET software.

With the help of the Analytik Jena Specord 200/210 UV-Vis photometer that we recommend, cycles in the 185 nm to 1200 nm range can be tested and evaluated with high efficiency. In connection with the maintenance-free pump PVP 820, the customer can trust on highest reliability in dissolution testing.

Art. No.	Dissolution Online System
28777	UV-Vis Online System w. Analytic Jena Specord 200, IPC 8 for DT 95x
27961	UV-Vis Online System w. Shimadzu 1900i Plus, IPC 8, Disso.NET 4.x Software for DT 95x
28778	UV-Vis Online System w. Analytic Jena Specord 200, PVP 820 for DT 95x
27963	UV-Vis Online System with Shimadzu 1900i Plus, PVP 820, Disso.NET 4.x for DT 95x

Dissolution Tester DT 950 & DT 9510 Series

The ERWEKA DT 950 / DT 9510 is the perfect dissolution tester for the ERWEKA dissolution online system. The DT 950 / DT 9510 ensures absolutely reliable and reproducible test results. 100% USP/EP compliant, with a novel, innovative design and the usual ERWEKA quality and with integrated automatic sampling station ASS-9 / 18 and automatic tablet drop.

High-precision pumping with the PVP or IPC pump

With the maintenance-free PVP 820 piston pump with almost wear-free ceramic pump heads, the samples are transported precisely from the dissolution tester to the Analytik Jena Specord 200/210 Photometer. You can choose to integrate the cost-effective IPC 8 peristaltic pump into our dissolution online systems.

Analytik Jena Specord 200/210 UV-Vis Photometer

The Analytik Jena Specord 200/210 is an ultra-fast UV-Vis photometer that is effective in tracking chemical reactions in a short time. It is completely USP/EP compliant and enables cycles in a 185 nm to 1200 nm range. It is completely integrated in the Disso.NET from hardware conrol up to data evaluation and can be qualified on request. Other available photometer brands: Thermo Fisher, Shimadzu.

Complete control with Disso.NET

The Windows software Disso.NET completely controls the entire dissolution system, manages methods with tests and generates the associated reports. The software tracks all changes that are made using the integrated 21 CFR part 11 compliant audit trail. Thanks to the full integration of the Analytik Jena Specord 200/210, the UV-Vis evaluation takes place directly in the Disso.NET - so the user has all the data of the dissolution test in one place. Disso.NET features user management with Active Directory integration, allowing seamless system-wide login credentials for users. The USP / EP photometer qualification can also be done on request.

KEY FACTS

- USP methods 1, 2, 5 and 6
- 100% USP/EP/JP compliant dissolution testing
- Ultra-fast Analytik Jena UV-Vis Spectrophotometer
- Completely software controlled by Disso.NET
- Full integration of all system components in Disso.NET software
- User Management with Active Directory

DISSOLUTION ON-/OFFLINE SYSTEM WITH HPLC

HIGHLIGHTS

The ERWEKA Dissolution HPLC On-/Offline System is the semi-automatic solution for 100% USP/EP/JP compliant dissolution testing with HPLC online analysis. Up to 5 of 8 dissolution steps can be automated by combining one of our highly qualified DT 950 series dissolution testers with devices for CTC sampling and online HPLC chromatography. The entire system with all components is controlled by our easy-to-use Disso.NET software.

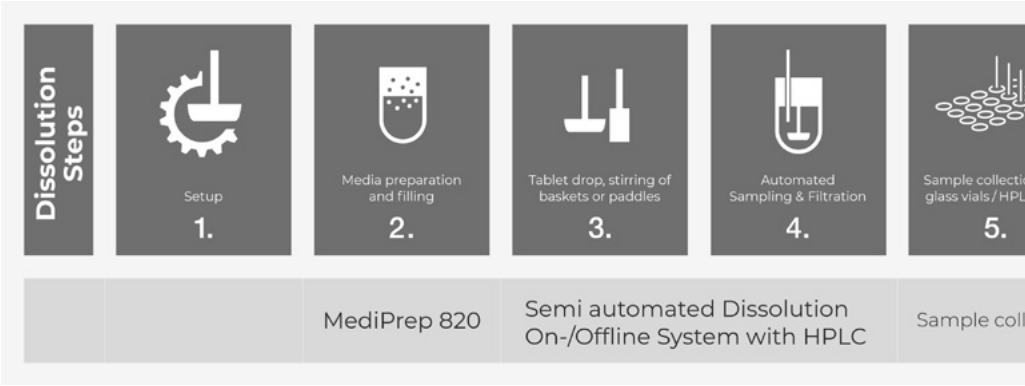
For filtrations up to 0.22 µm, our automated filter changer AFC 825 can be used in combination with our maintenance-free PVP pump. In addition, to a precise and simple control of the entire system, Disso.NET offers an accurate recording of the whole test process, from the automatic recording of the sampling time up to the recording of the temperature and rotation speed in each vessel (= Documentation of all system operations, audit trail).

Dissolution Tester DT 950 & DT 9510 Series

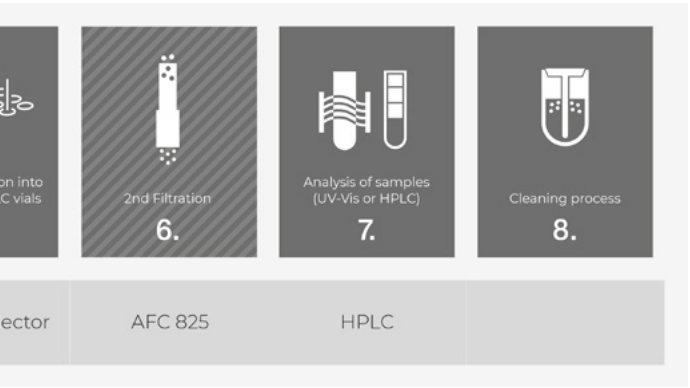
The ERWEKA DT 950 / DT 9510 is the perfect dissolution tester for the ERWEKA dissolution online system. The DT 950 / DT 9510 ensures absolutely reliable and reproducible test results. 100% USP/EP compliant, with a novel, innovative design and the usual ERWEKA quality and with integrated automatic sampling station ASS-9 / 18 and automatic tablet drop.

High-precision pumping with the PVP 820 pump

The test medium is transported with high precision and pressure via eight channels to the automated filter changer AFC 825 by the practically maintenance-free piston pump. In conjunction with the AFC 825, it enables a filtration with up to 0.22 µm flat membrane filters.



Note: HPLC analytic equipment not included in system configuration! Different manufacturers supported.



HPLC sample collection & analysis

With the HPLC sampler the samples can be collected (and cooled) and injected automatically in the HPLC system. Analysis and evaluation are done by the HPLC analysis device and the associated analysis software (different providers: Agilent, Shimadzu, Waters etc.).

Double filtration with AFC 825

In case of a HPLC analysis it is recommended to perform a double filtration, to avoid contamination or damage of the HPLC column due to particles, thus improving the accuracy of the HPLC analysis. The high-precision, practically maintenance-free PVP pump in combination with the automated membran filter changer are particularly suitable for this purpose. APC 825 for 6 or 8 stations.

Art. No.	Dissolution On-/Offline System HPLC
27969	HPLC On-/Offline Dissolution System w. PVP 620 pump, RSI sampler for DT 95x

KEY FACTS

- USP methods 1, 2, 5 and 6
- 100% USP/EP/JP compliant
- PAL RSI sample collector and sample storage for HPLC analysis
- 21 CFR Part 11 conform in conjunction with Disso.NET software
- 5 of 8 dissolution steps are automated
- Full integration of all system components in Disso.NET software

DISSOLUTION ON-/OFFLINE SYSTEM UV-VIS

HIGHLIGHTS

The ERWEKA Dissolution UV-Vis On-/Offline System with DT 950 or DT 9510 is the ideal system configuration for spectrophotometers. With the connected PC, the On-/Offline System can be conveniently controlled via our advanced Disso.NET software. Moreover, the software offers full control over all components and storage of all test results.

After analysis has been completed, the samples are comfortably stored by our very own sample collector FRL 654/754/854 for later HPLC analysis or as reference standard.

Art. No.	Dissolution On-/Offline System UV-Vis
28779	UV-Vis On-/Offline Dissolution System w. Analytic Jena Specord 200, IPC 8 for DT 95x
27965	UV-Vis On-/Offline Dissolution System Shimadzu 1900i Plus, IPC-8, Disso.NET for DT 95x
28780	UV-Vis On-/Offline Dissolution System w. Analytic Jena Specord 200, PVP 820 for DT 95x
27967	UV-Vis On-/Offline Dissolution System Shimadzu 1900i Plus, PVP 820 for DT 95x

KEY FACTS

- USP methods 1, 2, 5 and 6
- Advanced UV-Vis analysis
- 100% USP/EP/JP compliant
- Sample collector and storage
- Completely software controlled by Disso.NET

PUMPS FOR DISSOLUTION SYSTEMS

OVERVIEW

	Peristaltic pump	ERWEKA piston pumps	ERWEKA piston pumps
Pump	IPC 8 / 16	PVP 620 / 720 / 820	PVP 1220 / 1420
Channels	8 or 16	6 or 8	12 or 14
Valves	-	-	-
Accuracy	25 ml +/– 5%	25 ml +/– 5%	25 ml +/– 5%
Media replacement	Standard	Standard	Standard
Double filtration (optional)	Only when first filtration with poroplast filters. No media replacement possible when double filtration.	No media replacement possible when double filtration	No media replacement possible when double filtration
Required type of sample collector	FRL 624 / 724 / 824	FRL 624 / 724 / 824	FRL 624 -2 / 724-2 / 824-2
System compatibility	DT Offline / DT Online DT On-/Offline	DT Offline / DT Online DT On-/Offline	DT Offline / DT Online DT On-/Offline
Advantage	**Basic pump**, possible with DT 950/9510, needs regular replacement of tubing	Filtration down to 0.22 µm for flat membrane filters, **best choice for fully automated dissolution systems**	Filtration down to 0.22 µm for flat membrane filters, low maintenance even at high throug-hput, **best choice for dissolution systems**

FULLY AUTOMATED: ROBODIS II+

THE FLEXIBLE SPECIALIST FOR R&D

Many types of dosage forms

The RoboDis II+ can handle several types of dosage forms. No matter what you use - tablets, granulates or powders - the RoboDis II+ is the ideal, flexible and fully automated dissolution system for all your usage needs. It even handles Japanese Sinkers with a size of up to 34 mm with ease!

pH Half Change and pH Full Change (USP methods A & B)

The fully automated ph change (both half and full possible) is supported by the RoboDis II+. Just configure your method using the powerful Disso.NET software and run your test – the RoboDis II+ will automatically take care of the rest.

6 reference standards

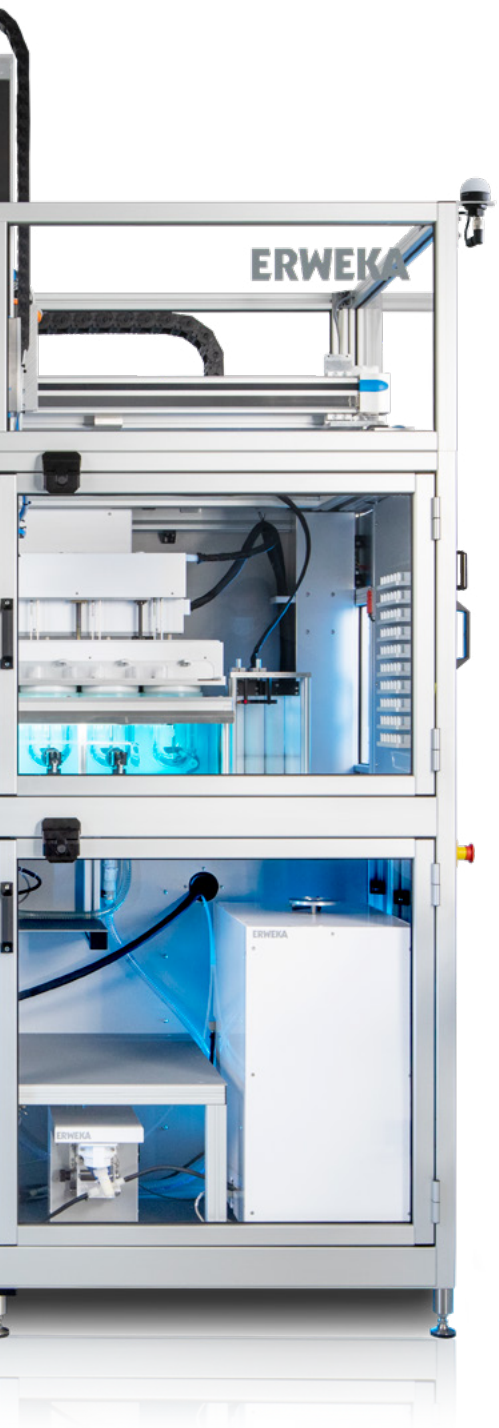
Mandatory in R&D: Flexible reference standards for quick testing of several formulations. Thanks to an integrated standard changer system, the RoboDis II+ handles them with ease.

Versatile filtration

Filtration with the RoboDis II+ has no boundaries - inline poroplast filters, membrane filters down to 22 µm and even double filtration are supported.

Broad range of analytics available

RoboDis II+ supports a broad range of analytical devices. UV-Vis spectrophotography, chromatography using HPLC or even a combination of both – the RoboDis II+ handles and controls all of them.



THE PRODUTIVITY BOOSTER FOR QUALITY CONTROL

Planned productivity with 10 or 40 batches

Productivity can be easily scheduled with the RoboDis II+. For example, the system can autonomously handle up to 40 batches during the weekend and then present all the results to the laboratory employee on the following workday for evaluation. With video recording and time-lapse function, a visual inspection of the completed test process is possible afterwards.

Parallel approach

The RoboDis II+ is following a parallel test approach: Tablet drops, sampling and emptying of the vessels are all done in parallel.

Space-saving footprint

To match the RoboDis II+s productivity with semi-automated systems, at least three Dissolution Online Systems and operators are needed to perform 10 batches per day. Convince yourself!

High volume – 40 batches

Testing, testing, testing - that is what the RoboDis II+ does best. The 40 batch option allows volumes that are usually only matched by a multitude of semi-automated systems, demanding a lot more laboratory space and staff then ERWEKA's RoboDis II+. Real productivity gain!

Robotic precision & integrated error control

Every dissolution step is fully automated and is completely tracked by the software itself (SST). This means, that all tasks performed by the RoboDis II+ during a test are identically repeated in the next test, thus removing the human error factor completely. The system offers highest reliability and allows the laboratory employees to concentrate on the analysis of the provided data.

THE PRODUCTIVITY BOOSTER

ROBODIS II+

The fully automated dissolution system is already used in quality control and R&D by several multinational companies and has brought a huge increase in productivity. It fully automatically handles 10 or 40 batches of dissolution testing USP method 1 basket or method 2 paddle in a parallel approach, therefore enables very short sampling points of 5 minutes, depending on product and method. As all ERWEKA products, the RoboDis II+ works 100% conform to all harmonized pharmacopoeias in every aspect.

All steps of the dissolution process - media preparation, filling, setup of dissolution tester, testing, automated sampling, online analytics (UV-Vis or HPLC) and the whole cleaning process are performed automatically and without the need of user intervention. The whole system is controlled by the ERWEKA Disso.NET software, from the robot arm to media preparation and analytic devices.

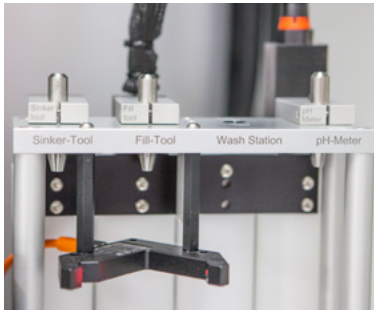
Supported by several integrated System Suitability Tests (SST) and light sensor checks, this system runs absolutely precise and reliable, minimizing human error. It is human error proofed so to say.

HIGHLIGHTS

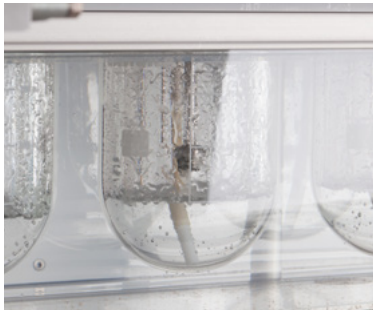
- 100% USP/EP/JP compliant
- Controlled by Disso.NET
- Online UV-Vis or HPLC analysis
- USP methods 1 and 2
- System Suitability Tests (SST)
- pH half change or full change
- 10 or 40 batches in one test run
- Video monitoring
- Vacuum degassing

Simultaneous tablet insertion allows high accuracy of processes.

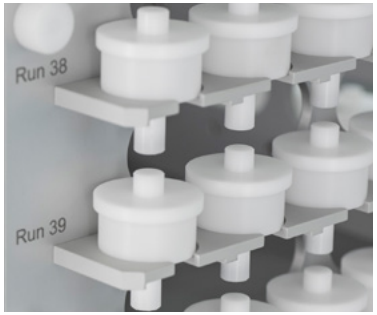
pH change in accordance with USP Method A (Half Change) and optional USP Method B (Full Change) possible.



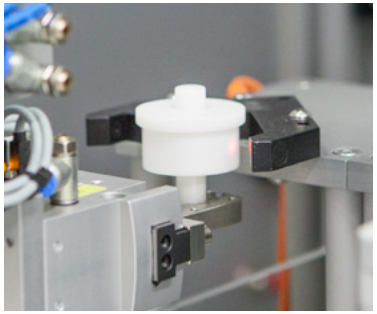
Different tools for different applications are available.



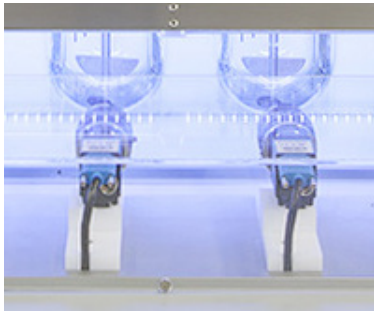
Automatic cleaning and result checks of the cleaning process (SST).



10 or 40 Batch sample magazine for continuous testing 24/7.



Continuous verification of processes with controlling sensors.



24/7 testing with LED light bar and six ethernet cameras.

HIGHLIGHTS

DISSO.NET 4 DISSOLUTIONSOFTWARE

The ERWEKA Disso.NET 4 is the perfect 21 CFR Part 11 compliant companion to all our Dissolution Systems, ranging from Dissolution Offline over Online to On-/Offline Systems up to the fully automated RoboDis II+ system. It has been developed to make laboratory processes more efficient and precise, combining numerous features that enable seamless integration and advanced analysis.

Among other features, the software provides an HPLC-ready signal that allows direct connection to HPLC systems, as well as automatic dilution of HPLC samples in the range of 1:1 to 1:10, saving valuable time in the laboratory. Thanks to its powerful UV evaluation with first derivative, users receive detailed and precise results. Additionally, Disso.NET enables integration of two photometers, allowing for extended measurements and parallel analyses.

With its versatility and user-friendliness, Disso.NET is not just software but a reliable partner for modern dissolution testing—flexible, efficient, and individually adaptable.

Supports Dissolution Systems, RoboDis II+

The Disso.NET 4 supports all ERWEKA Dissolution Systems and the fully automated RoboDis II+.

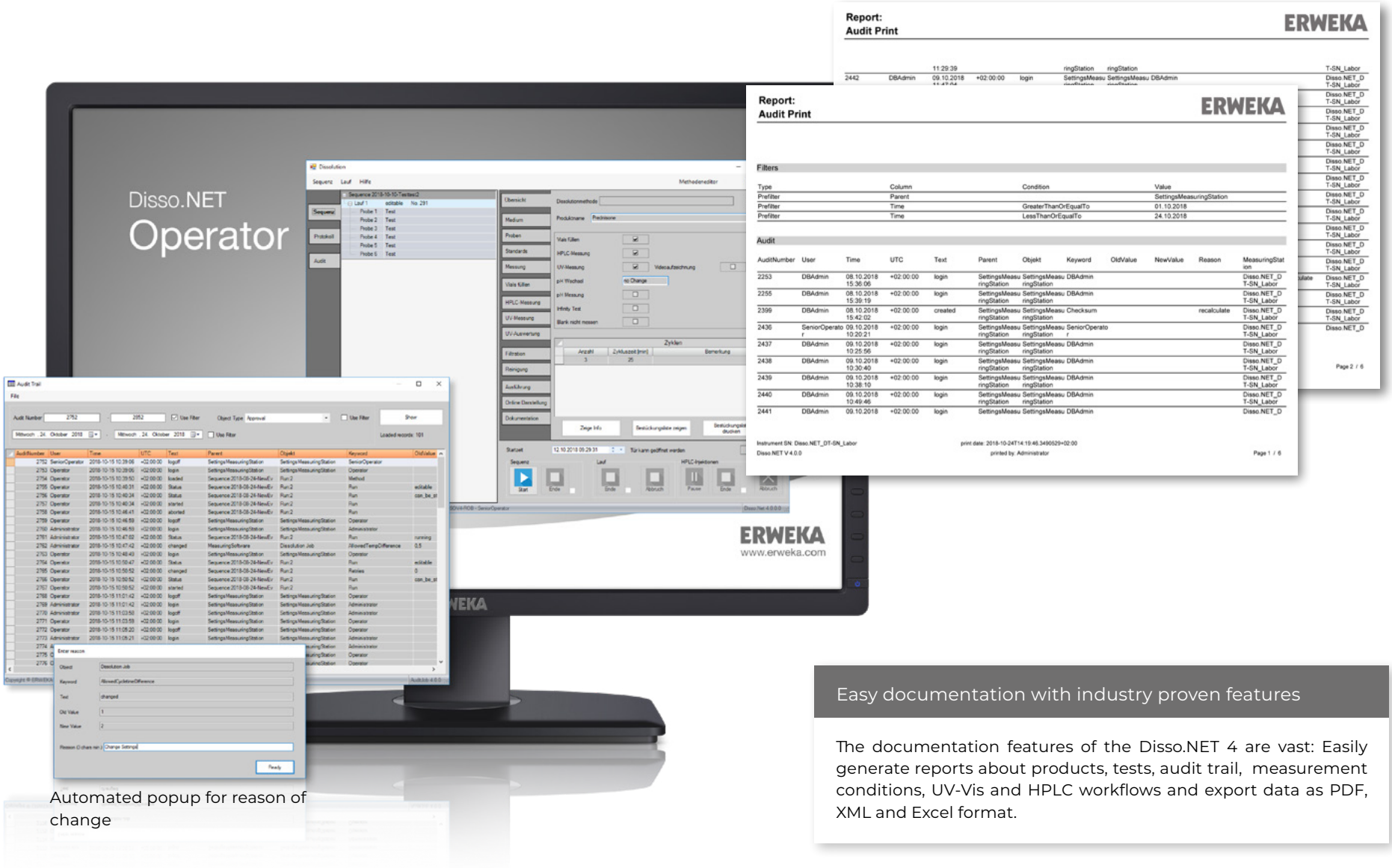
Full Audit Trail according to 21 CFR Part 11

The Audit Trail feature is implemented throughout the whole software, tracking each and every change (What, Who, When and Why). If data is changed by the user (e.g. when editing methods), the software requires a reason entered by the user.

In combination with our easily search- and filterable audit trail viewer, changes to the system and its data can be easily traced back to its origin and originator. With Disso.NET 4, it is not possible to delete data from the system to maintain data integrity.

KEY FACTS

- HPLC-ready-signal
- 1:1 to 1:10 dilution of HPLC samples
- UV evaluation: First derivative
- Integration of two photometers possible
- 100% Full Audit Trail according to 21 CFR Part 11
- MS SQL Database
- Support for USP methods 1, 2, 5 and 6
- User Management with Active Directory



Automated popup for reason of change

Easy documentation with industry proven features

The documentation features of the Disso.NET 4 are vast: Easily generate reports about products, tests, audit trail, measurement conditions, UV-Vis and HPLC workflows and export data as PDF, XML and Excel format.

ADVANCED MEDIA PREPARATION OF 16 LITERS IN LESS THAN 25 MINUTES

MEDIPREP SERIES - THE IDEAL COMPANION FOR OUR DISSOLUTION SYSTEMS

The MediPrep series offers quick and easy preparation of up to 16 liters dissolution media in less than 25 minutes. In a single pass, the media for dissolution tests can be precisely mixed, heated, degassed and gravimetrically filled into vessels. Foaming media like SDS (Sodium Dodecyl Sulfate) can also be used.

Gravimetrically controlled filling can be done at the integrated dosing port or with the optional remote filling hand directly into the vessels.

The MediPrep 820 provides one inlet for premixed media and one outlet for waste water. In comparison the MediPrep 1622 offers two additional inlets for media concentrates or premixed media. To prevent cross contamination, an automated cleaning procedure is integrated.

Up to 3x faster than manual media preparation

The devices of the MediPrep family allow up to 3x faster media preparation in comparison to a manual approach. Even better - while MediPrep does all the media preparation on its own, the laboratory employee can focus on other more imporant tasks, thus increasing productivity.

Art. No.	MediPrep Series
18605	MediPrep 820 (230 V) 8 liters with one inlet
27014	MediPrep 820 (115 V) 8 liters with one inlet
25813	MediPrep 1622 (230 V) 16 liters with two inlets
26943	MediPrep 1622 (115 V) 16 liters with two inlets

Highly precise filling

Thanks to gravimetric filling, the MediPrep works with the highest precision that the user can always rely on.

Complete GLP / GMP documentation

The ERWEKA MediPrep logs all important information according to GLP/GMP standards that arise during media preparation and can easily assign the data to a batch ID on the report.

Integrated cleaning procedure

Thanks to the integrated cleaning procedure, the MediPrep can automatically clean the built-in media container and all tubing. This leaves no residues and the user can easily prepare the next medium without wasting time.

KEY FACTS

- 8 l / 16 l — Available with 8 liter and 16 liter tank
- 100% — 100% USP/EP/JP compliant filling
- SDS — Up to 14 l 1 % SDS-containing medium with MediPrep 1622
- Memory for 100 methods
- GLP/GMP compliant documentation
- Memory for 50 users with three different access levels

CHEWING GUM TESTER

DRT

Testing for in vitro release of substances from samples into surrounding liquid medium

The ERWEKA DRT is the perfect device for testing of in vitro releases of substances from chewing gums and other dosage forms, that have to be masticated, into the surrounding liquid medium. The vertical up and down strokes of the lower jaw in combination with a revolving movement of the upper jaw provide ideal mastication of the chewing gum and at the same time an agitation of the test medium.

For manual sampling, emptying and cleaning the lower jaw with the test cell can be lowered into a down position, so that the chewing process stops. The test cell, the upper and lower jaw can then be easily removed. A water circulation system controls and regulates the water temperature in the test cell around the media. The chewing gum test apparatus is used to masticate gums and then analyzes the speed at which various substances leave the gum (release). In addition, the device is very helpful for developing candy chewing gums, but it can also be used for unusual purposes such as testing of snuff bags.

Art. No.	Chewing Gum Tester DRT
18620	DRT 1 Chewing Gum Tester (1 test station), incl. manual
18621	DRT 2 Chewing Gum Tester (2 test stations), incl. manual
18622	DRT 3 chewing Gum Tester (3 test stations), incl. manual
18623	DRT 4 Chewing Gum Tester (4 test stations), incl. manual
18624	DRT 5 Chewing Gum Tester (5 test stations), incl. manual
18625	DRT 6 Chewing Gum Tester (6 test stations), incl. manual

HIGHLIGHTS

- 100% USP/EP/JP compliant
- Movement by pneumatic cylinder
- Up to 6 test stations
- Mobile cart
- Temperature controlled water bath
- Easy cleaning

MULTIPLE MEDIA PH CHANGE DISSOLUTION TESTING FOR USP 3 AND 7

RRT 10 BIODIS

With the ERWEKA RRT 10, automatic dissolution testing of different extended and sustained release dosage forms has become easier than ever before. This unit is perfectly suited for simulating the pH changes within the human body. By placing different media in each row, the device reflects varying in vivo gastrointestinal conditions of the body. An automatic sample transport between the rows allows the reliable testing of the extended or sustained release from different dosage forms in various pH zones. The simple to program RRT 10 is the perfect unit for multiple media pH changes for IV/IVC testing and dissolution profiling of a variety of release dosage forms (e.g. tablets, coated tablets and oblongs).

Vessels are placed inside an acrylic water bath with an outlet valve for easy cleaning and the automatic cover system of the RRT 10 reduces media evaporation.

	USP 3	USP 7	USP 3 & USP 7
Height of stroke	100 mm	20 mm	100 mm & 20 mm (changable)
Vessel types	300 ml & 1000 ml for reciprocating cylinder	50 m, 100 ml, 300 ml & 1000 ml for different types of tools	50 ml, 100 ml, 300 ml & 1000 ml for different types of tools
User changeable method	-	-	✓

HIGHLIGHTS

100% — 100% USP/EP/JP compliant

Automated evaporation cover

USP 3/7 — 3 configurations available

Different tools available

Art. No.	RRT 10 BioDis
18534	BioDis dissolution tester RRT 10 USP method 3 & 7 user changeable, 8 rows

THE HIGHLIGHTS OF THE

USP 4 FLOW-THROUGH CELL DFZ II

The ERWEKA flow-through cell tester DFZ II can be used for various applications thanks to its wide range of available cell types, e.g. for testing poorly soluble products or low-dose formulations with sustained release.

Innovations as the cell design with increased leak-tightness and the optimized tubing system with quick locks allow a fast preparation and implementation of dissolution tests. The new leaner cell bodies ensure an improved cell warming and can be heated individually. All USP 4 DFZ II systems can be easily controlled with the Disso.NET 3.X software via a controller.

Standardized cell head

The cell head fits all offered cell bodies and thus enables a faster assembly of cells while offering lower purchasing costs. Through a quick lock in the cell head faster tube mounting is also possible.

Increased leak-tightness

Due to reducing the number of seals to 3 pieces per cell and using flat seals with an increased sealing surface, the process safety can be heightened.

Optimized cell bodies & individual cell heating

The reduction of the cell body provides a better heating and faster preparation of cells. Each cell can be heated individually via a rotary switch.

Compact & corrosion-resistant housing

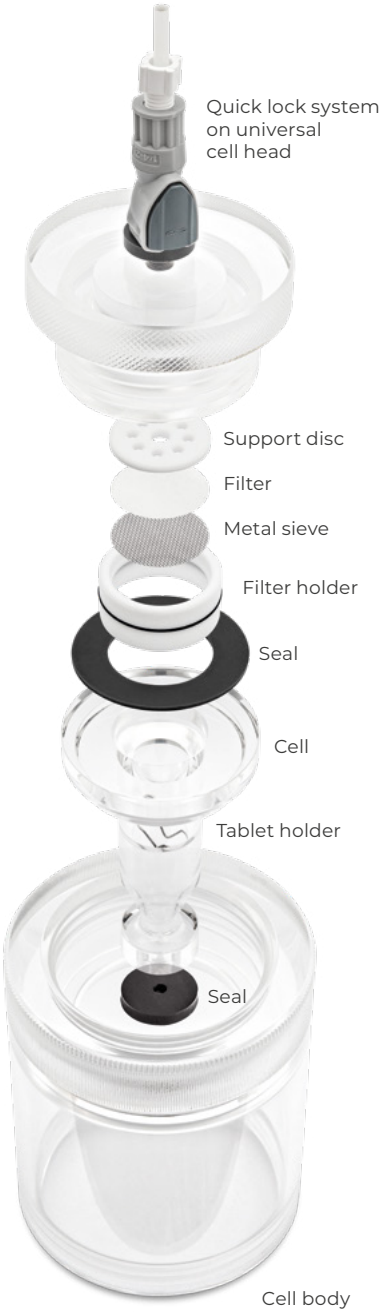
The smaller footprint with clear arrangement of cells in one line saves laboratory space and offers a perfect visual control of the cells at all times. In addition, the tube organizer on the back of the device prevents mixing up the cell tubes.

Easier cleaning

Due to the 3-way-valve for water emptying on the back of the device, the water bath cleaning can be handled much easier. In addition, simple water temperature and water level control are possible with the water level pointer (colour coding) and the two openings for PT 100 sensors on the device cover.

KEY FACTS

- 100% USP/EP/JP compliant
- Variety of different cells available
- Controlled by Disso.NET 3.X
- Independent, closed flow-through system



ADVANCED, NON-LEAKING

CELL DESIGN

Accompanying our flow-through systems, we offer a variety of different cells with a improved design for different purposes - from the standard tablet cell to granulate & powder cells to cells for implants, suppositories and stents.

The standardized cell head fits all offered cell bodies and facilitates along with the new standardized flat seals (only 3 pieces per cell: connection, head and body) handling and assembly of the cells. The optimized cell bodies with decreased cell wall thickness guarantee an improved cell heating.

Quick lock system on the cell head allows instant tube removing.

Thanks to this cell concept, the cells can be mounted easier to the flow-through tester DFZ II and thus enable a faster preparation and performance of dissolution tests.

HIGHLIGHTS

- Variety of different cells available
- 100% USP/EP/JP compliant
- Standardized cell head

Tool for removing the filter holder

DIFFERENT CELLS FOR DIFFERENT PURPOSES

OVERVIEW

Tablet cell 12 mm

Tablet cell 22.6 mm

Granulate & Powder cell

Implant cell

Suppository cell

Special temperature calibration head

Stent cell

Tablet cell 22.6 mm with one-way dialysis adapter

Tablet cell 22.6 mm with cream adapter

Tablet cell 22.6 mm with glass beads & tablet holder

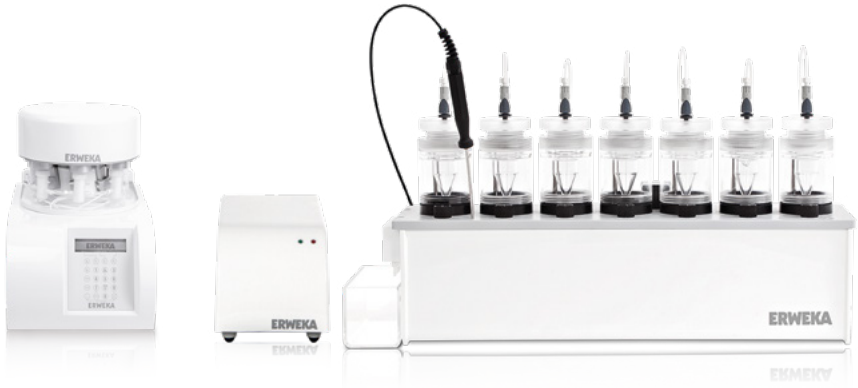
Tablet cell 22.6 mm with glass beads & without tablet holder

THE ENTRY INTO USP 4 TESTING

USP 4 STAND-ALONE SYSTEM

The ERWEKA stand-alone flow-through cell system is perfect for performing simple release tests with manual sampling. Therefore, the flow-through cell tester DFZ II offers with the ERWEKA piston pump HKP 720 and the ERWEKA heater an easy entry into testing with USP 4 systems for a small budget.

The valve-free piston pump transports the test medium with highest precision via seven channels to the flow-through cells and automatically adopts the setting of the flow rate. With the low-vibration heater the water in the water bath can be quickly heated to the required temperature.



Art. No.	USP 4 Stand-Alone System
23437	DFZ II Stand-Alone Flow-through-cell with HKP 720
23439	DFZ II Stand-Alone Flow-through-cell with HKP + temperature sensors
23440	DFZ II Stand-Alone Flow-through-cell with IPC-8

HIGHLIGHTS

100% USP/EP/JP compliant

7x Flow-through cell with 7 test stations

Simple release testing with manual sampling

USP 4 DISSOLUTION TESTING WITH AUTOMATED ANALYTIC

USP 4 CLOSED ONLINE SYSTEM

The USP 4 Closed Online System is our solution with automated analytic for the USP 4 flow-through cell. The software controlled USP 4 system integrates USP 4 flow-through cell testing with directly connected analytic UV/Vis online measurement, resulting in an automated USP 4 workflow.

Furthermore, all features of the stand-alone system can be applied to our online system: the valve-free piston pump with highest precision and the low-vibration heater steadily holds the requested temperature of the waterbath. And our new and improved DFZ II USP 4 cells are also integrated into the software dialogs, making the use of the system as easy as possible.

Art. No.	USP 4 Closed Online System
27735	UV-Vis Online System DFZ II, HKP720, IPC 8, Shimadzu 1900i Plus, Controller+Disso.NET
27736	UV-Vis Online System,HKP720,DFZ II-Temp., IPC8, Shimadzu 1900i Plus, Controller, Disso.NET

Art. No.	USP 4 Closed On-/Offline System
27738	Closed On/Offline System, DFZ II, PT 100, Shimadzu 1900i Plus, HKP, FRL, PC, Disso.NET
27739	Closed On/Offline System, DFZ II, Shimadzu 1900i Plus, HKP 720, FRL 754, PC, Disso.NET

HIGHLIGHTS

- 100% USP/EP/JP compliant
- Flow-through cell with 7 test stations
- Software controlled by Disso.NET
- Integrated UV-Vis analytic
- Audit Trail

USP 4 OPEN OFFLINE SYSTEM

Features of the automated USP 4 Open Offline System

- Handling of unlimited media for testing of low soluble drug substances
- Fully USP compliant
- Automated sample collection
- Sampling of complete fractions into glass vials
- Sampling of representative fractions by splitting into waste and glas vials

Art. No.	USP 4 DFZ II Open Offline System
27038	Open Offline System, DFZ II with HKP 720, FRL 754, Workstation, Disso.NET USP 4
27039	Open Offline System,DFZ II,Temp.Sensor, HKP 720, FRL 754, Workstation, Disso.NET
27037	Open Offline System, DFZ II, IPC-8, FRL 754, Workstation, Disso.NET
18590	Manual switching valve for pH change USP 4
18591	Electronic switching valves 4x for pH change for up to 4 media

USP 4 CLOSED OFFLINE SYSTEM

Features of the USP 4 Closed Offline System

- Specific amount of min. 2 ml to max. 32 ml of media is pumped through the cell continually
- Media transfer station LMT 2 with 8x 1000 ml vessels
- Fully USP compliant
- Fraction collection with 3-way valves
- Long duration test runs with optimized media evaporation
- Media replacement possible

Art. No.	USP 4 DFZ II Closed Offline System
27040	Closed Offline System DFZ II, HKP 720,IPC-8, FRL 754, Workstation, Disso.NET
27041	Closed Offline System DFZ II, temp.sensor, HKP 720, IPC-8, FRL 754, Workstation
17923	LMT 2 Closed Loop unit for USP 4 incl. 500 ml bottles (7 pcs)
19897	100 ml glass bottle (7 pcs.) with safety cap for LMT 2
19898	250 ml glass bottle (7 pcs.) with safety cap for LMT 2
20376	1000 ml glass bottle (7 pcs.) for LMT 2
18602	Filter for USP 4, 0.7µm, 25 pcs, 25 mm
18603	Filter for USP 4, 1.4µm, 25 pcs, 25 mm

EASY MEDIA TRANSFER WITH THE

LMT 2

With the compact ERWEKA media transfer station LMT 2 a closed loop for performing long-term dissolution tests according to USP 4 can be easily created. The LMT 2 is therefore used as a medium reservoir and ensures an optimal media mixing and distribution through the whole release test.

The optimized tubing system with a new tube holder and rotatable bottle caps (safety caps) makes handling easier and saves valuable laboratory space. Using standardized laboratory glass bottles as media vessels also enables an easier media transport for saving and further analysis. The glass bottles are available in 500 ml as standard size and optionally in the sizes 100 ml, 250 ml and 1000 ml. With the comfortable keypad the stirring speed can be easily set.

HIGHLIGHTS

- 100% USP/EP/JP compliant
- Improved tubing
- Wide range of vessel sizes
- Optimal media distribution

FULL DISSOLUTION SOFTWARE SOLUTION FOR FLOW-THROUGH CELL

DISSO.NET USP 4

The ERWEKA Disso.NET USP 4 Software is the perfect companion for our USP 4 systems. The software takes over full control of our USP 4 systems and offers support for all USP/EP dissolution cells used in these systems. It also supports cells for special applications (e.g. cell with cream adapter) and visual guides for formulation placing in the respective cells.

Disso.NET helps you with standard USP 4 dissolution jobs, handles qualifying tasks and provides control over each single function of the connected devices (e.g. pump, flow-through cell and sample collector). In addition, the software includes an easy to handle method editor for comfortable programming of dissolution methods (for highest safety in GMP environment). Our audit trail also generates detailed protocols of all events and times and thus enables tracing changes at any time.

HIGHLIGHTS

- 100% Audit Trail
- MS SQL Database
- Easy control of the USP 4 systems with Disso.NET
- Advanced report generation

DISSOLUTION TESTER

GENERAL OPTIONS

Art. No.	General Options
18334	Evaporation cover for DT HH
21795	Evaporation cover with anti-rotation device for DT HH with ASS-9/18
22342	Water stabiliser with colour indicator for DT, 100 ml blue

Evaporation cover for DT HH

Water stabilizer 100 ml, blue

Evaporation cover with anti-rotation device for DT HH with ASS-8/14 & ASS-9/18 sampling station

Art. No.	CoC (Certificate of Compliance)
18395	CoC for basket, per basket
20267	CoC for basket holders for LH / HH, per holder
18414	CoC for paddle over Disk, per Disk
20268	CoC paddle, per paddle
20269	CoC for shaft LH / HH, per shaft
22444	CoC for bundle, paddle, basket holder
18369	CoC for vessels, per vessel
20272	CoC for mini vessel, per vessel
22449	CoC for rotating cylinder, per rotating cylinder

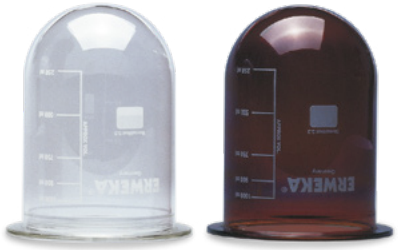
VESSELS AND MINI VESSELS

Art. No.	Vessels
18365	Vessel for DT, glass, 1000 ml, numbered
18366	Vessel for DT, UV-resistant amber glass, 1000 ml, numbered
18367	Vessel for DT, glass, 2000 ml, numbered
18368	Vessel for DT, UV-resistant amber glass, 2000 ml, numbered
19115	Apex Vessel for DT, glass, 1000 ml, numbered

Art. No.	Mini vessels
18373	Mini vessel for DT, glass, 400 ml, numbered
18374	Mini vessel for DT, UV-resistant amber glass, 400 ml
18375	Conversion ring for 400 ml Minivessel (excluding vessel)
18378	Automated sampling station (LH) for Mini vessel 400 ml, for DT 72x/82x
19978	Automated sampling station (HH) for Mini vessel 400 ml, for DT 72x/82x
22399	Conversion set 1000 ml to 400 ml including Mini vessel and Mini paddle LH
22398	Conversion set 1000 ml to 400 ml including Mini vessel and Mini paddle HH

100 ml and 400 ml Vessel

The 400 ml Mini vessel apparatus is a reduced scale of the USP method 2, commonly used for low-dose formulations and poorly available drugs.



Glass vessel and UV-resistant vessel

DISSOLUTION ACCESSORIES

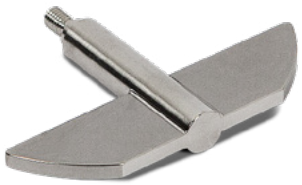
Art. No.	DT Shafts for USP Methods 1, 2, 5, 6
22391	Shaft unit LH for basket or paddle (st. steel) or Bundle (st. steel), incl. carrier, numbered
22436	Shaft unit LH for paddle (PTFE coated), numbered
22438	Shaft set (2) LH for bundle basket holder + PTFE coated paddle, numbered
22393	Shaft LH 2000 ml for basket, paddle (st. steel) or bundle (st. steel)
22394	Shaft unit HH for Basket or Paddle (st. steel) or Bundle (st. steel), numbered
22437	Shaft unit HH for PTFE coated Paddle, numbered
22439	Shaft set (2) HH for Bundle basket holder + PTFE coated paddle, numbered
22396	Shaft HH 2000 ml for basket, paddle (st. steel), or bundle (st. steel)

Art. No.	Baskets USP 1
22402	Basket holder, stainless steel, numbered
18391	Basket, mesh 10, stainless steel, numbered
18392	Basket, mesh 20, stainless steel, numbered
18393	Basket, mesh 40, stainless steel, numbered
18394	Suppository basket, plastic

Basket holder, stainless steel,
2 O-rings, numbered

Baskets mesh 10, 20 and 40 (standard)

Art. No.	Paddles USP 2
22403	Paddle, stainless steel, numbered
22404	Paddle (PTFE coated) for 1000 ml, numbered
22405	Paddle (PTFE coated) for 2000 ml, numbered
22406	Bundle, paddle and basketholder, stainless steel, numbered
22407	Bundle, paddle (PTFE coated), and basket holder, stainless steel, numbered



Paddle, stainless steel, numbered

Bundle, paddle (PTFE coated) & basket holder, stainless steel

Art. No.	Paddle over Disk USP 5
18412	Height Adjustment tool Paddle over Disk USP 5 Distance
18413	Paddle over Disk USP 5, incl. sieve mesh 125 µm, numbered

Paddle over Disk USP 5, for holding transdermal patch, mesh 125 µm, numbered

Rotating Cylinder

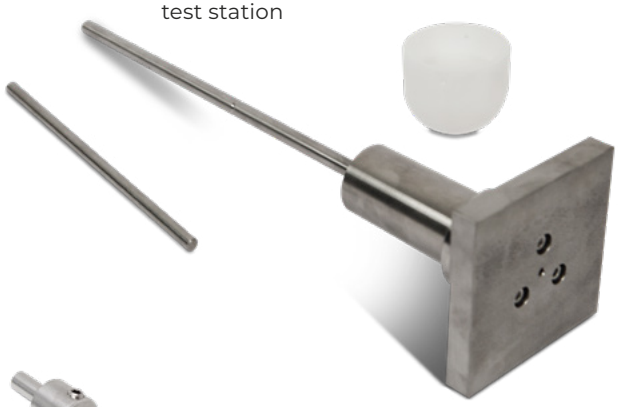
Extraction Cell

Art. No.	Felodipine basket
18422	Felodipine stationary basket for low-head use
18423	V-shaped low head vessel cover (plastics) for fixing Felodipine basket
18424	V-shaped vessel cover (PTFE coated) for fixing Felodipine basket
18425	Felodipine stationary basket for high-head use
18426	Low-evaporation high-head vessel cover (plastics) for fixing Felodipine basket
22411	ERWEKA Wood Apparatus (intrinsic) for 1 test station
18429	Manual hydraulic press for Wood Apparatus

Art. No.	Rotating Cylinders USP 6
22408	Rotating cylinder, stainless steel, short, numbered
22409	Rotating cylinder, stainless steel, long, numbered

Art. No.	Extraction Cell
18421	Extraction cell, ID=20/27 mm, acc. to EP 2.9.4
22252	Extraction cell, ID=32/38 mm, acc. to EP 2.9.4
22253	Extraction cell, ID=40/45 mm, acc. to EP 2.9.4
22254	Extraction cell, ID=50/52 mm, acc. to EP 2.9.4

Wood Apparatus for 1 test station



Felodipine stationary basket

Art. No.	Sinkers
18379	Japanese sinkers, set of 6 pcs, stainless steel, USP compliant
18380	Spider sinkers, plastic, set of 6 pcs

Japanese sinkers,
set of 6

Spider sinkers, plastic,
set of 6

Art. No.	Enhancer Cell
22400	Enhancer cell set, incl. 200 ml vessel round bottom and mini paddle HH shaft
22401	Enhancer cell set incl. 200 ml flat bottomed glass, mini paddle, HH shaft
18382	Vessel for Enhancer cell, 200 ml, glass, rounded bottom
18384	Enhancer cell PTFE coated for testing creams, ointments, gels
21612	Vessel for Enhancer cell, 200 ml, glass, flat bottom

Enhancer Cell

CONSUMABLES

Art. No.	Inline Filters
18430	Filters (1.000 pcs), Poroplast, 1 µm
18431	Filters (1.000 pcs), Poroplast, 4 µm
18432	Filters (1.000 pcs), Poroplast, 10 µm
21702	Filters (10.000 pcs), Poroplast, 10 µm
29581	Filters (1.000 pcs), Poroplast, 20 µm

MECHANICAL CALIBRAION

Art. No.	Tools Mechanical Calibration
18438	Dissolution tester validation kit according to FDA, certified
18439	Qualification kit (upgrade) according to Mechanical Calibration standards of FDA
18440	USP 5 Calibration Tool for height measurement, certified

DOCUMENTS

Art. No.	QA Documents
27425	SOP document for IQ/OQ of all dissolution testers in EN/DE
26980	IQ protocol for all dissolution testers in EN/DE
26981	OQ protocol for all dissolution testers in EN/DE
25150	PVT documents for all dissolution testers in EN/DE
29212	OQ evaporation test in EN/DE
25850	FIP (Final Inspection Protocol) for DT Dissolution Tester

Different types of filters

Art. No.	PVT Reference Tablets
29234	USP Reference Standard: Dissolution Performance Verification Standard - Prednisone
18442	Prednisone, 250 mg

Refernce Tablets

Tools Mechanical Calibration

MANUAL SAMPLING

Art. No.	Manual Sampling
18357	Manual sampling cannula LH USP 1 (basket), stainless steel
18355	Manual sampling cannula LH USP 2 (paddle), stainless steel
18361	Manual sampling cannula HH USP 1 (basket), stainless steel
20422	Manual sampling cannula HH USP 2 (paddle), stainless steel

AUTOMATED SAMPLING

Art. No.	Automated Sampling
18350	Cleaning reservoir (acrylic glass) for 8-station ASS
18352	Cleaning- and calibration reservoir for 8-station ASS
18351	Cleaning reservoir (acrylic glass) for 14-station ASS
23208	Cleaning- and calibrationreservoir for 14-station ASS

Automated sampling station ASS-9 on top of a DT from the DT 950 series

DT 950 OPTIONS

Art. No.	DT 950 Options
27237	Manual tool for configuring sampling height 1000ml, USP1 und USP2
27818	Manual tool for configuring sampling height 2000ml, USP1 und USP2
27345	Automated tablet drop magazine for DT 95x LH
27241	Manual sampling cannula, LH, USP 1 und USP 2 (Basket & Paddle)
27244	Manual sampling cannula, HH, USP 1 und USP 2 (Basket & Paddle)
27460	ASS-9 LH automatic sampling station, PTFE coated tubing 3.0 mm, DT 95x
27461	ASS-9 LH automatic sampling station, with 8 temperature sensors DT 95x
27563	ASS-9 HH automatic sampling station, PTFE coated tubing 3.0 mm, DT 95x
27562	ASS-9 HH automatic sampling station, with 8 temperature sensors DT 95x

Manual sampling cannula, LH USP 1 with syringe connected to stainless steel sampling probe

Manual sampling cannula, HH USP 1 with syringe connected to stainless steel sampling probe

Syringe connected to stainless steel sampling probe

DISSOLUTION SYSTEM OPTIONS

Art. No.	Filtration
18497	AFC 825 - 12 V membrane filter exchange system for 6 stations
18499	AFC 825 - 16 V membrane filter exchange system for 8 stations

AFC automatic membrane filter exchange system

Art. No.	Others
23172	Metrohm pH Meter for connection to Disso.NET

Art. No.	FRL sample collector racks
26990	Rack 26 x 8 for 12 ml glass tubes
26991	Rack 18 x 8 for 25ml glass tubes
18509	Rack for 26 x 8 HPLC vials, 1.8 ml
18510	Rack for 26 x 8 HPLC vials, 4.0 ml
18511	10 ml recalibration rack for HPLC vials 1.8 ml and 4.0 ml

Rack with HPLC vials

Art. No.	Glass tubes for FRL
18512	Glass tubes 12 ml for FRL, 100 pcs.
18513	Glass tubes 25 ml for FRL, 100 pcs.
18514	Glass tubes amber glass 25 ml, 100 pcs.

Sampling into UV-Vis glass tubes

Art. No.	Cuvettes for UV/Vis
18521	Cuvette, 10 mm path length, flow-through optimised (standard)
18518	Cuvette, 1 mm path length
18520	Cuvette, 5 mm path length

Art. No.	QA Documents
29228	Bundle IQ (Installation)/OQ at Disso.NET 4.x (USP 1/2/5/6) in EN/DE
29229	Bundle IQ (Installation and Migration) at Disso.NET 4.x (USP 1/2/5/6) in EN/DE
29230	Bundle IQ (Installation and Migration)/OQ at Disso.NET 4.x (USP 1/2/5/6) in E/D
27548	SOP IQ/OQ DT systems with Disso.NET, UV, FRL & HPLC Sampler in EN/DE
29180	SOP IQ/OQ/AVT DT Offline System (without Disso.NET)
28691	SOP AVT DT systems with Disso.NET, photometer, FRL & HPLC sampler in EN/DE
27706	IQ protocol DT systems with Disso.NET, photometer, FRL & HPLC sampler in EN/DE
29181	IQ protocol DT Offline System (without Disso.NET) in EN/DE
27708	OQ protocol DT systems with Disso.NET, photometer, FRL & HPLC sampler EN/DE
29182	OQ protocol DT Offline System (without Disso.NET) in EN/DE
29224	OQ photometer with Disso.NET according to USP & EP in EN/DE
24958	AVT protocol DT systems with Disso.NET, photometer, FRL & HPLC sampler in EN/DE
29183	AVT protocol DT Offline System (without Disso.NET) in EN/DE
27815	SOP for Disso.NET 4.x qualification (USP 1/2/5/6) in EN/DE
26382	IQ protocol for Disso.NET 4.x installation (USP 1/2/5/6) in EN/DE
26383	OQ protocol for Disso.NET 4.x (USP 1/2/5/6) in EN/DE
26384	IQ protocol for Disso.NET 4.x upgrade (USP 1/2/5/6) in EN/DE
26954	IQ protocol for Disso.NET 4.x migration from PC A to B (USP 1/2/5/6) in EN/DE
26870	SIP System Inspection Protocol for DT System with Disso.NET
26871	FIP Final Inspection Protocol for Offline System

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