

Risk guide

Protecting Clinical Output from Water Risks

How pure is pure?

When lives are at stake, there is no margin for error. Your clinical analyzer must receive a constant and reliable supply of CLRW water, regardless of the quality of the feedwater available.

The CLRW (Clinical Laboratory Reagent Water) guideline is a widely adopted standard for clinical diagnostics applications. It aims to guarantee the use of a basic level

of water purity so that assays can be run consistently with minimal risk to the analyzer and the clinical test results.

Why is purity key?

Poor water quality affects the tests themselves and impacts on all aspects of analyzer operation.

Design optimised for efficient water purification and recirculation is key to long term bacterial control. The right water system will enable increased productivity, efficiency and accuracy of workflow in your laboratory.

The wrong system will cause downtime and unforeseen expenditure in the long run.

Patient results can be seriously impacted by poor water quality feeding a clinical analyzer. This can arise from the use of a single-pass system, where water has stagnated and reduced in quality to unacceptable levels.

The risks of using insufficiently pure water can lead to a potentially catastrophic flow of events:



Inconsistencies in results, due to unnecessary contaminants



Misdiagnosed patients, who could then be incorrectly treated



Inconclusive results, so tests need to be repeated, losing valuable time



Potential litigation as a result of that mistreatment

If poor quality water is fed into the analyzer, this will ultimately lead to reduced efficiency in the laboratory workflow, increased costs and poor patient service.

Water in the clinical environment

Water is used in virtually all aspects of clinical analyzer processes:

- Washing reaction cuvettes
- Feeding wash stations for probes and stirrer paddles
- Diluting reagents, samples and detergents
- Incubator baths
- As an interface between syringe and sample

CLRW specifications limit 4 key types of impurities in pure water: ions, particulates, organics and bacteria. Unspecified bacterial by-products can also significantly impact the analyzer and results. Impurities in the water can impact your clinical analyzer's performance by

interfering with the chemistry of the tests that are performed in your analyzer. This can cause poor or inaccurate results. Water impurities can also induce errors in the instrument leading to increased maintenance downtime.

Impure water and end user impact

The impact of using impure water can be lengthy and expensive, causing downtime of your clinical analyzer, through the need for cleaning and/or the replacement of parts.

Water Impurity	Effect	End User Impact
Contamination by particles or bacteria	Reduced pipetting volume accuracy	Incorrect sample volumes, which may affect analyses and results
Particles or bacterial contamination in water bath	Photometric reading errors	May lead to inaccurate diagnosis, potentially leading to incorrect / delayed patient treatment.
Wash-water contamination with ions, organics or bacteria	Cuvette contamination / carryover sample and reagent probe contamination	Patient sample contamination may lead to misdiagnosis, sample contamination, patient receiving incorrect / delayed treatment.
Diluent contamination with ions, organics or bacteria	Errors in sample and reagent dilution, poor reagent stability	Increased running costs through having to purchase more reagents. Analyzer downtime for cleaning and maintenance. Patient sample backlog as a result of the downtime.
Zero standard water contamination (e.g. with Ca^{2+} , Mg^{2+} , PO_4^{3-} , HCO_3^-)	Reduced calibration stability and sensitivity	Costs of recalibrating the analyzer. Potentially incorrect patient results leading to incorrect / delayed treatment.
Particles or bacteria contamination or insoluble compounds	Capillary blocking	Analyzer downtime, parts replacement, backlog of tests to be run, delayed patient results and treatment.
Insoluble deposits — contamination with compounds which have low solubility	Scaling	Analyzer downtime, parts replacement, backlog of tests to be run, delayed patient results and treatment.

The importance of water purity

By ensuring CLRW resistivity of $>10\text{M}\Omega\text{-cm}$, the concentration of many ionic impurities can be restricted to ppb levels or less.

CLRW water is important because laboratories need accreditation. The College of American Pathologists (CAP) is a recognised global organisation who have endorsed and reinforced the CLRW, and CLSI sets recognised standards by experience and consensus.

CLRW Specification	
Bacteria	$< 10 \text{ CFU/ml}$
Resistivity	$> 10 \text{ M}\Omega\text{-cm}$
Total Organic Carbon (TOC)	$< 500 \text{ ppb}$
Particles	$0.2\mu\text{m}$ filtration or better
Silica (SiO_2)	50 ppb (type 1 for CAP)

It is important to ensure an absence of particles in all types of applications but especially when low liquid volumes are used. Particles can clog needles and sample handling manifolds. It encourages the formation of bacterial growth and, hence, biofilms,

which can further impede the accuracy of highly sensitive test results. Bacterial contamination has serious implications for the operation of analyzers. It is important to ensure they are consistently low in the feedwater.



Water contamination risks in the lab

There are many sources of water contamination within the laboratory, which can have a negative impact on experimental results. This highlights the importance of pure water in a clinical laboratory.

Incubator bath

Stagnant water provides a breeding ground for bacteria, which can affect photometric measurements. This can lead to inaccurate results and necessitate the analyser being shut down so that the entire system can be disinfected. Both of these consequences have serious implications for patient care and for the costs incurred by hospital laboratories.

Sample probe and wash station

Impure water can cause inaccuracy with probe calibration and encourage patient to patient sample contamination, which could lead to incorrect patient results.

Cuvette wash station

Impure water can not clean cuvettes correctly, leading to patient sample carryover and contamination. This may result in incorrect patient results.

Pipetting syringes

Impure water may lead to inaccurate and imprecise pipetting. Any residue buildup will interfere with sample aspiration and could hinder certain assays and falsify patient results or cause unnecessary repeats and reagent wastage.

Reagent probe and wash station

Impure water can cause reagent instability, leading to unnecessary and costly reagent wastage. A dirty probe will promote reagent to reagent contamination, potentially leading to incorrect patient results.

Internal reservoir

If there are bacteria in the water supply, the internal reservoir will be a perfect hiding place for them to thrive, resulting in numerous contamination issues potentially leading to analyzer downtime and associated cost, and patient treatment implications.

How Veolia ensures water purity

Your analyzer needs: Water purification technologies

To achieve the water purity required to meet the specifications of the CLRW standard and to satisfy the volume requirements of modern integrated clinical analysers, several purification technologies can be used:

Our Technology	Technology Function	Customer Benefits
Pre-filtration (Filters)	Reduces the amount of incoming particulates found in municipal water.	Helps to protect the mechanical parts of the product from larger particles which could cause damage.
Activated Carbon (AC)	Removes oxidative agents (chlorine & chloramine) and some organics present in tap water.	Protects the RO from chlorine/ chloramine damage ensuring it lasts longer and performs as expected to reduce total costs of ownership.
Reverse Osmosis (RO)	A membrane that is used to reduce the load of ions, organics, colloids and particulates. It is impacted by seasonal and geographical variations of the feedwater quality.	Removes up to 99% of impurities from the water.
De-gasser or eCartridge (DG)	Removes carbon dioxide which is a weakly charged ion.	Removes a percentage of the carbon dioxide to help improve EDI performance or extend DI pack life, reducing interventions to the water system.
Conditioning Cartridge or optimizer pack	A softening cartridge which specifically removes hardness-causing ions (Ca^{2+} and Mg^{2+}).	Protects the EDI by preventing scale from forming inside it. Ensures sustained performance of the EDI, thus reducing the total cost of owning the system.
Electrodeionisation (EDI)	EDI removes ions using selective anionic and cationic semi-permeable membranes and ion exchange resin which are constantly regenerated with a small electrical current.	Reduces the total cost of ownership by reducing the ionic load fed to the DI packs.
Deionisation (DI)	Deionisation removes the final remnants of ionic impurity in the water bringing the product water resistivity up to typically $> 15 \text{ M}\Omega\text{-cm}$.	Ensures the resistivity specification of the Medica* system meets CLRW requirements.
Water Storage	Water is stored in a reservoir with a composite vent filter (CVF) preventing airborne compromise of water quality by contaminants such as CO_2 , bacteria, particulates and volatile organics.	Maintains a ready supply of high quality water to ensure that the analyzer receives the volumes it requires to deliver laboratory productivity.

Our Technology	Technology Function	Customer Benefits
UV Purification	UV light alters the DNA and RNA of bacteria / preventing them from replicating.	Helps to achieve required product water Total Viable Count (TVC) levels.
Micro filtration (MF) 0.2µm Ultra filtration (UF) 0.05µm	Removes bacteria from the water flow through filtration.	Ensures bacterial specifications are met for the clinical analyzer reducing the need for decontamination of the analyzer.
Recirculation	Recirculation of water from the reservoir through water purification technologies and back into the reservoir prevents bacterial proliferation and ensures the quality of the water to feed the analyzer when it is needed.	Confidence that water of the correct purity will be available to the analyzer at all times.

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Removal	Enzymes inc. EIA	Toxicology TDM	Trace Elements	Molecular Testing	Analyzer Instruments	Purification Technologies
Ions	✓	✓	✓	✓	✓	RO, EDI, DI, DG
Organics	✓	✓		✓	✓	RO, AC, EDI
Bacteria	✓	✓	✓	✓	✓	RO, UF, UV, Recirculation
Bacteria byproducts	✓			✓		UV, DI, MF, Recirculation
Particles					✓	Filters, RO, MF, CVF
Silica					✓	RO, EDI, DI

The table above clearly indicates that bacteria and ions have an impact across the widest range of applications. Bacteria will grow in water and form biofilm on surfaces in contact with the water unless preventative measures are taken. Careful system design is essential to achieve bacterial control. To remove bacteria from water, Veolia systems use reverse osmosis, ultraviolet irradiation, and ultra-microfiltration.

However, these are not present at the point of dispense to the analyzer. Veolia systems use recirculation to avoid the problem of bacteria growing in static water during periods of low demand. Trust consistency within your clinical laboratory, supported by a global service network, with Veolia and the Medica* range.

