

# REINHELDT GmbH

## *Technical Specifications:*

Reinheldt DR Series Next Generation

Reinheldt DR Series – Precision. Performance. Compliance.

Reinheldt proudly introduces the Next Generation DR Series, engineered for unmatched accuracy, reliability, and regulatory compliance in pharmaceutical dissolution testing. Designed for modern laboratories, the DR Series offers advanced automation, smart user control, and robust data integrity across multiple configurations

## *Our Next Generation Models:*

### **Reinheldt DR-8 A / DR -14 A Series**

Basic dissolution system (8 or 14 Vessels)

### **Reinheldt DR-8 M / DR -14 M Series**

Manual sampling manifold (8 or 14 Vessels)

### **Reinheldt DR-8 X / DR -14 X Series**

Automated sampler (8 or 14 Vessels)

### **Reinheldt DR-8 P / DR -14 P Series**

Syringe pump, Full controller (8 or 14 Vessels)



## **R e i n h e l d t G m b H**

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## 1. Operating System & Software

The system utilizes the <sup>TM</sup> platform to ensure robust data integrity and operational efficiency.

- Data Protection: Features backup and restoration capabilities alongside an "Electronic Log Book" for tracking.
- Connectivity: Includes LAN connectivity, Network Time Protocol (NTP) synchronization, and fingerprint authentication for secure access.
- Operational Modes: Supports "Infinity Test" mode and offers a user-friendly touch screen interface.
- Reporting: Multi-level security settings with options for printing detailed reports.

## 2. Regulatory Compliance (21 CFR Part 11)

The device is engineered to meet strict regulatory standards:

- Access Control: Enforces limited system access with authority checks and device verification.
- Audit Ready: Maintains an accurate, complete audit trail with metadata storage.
- Disaster Recovery: Equipped with protocols for machine-to-machine data transfer and disaster management/recovery.

## 3. Reinheldt Dissolution Testing Systems

Core System Features (Common across All Models)

### 1. Display & User Interface

- 7-inch TFT touchscreen with intuitive alphanumeric data entry.
- Modern UI for easy test setup, monitoring, and reporting.

### 2. User Management & Security

- Supports up to 250 unique users with programmable user roles.
- Multi-level password protection to maintain system integrity.

### 3. Regulatory Compliance

- Fully compliant with USP, IP, Ph. Eur., and JP pharmacopeial standards.

### 4. Advanced Testing Functions

- Equipped with proprietary Timeaction<sup>TM</sup> technology allowing:
  - Automated media changeover
  - Infinite run modes for controlled / sustained-release dosage forms
- Automatic stirrer height adjustment for USP Methods 1, 2, 5, and 6 (Intrinsic test methods).

## 5. Hardware & Mechanical Design

- Molded clear water bath with bottom drainage for effortless cleaning.
- Vibration-free motorized lift with adjustable instrument leveling.
- Snap-fit shaft locking system to eliminate wobbles.
- High-precision vessel centring mechanism.

## 6. Temperature Control

- Independent temperature controller with a vibration-free circulation pump.
- Ensures stable and uniform bath temperature throughout testing.

## Data Management & Reporting Capabilities

### 1. Storage Capacity

- Stores up to 1,000 programmable products.
- Saves up to 50,000 test reports.

### 2. Sampling & Method Setup

- Supports 24 programmable sampling intervals for flexible test design.

### 3. Validation & Templates

- Includes 10 programmable report templates.
- Online validation for methods, monographs, system checks, and error logs.

### 4. Connectivity & Data Transfer

- Backup data and reports via FTP.
- Export test reports in PDF format with seamless FTP transfer support.

### 5. Alerts & Power Protection

- “D’light” audio-visual alert system for real-time status monitoring.
- Auto-resume function ensures data safety during unexpected power failures.

## 5. Model Variations

### A. Reinheldt DR-8 (A) / DR-14 (A) Series

A high-precision, entry-level dissolution platform built for routine testing with consistent performance and regulatory alignment.

## Reinheldt DR - 8 A, Series

Next Generation, Manual Sampling, No Automation

Basic dissolution system (8 Stations)



## Reinheldt DR - 14 (A) Series

Next Generation, Manual Sampling, No Automation

Basic dissolution system (14 Stations)



## Reinheldt DR - 14 (M) / DR-14 (M) Series

### B. Manual Syringe System (RDR (M), Series – 8 or 14 Stations)

The RDR M Manual Syringe System brings a new level of flexibility and precision to manual sampling operations.

#### Unique Feature – Variable Dilution Capability

Unlike conventional manual systems, the RDR M model offers:

- Programmable variable dilution, allowing different aliquot volumes at each sampling interval.
- Enhanced control for method development, multi-point sampling, and complex dissolution profiles.
- Greater accuracy in concentration adjustments and sample preparation.

This advanced feature makes the DR-8 M / DR-14 M Series the preferred choice for laboratories that need manual flexibility without compromising precision or reproducibility.

## Reinheldt DR - 8 (M), Series

Next Generation RDR (M) 8 stations Manual syringe system



## Reinheldt DR - 14 (M), Series

### Unique Feature – Variable Dilution Capability

- Programmable variable dilution, allowing different aliquot volumes at each sampling interval.
- Enhanced control for method development, multi-point sampling, and complex dissolution profiles.
- Greater accuracy in concentration adjustments and sample preparation.

## Reinheldt DR - 14 (M), Series

Next Generation RDR (M) 14 stations Manual syringe system



## Reinheldt DR-8 (X) / DR-14 (X) Series

### Automated Sampling System – 8 or 14 Stations

The Reinheldt DR-8 X and DR-14 X Series offer a fully automated sampling solution engineered to enhance workflow efficiency, reduce manual handling, and ensure reliable, contamination-free sample collection. Designed for high-performance dissolution testing, this series provides unmatched precision and consistency.

### C. Next Generation RDR – 8 or 14 Stations with X Sample Collector

The Next Generation RDR X Series sets a new standard in automated dissolution sampling, combining smart technology with robust engineering.

### Key Advanced Features

- Intelligent Loop-Back & Error Detection

Ensures continuous monitoring of the sampling process. The system automatically identifies errors and performs loop-back correction to maintain sampling integrity and avoid test interruption.

- Universal Tray Versatility

Compatible with multiple tray formats to support diverse analytical needs:

- 1.5 ml trays
- 10 ml trays
- 20 ml trays
- Mixed/combination tray configurations this flexibility makes the system ideal for labs requiring multi-volume sampling capability.

## Reinheldt DR-8 (X) Series

Next Generation RDR 8 stations with X sample collector



## Reinheldt DR-14 (X) Series

Next Generation RDR 14 stations with X sample collector



# Reinheldt DR-8 (P) / DR-14 (P) Series

## Next Generation Syringe Pump System – Full Controller

A state-of-the-art dissolution sampling platform that combines precision pumping, intelligent control, and flexible automation to support modern pharmacopeial testing.

### D. System with Syringe Pump & Sample Collector (DC)

The P-Series introduces a powerful combination of controlled media handling and automated sample collection—ideal for complex dissolution protocols, multi-point sampling, and high-throughput laboratories.

### Unique Features

#### 1. High Efficiency – Over 60% Operational Savings

The intelligent syringe pump system significantly reduces manual labor, operational time, and resource consumption—delivering more than 60% overall efficiency gains compared to conventional sampling systems.

#### 2. Intelligent Automation Enhancements

Optional add-on modules further elevate system capability:

- **AutoDropSync**  
Ensures precise, synchronized tablet or dosage introduction, improving timing accuracy and reproducibility.
- **Auto Dispenser**  
Automates media dispensing for consistent volume control and contamination-free operation.
- **Quality by Design (QbD) Tools**  
Provides enhanced control over process parameters, supporting method development, robustness studies, and regulatory compliance.

#### 3. Precision Syringe-Pump Sampling

Delivers consistent flow rates, repeatable sample volumes, and controlled withdrawal speed—ideal for sensitive or low-volume sample methods.

#### 4. Seamless Integration

Engineered to work effortlessly with dissolution vessels, heaters, and data systems, offering a fully unified workflow from test start to sample collection.

## Reinheldt DR-8 (P) Series

Next Generation RDR 8 stations Syringe Pump System



## Reinheldt DR-14 (P) Series

Next Generation RDR 14 stations Syringe Pump System & Sample Collector (DC)



## Next Generation Reinheldt DR Series – Model Comparison Table

Feature / Specification	DR-8 A / DR-14 A Basic System	DR-8 M / DR-14 M Manual Sampling	DR-8 X / DR-14 X Automated Sampling	DR-8 P / DR-14 P Syringe Pump System
Vessel Capacity	8 or 14 vessels	8 or 14 vessels	8 or 14 vessels	8 or 14 vessels
System Type	Basic dissolution system	Manual sampling manifold	Automated sampling system	Syringe pump system with full controller
Sampling Method	Manual (standard)	Manual syringe manifold	Automated sample collector	Syringe pump + automated collector (DC)
Automation Level	Low	Low to Medium	High	Highest
Unique Feature	Core standard features	Variable dilution capability (programmable aliquot volumes for each interval)	Loop-back & error detection, multi-tray compatibility (1.5 ml / 10 ml / 20 ml / mixed)	60% operational savings, optional AutoDropSync, Auto Dispenser, QbD tools
User Interaction	Manual operation	Enhanced manual control	Fully automated sampling	Fully automated precision-pump driven sampling
Tray Compatibility	—	—	Supports 1.5 ml, 10 ml, 20 ml & combination trays	Supports advanced automated modules
Ideal For	Standard routine dissolution tests	Labs needing manual flexibility & method development	High-throughput, automated testing workflows	High-precision, controlled sampling with advanced automation
Optional Add-ons	—	—	Combination tray formats	AutoDropSync, Auto Dispenser, QbD modules
Best Use Case	Standard pharmacopeial dissolution testing	Multi-point manual sampling & flexibility	Automated, error-free sampling	Precision media handling & efficient automated operation

## 6. Component & Accessory List

Item Description	Technical Specs / Notes	Reference No.
Apex Hexa Vessel	1000ml Clear (Sigma Delta Cert. w/ Laser Marking)	RH-VES-001
Apex Hexa Vessel	1000ml Clear (Standard)	RH-VES-002
Apex Hexa Vessel	1000ml Clear (Amber Delta Cert. w/ Laser Marking)	RH-VES-003
Apex Hexa Vessel	1000ml Amber	RH-VES-004
Multishield Top Plate	For EDT-14 Bath Station (Aluminum)	RH-ACC-001
Multishield Top Plate	For 8-Station Dissolution (Aluminum)	RH-ACC-002
Sampling Camula	Adjustable, for Low Evaporation Jar Lid (Set of 6)	RH-ACC-003
Validation Kit	EDT Digital Validation Kit	RH-VAL-001
Validation Gauge	EDT Basket Validation (with Certificate)	RH-VAL-002
Cooling Instrument	EDT Model (Enabled 10°C to 40°C)	RH-INS-001
Cleaning Agent	EDT Deconex 12 Basic (500ml)	RH-CON-001
Combination Tray	ESC 12DX (HPLC 1.5ml XPP / Glass Tubes 20ml)	RH-ACC-004
Transdermal Cylinder	EDT Model (Height: 107.9 mm)	RH-ACC-005
Small Vol. Dissolution	Range: 150 ml - 250 ml	RH-ACC-006
Microscope	Mesh Integrity Microscope	RH-INS-002
Depth Gauge	Compatible with POD & Apex vessels	RH-VAL-003

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