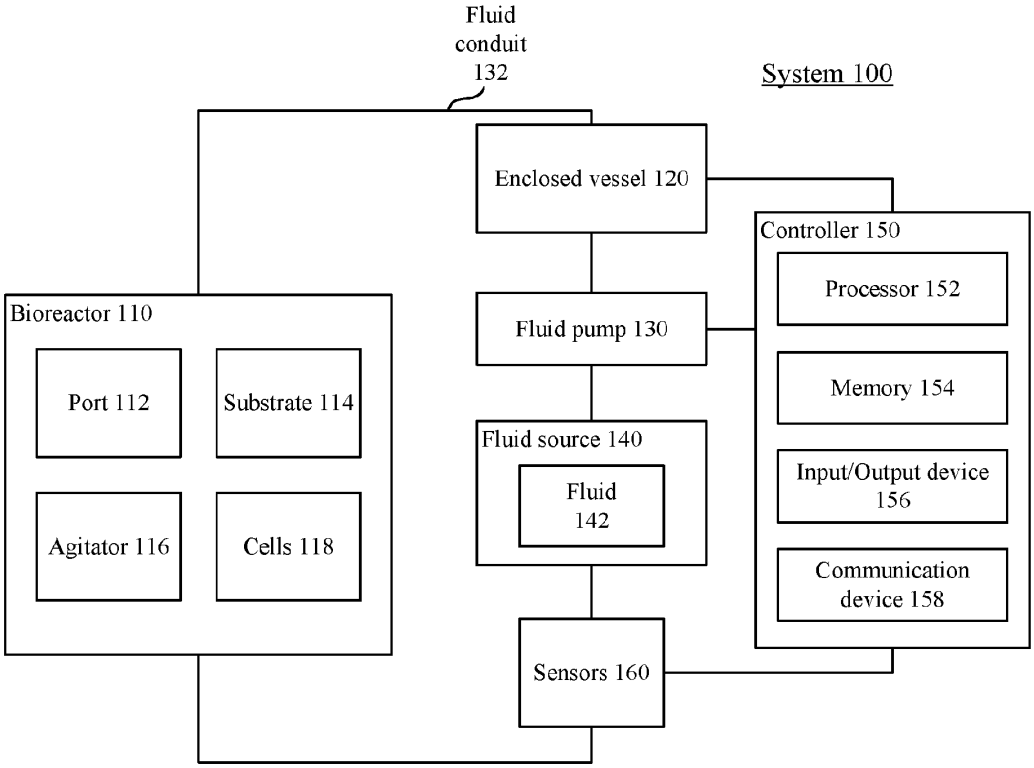

Fluid conduit 132
System 100
Enclosed vessel 120
Controller 150
Processor 152
Bioreactor 110
Fluid pump 130
Memory 154
Port 112
Substrate 114
Fluid source 140
Input/Output device 156
Fluid 142
Agitator 116
Cells 118
Communication device 158
Sensors 160

FIG. 1A

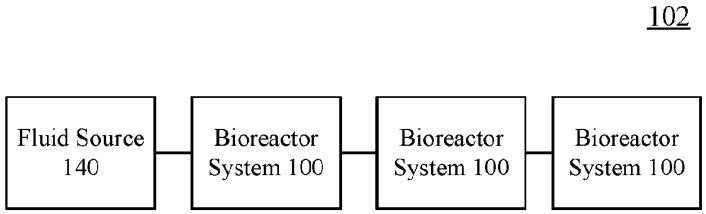

102
Fluid Source 140
Bioreactor System 100
Bioreactor System 100
Bioreactor System 100

FIG. 1B

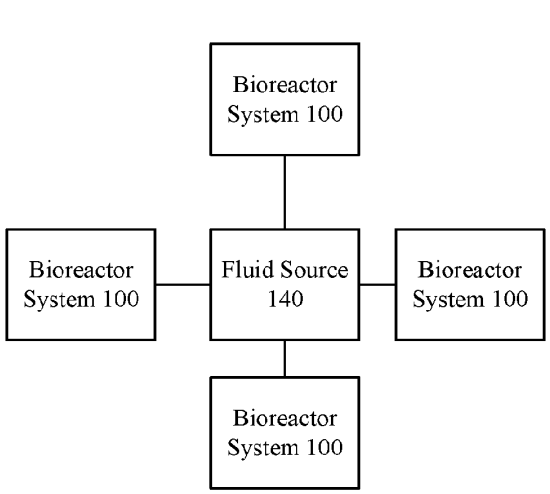

104
Bioreactor System 100
Bioreactor System 100
Fluid Source 140
Bioreactor System 100
Bioreactor System 100

FIG. 1C

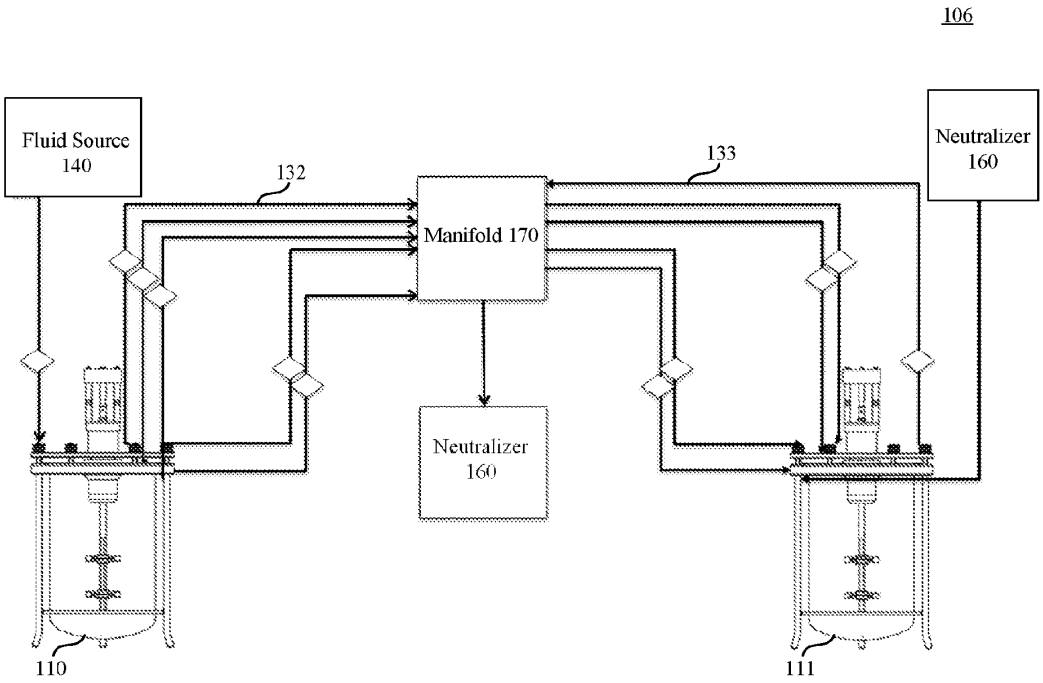

106
Fluid Source
140
132
133
Neutralizer
160
Manifold 170
Neutralizer
160
110
111

FIG. 1D

| | Chlorine Dioxide Gas | Vapor Phase Hydrogen Peroxide | Ozone Gas | Peroxide Peracetic Acid Fogging | Ethylene Oxide Gas | Nitrogen Dioxide Gas (dinitrogen tetraoxide) |
|---|---|---|---|---|---|---|
| Volumes of area to be sterilized | Very large | Small | Small | Very Small | Small | Undetermined |
| Shape of the area being sterilized | No effect | Poor Diffusion into areas not in line of sight with the generator | Inactivated before it reached all areas of some shapes | Poor Diffusion | No effect | No effect |
| Shadow Areas such as equipment in the area being sterilized | No effect | Equipment can act as barriers | Some issues | Poor diffusion around equipment | No effect | No effect |
| Temperature | Above 11C | Above 109C | ~60C | 18C-30C | 37C – 60C | 10C – 30C |
| Relative Humidity | 60-75% | >85% | 80% | >85% | 40-80% | 80% |
| Wet surfaces | Yes | Yes | Yes/No | Yes/No | Yes | Yes/No |
| Injection rate | Static | Affected by shape of the area being sterilized | Affected by shape of the area being sterilized | Affected by shape of the area being sterilized | Static | Static |
| EPA Registration as a Sterilant | Yes | Yes | Purpose dependent | Formulation dependent | Formulation dependent | Unknown |
| Diffusion/Distribution | Very Good | Poor | Poor | Poor | Good | Very Good |
| Penetration | Very Good | Very Poor | Poor | Poor | Good | Very Good |
| Concentration Monitoring | Yes | Yes | Yes | No | Yes | Yes |
| GRAS | Yes ( meat and poultry) | Yes (meat and poultry) | Yes ( meat and poultry) | No | No | No |
| Safety profile | Good | Good | Good | Poor | Very Poor | Good |
| Material Compatibility | Low oxidation potential (0.95V) | Moderate Oxidation potential (1.78V) | High oxidation potential (2.07V) | High oxidation potential (1.81V) | Formulation dependent | Not an oxidant, known incompatible compounds include polyurethane nylon, Delrin, Cellulose, Copper |
| Explosive capability | 10% in air | Low potential | Highly explosive at high temp | 15% peracetic acid | 3% in Air, up to 12% in hydrocarbons, 7% in CO2 | Not explosive |
| Environmental safety | Very Good | Good | Good | Poor | Very Poor | |
| Toxicity | moderate | Low | moderate | High | Very High | No |
| Carcinogenicity | No | No | No | Yes | Very Carcinogenic | No |

FIG. 2

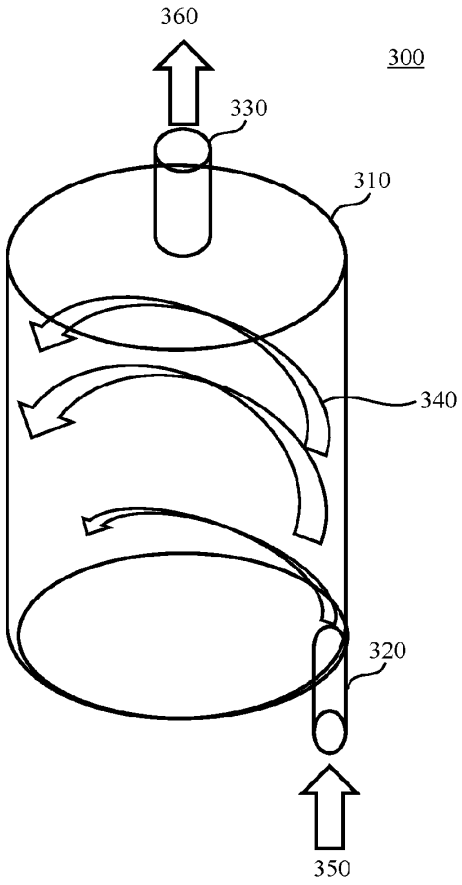



FIG. 3

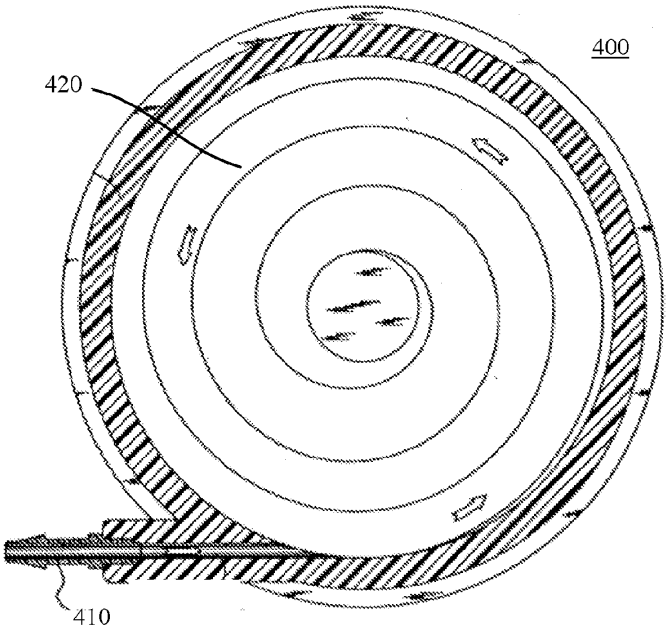



FIG. 4A

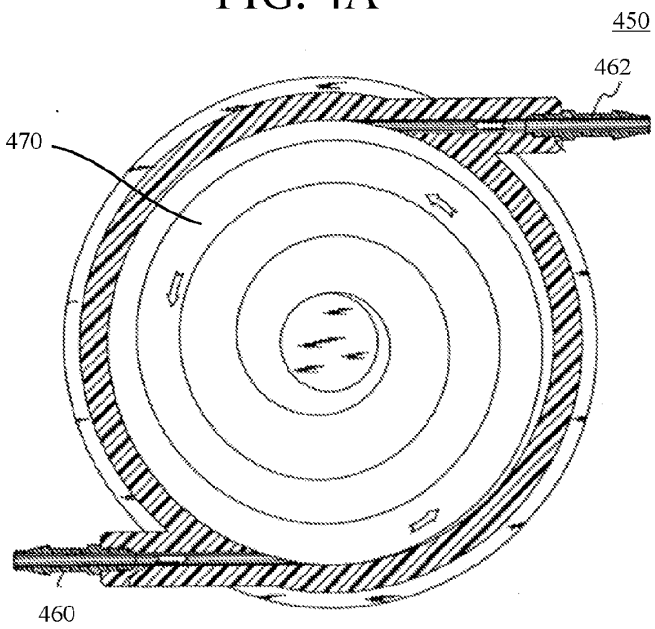



FIG. 4B

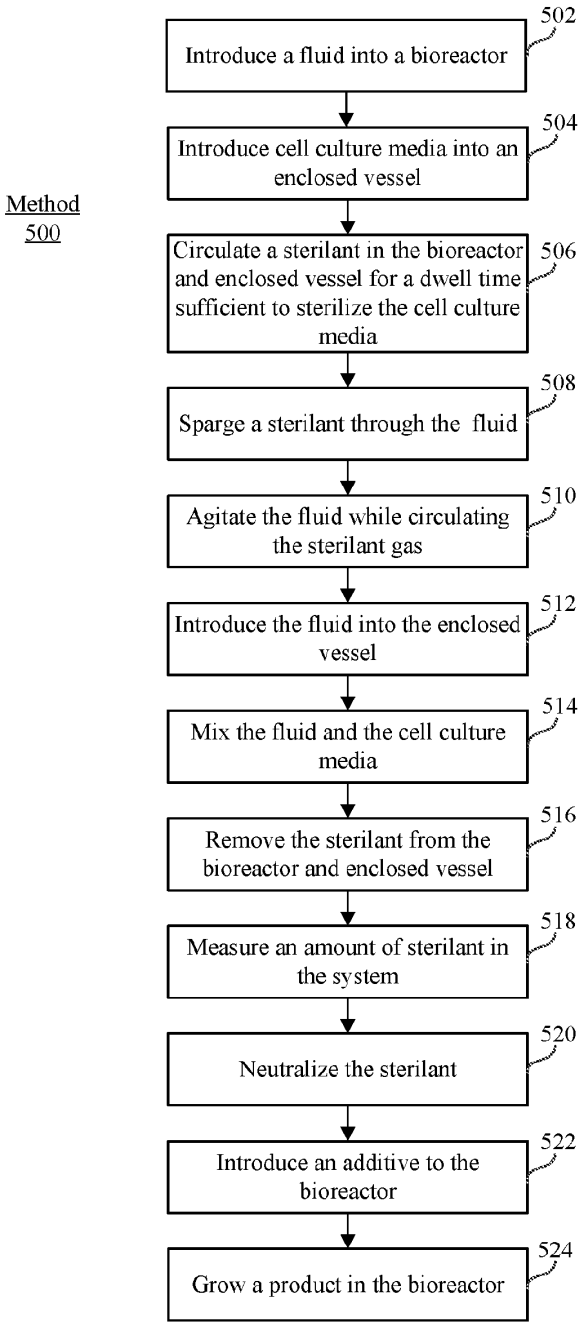

Method
500
Introduce a fluid into a bioreactor
502
Introduce cell culture media into an enclosed vessel
504
Circulate a sterilant in the bioreactor and enclosed vessel for a dwell time sufficient to sterilize the cell culture media
506
Sparge a sterilant through the fluid
508
Agitate the fluid while circulating the sterilant gas
510
Introduce the fluid into the enclosed vessel
512
Mix the fluid and the cell culture media
514
Remove the sterilant from the bioreactor and enclosed vessel
516
Measure an amount of sterilant in the system
518
Neutralize the sterilant
520
Introduce an additive to the bioreactor
522
Grow a product in the bioreactor
524

FIG. 5

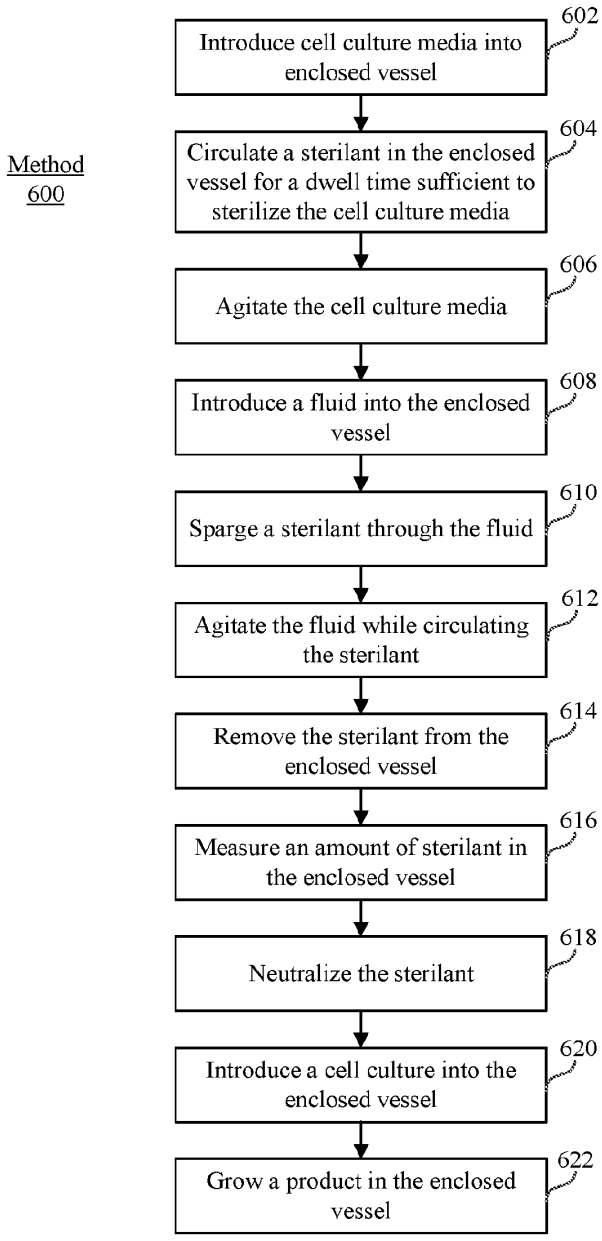

Method 600
Introduce cell culture media into enclosed vessel
602
Circulate a sterilant in the enclosed vessel for a dwell time sufficient to sterilize the cell culture media
604
Agitate the cell culture media
606
Introduce a fluid into the enclosed vessel
608
Sparge a sterilant through the fluid
610
Agitate the fluid while circulating the sterilant
612
Remove the sterilant from the enclosed vessel
614
Measure an amount of sterilant in the enclosed vessel
616
Neutralize the sterilant
618
Introduce a cell culture into the enclosed vessel
620
Grow a product in the enclosed vessel
622

FIG. 6

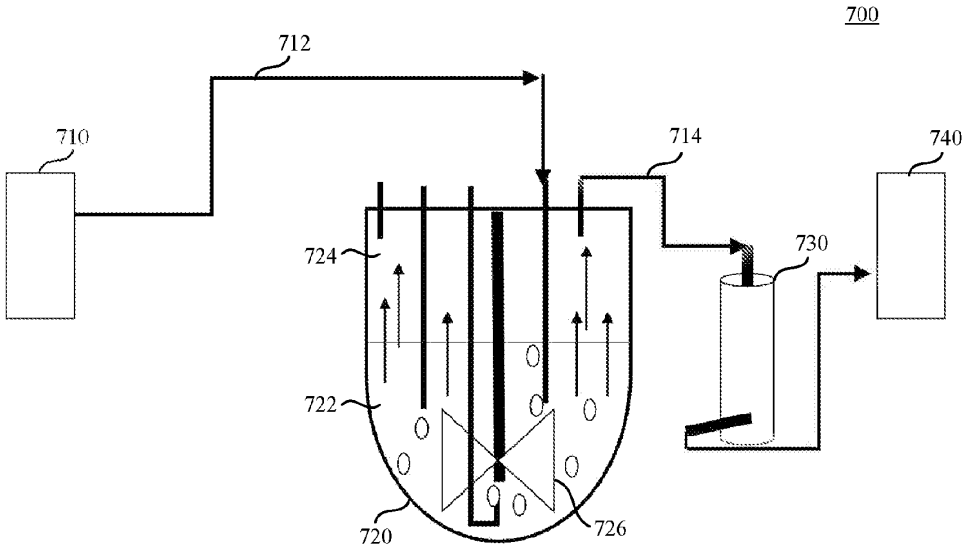

700
712
710
714
740
724
730
722
720
726

FIG. 7A

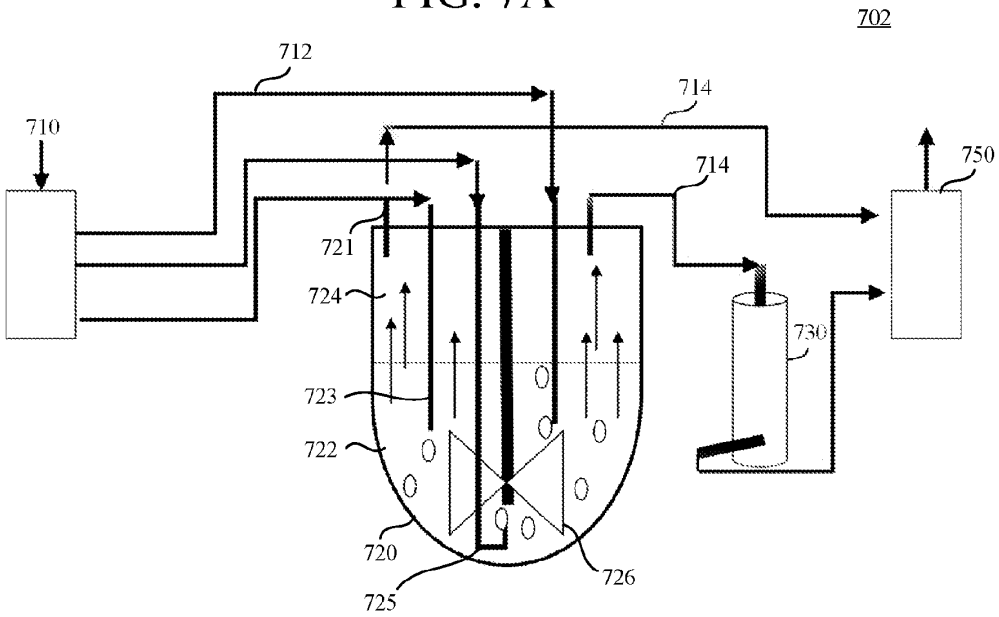

702
712
714
710
750
714
721
724
730
723
722
720
726
725

FIG. 7B

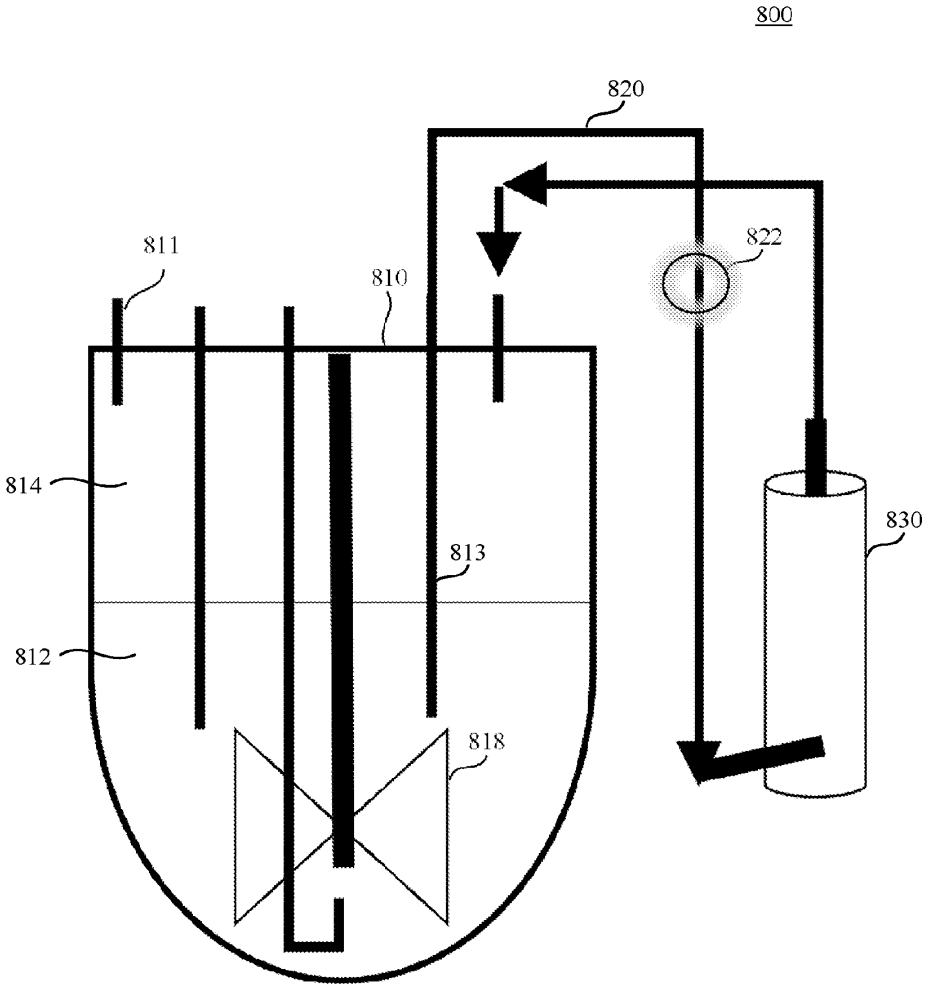



FIG. 8