

White Paper: Aqua-Nova COMBI unit - Two in One

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“WFI Still and Pure Steam Generator in one unit”

WFI and Pure Steam: two similar and yet different fluids

Simultaneous production is possible thanks to the unique Aqua-Nova technology. Here's how!

Following strong interest from our customers for combination units where Water For Injection and Pure Steam is generated simultaneously. AQUA-NOVA developed its first Combi unit in the mid 90s and whose first unit was delivered in 1995.

The special characteristics of Combi units are producing the required amount of WFI and simultaneously the amount of pure steam needed without affecting the production of distillate.

Since 1995, the Combi unit has been continuously developed. Combi AQUA-NOVA units can automatically switch from one to the other of these three basic modes:

- 1. *Simultaneous production of WFI and pure steam***
- 2. *Production of only WFI***
- 3. *Production of only pure steam***

The regulation of pure steam, heating steam, feed water and cooling water is proportionally controlled, ensuring a stable output in all modes and under different conditions.

These superior features bring value to the customer:

- 1. *Reduced investment and maintenance (one machine instead of two - TWOinONE)***
- 2. *Reduced space requirement, maintenance and installation costs***
- 3. *Reduced validation***

The basic reliable and robust function which was first introduced by AQUA-NOVA has remained the same:

- *Steam at low speed <1.0 m / sec.*
- *Three stage droplet separation including superior cyclone separation (micron size) with direct draining to atmospheric pressure.*
- *Floating heat exchangers, fully immersed in the water, thereby minimizing the risk of formation of microcracks.*
- *Proportional control of utilities.*
- *Easy inspection and maintenance.*

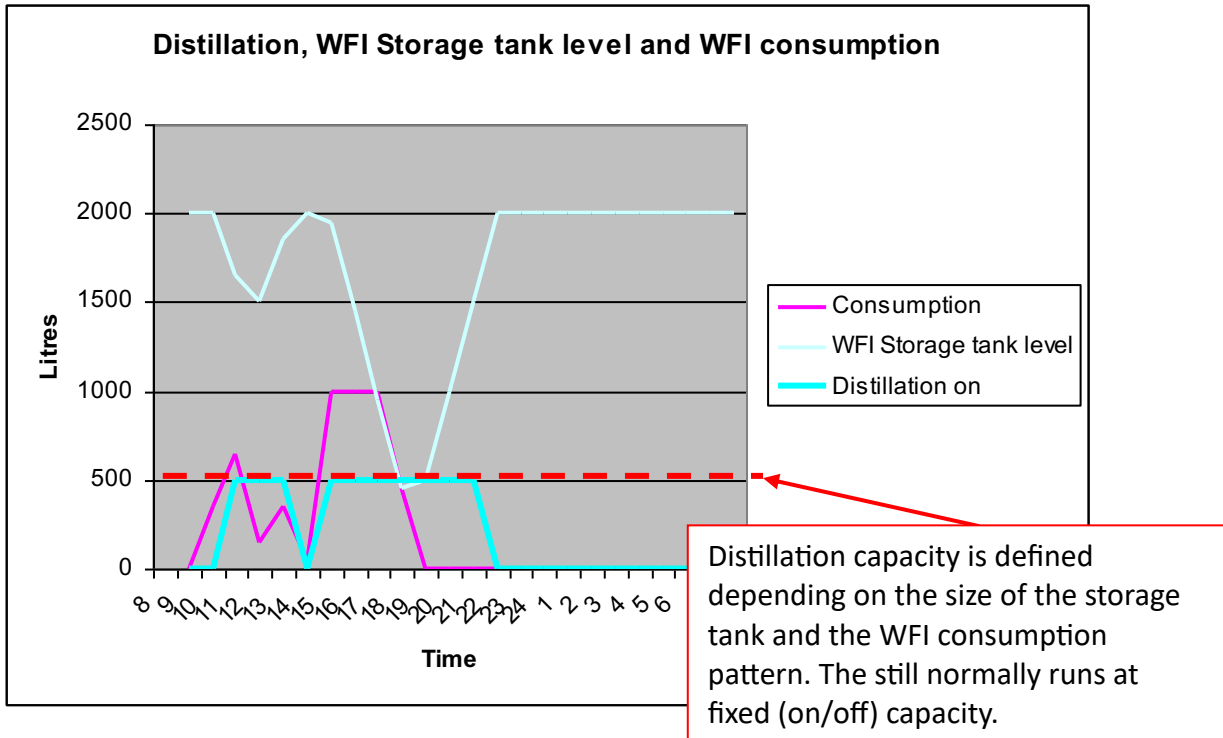
SIMULTANEOUS PRODUCTION OF WFI AND PURE STEAM

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

To understand this concept, we have prepared a small summary of the differences between WFI distillation and generation of pure steam.

WFI - production at constant capacity into a WFI storage tank

WFI is produced according to the average consumption over a period (usually one day). Thanks to the storage tank, momentary consumption peaks are smoothed over a longer period. The WFI still is normally set at a fixed production rate.



Distillation is turned on and off according to the level in the storage tank.

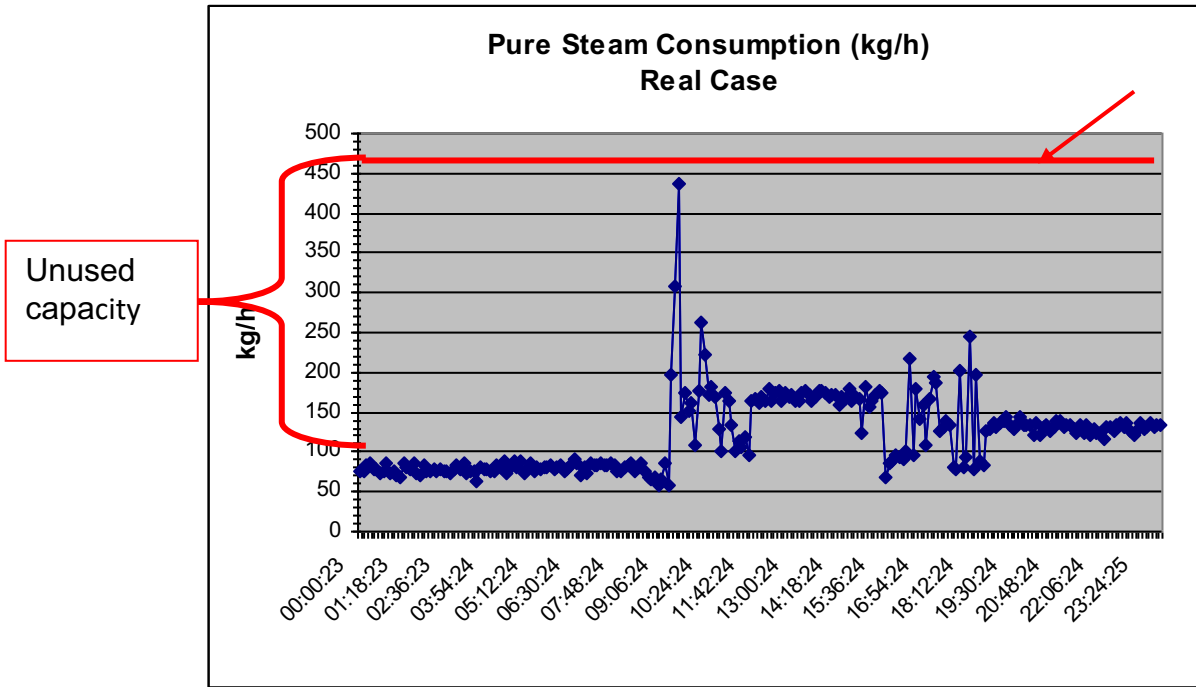
Pure steam - Instant consumption

Pure steam is a utility that it is normally not possible to store and must therefore be produced on demand. The size of the generator depends on the maximum simultaneous consumption of autoclaves and other pure steam applications.

Even a momentary of lack of steam may have a negative impact on sterilisation and so on production processes.

Because of this, the production capacity of the PSG is set to the maximum potential (worst case) consumption. Most of the time consumption is well below the maximum consumption.

Minimum capacity of the PSG to ensure availability at all moments.

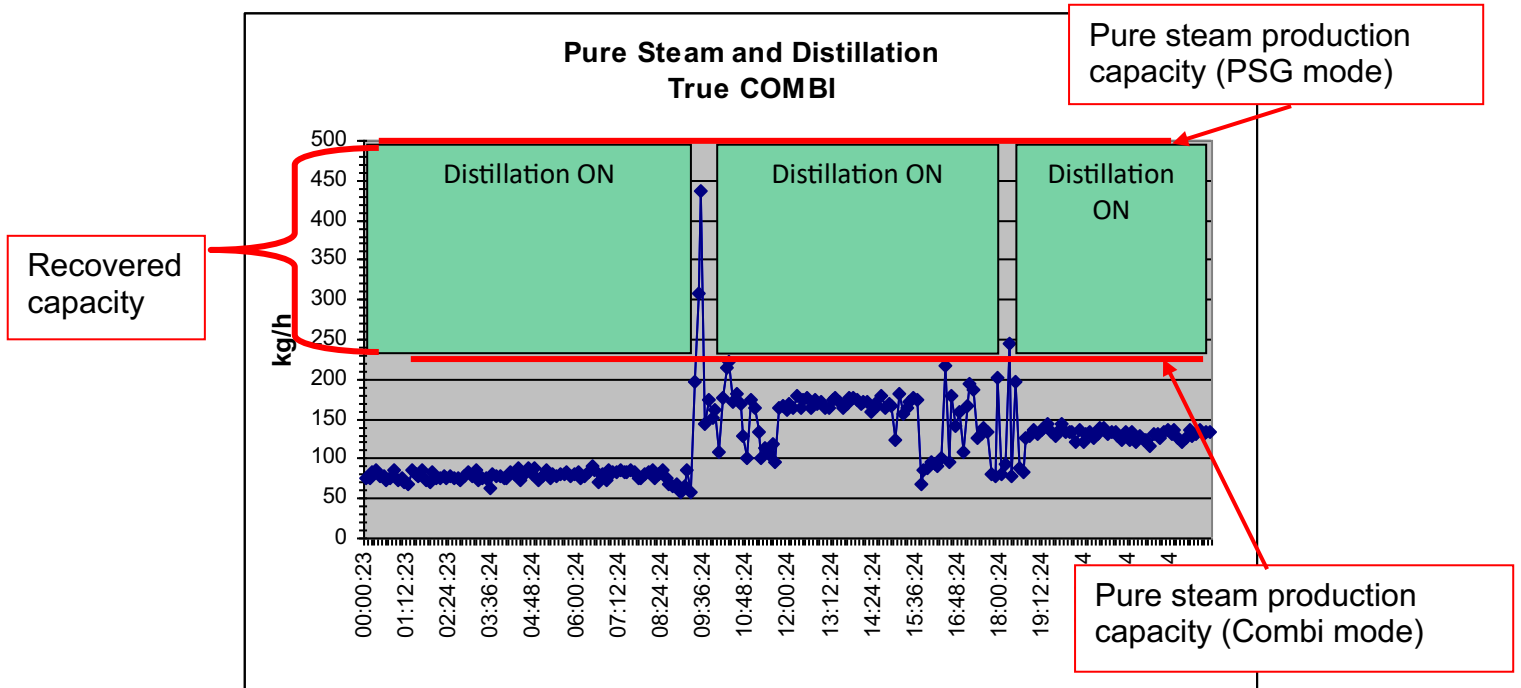


The unique Aqua-Nova Technology

Simultaneous production of pure steam and WFI is made possible thanks to the 4-stage Aqua-Nova entrainment separation technology that maintains its efficiency despite changes in the pure steam pressure.

Furthermore, to always ensure adequate pure steam pressure and WFI capacity, the unit automatically switches between these three modes

1. **Production of only WFI (WFI mode)**
2. **Production of only pure steam (PSG mode)**
3. **Simultaneous production of WFI and pure steam (Combi mode)**



In case of simultaneous production of WFI and pure steam, the WFI production rate is fixed while the pure steam is produced depending on the instantaneous consumption.

If the instantaneous demand of pure steam exceeds the production capacity in Combi mode, the unit automatically enters PSG mode. In PSG mode, the pure steam capacity is increased, while the WFI production is stopped. When demand of pure steam has returned to normal the unit goes back to Combi mode. These instances of stopped distillation are normally of very short duration (<20 minutes) and do not affect the overall productivity of the distiller.

To cope with the varying demand of pure steam and WFI, the unit gives priority to the pure steam to ensure a sterilisation process without risk.

The maximum demand of pure steam is produced without over-sizing the device and excess capacity is used to produce WFI.

A short stop of WFI production, while momentarily giving priority to the pure steam, will not affect the overall availability of WFI stored in the WFI tank.