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White Paper
Biomedical

Maximizing Water Purification System Uptime:
A Guide for More Efficient Clinical Laboratories

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In clinical laboratories, the analyzers performing chemistry, hematology and immunology assays require large quantities of water to correctly perform their high-throughput operations. Hundreds to thousands of liters of purified water can be used by these clinical analyzers every day, within the assays themselves and to rinse and clean the automates.

Any water issue—whether related to contaminants, quality fluctuations or supply continuity—could cause analyzer downtime, resulting in a loss of laboratory productivity and a delay in delivering results to physicians and their patients. This makes the water purification system one of the most critical instruments in any biomedical laboratory.

This document aims to help clinical lab managers understand the features available within modern water purification systems that can assist in assuring their productivity. Purification technologies, system design features, and service capabilities that can prevent, reduce, and mitigate downtime of the water purification system are described. Innovations that limit water consumption, thereby reducing running costs and supporting greater laboratory efficiency are also discussed.

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

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Advanced Purification Technologies Assure Quality, Continuity & Efficiency

Appropriate water purification is the first step to assuring operations and protecting the lifespan of laboratory analyzers. The Clinical and Laboratory Standards Institute (CLSI) defines the quality of water required for clinical analyzers as Clinical Laboratory Reagent Water (CLRW; **Table 1**).[1] The use of highly purified CLRW-grade water serves two main purposes:

- Delivering accurate and reliable clinical analyses
- Safeguarding sensitive analyzer components from contamination, clogging and damage

Table 1 also describes the impact of water contaminants on various analyses, and the water purification technologies able to decrease or eliminate them. A reliable water system should incorporate a combination of purification technologies to efficiently remove water contaminants and to maintain consistent water quality over time.

It is important for laboratories to stay updated on recent advancements that not only ensure water purification but also enhance water system uptime and overall operating efficiency. Some of these innovations minimize the need for regular water system maintenance, simplify maintenance procedures when required, and reduce chemical and water waste. Further details on these advancements are provided in the subsequent pages.

Parameter	CLRW Value	Concerned Impurities	Impact	Purification Technologies
Resistivity	> 10 MΩ.cm at 25 °C	Ions (sodium, calcium, magnesium, chloride, bicarbonate, etc.)	Act as catalysts in organic and biochemical reactions	RO DI/EDI IEX resins
Total organic carbon (TOC)	< 500 ppb	Dissolved organic molecules	May disturb biological experiments and analytical techniques (e.g. LC-MS)	RO AC 185/254 nm UV
Bacteria plate count method or epifluorescence	< 10 cfu/mL	Bacteria and their by-products (nucleases, alkaline phosphatase)	Contaminate samples; Disrupt instrument operations	Filters (0.22 µm, UF) 254 nm UV Chemicals
Filtration	0.22 µm	Particulates, micro-organisms and colloids (e.g. silica, pollen, salt, crystals)	Interfere with analyses; Disrupt instrument operation (clogging); Reduce system lifetime	Filters (0.22 µm, RO, UF)

Table 1. Quality Standard for Clinical Laboratory Reagent Water (CLRW) defined by the Clinical and Laboratory Standards Institute (CLSI)[1], the impact of concerned water contaminants on various methods and assays, and the purification technologies that can decrease or eliminate such contaminants.
AC, activated carbon; DI, deionization; EDI, electrodeionization; IEX, ion exchange; RO, reverse osmosis; UF, ultrafiltration.

Minimize Planned Downtime to Maximize Uptime

To guarantee the continuous production, storage and distribution of CLRW-grade water, the laboratory's water purification system must be properly maintained.

Correct water system care requires:

- **Regular maintenance** of the technologies within, covering both hydraulics and electronics
- **On-time replacement** of purification consumables

Both maintenance and consumable changes require a planned amount of system downtime, which is ideally limited in order to preserve laboratory efficiency. By assuring these steps, laboratories limit fluctuations in water quality and unexpected system maintenance or other issues, and they can prolong system lifetime—all critical to preserving laboratory efficiency and analysis reliability.

Alleviating the Burden of Deionization

The requirement for CLRW-quality water to maintain a resistivity of at least 10 MΩ.cm places a burden of regular water quality control and water system maintenance on the laboratory.

Standard deionization (DI) bottles become regularly exhausted and need periodic replacement or chemical regeneration to restore their resin capacity. As a result, DI resins are the most frequently managed consumable in a typical water purification system. The DI maintenance process poses challenges as it may require advanced planning of service engineer visits, downtime of the water purification system, and a need to align with the clinical analyzer manufacturer. The heads of clinical labs, often pressed for time, must arrange these maintenance tasks, thereby consuming valuable employee hours. Furthermore, frequent service visits may not align with the stringent standards upheld by clinical labs. The use of DI bottles can also impact the reliability of results due to the following factors:

1. Risk of reduced water resistivity as DI resins near exhaustion, potentially destabilizing results.
2. Increasing risk of contamination during DI bottles replacement.

Electrodeionization (EDI) is an alternative purification technology used in high-quality water purification systems. Through a combination of electrodialysis and continuous self-regeneration of ion-exchange resins, EDI technology decreases the need for frequent water system maintenance involving DI cartridge changes or hazardous chemical regeneration procedures. As illustrated in **Figure 1**, EDI water has a much more stable resistivity compared to water from standard ion-exchange resin packs, where resistivity drops dramatically when DI packs are exhausted.

The EDI module should be of high-quality design that does not require preconditioning cartridges, which negate the environmental advantages of the EDI concept. For instance, the Elix® EDI module (Merck KGaA, Darmstadt, Germany) allows water systems to be installed in moderate to high hardness tap water areas without the need of softeners.

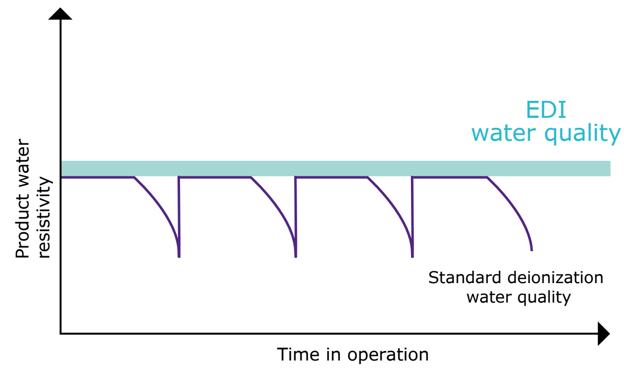

Figure 1. Stability of resistivity of water produced using EDI technology vs. standard ion-exchange resin packs. Resistivity drops dramatically when resin packs are exhausted.

Overall, the Elix® module ensures consistent, reliable water quality without the need for harsh chemical regeneration procedures, softeners, chemical or resin disposal (and associated costs), or frequent maintenance, consequently leading to decreased expenses.

Simplified Consumables Replacement

On any water system, purification consumables need to be changed to assure a constantly high level of water purity. Changing consumables may take some time, requiring a user manual or several tools.

To reduce maintenance time, a water purification system should have an ergonomic pack-locking consumable replacement system, step-by-step on-screen replacement guides, and short pedagogical videos that are clear for any laboratory employee. In short, the replacement of consumables should be achievable in-house, without the need for third-party involvement.

Mitigate the Risk of Unplanned Downtime

Mirror Installations

In clinical laboratories, an analyzer mirror installation is a privileged solution that provides an immediate backup if one of the analyzers is temporarily non-operational. Similarly, a duplex water purification system configuration is key to optimizing and ensuring water supply for the analyzers. The setup enables constant production, storage, and distribution of CLRW-grade water to the analyzer in times of high demand, or in case one of the water systems experiences down time. As per the most recent publication of ISO 15189:2022, clinical laboratories should minimize the risk of single points of failure, and a duplex/multiplex water solution for the provision of CLRW-grade water to analyzers is essential for the continuous operation of a clinical laboratory.[2]

Emergency Bypass

If an external power failure or an internal technical problem renders the distribution pump inactive, an emergency bypass can temporarily feed water to the analyzers. A water purification system with an easily accessible emergency bypass is a solution that ensures a continuous water supply to analyzers in the event of power failure or other technical issue that causes the water system or distribution pump to become inoperative. To supply water temporarily to analyzers, the feed water inlet is directly connected to the emergency bypass port during the distribution process. The water is still purified by a polishing cartridge and a 0.22-µm final filter, following the CLSI guideline. This setup enables laboratory staff to continue analyzer operations and maintain the delivery of biomedical tests until normal operating conditions can be restored, ensuring an uninterrupted workflow. This also allows for the analyzers to be safely shut down without losing any samples, until the power in the laboratory is restored.

Adequate Water Storage

Storage tank volume is an important and often overlooked feature of water purification systems. It serves as a valuable backup if the production process faces issues. For example, if an analyzer consumes water at a rate of 15 L/h, a tank volume of 140 L ensures that the laboratory can continue operating their analyzer for about 9 hours (**Figure 2**).

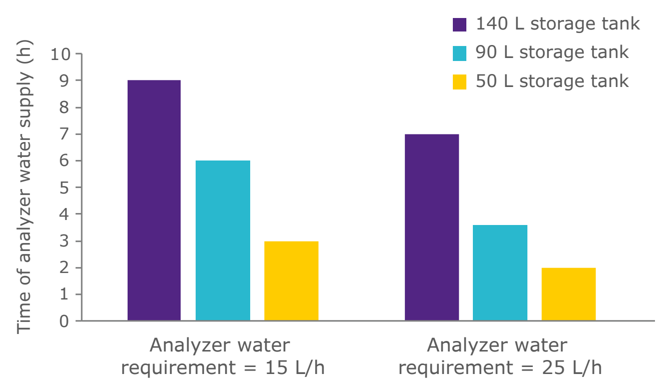

Figure 2. Impact of the storage tank volume on analyzer operating time.

Assure Rapid Quality Service Support, In Person & Online

Remote Monitoring Service Capabilities

Since clinical analyzers depend on water systems, they can be considered a unit. Water purification systems should therefore also be securely connected via the local internet and remotely monitored and managed by the lab manager, as well as serviced by the specialist service provider. This benefits laboratories by optimizing system uptime, minimizing downtime, and avoiding unplanned service interventions.

By implementing online monitoring, laboratories gain remote access to real-time system performance information, water quality data, anticipated maintenance requirements, consumable replacement dates, service history, and contract management. If any issue arises, responsible personnel can be notified promptly. This allows for rapid troubleshooting, which can prevent the development of more serious problems.

Connectivity not only supports laboratory personnel to assure productivity, but also provides the service support team with a remote view of the water system. This enables remote diagnostics and troubleshooting, potentially eliminating the need for a service engineer visit. In cases where a visit is necessary, the engineer can arrive prepared with the right equipment and parts for the already diagnosed issue.

Certified Support Services

For lab managers, it is essential to ensure the optimal performance and long-term reliability of their laboratory's water systems. Having a dedicated service team, who receives continuous and direct training on the water systems, is crucial for achieving efficient and lasting repair operations, and to minimize the need for repeated service visits. This approach of relying on targeted expertise enables prompt and effective resolution of any issues that arise, and supports uninterrupted productivity.

Limit Environmental Impact & Running Costs

Reverse osmosis (RO) technology can generate a significant amount of water waste. During the RO process, a portion of the feed water passes through the semipermeable membrane and is recovered as permeate. The remaining water, with an increased concentration of ions, is discharged as wastewater. Due to the high workload of a typical clinical laboratory, the amount of wastewater is significant and affects both the environmental impact and utility costs of the laboratory.

The RO recovery rate is the ratio of RO permeate water volume to feed water volume. RO recovery across a single membrane is calculated to be about 15%[3] and is higher for membranes in series.

To mitigate this issue of water waste, modern water purification systems are fitted with a **recirculation loop** that collects and recirculates a portion of the RO reject water back over the RO membrane, where it is mixed with tap water and further purified. By recycling this wastewater, the efficiency of the RO process is improved, resulting in reduced water waste and longer lifetimes of pretreatment cartridges.

Water savings can be further improved by employing **E.R.A.® (Evolutive Reject Adjustment) technology**. This patented technology automatically calculates the optimal water recovery, typically between 45% and 75%, according to the analysis of the incoming feed water quality. The system then automatically adjusts the motorized valves to optimize water consumption accordingly. This ensures constant flow rate, efficient operations and minimal wastewater.

Even though tap water utility costs are generally low, the thousands of cubic meters of water saved per year amounts to considerable cost savings, addressing both environmental and financial targets. **Figure 3** illustrates how yearly water usage can be drastically decreased by implementing RO recovery technologies. Combined, an RO recirculation loop and E.R.A.® technology contribute to both cost savings and more sustainable laboratory operations.

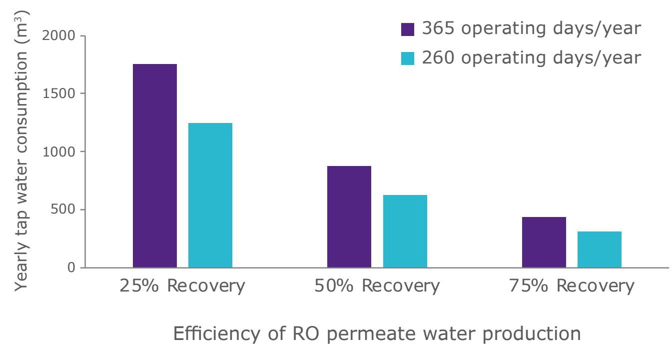

Figure 3. Impact of RO recovery rate on water consumption over one year to produce 1.2 m³/day (1200 L/day) RO permeate water. Operation of the RO system over 7 days/week (purple, 438 m³/y permeate) and 5 days/week (cyan, 312 m³/y permeate) are both considered.

Article Highlights

- To avoid disruptions in clinical laboratory operations, a reliable supply of CLRW-grade water is required to feed analyzers.
- Clinical lab managers should perform a risk assessment to identify risks in their water supply and take proactive measures to mitigate them.
- High-performance water purification systems minimize instrument contamination, water quality variations, and maintenance interventions.
- Advanced water system technologies ensure reliable purification, require minimal maintenance time, and decrease water and chemical waste.
- Redundancy with multiple water systems and pumps ensures continuous operation 24/7.
- Online water system performance monitoring and a dedicated water system service team allow more rapid issue identification and resolution of potential issues.
- A modern, high-performance water purification system ultimately can improve patient care by ensuring the reliable provision of test results to consultants.

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Lit. No. MS_WP13241EN