STERILE DOCKING USING MICROWAVE HEATING

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ABSTRACT

Peritonitis is the single most limiting factor for patients undergoing Continuous Ambulatory Peritoneal Dialysis (CAPD), a treatment associated with End Stage Renal Failure (ESRD). A device which destroys microorganisms that are recognized to be the most problematic in causing peritonitis has been developed and will be described. Moist heat has proven to be the most effective technique for disinfecting the inner lumen of commercially available medical connectors. Moist heat, using microwave heating, has proven to be the most effective and rapid technique. This device represents the first microwave-based medical product specifically designed for home or office use by the patient.

INTRODUCTION

The standard methods for treatment of kidney failure are transplantation, hemodialysis and peritoneal dialysis.

A kidney transplant is the preferred method of treatment. However, this is often not a viable option. Many patients are poor surgical risks due to age and often co-existing health problems. In addition, the availability of a suitable kidney donor is a significant problem.

Renal dialysis is a filtration process across a semipermeable membrane to eliminate bodily waste.

Hemodialysis involves the cleansing of the blood by circulating it through an artificial kidney machine. It normally requires three weekly sessions of four to six hours each.

Peritoneal dialysis is an alternate therapy to hemodialysis. With peritoneal dialysis, the peritoneal cavity located within the abdomen and its associated membrane lining (the peritoneum) are used to perform the filtration cleansing process.

The most recent development in peritoneal dialysis is continuous ambulatory peritoneal dialysis (CAPD), which was approved by the FDA in 1978. To undergo CAPD, the patient has a small, flexible catheter surgically implanted into the peritoneal cavity within the abdominal cavity. A plastic bag containing the dialysate, a sterile sugar and water solution, is attached to the catheter and elevated so that the approximately two liters of fluid can gravity drain into the peritoneal cavity. The dialysate remains in the abdomen from four to six hours while the peritoneum filters impurities through the process of natural osmosis. At the end of that time, the impurity-laden fluid is drained out of the abdomen and discarded. A new bag of dialysate is attached and the process is repeated, normally four times a day. Each exchange of dialysate takes about 20 minutes. The scheduling of exchange permits eight hours of undisturbed sleep each day.

CAPD offers many benefits to the patient. It basically eliminates dependence on a dialysis machine and increases mobility, resulting in a better quality of life and allowing many patients to conduct a full work schedule. Often, however, bacteria introduced into the dialysis solution during the frequent exchanges cause peritonitis. Peritonitis, the inflammation of the peritoneal cavity, is the major complication associated with peritoneal dialysis and the leading obstacle to wider acceptance. Over time, approximately 30% of all peritoneal dialysis patients change modality or return to hemodialysis. The majority leave due to peritonitis. In 1990, there were over 140,000 kidney dialysis patients in the U.S. alone . . . of which only 21% or 30,000 were on peritoneal dialysis, the preferred treatment modality.

TECHNICAL DISCUSSION

The design concept using moist heat generated by microwave energy to disinfect the inner lumen of commercially available connectors is quite simple. Moist heat has proven to be the most effective technique for disinfecting the inner lumen of commercially available medical connectors [1,2]. Moist heat, using microwave heating has proven to be the most effective and rapid technique [3-6]. The patented peritoneal dialysis

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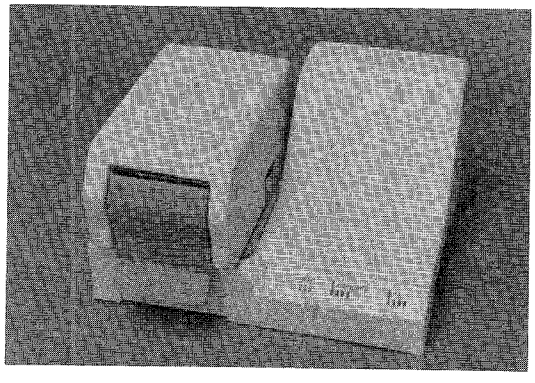
moist heat device (PDM) is safe, cost effective, and simple to operate. The unit was designed for operation by visually or otherwise physically-impaired patients. The PDM device shown in **Figure 1** consists of three basic elements integrated into a single compact unit:



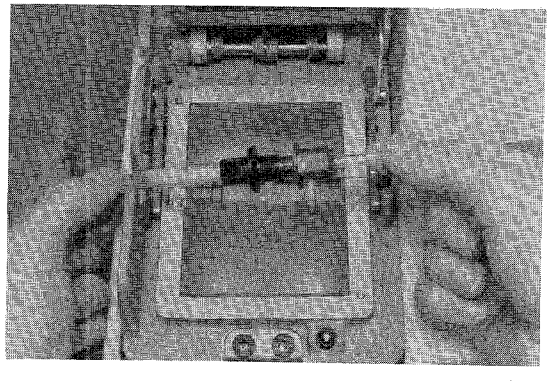


Figure 1

1) The heating cavity or enclosure that couples microwave energy to heat the solution contained in the mated CAPD connector;

2) The 25-watt solid state microwave source operating at 915 MHz; and

3) The controller, a microcontroller for monitoring and maintaining the heating cycle.

The microwave cavity contains a dielectric insert which is contoured to position and support the mated connector pair. The microwave cavity provides a fully-shielded enclosure. The connector material is transparent to microwave energy, allowing the dialysate contained within the connector to rapidly absorb microwave energy.

The closing of the cavity provides clamping of the tubing adjacent to the connector which holds the liquid at a constant volume. The pressure inside the connector increases during the heating cycle, allowing the liquid temperature to rise well above normal boiling temperature. A pressure of three atmospheres will result in a temperature of approximately 140°C. Since the plastic is transparent to microwave energy, the outside surface of the connector remains lukewarm and safe to touch.

The solid state transmitter design allows operation from a 12VDC power source. This permits an exchange to be made in a motor vehicle, providing increased patient mobility.

Figure 2 illustrates the time required to achieve clinical sterilization as a function of temperature.

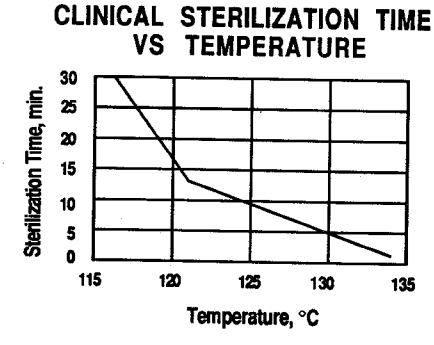


Figure 2

Figure 3 illustrates the rate of temperature rise with full power (25 watts) applied for 30 seconds. The maximum temperature achieved within the 30-second period was 140°C. To evaluate the temperature distribution within the connector, non-perturbing temperature probes (Luxtron Model 755 Multi-Channel Fluoroptic Thermometry System) were placed at the center and each end of the mated connector (i.e., the middle, patient side, and bag side of the connector). The results are included in **Figure 3**.

One serious problem encountered was the compatibility of the existing commercially avail-

able connectors with the sterilization process (i.e., the ability of the material to withstand the temperature and pressure experienced during the sterilization process). For this reason, a power profile was established that restricted the maximum temperature to 125°C. From initial turn-on through 46 seconds, the power is maintained at 18.5 watts. The power is then reduced to 13 watts. The entire heating cycle is 54 seconds.

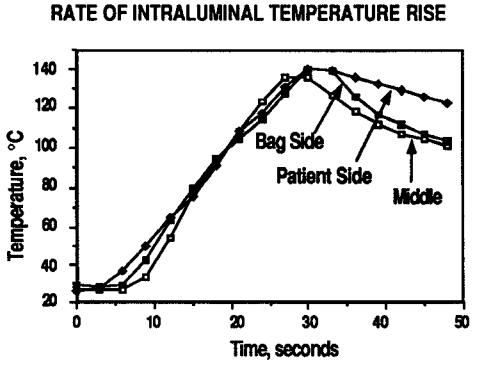


Figure 3

TEST RESULTS

Solutions containing a concentration of various microorganisms were prepared. **Figure 4** illustrates the Safe-Lock™ CAPD connectors used for this evaluation. The total liquid volume contained within the mated pair is 0.7ml. Microorganisms tested included those most prevalent and most problematic in causing peritonitis. Suspensions of 0.1ml at 10^7 organisms per ml were prepared in physiological saline. Cell suspensions of *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Aspergillus niger* were used.

Preliminary testing was performed to determine approximate heating and kill times. The degree of disinfection was determined using viable cell colony counts of sample solution after heating. Comprehensive tests were performed according to U.S.P. 21 Sterility Testing Determination [7]. Solution samples were performed after heating and put into tubes containing Soybean Casein Digest U.S.P. (TSB) media which were then sealed and incubated for 14 days. Bacteria and yeasts were incubated at 32°C whereas mold cultures were kept at room temperature. Absolute growth versus no growth was determined by microscopic observation. Controls were done in the same manner. Positive controls were performed without heat, whereas negative controls were done in the absence of test organisms.

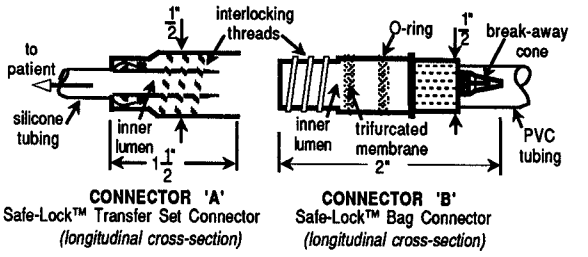


Figure 4
Safe-Lock™ Connector

Preliminary tests showed that after 54 seconds of heating at temperatures ranging from 100°C to 120°C (**Figure 5**), no viable organisms as determined by viable colony counts were recovered from test suspensions. Positive controls demonstrated viable microorganisms recovered from unheated samples. No viable microorganisms were recovered from negative control samples.

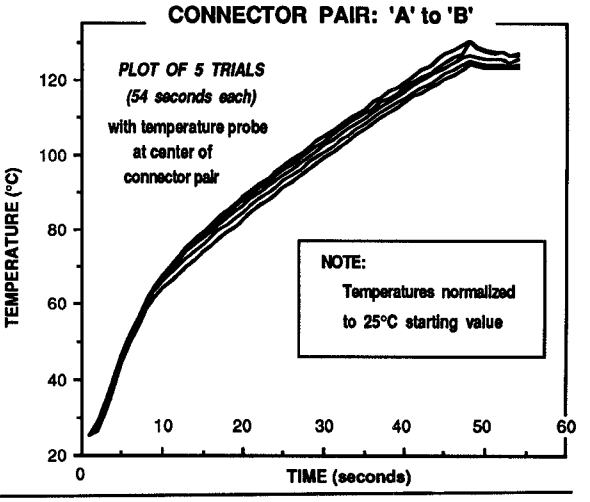


Figure 5
Temperature curve showing temperature achieved during testing

Subsequent trials were performed according to U.S.P. 21 Sterility Testing Determination [7] protocols. In this case, positive controls were performed in a similar manner. Testing showed *Aspergillus niger* to be the most resistant to microwave heat disinfection.

Figure 6 is a plot of survivor population with respect to microwave heating time for the heat resistant spores of the fungus, *Aspergillus niger*. The results confirm that all organisms tested showed a 10^6 population reduction in less than 54 seconds. A summary of disinfection levels and parameters is shown in **Figure 7**.

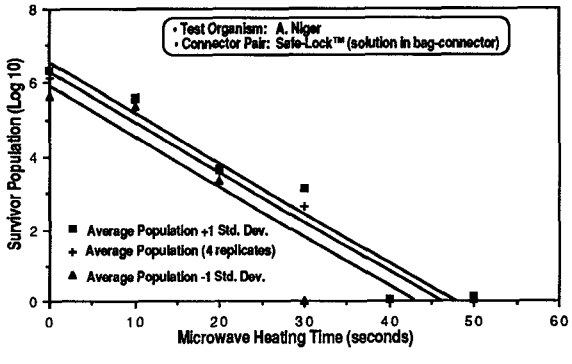


Figure 6

DISINFECTION CYCLE PARAMETERS:

• Kill Time:	54 seconds
• Microwave Energy:	18.5 watts (0 to 46 secs) 13 watts (47 to 54 secs)
• Temperature:	100°C minimum (@ 54 secs) (intraluminal solution temperature)

DISINFECTION LEVEL:

- Population Reduction: 10^6 microorganisms
- Microorganisms Destroyed:

GRAM POSITIVE	(Staphylococcus epidermidis)
GRAM NEGATIVE	(Pseudomonas aeruginosa)
YEAST	(Candida albicans)
MOLD	(Aspergillus niger)

Figure 7
Summary

CONCLUSION

The microwave heating technique showed efficient intraluminal disinfection of CAPD connector pairs. A 10^6 population reduction of various organisms which are the most prevalent and problematic in causing peritonitis was accomplished with a very short heating cycle. This process is effective due to the rapid heating of the solution contained within the connectors. Since plastic is transparent to microwave heating, the external surface of the plastic connector remains lukewarm during the process. These studies further substantiate this technology is a safe and effective means of intraluminal disinfection.

FDA permission to market this device without restriction has been granted. This represents the first microwave-based medical product specifically designed for home/office use by the patient. This sterile docking device greatly reduces the incidence of peritonitis and improves the quality of life for renal failure patients.

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