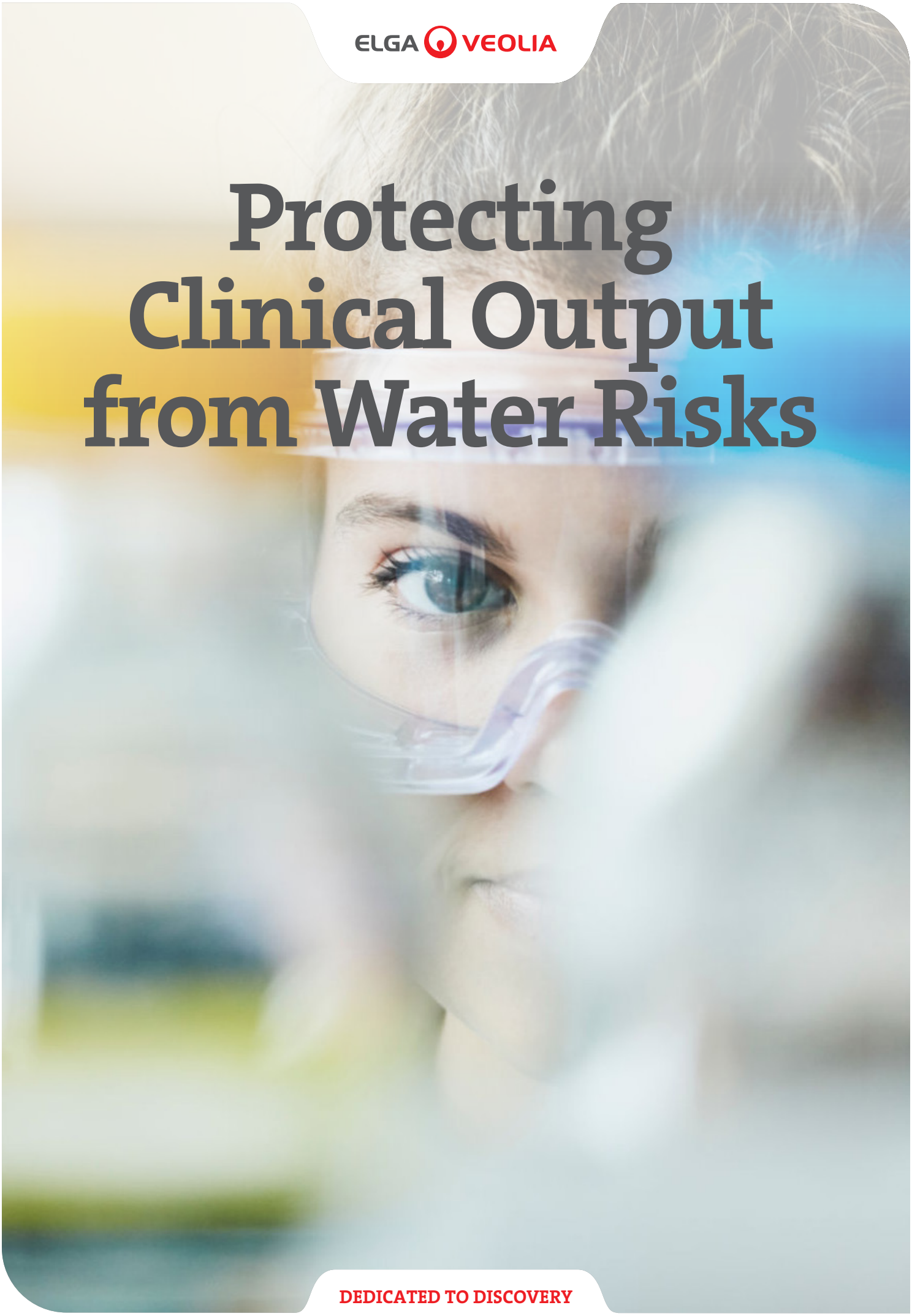
ELGA VEOLIA

Protecting Clinical Output from Water Risks



DEDICATED TO DISCOVERY

How pure is **pure**?

When lives are at stake, there is no margin for error. Your clinical analyser must receive a constant and reliable supply of CLRW™ (Clinical Laboratory Reagent Water) regardless of the quality of the feedwater available.

The CLRW guideline is a widely adopted standard for in vitro diagnostics applications. It aims to guarantee the use of a basic level of water purity so that clinical chemistry assays can be run consistently with minimum risk to the analyser and the clinical test results.

Why is **purity** key?

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

Good water purification system design, providing recirculation, is the key to long-term bacterial control.

The right water system will enable increased productivity, efficiency and accuracy of workflow in your laboratory.

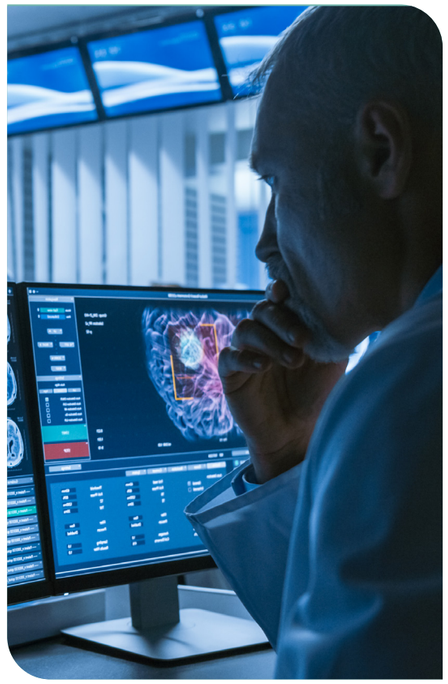
The wrong system will cause downtime and unforeseen expenditure in the long run.

Patient results can be seriously impacted by poor water quality feeding a clinical analyser. 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, arising from unnecessary contaminants
- Inconclusive results, so tests need to be repeated, losing valuable time
- Misdiagnosed patients, who could then be incorrectly treated
- Potential litigation as a result of that mistreatment.

If poor quality water is feeding into the analyser, 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 analyser 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. These are ions, particulates, organics and bacteria. Unspecified bacterial by-products can also significantly impact the analyser and results.

Impurities in the water can impact your clinical analyser's performance by interfering with the chemistry of the tests that are performed in your analyser. This can cause poor or inaccurate results. Water impurities can also induce errors in the instrument, leading to maintenance downtime due to contaminant load.

Impure water and end **user impact**

The potential impact on your lab of using impure water in your clinical analyser is huge. It can result in lengthy and costly downtime, due to the need for extensive cleaning, and for parts to be replaced.

Water impurity	Effect	End user impact
Particles or bacterial contamination	Reduced accuracy of pipetting volume	Inaccurate sample sizes which could affect testing 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 / carry-over 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. Analyser 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, HCO_3)	Reduced calibration stability and sensitivity	Costs of recalibrating the analyser. Potentially incorrect patient results leading to incorrect / delayed treatment.
Ionic contamination producing low resistivity	Incorrect level sensor operation leading to reagent wastage	Increased operational costs, incorrect patient results which may lead to incorrect / delayed treatment.
Particles or bacteria contamination or insoluble compounds	Capillary blocking	Analyser downtime, parts replacement, backlog of tests to be run, delayed patient results and treatment.
Insoluble deposits — contamination with low soluble compounds	Scaling	Analyser 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 MΩ-cm, the concentration of ionic impurities can be restricted to ppb levels or less. This is assisted by the removal of carbon dioxide.

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 CFU/ml
Resistivity	> 10 MΩ-cm
Total Organic Carbon (TOC)	< 500 ppb
Particles	0.2µm filtration or better
Silica (SiO2)	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 analysers. It is important to ensure they are consistently low in the feedwater.

Water contamination risks in **the lab**

Here you can see some of the many origins in the lab of contaminated water, and how it negatively impacts experimental results. These reasons alone showcase the importance of pure water in the lab.

INCUBATOR BATH:

A breeding ground for bacteria which can interfere with the photometric readings potentially resulting in **incorrect patient results** and analyser downtime to sanitise the whole system. Both of these have serious impacts on patient treatment and hospital laboratory costs.

SAMPLE PROBE AND WASH STATION:

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

CUVETTE WASH STATION:

Impure water cannot clean the cuvettes correctly which will lead to patient sample carryover and contamination which 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 therefore resulting in unnecessary reagent wastage which in itself is an expense. A dirty probe will promote reagent to reagent contamination which potentially leads 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 the numerous contamination issues potentially leading to **analyser downtime** which has multiple cost and patient treatment implications.

How **ELGA ensures** water **purity**

YOUR ANALYSER NEEDS: WATER PURIFICATION TECHNOLOGIES

To achieve the purity of water required to meet the CLRW specifications and the volumes needed by modern integrated clinical analysers, a number of purification technologies are needed:

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 fluorine) and some organics present in tap water, for the control of microorganisms.	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 as a percentage of the content in the water. It is impacted by seasonal and geographical variations of the feedwater quality.	Removes up to 99% of impurities from the water.
De-gasser (DG)	Removes carbon dioxide which is a weakly charged ion.	Removes a percentage of the carbon dioxide to help extend the life of the DI packs and reduce interventions to the water system.
Conditioning Cartridge (EDI systems only)	A softening cartridge which specifically removes hardness-causing ions (Ca and Mg).	Removes calcium and magnesium ions to protect the EDI by preventing scale from forming to ensure the EDI works to its maximum, thus reducing the total cost of owning the system.
Electrodeionisation (EDI)	EDI removes ions (inorganic and organic), 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 of the system by removing cations and anions to provide a regular quality of water onto the DI packs.
Deionisation (DI)	Deionisation removes the final remnants of ionic impurity in the water bringing the quality up to typically >15 MΩ-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) also protects against organic vapours. which protects the water from airborn CO2 and bacterial ingress.	Guarantees a supply of quality water to ensure that the analyser receives the volumes it requires to deliver laboratory productivity.

Our Technology cont.	Technology Function cont.	Customer Benefits cont.
UV Purification	254nm wavelength UV light alters the DNA and RNA of bacterium killing them by preventing it from replicating.	Helps to achieve required product water Total Viable Count (TVC) levels.
Micro filtration (MF) 0.2µm Ultra filtration (UMF) 0.05µm	Removes bacteria from the water flow through filtration.	Ensures bacterial specifications are met for the clinical analyser reducing the need for decontamination of the analyser.
Recirculation	Recirculation of water from the reservoir through all of the water purification technologies and back into the reservoir at a flow rate of >1L/min prevents bacterial growth and ensures the quality of the water to feed the analyser by passing it through all the technologies regularly.	Further helps prevent the risk of bacterial growth and development, so the clinical analyser is less likely to require decontamination.

HOW ELGA ENSURES THE WATER PURITY YOUR ANALYSER NEEDS: ELGA MEDICA SYSTEM BENEFITS

Removal	General Chemistry	Enzymes	Toxicology TDM	EIA	Trace Elements	Molecular Testing	Analyser Instruments	Purification Technologies
Ions	✓	✓	✓	✓	✓	✓	✓	RO, EDI, DI, DG
Organics		✓	✓	✓		✓	✓	RO, AC, UV
Bacteria	✓	✓	✓	✓	✓	✓	✓	RO, UF, UV, Recirculation
Bacteria byproducts		✓		✓		✓		UF, Recirculation
Particles							✓	Filters, RO, UF
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. 0.2 µm filters can be used to remove bacteria, but if the feed water is already too contaminated, the challenge on any water purification system or downstream analyser will be too great. This will result in high build up on the membrane, increasing the risk of bacterial growth breaking through to the analyser. Careful system design is essential to achieve bacterial control.

To remove bacteria from water, ELGA systems use reverse osmosis, ultraviolet irradiation, and ultra-microfiltration. However, these are not present at the point of dispense to the analyser. Water will sit statically until there is a demand. This means in periods of low demand, such as overnight, there is an opportunity for bacteria to grow. ELGA systems use periodic recirculation to avoid this problem.

The reduction of ionic content in the water of ELGA LabWater's MEDICA product range is a process that involves reverse osmosis, and deionisation, plus electrodeionisation (EDI) when used.

ELGA VEOLIA

Dedicated to Discovery

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ELGA Labwater are specialists in the engineering, service & support of water purification systems.

Unrivalled product design has achieved international recognition and awards.

Worldwide technical service teams support science & healthcare globally with specialist expertise.

Global digital performance monitoring from AQUAVISTA ensures laboratory work is uninterrupted.

A global supply chain supports clients from regional centers on every continent.

To find your nearest ELGA representative, go to *www.elgalabwater.com* and select your country for contact details.

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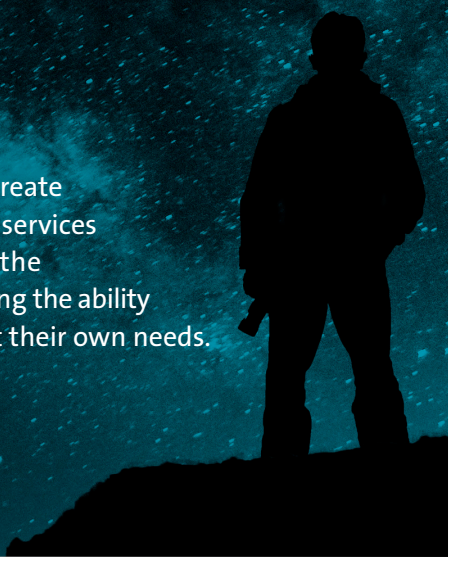
ELGA builds for sustainable development by aspiring to create laboratory and clinical water services that will meet the needs of the present without compromising the ability of future generations to meet their own needs.



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