

Let Kanomax Help You Meet USP 797 Regulations



KANOMAX
The Ultimate Measurements

Application Note

USP 797 sets standards for compounding sterile preparations to ensure patient and worker safety

USP chapter 797 is an enforceable regulation from the United States Pharmacopeia that addresses safety concerns regarding Compounded Sterile Preparations (or CSP for short). USP 797 came about due to several incidents of contamination that were introduced during the compounding process. This contamination caused several fatalities prompting the need for an enforceable regulation to govern the compounding of sterile preparations. While it is not federally regulated, nearly all states do have laws that refer to USP 797 either directly or indirectly, and even in the few states where there is no regulation a hospital or pharmacy may still want to follow USP 797 as a best practice to maximize patient safety and minimize liability.



A sterile, controlled environment is key to safe compounding and compliance with USP 797

The purpose of this application note will not be to explain USP 797 in detail, but to explain how you can use our particle counters and other Kanomax products to help your business comply with the regulation. The regulation specifies that an ISO class 5 clean room environment is required for critical areas where the compounding preparation is exposed to ambient air. A class 7 buffer zone is required around critical areas and there also needs to be a class 8 anteroom for gowning and preparation. These ISO classes are all guidelines to how many particulates

can be present within the controlled environment. Airborne particulates can pose a hazard because some of them may be biological contaminants such as bacteria or mold, and even inorganic particulates may be pyrogenic in nature or pose risk of infection. Limiting the amount of particulates present in the compounding area lowers the risk of contamination.



The Model 3905 or 3910 portable particle counter is a versatile tool not only for particle counting, but also for air velocity, temperature, humidity and pressure measurements

Kanomax offers several particle counters that can help your pharmacy or hospital meet the requirements of USP 797. Model 3887 is an economical handheld unit suitable for spot-checking non-viable particles or even certifying smaller cleanrooms in the ISO class 5-8 range. The optional printer is highly recommended for this application as tamper-proof hard copies are an important part of documenting compliance. We also offer higher flowrate portable units (models 3905 and 3910) that come with a built-in printer and can be used to certify a cleanroom much faster than a smaller handheld unit can. These portable units are best suited for larger areas where multiple samplings are required at many different points (per the ISO procedure). The portable units are designed to make certification easy with pre-programmed standards modes that can guide you by providing the correct number of points to sample and automatically calculating the results.

The smaller handheld units can also be used to check the effectiveness of HEPA filters in the field. By sampling the air on each side of the filter you can identify if there's a problem or make an informed decision about when to replace the filter. Similarly the AES-1000 wall-mount unit is a good choice for the anteroom area as its easy-to-see visual indicator and audible alarm can alert personnel of potential contamination in the anteroom before it spreads into other areas. The AES-1000 can easily be linked into your existing ethernet network to provide remote reports and warnings.

Kanomax also offers many options for checking airflow and air exchange rates within the cleanroom. In order to effectively control particulates the ventilation system in the cleanroom must have a laminar flow that evenly pushes air and particulates in one direction so they are removed from the cleanroom or it needs to perform sufficient number of air exchanges per hour to ensure particles are being effectively removed through the dilution process. Our handheld anemometer line and airflow capture hood are perfect choices to help regulate air flow and exchange rates within a UPS 797-compliant cleanroom. The 2% accuracy of the Climomaster™ makes it a very good choice for performing airflow measurements to check a cleanroom or PEC (Primary Engineering Control such as a laminar flowhood or biosafety cabinet). Using a less accurate tool introduces uncertainties that can make regulating the ventilation difficult.



The Climomaster™ features a 2% accuracy and can also measure temperature, humidity and pressure depending on the options and probe selected

Finally we offer several ways to test temperature, humidity and pressure levels which is also a requirement of USP 797. The Climomaster™ and portable particle counters have the capability of measuring these additional parameters if you're looking for a consolidated or all-in-one testing. We also offer a 24/7 cleanroom monitoring system and IAQ monitor that can be setup in your cleanroom to monitor particulates, temperature and humidity continuously. Finally we have a variety of ways to check pressure such as the optional differential pressure sensor on the Climomaster™ or the portable particle counters as well as a wide range of pitot tubes.

About Kanomax USA, Inc.

Kanomax has delivered the best measurement solutions in its products and services that adapt precision measurement technology for fluids and particles. Kanomax product lines include anemometers, particle counters, dust monitors, and IAQ monitors. Kanomax is contributing to technological innovation and quality improvement for the processes of quality management, environment management, and technology development in the areas of environment, health, and energy, which are essential to sustain human well-being, as well as in other industrial areas including automobile, aerospace, semiconductor, electronics manufacture, heavy industry, steel, shipbuilding, pharmaceutical, biotechnology, food-processing, medical, construction, and civil engineering.



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