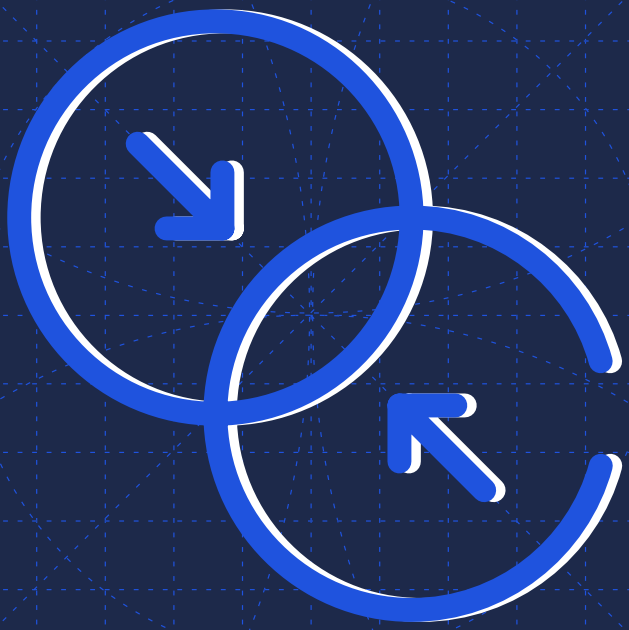
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Aqua-Nova Combi Unit

Two in One

White Paper

WFI Still and Pure Steam Generator in one unit

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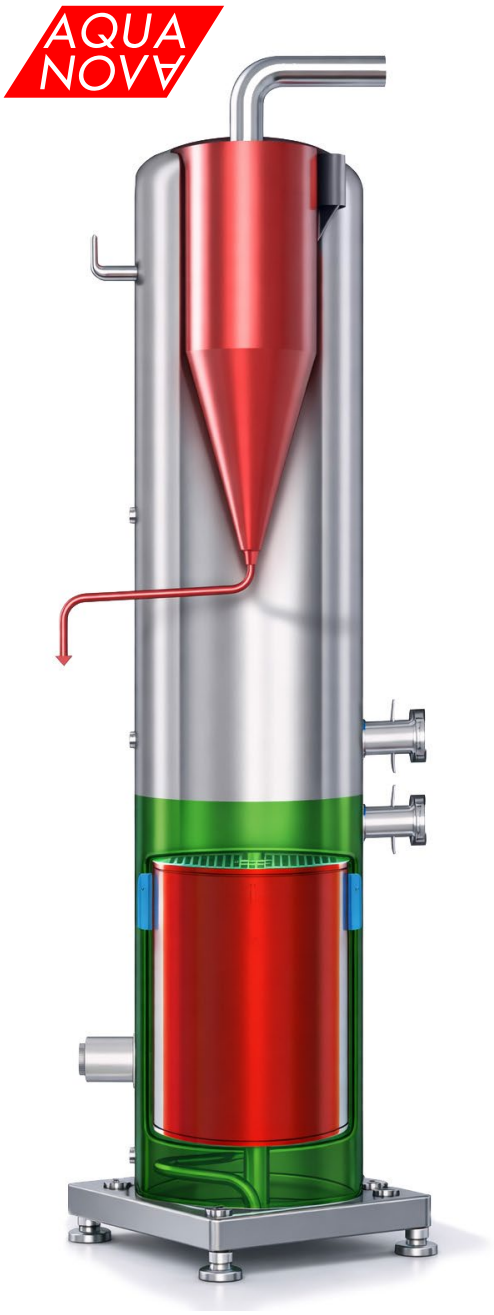
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Helena specialises in pharmaceutical sterilisation and powder handling, bringing extensive application expertise to complex processing challenges, from depyrogenation and drying to containment, dosing and bulk material handling.

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WFI and Pure Steam:
two similar and yet different fluids



Simultaneous production of Water for Injection (WFI) and Pure Steam is made possible by the unique Aqua-Nova technology. This paper explains how.

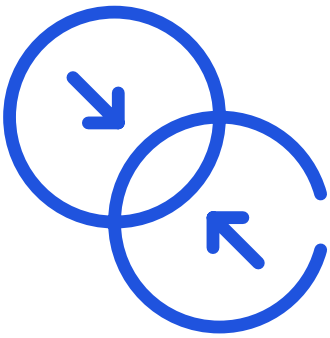
Following strong customer interest in combination units capable of producing WFI and Pure Steam simultaneously, Aqua-Nova developed its first Combi unit in the mid-1990s, with the first unit delivered in 1995. The defining characteristic of a Combi unit is the ability to deliver the required volume of WFI and the required quantity of Pure Steam at the same time, without compromising distillate production.

Since 1995, the Combi unit has been continuously developed. Aqua-Nova Combi units can switch automatically between three basic operating modes:

- **Simultaneous production of WFI and Pure Steam**
- **Production of only WFI**
- **Production of only Pure Steam**

The regulation of Pure Steam, heating steam, feed water and cooling water is proportionally controlled, ensuring a stable output across all modes and under varying conditions.

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Value to the customer

- **Reduced investment and maintenance — one machine instead of two (TWO in ONE)**
- **Reduced space requirement and installation cost**
- **Reduced validation effort**

Core functional principles

The reliable, robust operating principles first introduced by Aqua-Nova remain at the heart of every Combi unit:

- Low steam velocity, typically below 1.0 m/s.
- Multi-stage droplet separation, including true cyclone separation with direct discharge to drain at atmospheric pressure.
- Floating heat exchangers, fully immersed in water, minimising the risk of micro-crack formation.
- Proportional control of utilities.
- Easy inspection and maintenance.

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Simultaneous production of WFI and Pure Steam

The Aqua-Nova distiller and Pure Steam generator is designed for automatic and simultaneous production of WFI and Pure Steam. This is made possible by the unique Aqua-Nova technology, including column design and process control.

To understand the concept, it helps to consider how WFI distillation and Pure Steam generation differ.

WFI — production at constant capacity into a WFI storage tank

WFI is produced according to average consumption over a period — typically one day. A storage tank smooths short-term consumption peaks over a longer period, and the still normally runs at a fixed production rate. Distillation capacity is defined by the size of the storage tank and the consumption pattern, and the still cycles on and off according to tank level.

Distillation, WFI Storage tank level and WFI consumption

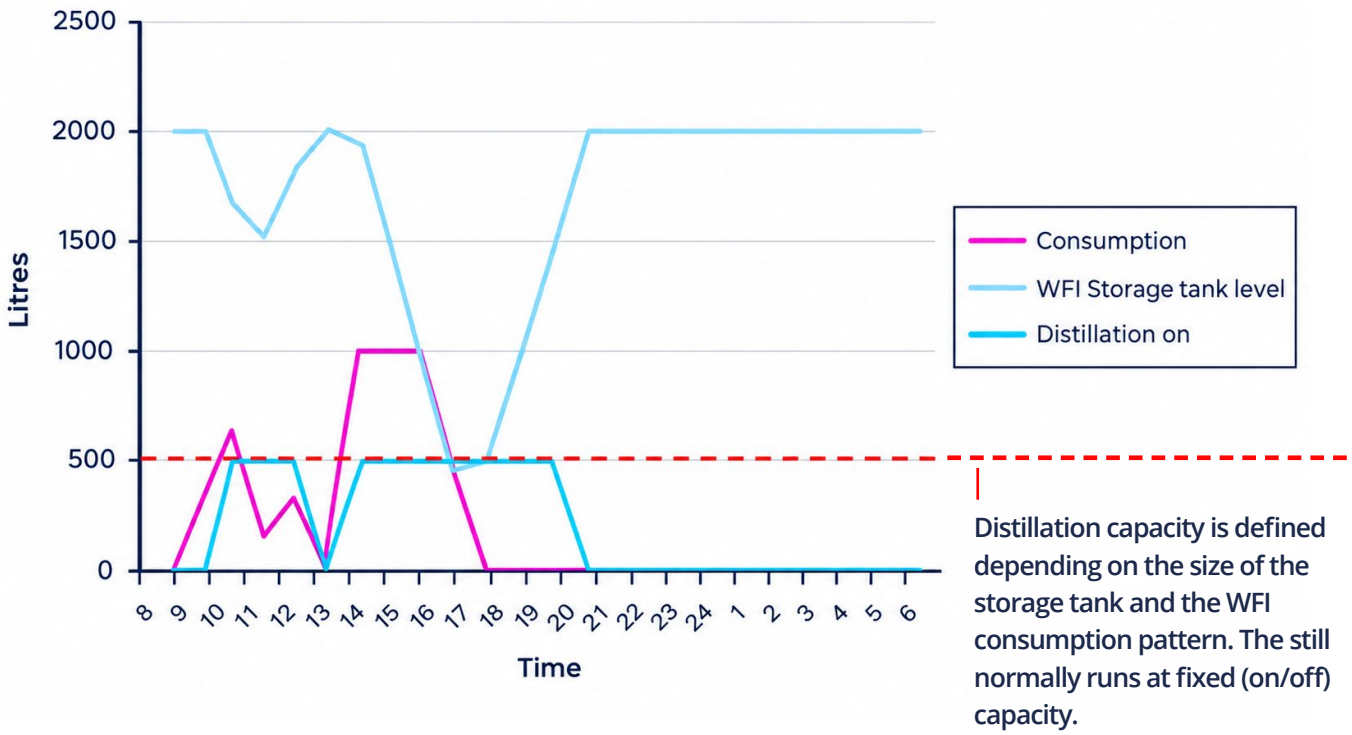


Figure 1 — Distillation, WFI storage tank level and WFI consumption.

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Pure Steam — instant consumption

Pure Steam cannot normally be stored and must be produced on demand. The generator must therefore be sized for the maximum simultaneous demand of autoclaves and other Pure Steam applications. Even a momentary shortfall in steam supply can have a negative impact on sterilisation cycles and downstream production processes.

For this reason, Pure Steam capacity is dimensioned for worst-case consumption — although in practice consumption is usually well below this maximum, leaving significant unused capacity in conventional designs.

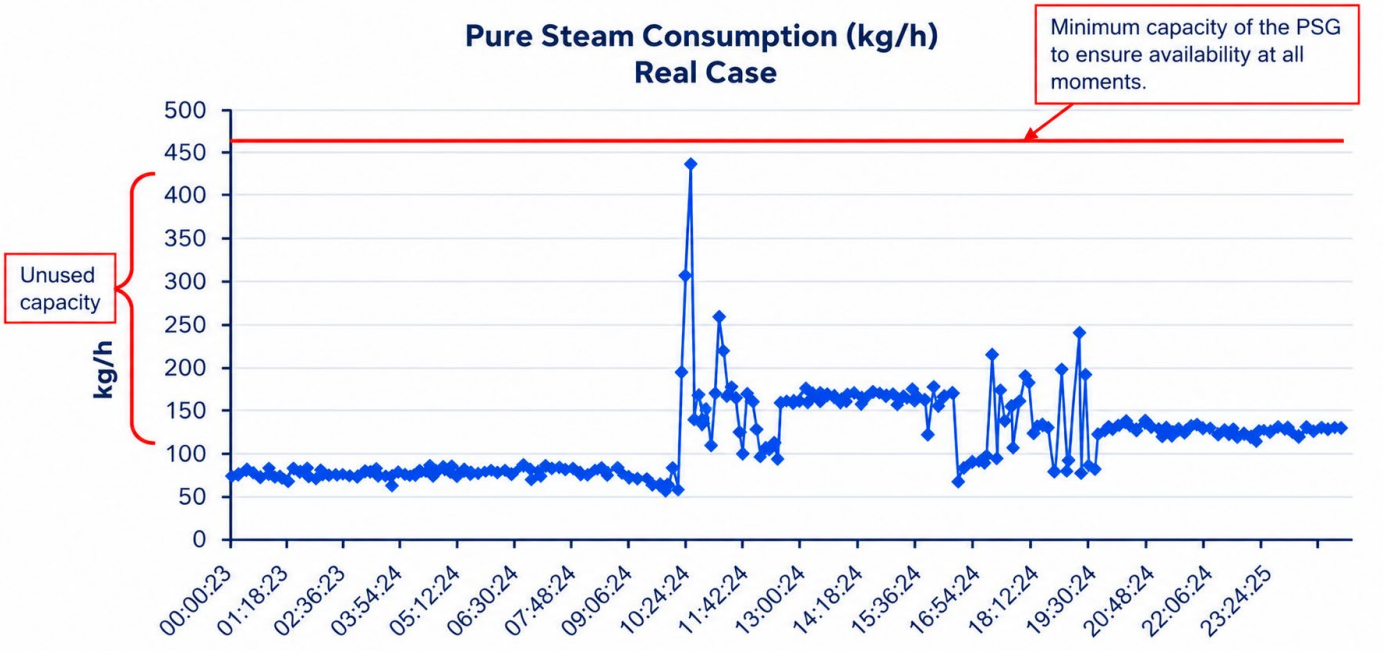


Figure 2 — Pure Steam consumption profile (real case). The gap between actual consumption and installed PSG capacity is the unused capacity in a conventional design.

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The unique Aqua-Nova technology

Simultaneous production of Pure Steam and WFI is made possible by the four-stage Aqua-Nova entrainment separation technology, which maintains its efficiency despite changes in Pure Steam pressure.
To ensure adequate Pure Steam pressure and WFI capacity at all times, the unit switches automatically between three modes:

- **WFI mode** — production of WFI only
- **PSG mode** — production of Pure Steam only
- **Combi mode** — simultaneous production of WFI and Pure Steam

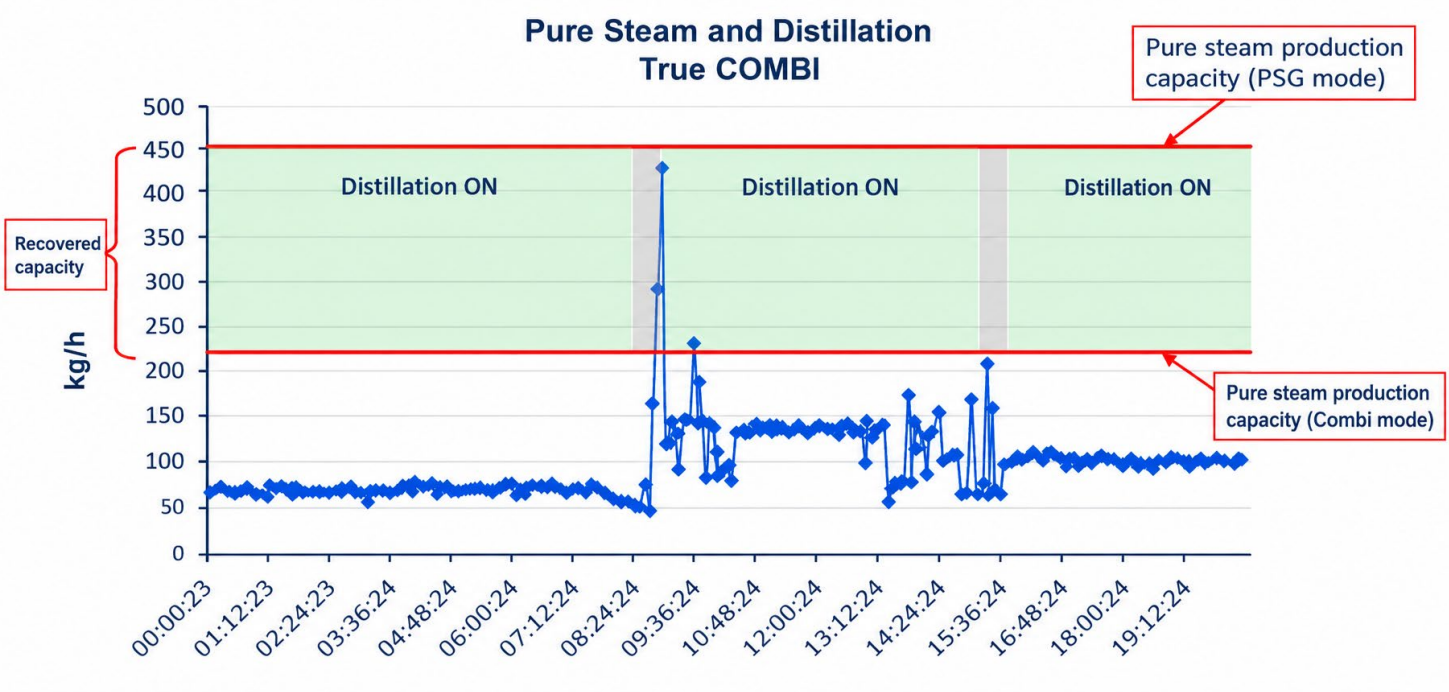


Figure 3 — Pure Steam and distillation in true Combi operation. Capacity that would otherwise be unused (Figure 2) is recovered to produce WFI, while the unit gives priority to Pure Steam to safeguard sterilisation.

In Combi mode the WFI production rate is fixed, while Pure Steam is produced according to instantaneous demand. If Pure Steam demand exceeds the Combi-mode capacity, the unit automatically switches to PSG mode — increasing Pure Steam capacity while temporarily halting WFI production. When demand returns to normal levels, the unit reverts to Combi mode.

These interruptions to distillation are typically very short — less than 20 minutes — and do not affect overall distiller productivity. To cope with varying demand, the unit gives priority to Pure Steam to safeguard the sterilisation process. Maximum Pure Steam demand is satisfied without over-sizing the equipment, and any excess capacity is used to produce WFI. A brief pause in WFI production does not affect the overall availability of WFI in the storage tank.

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Inherent safety by design

Beyond welding procedure control and metallurgical quality assurance, Aqua-Nova technology includes several intrinsic design features that help reduce material stress and support long-term operational reliability compared with more conventional high-velocity designs.

Aqua-Nova's position on long-term reliability is anchored in specific design choices rather than in broad claims. The features described below each address a defined mechanical or process condition that can otherwise contribute to long-term reliability problems in Pure Steam or WFI distillation systems.

Tensionless float-type heat exchangers, submerged in water

Aqua-Nova heat exchangers are designed to operate fully submerged, with low mechanical stress separated from the column shell. This helps avoid thermal tension in the material and thereby reduces the risk of micro-crack formation.

A further important benefit is that this design avoids dry heat transfer surfaces, thereby reducing the risk of local concentration of chlorides or other impurities that could otherwise contribute to corrosion mechanisms over time.



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Thermosiphon effect and self-cleaning heat exchanger operation

The natural circulation created in the columns improves heat transfer efficiency and contributes to a self-cleaning effect in the tubes, helping to reduce deposit build-up, fouling and local concentration effects.

Low steam velocity design

The columns are dimensioned to maintain very low steam velocity, typically below 1 m/s, allowing natural droplet separation by gravity and reducing droplet carry-over.

True cyclone separation with direct discharge to drain

Aqua-Nova uses individually dimensioned cyclones for each column, with direct discharge of separated remaining droplets to drain rather than feeding them back into the process.

Clean-side pressure advantage in the cyclone design

The cyclone geometry is designed to maintain a higher pressure on the clean side, supporting effective final steam polishing and separation efficiency.

Condenser design with seamless coils and efficient degassing

The condenser uses seamless coils instead of straight tubes and avoids internal welds in the critical condensing section, reducing thermal stress concentrations and potential weak points. Its efficient degassing design supports stable operation and consistent distillate quality, while the replaceable coil design also simplifies service if internal scaling should occur.

A note on long-term corrosion and stress-cracking

These features do not replace good metallurgy or welding practice, but they do reduce thermal and mechanical stress, dry-surface exposure and deposit-related concentration effects, all of which are highly relevant when assessing long-term corrosion and stress-cracking risk.

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7. Summary

Taken together, these design principles provide inherent safety by design and help minimise several of the mechanical and process conditions that can otherwise contribute to long-term reliability problems in Pure Steam or WFI distillation systems. Combined with the operational flexibility of the Combi unit — automatic switching between WFI, PSG and Combi modes, with priority given to Pure Steam to safeguard sterilisation — Aqua-Nova delivers a compact, validated and dependable solution for pharmaceutical and biotech operations.



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