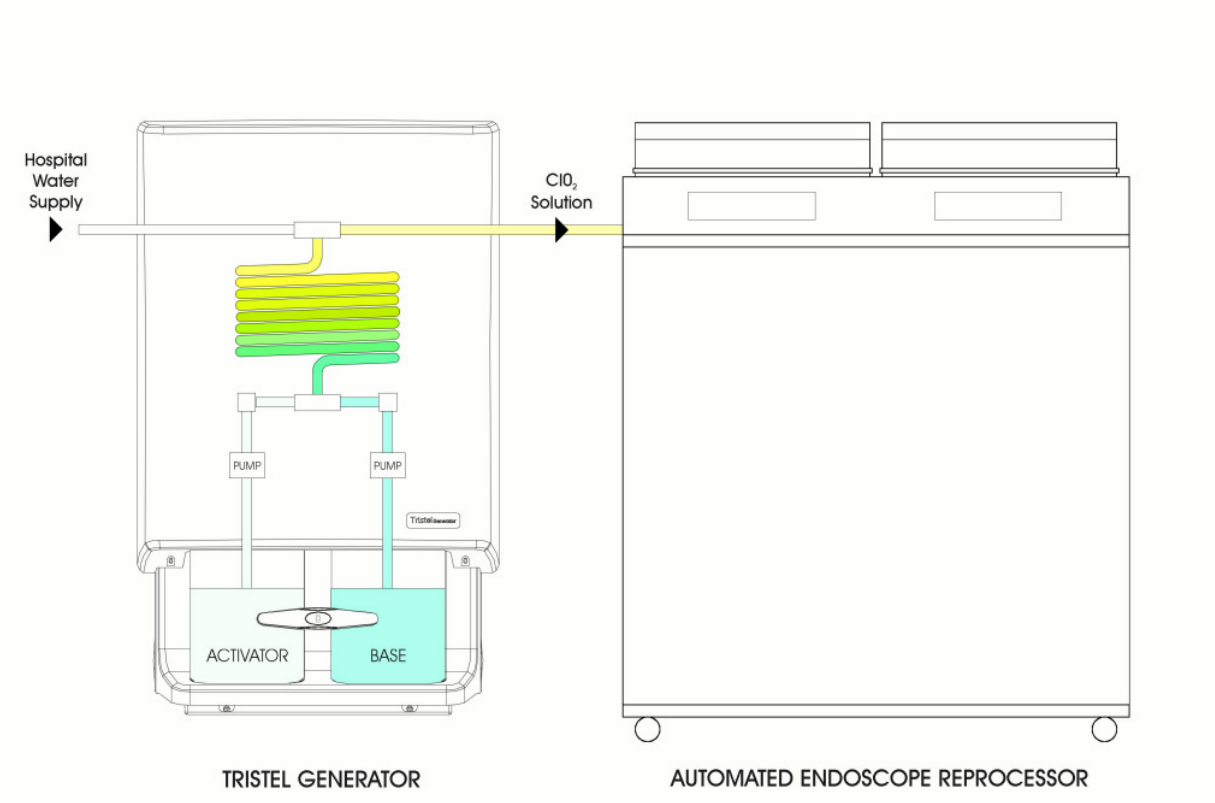
The Tristel Generator

The Tristel Generator is a microprocessor controlled dosing system that has been designed by Tristel specifically to dispense its patented chlorine dioxide chemistry for applications in the healthcare market.

How the Generator works

The Tristel Generator doses a chlorine dioxide solution into a water supply passing through it. The ClO2 concentration is pre-selected by the user for the intended application and accurately controlled.



Amongst its many potential applications, the Tristel Generator has been designed to supply high-level disinfecting solutions to automated endoscope reprocessors (AER). All Tristel solutions are sporicidal.

Combining the Tristel Generator with an AER has many advantages. They are:

- **Combining technologies delivers the best results**

Tristel's background is chemistry and its expertise is in the generation, dosing, control and measurement of its proprietary chlorine dioxide chemistry. AER manufacturers are experts in engineering, fluidics, and process control. They know best how to wash, irrigate, immerse and rinse endoscopic instruments.

Combining Tristel's expertise with that of the AER manufacturer delivers optimum results for the end user.

- **Precision and accuracy**

The Tristel Generator delivers a precise concentration of biocide with an accuracy that exceeds that of a typical AER's dosing and mixing system.

The Tristel Generator uses Swiss manufactured high precision diaphragm pumps in preference to higher maintenance peristaltic pumps used in other systems. The pumps are controlled by precision stepper motors, which provide significantly greater motor control and pump accuracy than conventional electric motors. Encoders fitted to the motors ensure precise indexing of the pumps at all times. Consequently the Tristel Activator and Base solutions are injected into the patented ClO_2 mixing coil with great precision.

A digital flow meter incorporated into the water inlet provides data to the Generator's microprocessor control system that controls the speed of the pumps. The microprocessor uses an algorithm to translate the output from the flow meter into pulses applied to the pump stepper motors to ensure that the volumes of Activator and Base solutions injected into the water supply are constant, irrespective of changes in water flow rates.

In addition, the Generator incorporates a patented pumping system, using pressure control valves, to ensure that each time the pumps dispense a Bolus (packet) of Activator or Base solution, the volume dispensed is absolutely constant irrespective of changes in water pressure in the system. So variations in both water pressure and flow rate are automatically compensated for to ensure total accuracy of the dosed output.

As an example, if the Tristel Generator is programmed to produce chlorine dioxide at a concentration of 150 ppm and a tap is opened within the hospital's water circuit that changes the flow rate and system pressure of water entering the Generator, the flow meter will instantly detect the change and instantaneously adjust the pump rate to ensure that the chlorine dioxide concentration produced by the Tristel Generator remains constant.

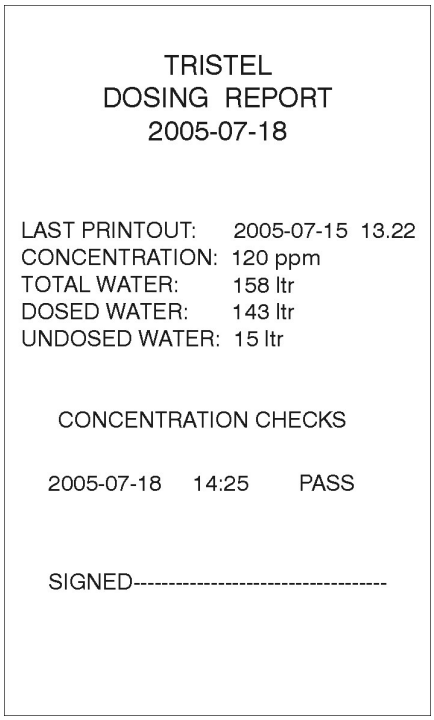
- **Security**

The Tristel Generator incorporates a watchdog system employing two microprocessors. Whilst the primary microprocessor is controlling the Generator, the secondary processor is verifying the functionality of the first processor. If the output from the two microprocessors is not identical the Generator will report a fault condition.

- **Validation and data capture**

The Tristel Generator incorporates a chlorine dioxide, ion selective electrode (ISE) sensor, which measures the chlorine dioxide concentration dispensed by the system and validates that the dosed output is within the parameters set by the user.

The data interface between the Tristel Generator and the AER not only allows the two devices to communicate with each other, but also allows either the AER or the Generator to print out a validation report ticket. An example of the information that can be printed on the ticket is shown below:



TRISTEL
DOSING REPORT
2005-07-18

LAST PRINTOUT: 2005-07-15 13.22
CONCENTRATION: 120 ppm
TOTAL WATER: 158 ltr
DOSED WATER: 143 ltr
UNDOSED WATER: 15 ltr

CONCENTRATION CHECKS

2005-07-18 14:25 PASS

SIGNED----------

The probe system is programmable under software control to take a sample per batch of chlorine dioxide solution delivered to the AER, (i.e. one sample each time a batch is requested), or a predetermined number of cycles per day (applicable where the Generator is continuously producing chlorine dioxide solution and samples are automatically taken at intervals defined by the user).

The ISE sensor is housed within a stainless steel manifold block that incorporates patented technology to ensure reliable and consistent results.

- **Safety**

The Tristel Generator has many safety features, which an AER, unless specifically designed to use chlorine dioxide, will not have. They are:

- ✓ The helical coil mixing chamber and all internal components of the Generator system are manufactured from high grade 316 stainless steel. This eliminates the risk of chlorine dioxide spillage caused by failure of plastic pipes and fittings and ensures long service life.

- ✓ The pump diaphragms are PTFE coated and all internal system seals manufactured from VITON to ensure long life, minimum service down time and reduced risk of chemical spillage.

- ✓ Bottle retainers lock the Activator and Base solution bottles securely in place on the Generator to minimise risk of spillage. Each bottle locates into an individual bottle compartment to prevent mixing of any spillage that could occur in the event of an accident.

- ✓ Security caps ensure that each bottle is sealed as an additional safety feature to prevent spillage.

- ✓ The Activator and Base bottles are individually colour coded with labels that correspond with similarly colour coded labels on the Generator. This ensures that the user does not load two identical bottles into the Generator, or accidentally load a bottle of Activator into the Base compartment or vice versa. The failsafe system provide by the ISE sensor also ensures that if two identical bottles of solution are inserted into the Generator the system will recognise that chlorine dioxide of the correct concentration has not been produced and an alarm will sound to warn the user.

- ✓ Bottle fluid level sensors will automatically tell the user when it is time to change bottles.

- **Regulatory compliance**

Both the Tristel Generator and the Tristel Generator Activator and Base solutions are classified as Class 2a medical devices under MDD93/42. This makes the combination of the Tristel Generator with an AER device an attractive system package in terms of regulatory compliance conformity.