Formaldehyde gas sterilizer

Country of origin | Japan

Health problem addressed
It is common knowledge that the sterilization of medical equipment parts is very important in infection control. Sterilization is mainly performed using Autoclave. Non-heat-resistant items such as endoscopes must be sterilized using low temperature gas sterilization such as ethylene oxide (ETO) gas. However, ETO gas must aerate over a long period of time to secure safety. It requires 24 hours or more, and in some countries its emission is the subject of regulations due to toxicity.

Product description and functionality
This device sterilizes using formaldehyde gas produced by vaporising 12% aqueous formalin solution in a chamber set to 50 degrees Celsius and adjusting pressure from -0.08 Mpa to -0.01 Mpa. The residual gas after the sterilization is decomposed and detoxified by the oxidation reaction of the catalyst. It uses the ammonia which vaporized it as a purification accelerant in this process. Therefore, it does not directly emit formaldehyde gas into the environment after sterilization.

Developer’s claims of product benefits
Non-heat-resistant items must be sterilized with a low temperature sterilizer. But, ETO gas and H2O2 gas are expensive, and difficult to obtain in some regions and countries. Above all, it must aerate over a long period of time to secure safety. It requires 24 hours or more. This product uses formalin, which is cheap and can be obtained easily in many countries and areas, as a sterilization medium. The processing time is 310min. It can be operated several times in a day. It doesn’t require special training.

Suitability for low-resource settings
The formalin solution used as a sterilization medium is cheap and easy to obtain, as is the ammonia used as a purification accelerant for the gas decomposition. The device is powered only by electricity, so it does not need steam or water supply and drainage. Therefore, installation is extremely simple. It requires a stable electric supply, but the device is sealed in case of a blackout, and has infallible gas leak safety measures.

Operating steps
Push the power button, Open the door of chamber, Close the door after putting the sterilizing objects in the chamber, Push the start switch of the touch panel. After the processing, open the door and take the sterilizing objects.

Regulatory approval
It is approved by Ministry of Health, Labour and Welfare Government of Japan and ISO-13485

Future work and challenges
A small-sized 100V formaldehyde gas sterilizer is planned, and we intend to make it operable by battery.

Use and maintenance
User: Nurse, Midwife, Cleaning Staff
Training: The distributor performs simple handling explanation at the setting place for about 15 minutes.
Maintenece: NA

Environment of use
Setting: Rural and Urban Settings, Indoors, Primary, Secondary and Tertiary levels
Energy requirements: Continuous power supply of 200V for 6 hour recharging
Facility Requirements: System requires an air exhaust duct

Product specifications
Weight (kg): 460kg
Dimensions: 840mm x 940mm x 1745mm
Consumables: Formalin 12% solution and Ammonia 9% solution
Lifetime: 10 years
Shelf Life: 10 years
Retail price (USD): 161,000

Price of consumables (USD): 3
Other features: Once installed, can be a mobile unit
Year of commercialization: August, 2008
Currently sold in: Russia, Saudi Arabia, United Arab Emirates, Vietnam. Malaysia, Singapore, China, Korea and India

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http://www.who.int/medical_devices