

Managing Sterilization through Calculation of the Fo Value

Industry: Pharmaceuticals, Food
Product: Paperless Recorder (DX/DXP)

Overview

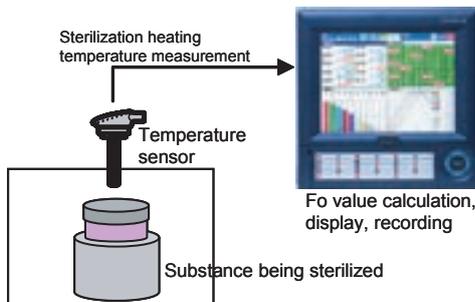
In the sterilization process during pharmaceutical and food manufacturing, the “Fo” value is used as a benchmark for the sterilization time. The Fo value expresses the heating time required for disinfection, and varies according to fluctuations in heat applied to the substance being sterilized. The DX automatically calculates this Fo value from the heating temperature (the temperature measured on the DX), and is useful in managing the sterilization process by displaying and recording the value together with the heating temperature. Such careful monitoring and control allows minimization of sterilization time while maintaining the nutritional properties of the food.

Customer Needs

- To automatically calculate the Fo value, record it along with heating conditions, and use these as QC data
- To monitor the Fo value by heating temperature, shorten the heating process, and stabilize food quality
- To install a simple, low cost, highly reliable system without using external instruments or computers

Process Outline

The heating temperature of the substance being sterilized is measured on the DX Paperless Recorder. The Fo value is automatically calculated according to the heating temperature (temperature measured on the DX) by the DX's mathematical functions. Computed results are displayed and recorded together with heating temperature and other parameters, and saved as quality data.



Also, the DXP supports 21CFR Part 11, and allows you to save formal pharmaceutical sterilization management data for approvals.



Displays and records the heating temperature and Fo value.

Definition of the Fo Value

$$Fo = \Delta t \sum 10^{(T-Tb)/Z}$$

- Δt Measurement interval
- T Heating temperature (temperature measured on the DX)
- Tb 121.1°C (for steam pasteurization)
- Z Temperature unit of logarithmic sterilization capability changes (generally, 10 °C is used).

Example of Calculation of the Fo Value on the DX

$$31 = (K01 * (K03^{((01-K02)/K03)})) / K04 + 31$$

- 01 Heating temperature (temperature measured on the DX)
- 31 Fo value calculation result
- K01 1 sec or 0.125 sec (DX's measurement interval)
- K02 121.1 °C (Fixed. Equivalent to Tb in the Fo equation)
- K03 10 °C (Fixed. Equivalent to Z in the Fo equation)
- K04 60 (sec, for conversion to units of minutes)

Yokogawa's Solution



DX/DXP series paperless recorders capable of automatically calculating the Fo value.

- Fo value calculated automatically by a math function (optional)
- Measured and calculated results saved electronically to local media while being displayed in real time on the large, color TFT display
- Also enables data sharing on the network (Ethernet compatible)

Conclusion

DX/DXP series instruments allow you to automatically calculate and process Fo values as manufacturing/quality data at a reasonable cost. Also, by constantly ascertaining the Fo value according to the heating temperature, you can optimize (shorten) the heating process, and in the case of foodstuffs, minimize excessive heating which can damage the nutritional elements in foods.