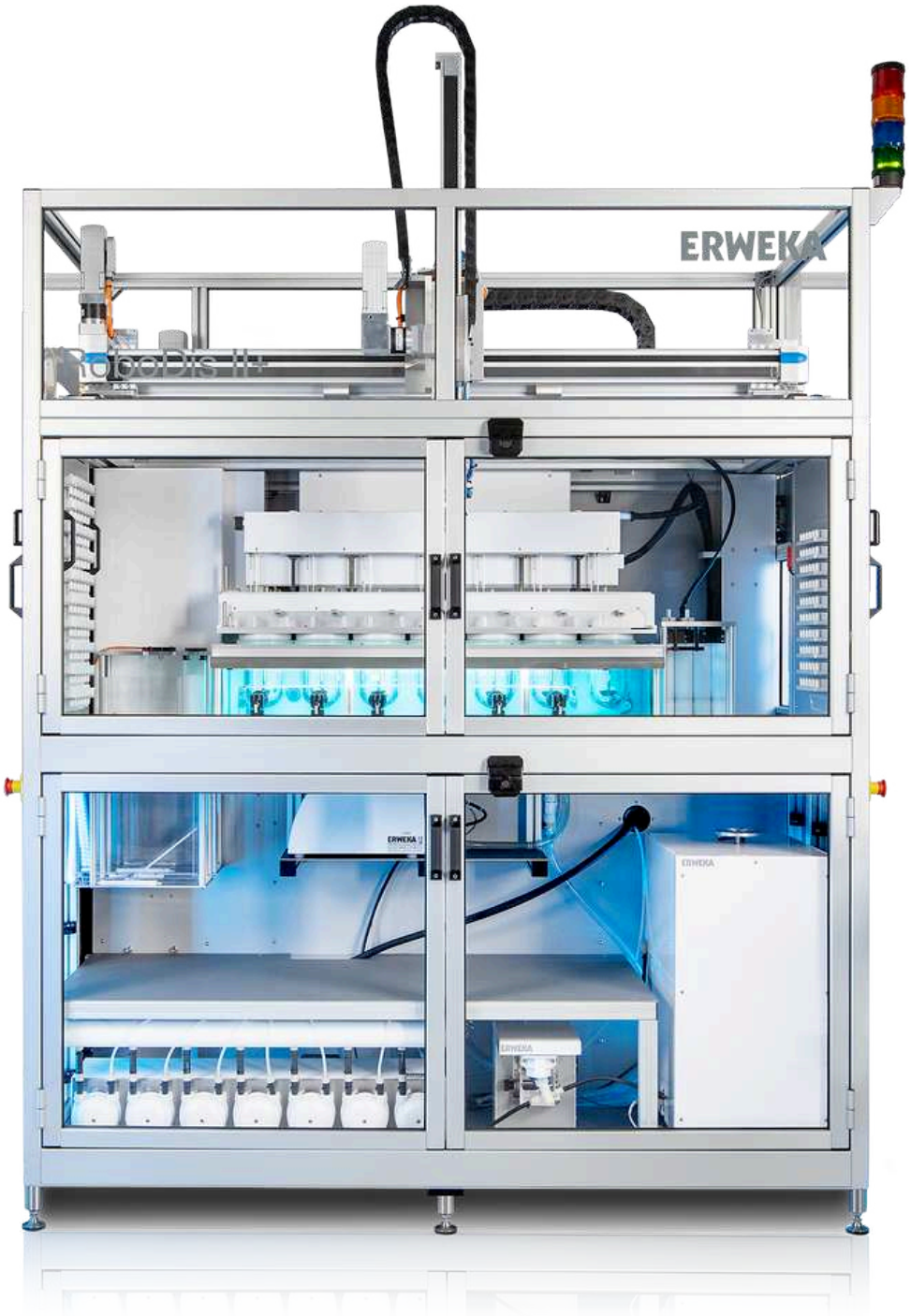
ERWEKA
a VERDER company



FULLY AUTOMATED DISSOLUTION SYSTEM

ROBODIS II+

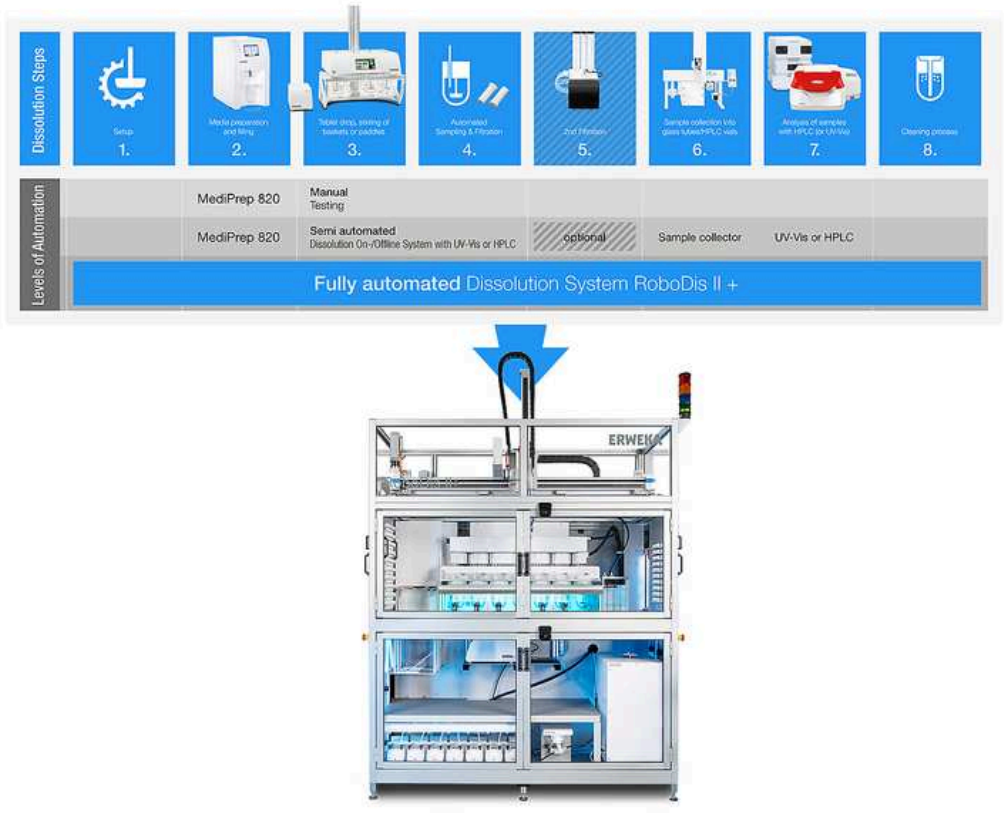
RoboDis II+ is the only simultaneously operating, fully automatic dissolution test system currently on the market. All stages of the dissolution processes are computer-controlled and are therefore carried out completely without user intervention.

The key element of the fully automated system is the Disso.NET software developed by ERWEKA, which controls all system functions, including precise movement of the robot arm, control of the analyzers, data processing and full documentation.

In the standard configuration, the RoboDis II+ tests up to 10 batches according to USP methods 1 (basket) or 2 (paddle). The parallel sampling approach enables very short cycle times for recording detailed drug release profiles, which can be selected by the user. Integrated System Suitability Tests (SST) and video monitoring ensure a high level of reliability. Like all ERWEKA products, the RoboDis II+ is fully USP / EP / JP compliant.

FULLY AUTOMATED DISSOLUTION SYSTEM ROBODIS II+

SMALL FOOTPRINT, GREAT RESULTS



Three complete semi-automatic dissolution testers including media preparation and vessel cleaning - that's how much floor space can be saved with a RoboDis II+ 10-batch system that requires no more than 2x1 m of floor space. With the RoboDis II+, the entire dissolution process can be automated. This enables fully automated testing, including set-up, media preparation and the automatic cleaning process.

ADVANCED RESOLUTION SYSTEM WITH NUMEROUS FUNCTIONS

VERSATILE APPLICATIONS

PRODUCTIVITY BOOSTER

ROBODIS II+ FOR QUALITY CONTROL

- Planned productivity to suit your requirements with 10 or 40 batches
- Non-stop testing: high sample volumes - 40 batches
- Parallel action
- Robotic precision & fault monitoring
- Space-saving footprint

FLEXIBLE SPECIALIST

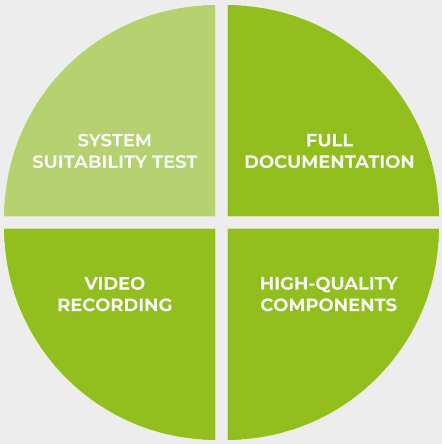
ROBODIS II+ IN R&D

- Multiple dosage forms
- Flexible filtering options
- pH change: half change and optional full change
- Various options for connecting to analytic devices
- Six reference standards

INNOVATIVE ROBODIS II+ SAFETY SYSTEMS

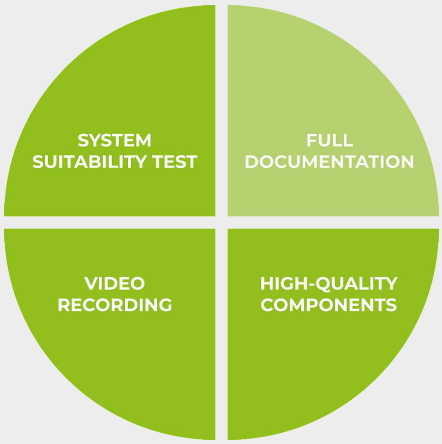
NOT SMARTER, BUT MORE RELIABLE

RoboDis II+ performs routine tasks more precisely than any human operator - but without a human operator, all its powerful, fully automated functions would be of no value. It is the operator who defines the test methods, checks the plausibility of the results and interprets the obtained data. To enable the operator to focus on these tasks, the RoboDis II+ has been equipped with a range of safety functions.



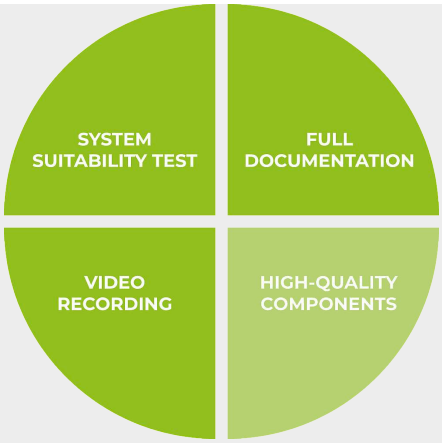
System Suitability Test

In each individual process step, the RoboDis II+ checks itself using integrated System Suitability Tests (SSTs). Several built-in light barriers validate the steps performed by the RoboDis II+, preventing false starts.



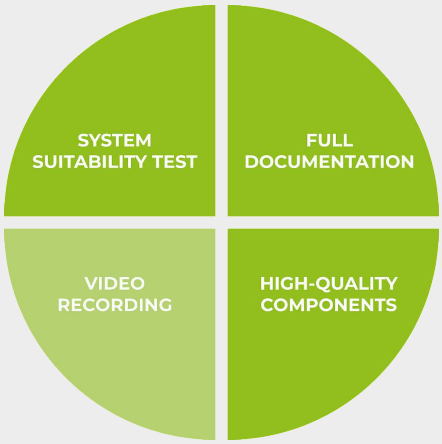
Full Documentation

Each step of the test is logged in accordance with industry standard 21 CFR Part 11. This, for example, allows for checking whether the RoboDis II+ has fully tested all 40 batches over the weekend.



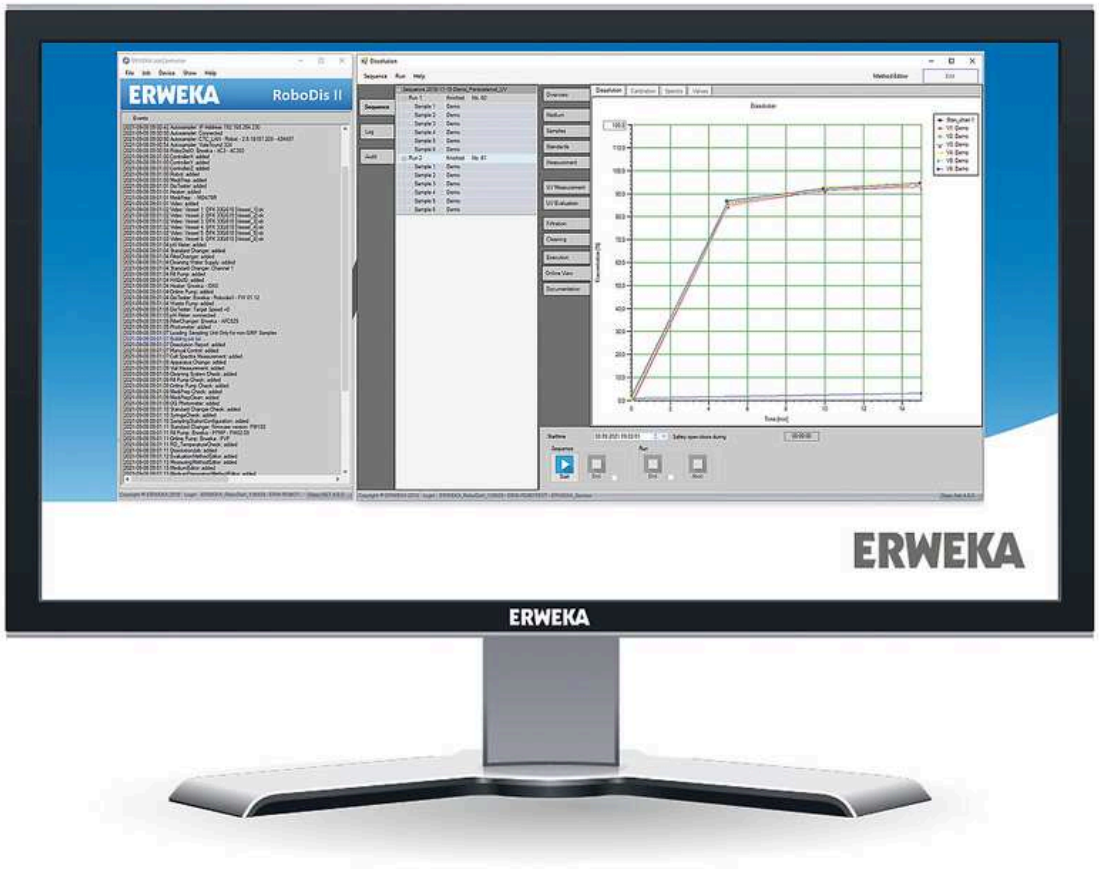
High-Quality System Components

RoboDis II+ is built with proven, reliable system components. Among these are the maintenance-free PVP pump from ERWEKA and the robot arm from the internationally renowned pneumatics manufacturer Festo. The use of premium components guarantees maximum precision and minimum downtime.



Video Recording

The RoboDis II+ optionally records the entire resolution process with six integrated video cameras. This enables the validation of the entire test after completion or the overlaying of the dissolution curve with a time-lapse video recording. Thanks to the LED light bar, the water bath can be illuminated at night, enabling 24-hour video recording without the need for external lighting.



ROBODIS II+ KEY ELEMENT

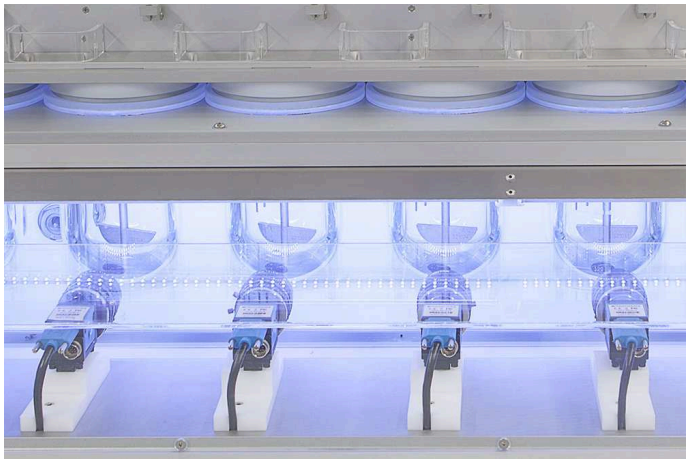
DISSO.NET

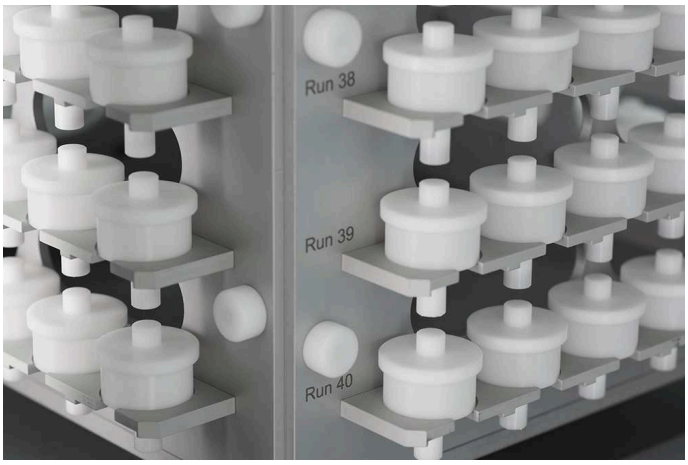
The RoboDis II+ is operated fully automatically via its integrated controller, which is equipped with the Disso.NET software. The software, specially developed by ERWEKA for this purpose, is the key element of the RoboDis II+ system: the desired dissolution test methods can be defined and started using a user-friendly editor. Disso.NET then controls all steps of the dissolution process from media preparation to analysis. The software also controls the precise movement of the robot arm and the connected analyzers. Disso.NET logs all test results and times, automatically creating an audit trail. Once the test is complete, the software generates comprehensive reports and allows all results to be exported. In addition, the software controls the System Suitability Tests (SST) and the video recording functions.

HUMAN-ERROR PROOF

REAL 24/7 TESTING

Thanks to the newly developed LED light strip, the water bath can also be illuminated at night, making 24-hour video recordings possible without the need for external lighting. The LED light bar is very energy efficient and provides the perfect brightness for the new gigabit Ethernet camera system. The RoboDis II+ supports up to six of these new cameras, which are simply connected to the controlling PC using the existing Ethernet network connection in the RoboDis II+.





PERFECT FOR HIGH VOLUME TESTING

HIGHLY PRODUCTIVE: 40-BATCH SOLUTION

Our 40-batch magazine for the RoboDis II+ ensures fully automated dissolution test runs with up to 40 sample batches. In addition to the 40-batch sample holder, the RoboDis II+ also offers a 40-batch filter holder. In combination with the LED light bar, the RoboDis II+ is now able to continuously test samples 24 hours a day, 7 days a week.

FULLY AUTOMATED DISSOLUTION SYSTEM ROBODIS II+

PRODUCT HIGHLIGHTS

ROBOTIC ARM

At the core of the RoboDis II+ testing process is our advanced pneumatic robotic arm. This arm assembles all samples, adds and removes filters and is even responsible for filling and cleaning the vessels, saving operators an enormous amount of time on these repetitive tasks.

SEVEN TEST VESSELS

Seven USP-compliant test vessels in the RoboDis II+ system support testing in R&D and quality control. In quality control, for instance, six samples can be compared with a reference sample. Alternatively, seven different samples can be tested in parallel in R&D.

VIDEO RECORDING

The RoboDis II+ is equipped with 6 video cameras and an LED light strip. The water bath can be easily illuminated and the new video capturing capabilities can be used without external lighting. In addition, video recording of the dissolution process is possible in time-lapse mode.

BASKETS, PADDLES & SINKERS

The RoboDis II+ supports the use of both paddles (USP 2) and baskets (USP 1), both of which can be exchanged by the user. It also supports the use of sinkers measuring up to 34 mm. The dropping and removal of sinkers is fully automatic using the sinker tool supplied.

SAMPLE MAGAZINE FOR 10, 20 OR 40 BATCHES

In the version with 40 batches, the RoboDis II+ enables genuine 24/7 testing and is able to process 40 batches without human intervention.

PH CHANGES

The optional pH measurement permits pH changes according to USP method A (half change) and method B (full change).

FILTER MAGAZINE

Poroplast filters are fitted fully automatically by the robot arm for each test.

ONLINE UV-VIS ANALYSIS OR HPLC

RobDis II+ supports integrated online UV-Vis or HPLC analytical devices. The samples are taken fully automatically and transferred to the analyzers.

PREMIUM SERVICE FOR A PREMIUM PRODUCT

360° SERVICE

Installation

One-week professional installation and commissioning of the RoboDis II+ by certified ERWEKA technicians

Qualification

Professional implementation of the necessary qualifications for the RoboDis II+

Preventive Maintenance

Preventive half-yearly maintenance services ensure a long service life for the RoboDis II+

Device Trainings

Profound user knowledge through hands-on courses and training

24h RoboDis Hotline

Personal advice and direct clarification of questions through a 24-hour RoboDis hotline

Fast Repair Service

Reliable, quick repair service by highly qualified staff or directly at the ERWEKA premises

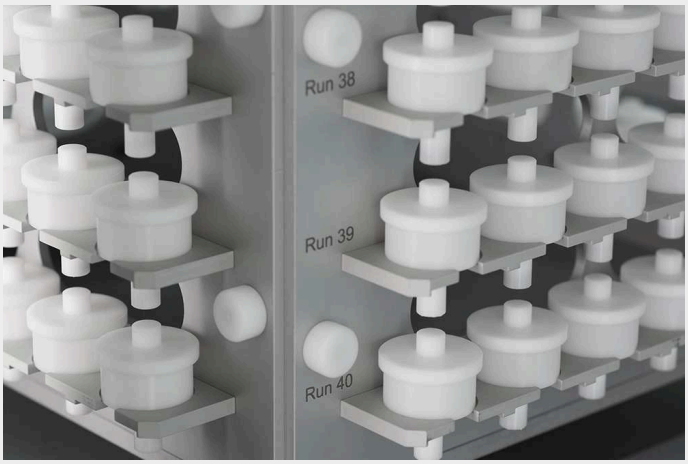
Service Contracts

Customized service contracts to ensure the durability and high precision of the testing equipment and maintain control of operating costs for years to come

Highly-Qualified Customer Support

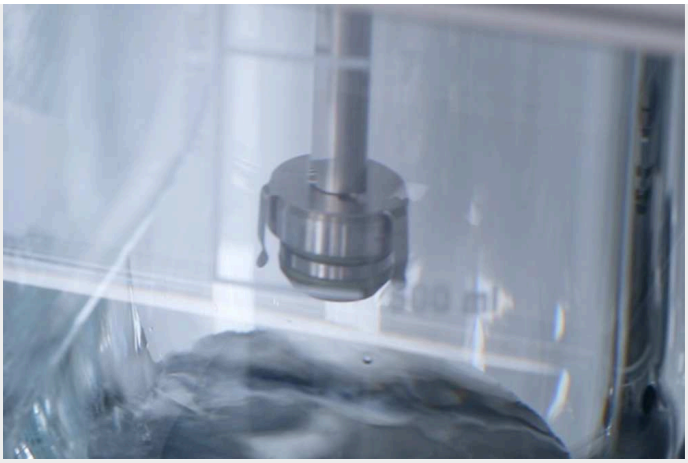
Powerful, global service network with highly qualified and experienced service employees

KEY FEATURES



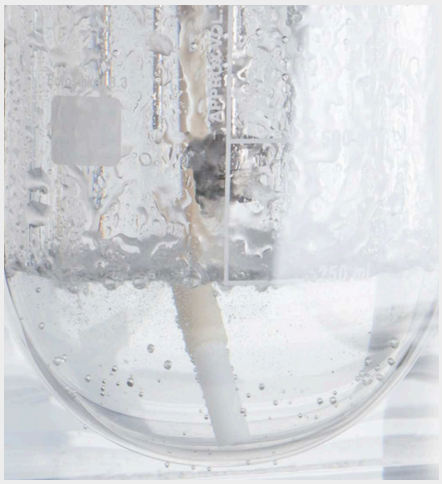
Massive Throughput for Maximum Time Reduction

- Fully automatic dissolution tests for up to 10 batches (standard version)
- Fully automatic dissolution tests for up to 40 batches
- 100% USP / EP / JP compliant
- Full system control using a reliable industrial robotic arm
- Parallel sampling approach for the next release medium
- Control by validated Disso.NET software based on Microsoft SQL server (state-of-the-art dissolution software)
- Integrated, flexible bidirectional interface to various IT systems



Versatile Methods & Full Support for pH Changes per USP

- USP methods 1 and 2: basket and paddle
- pH changes according to USP method A (half change) and USP method B (full change)
- pH measurement in each vessel
- Handling of the pH sensor by robotic arm
- Documentation of all obtained data, including pH meter calibration
- Parallel tablet drop
- Handling of sinkers up to 34 mm and "Japanese sinkers"
- High accuracy and reliability of process steps
- Support pellets and granulates
- Baskets mounted by robotic arm
- Used baskets are automatically discharged into cleaning container
- Handling of up to 6 different media / concentrates

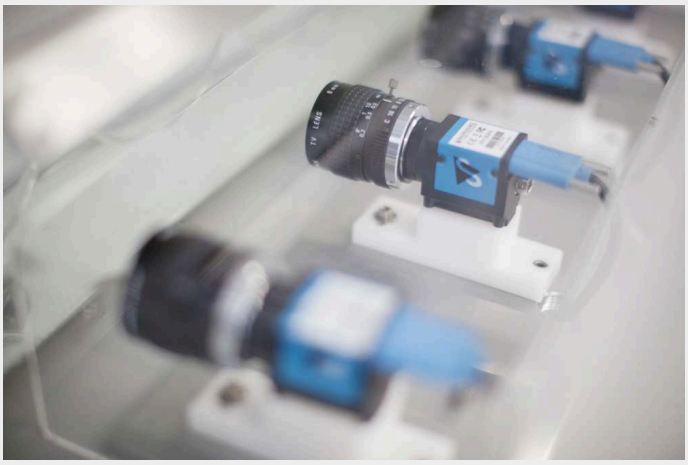


Massive Time Savings Due to Integrated Media Preparation & Cleaning Routines

- Automatic media preparation and supply
- Mobile tank for 120 liters of medium with optional stirrer
- Supports up to 6 (SUPAC) different media or media concentrates per start
- Preheating and vacuum degassing in accordance with USP guidelines
- Dosing with gravimetrically controlled precision piston pump
- Parallel preparation of the next medium during dissolution test run
- Supports the handling of foaming media
- Parallel cleaning takes place automatically
- Number of cleaning steps can be freely selected
- Result of the cleaning process is checked (SST)
- Contaminated media can be separated
- Integrated water stop

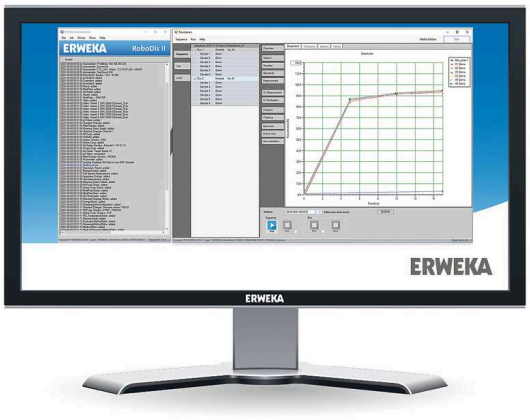
Broad Support for Different Types of Analyzers

- Standard filtration with 1 µm to 20 µm inline filters in accordance with USP
- Additional filtration with flat membrane filters (≥ 0.22 µm)
- Support of various brands of photometers and HPLC systems (e.g. Agilent, Waters, Shimadzu, Perkin Elmer, Hitachi, Analytik Jena)
- Closed-loop sampling system available for UV online and / or HPLC online / UPLC online
- Parallel sampling with valve-free ceramic piston pump PVP, virtually maintenance-free
- Sampling time points independent of HPLC run time
- Fraction collection in glass tubes or Peltier-cooled HPLC vials



Featuring 40 Batches & Video Recording

- 10, 20 or 40 batches
- LED light strip illuminates water bath, allowing the use of new video recording functions without external lighting
- Perfect brightness for night-time recordings without illumination of the entire tab
- Video recording of the dissolution process in time-lapse mode
- Energy-efficient
- Support for formulation and dissolution method development
- Gigabit Ethernet camera connection - high bandwidth and easy integration into local RoboDis II+ network



Full System Control

- 21 CFR Part 11 compliant Disso.NET software suite according to GAMP 5
- Interactive communication between RoboDis II+ and analysis method
- User-defined reports via "Crystal Reports"
- Online control of rpm and temperature
- Bidirectional LIMS interface via XML
- User administration with Active Directory

FULLY AUTOMATED DISSOLUTION SYSTEM ROBODIS II+

TECHNICAL DATA

Weight	760 kg, note floor load capacity
Dimensions Housing, Transport (H x W x D)	1800 x 2020 (total) x 1020 (total) mm
Dimensions Housing, Installation (H x W x D)	2800 x 2020 (total) x 1300 mm
Power supply: Type	Tri-phase four-conductor system (L1-L3/N/PE)
Operating voltage	400 VAC, 50/60 Hz
Control voltage	24 VDC
Power rating	approx. 5.2 kW
Fuse	32 A
Water	Connections for cleaning and demineralized water max. 5 bar (0.5 Mpa) set to approx. 3-4 bar for MediPrep max. 60 °C Connection for 1/2-inch hose
Connection for waste water with low contamination level	Connection for 3/4-inch hose
Connection for waste water with high contamination level	Connection for 3/4-inch hose
Height of the waste water connections	Max. 20 cm above the ground
Connection for media tank	Norprense® hose ID 1/4-inch
Doors	Two-leaf, makrolon, transparent, safety lock
Robot Supplier	Festo
Model	RP (room portal)
Frame material	Aluminium
Operating range	1420 mm x 540 mm x 600 mm (xyz)
Interfaces (control)	ModBus TCP/ EtherCAT
Interfaces (configuration)	Standard Ethernet LAN
Angle of rotation	180° (electrical rotary drive)
Robotic tools	Filling and cleaning tools, pH probe
Number of testers	1
Test stations	7 in a row
Test station connections	With toothed belt and gear wheel
Agitators (shaft and stirring elements)	Stainless steel 1.4571 (316Ti)
Stirring element	Paddle (standard), basket (optional)

Operation	DC motor with speed sensor, sequential agitator switch (stepper motor)
Vessel	Glass (borosilicate)
Evaporation	Less than 1% in 24 hours
Time measurement	Time in realtime, tolerance ± 1 sec.
Temperature measurement	PT 100 sensor
Temperature control	± 0.1 °C
Temperature in the vessel	37 °C ± 0.5 °C; temperature range +4 °C (RT) to 40 °C ± 0.5 °C
Stirring speed	25 min ± 2 min up to 200 min ± 4 min
Water bath	Acrylic glass
Water bath volume	Approx. 30 l
SPS	CodeSys Version 3.5
Other connections	PT 100 connection, heating connection and interface
Control/operation	Controller, monitor, keyboard, mouse, WIN software
Software	ERWEKA Disso.NET software, video software
Heating system	Flow-through, type ERWEKA DH 1520
Heating capacity	1500 W
Flow-through speed	6 l/min
Interface	RS 232
Automatic production/degassing/ heating	MediPrep (ERWEKA)
Production	Made from up to 6 concentrates + de-ionised water or pre-mixed medium; Vmax MediPrep: 8000 ml
Degassing	Vacuum > 190 mbar absolute
Heating	Flow-through heating 1500 W, max 40 °C
Dosing	Dosing via filling pump
Scale	SST with load cell
Pump type	Piston pump, ceramic head
Pump Interface	RS-232
Vessel filling	250 ml - 1000 ml +- 1% (volumetric filling)
Magazines, basket	Two, each with 6 x 10 rows - USP Method 1 (only for 40-batch)
Magazines, tablet holder	Tablet size max. ø 35 mm
HPLC device	max. 2 HPLC systems
Automatic filter changer (opt.)	AFC (ERWEKA)
Flow-through cuvette (opt.)	1-10 mm

Cleaning: Suction pump	CP 7+ diaphragm pumps
Cleaning: Flow-through	Approx. 1000 ml/min
Cleaning: Hoses	Norprene®
Protection type	I/EN 61140
Protection class	IP 21/IEC 529
Ambient temperature in operation	+10 °C to +30 °C (Ambient temperature at least 5 °C lower than test temperature)
Storage and transport temperature	+5 °C to +40 °C
Relative humidity	25 to 80 % non-condensing