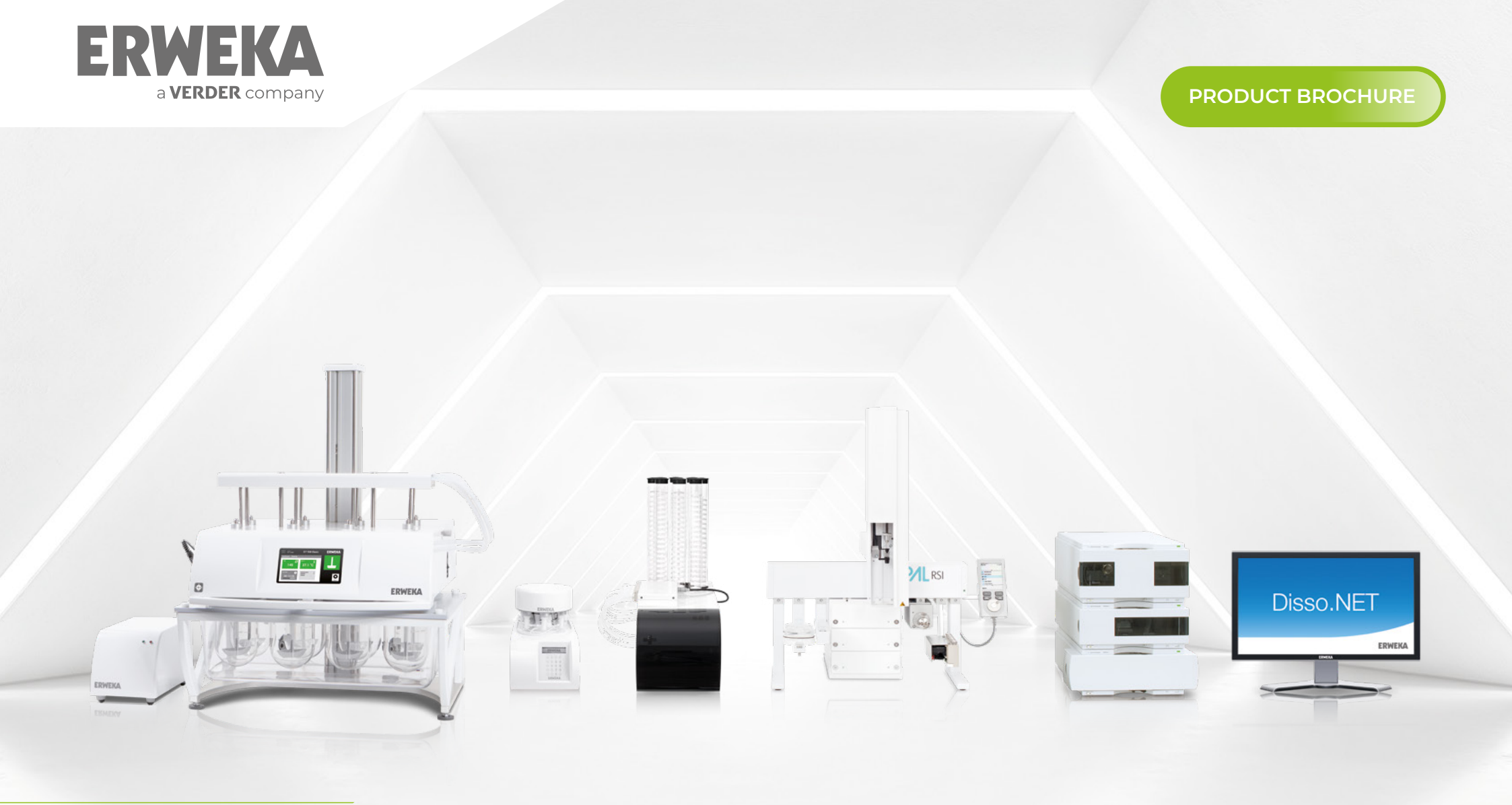
ERWEKA
a VERDER company

PRODUCT BROCHURE




DISSOLUTION ON-/OFFLINE SYSTEM WITH HPLC

# SEMI-AUTOMATED DISSOLUTION TESTING WITH HPLC ANALYSIS

# SEMI-AUTOMATED DISSOLUTION SYSTEM

## WITH HPLC ANALYSIS

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 RSI sampling and online HPLC chromatography. The entire system is controlled by our Disso.NET software.

For standard filtrations (0.45 µm pore size), our automated filter changer AFC 825 can be used in combination with our maintenance-free PVP pump. Other pore sizes are available upon request. In addition to providing precise and simple control of the entire system, Disso.NET enables accurate documentation of the complete test process, including an audit trail that records all system operations—from automatic logging of sampling times to continuous recording of temperature and rotation speed in each vessel.


100%
USP/EP/JP
compliant

RSI sample collector
and sample storage for
HPLC

21 CFR Part 11 conform
in conjunction with
Disso.NET software

5 of 8 dissolution steps
are automated

### Dissolution Tester DT 950 & DT 9510 Series

The dissolution tester of the DT 950 & DT 9510 series are 100% compliant to USP methods 1, 2, 5 and 6 and can be operated in high-head as well as low-head mode. The 7” touch display shows the 3 main parameters during the test.

### 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 with almost wear-free ceramic pump heads.

### Double filtration with AFC 825

For HPLC analyses, fine-pore filtration is often required to prevent particle-related contamination or damage to the HPLC column. Suitable pore sizes (e.g. 0.45 µm) are available. The high-precision, practically maintenance-free PVP pump in combination with the automated filter changer are particularly suitable for this purpose.

### HPLC sample collection & analysis

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

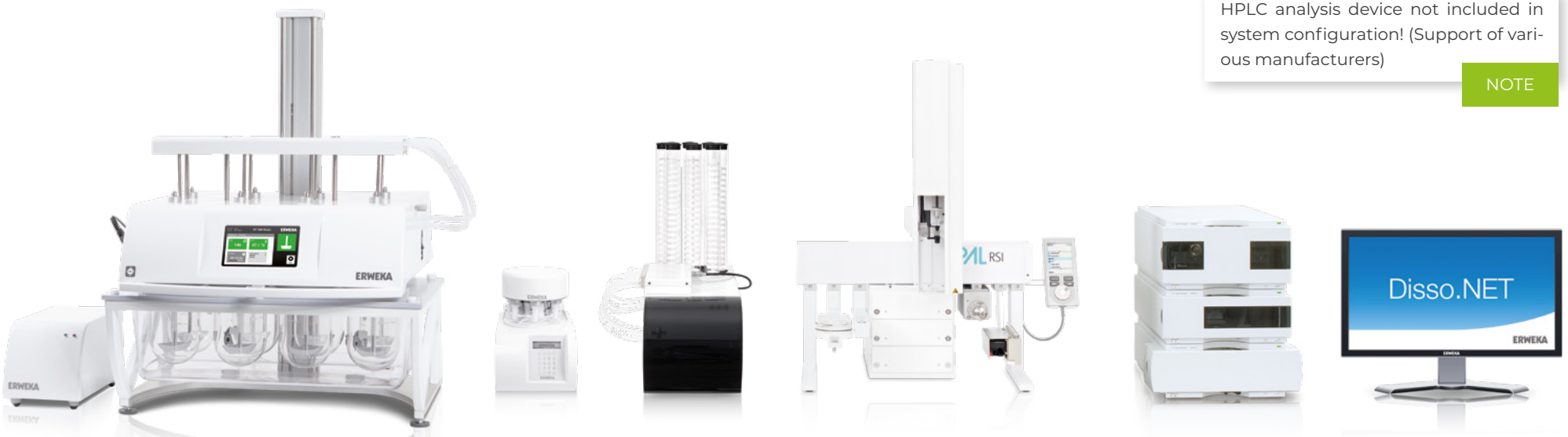
### Disso.NET Software

Our advanced dissolution software solution Disso.NET takes over full control of the dissolution system and offers extensive functions, enhanced user management and diverse data export options (e.g. LIMS connection).

| Dissolution Steps | Setup 1. | Media preparation and filling 2. | Tablet drop, stirring of baskets or paddles 3. | Automated Sampling & Filtration 4. | Sample collection into glass vials / HPLC vials 5. | 2nd Filtration 6. | Analysis of samples (UV-Vis or HPLC) 7. | Cleaning process 8. |
|---|---|---|---|---|---|---|---|---|
| | | MediPrep 820 | Semi automated Dissolution On-/Offline System with HPLC | | Sample collector | AFC 825 | HPLC | |

HPLC analysis device not included in system configuration! (Support of various manufacturers)

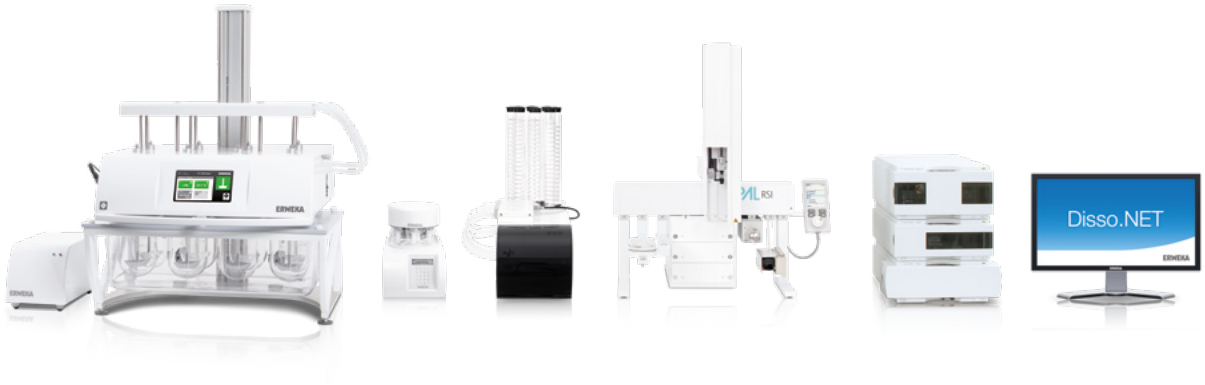
NOTE

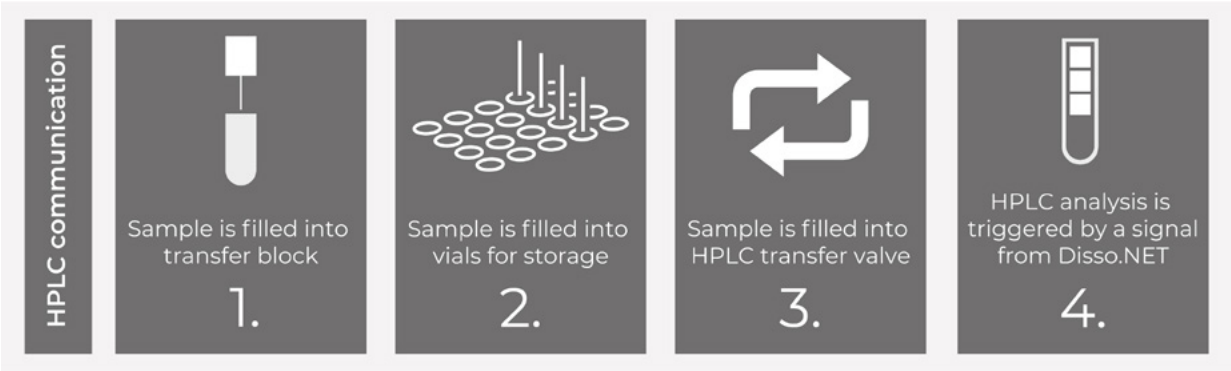


# A SIMPLE WAY TO HPLC ANALYSIS

After dissolution testing* with the DT 950 and double filtration with the PVP 820 pump and the AFC 825, the medium is transferred to the HPLC sampler. There, the medium is first filled in a transfer block, before being filled into corresponding HPLC vials using the high-precision syringe of the autosampler. If required, the samples can be diluted for immediate analysis or cooled** and stored temporarily against UV radiation for later analysis. The HPLC analysis starts as soon as a sample is filled into the HPLC valve of the sampler and a trigger signal via the standard remote port is sent by the Disso.NET to the HPLC device. The analysis as well as the evaluation are done by the analysis software of the corresponding HPLC manufacturer on a separate PC. As the analysis times of the samples are defined beforehand via the Disso.NET software, the sampler steadily passes the samples to the HPLC device (even after the termination of the release). Consequently, the dissolution test with HPLC analysis can be performed automatically without an operator (e. g. also at night).

The results of the HPLC analysis are displayed on a separate PC after completion of the analysis using HPLC software.




Not included in system configuration:

- HPLC analysis device
- HPLC analysis software (on a separate PC)

Our Dissolution On-/Offline System with HPLC supports different manufacturer (e.g. Agilent, Shimadzu, Waters).

NOTE

*Also during the test, at certain sampling times.

** Option

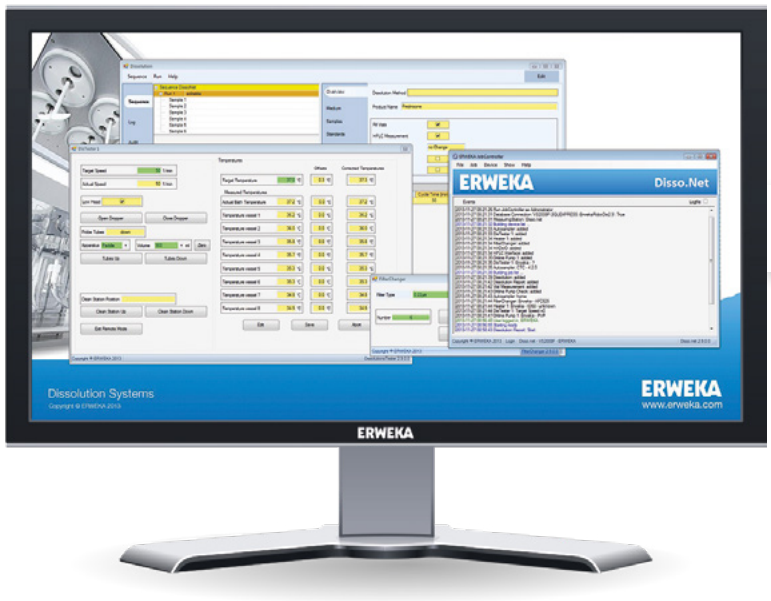
# FULL DISSOLUTION SOFTWARE SOLUTION

## DISSO.NET

The ERWEKA Disso.NET software is the perfect companion for the semi-automated dissolution HPLC On-/Offline systems. The software takes over full control and offers support for all test methods, that can be applied with the dissolution system with HPLC analysis.

Disso.NET helps you with standard dissolution jobs, handles qualification tasks and provides control over each single function of the connected devices (e.g. DT, PVP and auto sampler). In addition, the software includes an easy to handle method editor for comfortable programming of dissolution methods (for highest safety in GMP environment). The audit trail also generates detailed protocols of all events and times and thus enables tracing changes at any time. After finishing the dissolution test, Disso.NET creates comprehensive reports (as PDF-files or printouts) and can export all results in various formats (e. g. as XML file).

Full control with Disso.NET software




NOTE

Upon request data export to LIMS systems!

## KEY FACTS

- 100% — Audit Trail
- Disso.NET — Easy control of the On-/Offline systems
- MS SQL Database
- Advanced report generation
- AD — User management with Active Directory

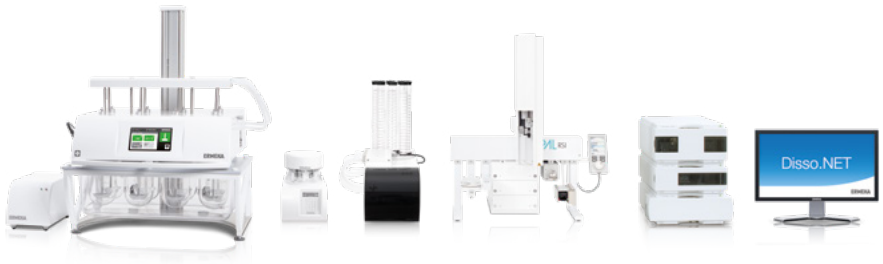
# COMPREHENSIVELY CONFIGURABLE

## OUR SYSTEMS WITH HPLC ANALYSIS

Our semi-automatic Dissolution On-/Offline Systems with HPLC distinguish themselves in particular through a high degree of automation and flexibility. This enables you to specify your HPLC system tailored to your individual needs.

We offer the following configurations (Note - HPLC analysis device is not included):

- HPLC On-/Offline Dissolution System with DT 950, PVP 820 Pump and AFC 825 (recommended)
- HPLC On-/Offline Dissolution System with DT 950, IPC 8 Pump and AFC 825
- Optional: Connection of 2 DTs (including 2 x PVPs or IPCs) to a HPLC Sampler with 2 transfer blocks (PEEK blocks)



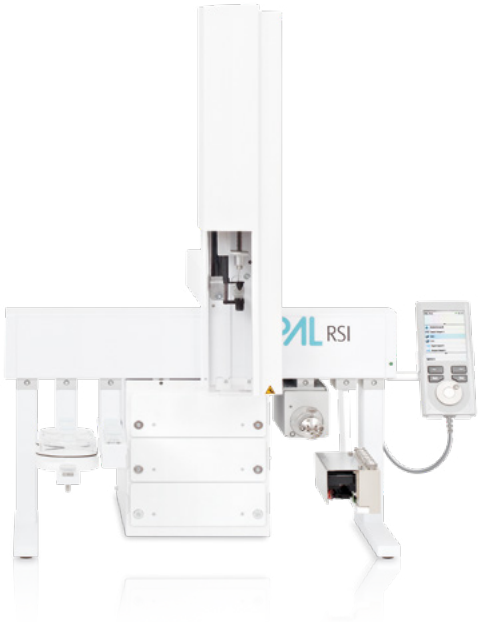

# HPLC SAMPLER

## RELIABLE AND FLEXIBLE COLLECTION OF SAMPLES

With the HPLC sampler samples can be collected and stored reliably and flexibly for subsequent HPLC analysis. It excels through its mechanical precision and its compact design. In addition, the open and modular unit design enables the exchange of single components within a short period of time.

If required, the collected samples can be diluted or stored temporarily cooled and UV-protected for later analysis. This is customizable. The HPLC sampler reacts to resistance via a sensor and automatically detects the correct position of the injection syringe, thus ensuring a quick, reproducible injection of the samples into the vials.

The sampler is easily controlled by the Disso.NET software.



# MEDIA REPLACEMENT WITH MEMBRANE FILTERS

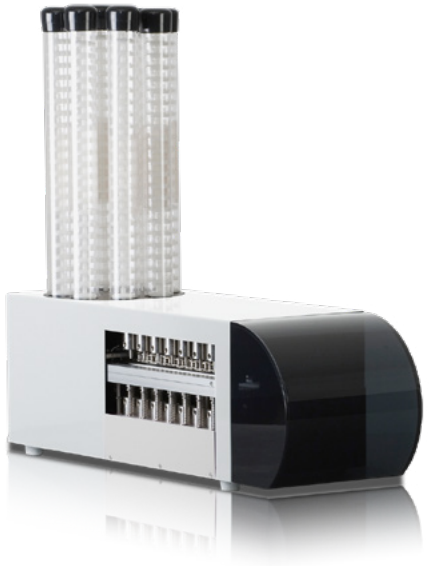
## AUTOMATIC FILTER CHANGER AFC 825

We recommend the implementation of a second filtration to avoid contamination or damage of the HPLC column due to particles, thus improving the accuracy of the HPLC analysis. In combination with the high-precision, practically maintenance-free PVP pump, we offer an additional device: the automated filter changer AFC 825.

The AFC 825 enables the automatic exchange of the used membrane filters (e. g. 0.45 µm) after each sampling or each test run. In addition, the media replacement can be conducted via the integrated bypass. As most of the filters are uni-directional - i.e. media is pumped in only one direction - the bypass prevents the media from being pressed back through the used membrane filters, thus avoiding the risk of filter damage.

The automated filter changer features a magazine with eight positions for membrane filters (max. 8x25 filter) and comes in two configurations:

- AFC 825 with 12 valves for 6 stations
- AFC 825 with 16 valves for 8 stations



## KEY FACTS

- No plugging of the HPLC column!
- Automated filter change
- Integrated in Disso.NET

# TECHNICAL DATA

## DT 950 / DT 9510 SERIES & ON-/OFFLINE HPLC COMPONENTS

### DT 950:

| | |
|---|---|
| Test stations | 6 in 2 rows (DT 956)<br>7 in 2 rows (DT 957)<br>8 in 2 rows (DT 958) |
| Speed | 20-250 U/min |
| Vessel volume | 400 ml, 1000 ml, 2000 ml |
| Operation | Touchscreen 7“, 800x480 Pixel |
| Sampling positions | High-head, Low-head, Cleaning mode |
| USP methods | USP 1, USP 2, USP 5, USP 6 |
| Ambient temperature during operation | +10 °C to +30 °C<br>(Ambient temperature min. -5 °C below set temperature) |
| Storage & transport temp. | +5 °C to +40 °C |
| Relative humidity | 25-80 % non condensing |
| Interfaces | 1x RS-232, 2x USB, 2x Ethernet/RJ45 |
| Power supply | 115/230 V, 50/60 Hz |
| Fuses | 2 A |
| Protection class | I/EN 61140 |
| Protection type | IP 21/IEC 529 |
| Weight | 42 kg |
| Dimensions (W x H x D) | 650 x 850 x 650 mm |

### DT 9510:

| | |
|---|---|
| Test stations | 12 in 2 rows (DT 9512)<br>13 in 2 rows (DT 9513)<br>14 in 2 rows (DT 9514) |
| Speed | 20-250 U/min |
| Vessel volume | 400 ml, 1000 ml, 2000 ml |
| Operation | Touchscreen 7“, 800x480 Pixel |
| Sampling positions | High-head, Low-head, Cleaning mode |
| USP methods | USP 1, USP 2, USP 5, USP 6 |
| Ambient temperature during operation | +10 °C to +30 °C<br>(Ambient temperature min. -5 °C below set temperature) |
| Storage & transport temp. | +5 °C to +40 °C |
| Relative humidity | 25-80 % non condensing |
| Interfaces | 1x RS-232, 2x USB, 2x Ethernet/RJ45 |
| Power supply | 115/230 V, 50/60 Hz |
| Fuses | 2 A |
| Protection class | I/EN 61140 |
| Protection type | IP 21/IEC 529 |
| Weight | 110 kg |
| Dimensions (W x H x D) | 1062 x 850 x 650 mm |

## HPLC SAMPLER (PAL RSI):

| | |
|---|---|
| Sample capacity | Tray holder with<br>I 3 MT/DW discs<br>I 3 VT 54 (162 x 2ml vials)<br>I 3 VT 70 (210 x 1ml vials) |
| Sample capacity, temperature-controlled (4-40° C) | 1 peltier modul, up to (with 6 DW):<br>I 6 MT / DW discs<br>I 6 VT 54 (324 x 2 ml vials)<br>I 6 VT 70 (420 x 1 ml vials) |
| Weight | 17.8 kg |
| Dimensions with standard legs (W x H x D) | 600 x 770 x 795 mm |
| Work surface (W x H x D) | 420 x 420 x 255 mm |

## PVP PUMP X20:

| | |
|---|---|
| Pump | PVP 620/720/820 (for DT 950)<br>PVP 1220/1420 (for DT 9510) |
| Channels | 6, 7 or 8 (PVP 620/720/820)<br>12 or 14 (PVP 1220/1420) |
| Valve | - |
| Accuracy | +/- 0.5 ml |
| System compatibility | DT Offline System, DT Online System, DT On-/Offline System |
| Benefits | Filtration down to 0.22 µm with a flat membrane filtration. Particularly suitable for fully automatic dissolution systems. |
| Power connection | 115 V or 230 V, 50/60 Hz |
| Weight | 21 kg (PVP 620/720/820)<br>28 kg (PVP 1220/1420) |
| Dimensions (W x H x D) | 280 x 420 x 475 mm (PVP 620/720/820)<br>275 x 420 x 575 mm (PVP 1220/1420) |

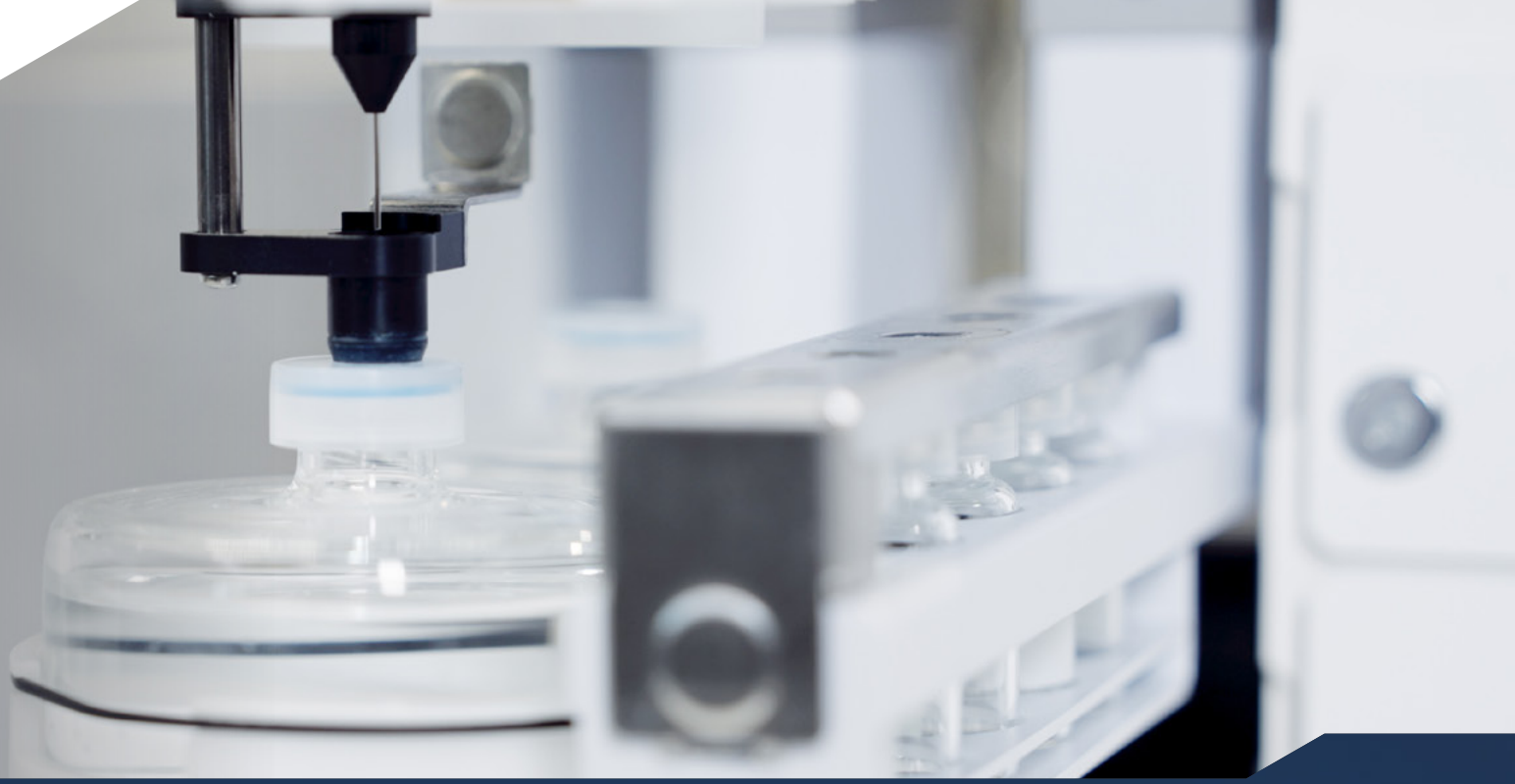
## AFC 825:

| | |
|---|---|
| Appliance details | Automated filter changer |
| Dimensions (W x H x D) | 215 mm (without filter refill) or 580 mm (with filter refill) / 610 mm / 200 mm (without valves) or 215 mm (with valves) |
| Filter requirements | I Pore size examples: 0.45 µm, with other sizes on request<br>I Diameter: ≤ 30 mm for automation |
| Power | 100-240 VAC +/- 10% / 50 and 60 Hz |
| Fuses | 115 V / 250 V, 2 x 3.15 A |
| Interfaces | RS 232 |
| Supported filters | I PALL Membrane Filter ACRODISC<br>I Whatman Roby 25 syringe filters for robotic systems |

## HEATER DH 1520I:

| | |
|---|---|
| Power | 1500 W |
| Temperature | 30-45 °C (± 0.2) |
| Interface | RS-232 |

ERWEKA
a VERDER company



**ERWEKA GmbH**

Pittlerstraße 45
63225 Langen
Germany

Phone: +49 6103 92426-200

sales@erweka.com www.erweka.com

VERDER

VERDER SCIENTIFIC

# ENABLING PROGRESS.

Under the roof of VERDER SCIENTIFIC we support thousands of customers worldwide in realizing the ambition we share.

As their technology partner behind the scenes, we deliver the solutions they need to make progress and to improve the everyday lives of countless people. Together, we make the world a healthier, safer and more sustainable place.

CARBOLITE
ELTRA
Retsch
QATM
MICROTRAC
ERWEKA