

Buyers Guide

Clinical Diagnostics

Choosing the right water purification system for clinical diagnostics.



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In a clinical environment, the lives of patients depend on accurate analysis. 70% of all medical decisions rely on laboratory results¹, leaving no margin for error.

Water quality is key to many of the methodologies and testing protocols performed in a clinical diagnostic laboratory.

Clinical analyzers frequently rely on a constant supply of Clinical Laboratory Reagent Water (CLRW), regardless of the quality of the feedwater available.

CLRW Specifications	
Bacteria	< 10 CFU/ml
Inorganics (resistivity at 25°C)	> 10 MΩ.cm
Total organic carbon (TOC)	< 500 ppb
Particles	0.2 µm filtration or better

Using insufficiently purified water in clinical applications can lead to analyzer downtime and reduced performance, inconsistent and inconclusive results, and misdiagnoses.

The questions you should consider before choosing a water system:

1	What level of water purification do I need?
2	What are my laboratory's throughput and water demands?
3	Where will a unit be located and how much space do I have?
4	What is my budget and what would be the consequences of choosing cost over quality?
5	How crucial is system uptime to my laboratory's workflow?
6	Do I require flexibility and future-proofing?
7	Can I trust the system has been fully certified and will be safe to use in my laboratory?

¹Facts & Figures. The British In Vitro Diagnostics Association (BIVDA). <https://www.bivda.org.uk/The-IVD-Industry/Facts-Figures>

The following pages will guide your answers to these questions, but for further information, take a look at the resources available on the ELGA website, or speak directly to a member of the ELGA team.

1. Water Purity

The CLRW guideline, set by the Clinical and Laboratory Standards Institute (CLSI), is a widely adopted standard for clinical applications, endorsed and reinforced by the globally-recognized College of American Pathologists (CAP).

CLRW specifications limit four key impurities in water: [ions](#), [particulates](#), [organic contaminants](#) and [bacteria](#).

All can impact the performance of clinical analyzers, either by directly interfering with the chemistry of tests, or by indirectly introducing measurement errors.

It is important to choose a water purification system that will provide reliable, consistent and uninterrupted CLRW water to your clinical analyzer(s).

2. Volume Requirements

How much pure water is required per hour?	Choose a water purification system that includes technologies that protect both stored and recirculating water from airborne CO ₂ and bacteria, guaranteeing a consistent supply of quality and compliant water in volumes that your clinical analyzer(s) need to deliver on laboratory productivity.
How quickly must the water be delivered to your clinical analyzer(s)?	
Is the purification system delivering water to a single or multiple clinical analyzer(s)?	Your water purification system should allow for multiple configurations, to not only support your laboratory's current needs, but to enable future proofing for your laboratory.

3. Space-saving technology

What is the overall footprint of the purification system(s) and its components?	The range of water purification systems from ELGA are compact with built-in, wrap-around reservoirs and flexible design, that can be conveniently placed, even where laboratory space is at a premium.
Where will the system be located in your lab?	ELGA systems maintain complete flexibility, so can be installed under bench or wall mounted, to minimise system footprints, and to prevent workflow interruptions.

4. Cost Effectiveness

What are the repercussions of saving costs rather than choosing a premium product?	Cheaper water purification options can pose a multitude of risks to your clinical processes and turn into costly decisions. Poorly constructed water systems can cause contamination within your clinical analyzer, due to their lack of advanced, protective technologies. Choose systems that are fully certified to provide CLRW water.
What will the cost of ownership be over the lifetime of your water system? How often do consumables need to be replaced?	Choose a supplier that offers a pre-installation site survey and provides realistic information on the cost of ownership. Select an instrument that incorporates built-in technologies, such as electrodeionization (EDI), to significantly reduce running costs and consumable requirements. ELGA's consumables calculator can provide you with an estimate of your predictable running costs using its systems.

5. System Uptime

What quality guarantee does the water purification provider offer?	To prolong the longevity of your clinical analyzer(s) and other laboratory equipment, choose a water purification system that incorporates preventive steps, such as EDI or degassing systems, to provide consistent CLRW quality water to enable uninterrupted clinical diagnostic testing and to reduce the ionic load on downstream technologies.
What kind of warranty and maintenance service is available?	Choose reliable equipment supported by a global service network and supplied with long warranties as standard (not at extra expense).
How will your laboratory manage in the event of instrument downtime?	Select a supplier that offers remote monitoring with their systems, to ensure a preemptive response if any downtime is anticipated or unexpected. Employ solutions with emergency bypass options, enabling water to divert through the purification technologies and allow you to finish your tests in the event of unexpected downtime. With ELGA, you can.

6. Flexibility

Can the system be expanded if demand increases?	Choose water purification systems with upgradable configurations. This enables increased capacity, without expanding the unit's footprint, for if and when your demand for pure water increases.
Do the systems meet your current and expected sustainability targets?	Water purification is a resource-intensive process, so select products designed to have the lowest possible environmental impact. Your equipment should save you water and energy, reduce plastic use and chemical waste, and eliminate mercury.

7. Certifications

When considering the right water purification system, it is important to safeguard your equipment and to provide a safe environment for those that use them. Fully certified

laboratory equipment ensures that systems have been thoroughly tested and fulfil requirements to provide the grade of water required, safely and efficiently.



Global – IEC & UL certification

Certifications from International Electrotechnical Commission (IEC) and Underwriters Laboratories (UL) provide a framework globally for ensuring safety and quality of electrical and electronic products and systems.



EU – EMC & CE certification

Electromagnetic Compatibility certification (EMC) ensures electrical and electronic devices can operate reliably, without causing or being affected by interference from other devices. Conformité Européenne (CE) marking appears on products that meet essential requirements of relevant European Union (EU) directives, ensuring they are safe for sale and use within the European Economic Area (EEA).



UK – UKCA

The British equivalent of CE marking, UKCA marking is a conformity marking for products placed on the market in Great Britain (England, Scotland & Wales). UKCA certification indicates that a product meets specific UK safety and environmental requirements.



USA – EPA & FCC

Certifications from the United States Environmental Protection Agency (EPA) indicate equipment that meets the standards for environmental protection. Certification from the Federal Communications Commission's (FCC) ensures equipment comply with regarding radio frequency (RF) emissions to prevent interference with other devices.



Canada – CSA

Equipment certified by the Canadian Standards Association (CSA) ensures products meet safety and performance standards.

ELGA LabWater: Dedicated to Discovery

Since 1937, ELGA LabWater has been innovating water purification technologies and working in partnership with major clinical diagnostics suppliers and laboratories to support clinical diagnostic testing around the world.

We understand that clinical laboratories require seamless and uninterrupted workflows. The MEDICA range has been designed to give you peace of mind that your water purity is in good hands.

Introducing MEDICA®

MEDICA® has been integral to clinical diagnostics labs since 1995. MEDICA 150 has increased sustainability and ease-of-use, modern technology, software and a new design. Still supported by our global service network, MEDICA allows clinic processes to continue seamlessly, maximising uptime and lab workflow efficiency.

System uptime aligning with analyzers uptime of 98%

Unique combination of technologies offers efficient operation and maximum performance

Make up rate of 150 l/hr with delivery flow rate of up to 4.5 l/min

Improved RO performance allows for enhanced salt rejection and improved water recovery

Supports all major clinical analyzer manufacturers

Supported by our global service network



The MEDICA® Range

	MEDICA® 100/150	MEDICA®-R/D 7/15	MEDICA® EDI 15/30
			
Inorganics (resistivity at 25°C)	>10 MΩ.cm	>10 MΩ.cm	>10 MΩ.cm
TOC	<30 ppb	<30 ppb	<30 ppb
Bacteria	<1 CFU/ml**	<1 CFU/ml**	<1 CFU/ml**
Particles	0.2 µm filter	0.2 µm filter	0.2 µm filter
Silica	<0.05 mg/l	<0.05 mg/l	<0.05 mg/l
Feedwater quality	Potable water***	Potable water***	Potable water***
Water purity	CLRW grade water High volume and high purity for high usage with more predictable running costs	CLRW grade water Reliable and economical supply for low usage	CLRW grade water Reliable and economical supply for analyzers that require higher volumes of water
Make up rate	150 litres / hour	7 or 15 liters/hour	15 or 30 liters/hour
Flow rate	4.5 litres / minute @ 14 psi (1 bar) pressure	Up to 1.8 liters/minute	Up to 1.5 litres/minute
Integrated storage	Integrated internal 75L reservoir		
Typical applications	Single clinical analyzers or linked multiple analyzers	Single clinical analyzers	Single or multiple clinical analyzers

* With ion-exchange cylinder installed. (Nuclear or Hypex grade resin)

** Subject to correct operating and maintenance procedures.

*** The quality of potable water can vary dependent on location.

Feed water specifications can be found in the operators manual and the data sheet of the product.

The MEDICA® Range

	MEDICA® PRO-R/RE 30/60/120	MEDICA® PRO EDI 60/120	MEDICA® Pro LPS	MEDICA® R-200
				
Inorganics (resistivity at 25°C)	>10 MΩ.cm	>10 MΩ.cm	>10 MΩ.cm	>10 MΩ.cm*
TOC	<30 ppb	<30 ppb	<30 ppb	<30 ppb*
Bacteria	<1 CFU/ml**	<1 CFU/ml**	<1 CFU/ml**	<5 CFU/ml**
Particles	0.05 µm filter	0.05 µm filter	0.05 µm filter	0.2 µm filter
Silica	<0.05 mg/l	<0.05 mg/l	<0.05 mg/l	<0.05 mg/l
Feedwater quality	Potable water***	Potable water***	Potable water***	Potable water***
Water purity	CLRW grade water High volume and high purity for high usage	CLRW grade water High volume and high purity for high usage with more predictable running costs	CLRW grade water Variable water specifications across a laboratory	CLRW grade water High purity for the highest usage
Make up rate	30, 60 or 120 liters/hour	60 or 120 liters/hour	130 liters/hour	200 liters/hour
Flow rate	Up to 4 liters/minute @ 14 psi (1 bar)	Up to 2.5 liters/minute	Up to 4 liters/minute	18-21 liters/minute
Integrated storage	Integrated wrap-around 50 liter reservoir		Integrated wrap-around 50 liter reservoir	Integrated wrap-around 350 liter reservoir
Typical applications	Large clinical analyzers or linked multiple analyzers	Large clinical analyzers or linked multiple analyzers	Multiple clinical analyzers installed into a lab with low quality feed water	Large clinical labs with multiple linked analyzers or standalone analyzers in different labs and on different floors
<p>* With ion-exchange cylinder installed. (Nuclear or Hypex grade resin) ** Subject to correct operating and maintenance procedures. *** The quality of potable water can vary dependent on location. Feed water specifications can be found in the operators manual and the data sheet of the product.</p>				

Additions to the MEDICA® Range



MEDICA® BIOX

A fluid waste treatment system designed to remove microplastics and control the level of biohazards within clinical analyzer wastewater.



HUBGRADE

An online equipment reporting and management service designed to digitally connect ELGA water purification systems.



**We'll deal with the details,
so you can make the
breakthroughs!**

Water quality is extremely important in a clinical environment. It is essential that your laboratory has access to a reliable supply of high purity water to ensure accurate and reproducible results, prevent misdiagnosis and optimise the uptime of your clinical analyzers. MEDICA® Clinical Water Purification Systems are designed to eliminate water impurities to CLRW standards, so that you can confidently continue your diagnostic work, without interruption.

Resourcing the world  **VEOLIA**

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