SYSTEMS, METHODS, AND APPARATUSES FOR PRODUCING AND PACKAGING FLUIDS

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0001] This invention was made with Government support under Agreement HHSO100201900017C, awarded by HHS. The Government has certain rights in the invention.

BACKGROUND

Field of Disclosure:

[0002] This disclosure relates to medical fluids. More specifically, this disclosure relates to the generation and packaging of medical fluids.

Description of Related Art

[0003] Almost every hospitalized patient is administered saline or a saline based solution. As a result, the quantity of saline solution consumed is very large. More than a billion bags of saline are used per year in the US alone. Despite the demand, there are only a small number of different saline manufactures which provide this solution for the US market. Unfortunately, manufacturing challenges which limit production from one manufacturer can and do cause shortages of saline in the United States. Compounding the issue, these manufactures have uneven market share in regards to all bagged saline products. For instance, 50% of 250ml or smaller saline bags are provided by a single manufacture. As a result, when such a manufacturer faces production problems, the impact on the availability of that particular type of bag is much greater.

[0004] Most recently, the media spotlight has been shown on delays caused in the wake of hurricane Maria which have led to a shortage of small volume saline bags. According to the American Society of Health-System Pharmacists, shortages for large volume bags and bags of saline for irrigation purposes also currently exist. An alternative means of producing medical fluid bags which may perhaps be locatable in the institution using the bag would be desirable.

SUMMARY

[0005] In accordance with an embodiment of the present disclosure, a sealing member dispenser may comprise a dispenser body including at least one trough configured

What is claimed is:

1. A system for producing and packaging medical fluid proximate a point of use comprising:

a source input;

at least one treatment apparatus for producing water conforming to a predefined standard from fluid received from the source input;

a mixing circuit in communication with an output of the at least one water treatment apparatus and including a source of concentrate, the mixing circuit configured to adjust flow of fluid through the mixing circuit so as to generate a fluid of a predefined composition;

an enclosure having a packaging compartment;

a reservoir feeder in the enclosure and having a supply of reservoirs to be filled, the reservoir feeder configured to feed reservoirs of the supply of reservoirs through the reservoir feeder to an output of the reservoir feeder;

a fluid dispensing station in the enclosure, the fluid dispensing station coupled to the mixing circuit and including a reservoir capacity sensing assembly;

a reservoir closure station in the enclosure;

a reservoir labeler assembly in the enclosure; and

a repository having a plurality of reservoir holders configured to retain filled reservoirs in the enclosure.

2. The system of claim 1, wherein the at least one purification apparatus comprises a water distillation device and at least one of a reverse osmosis unit, plurality of charcoal filters, and an ultrafilter.

3. The system of claim 1, wherein the concentrate source is a reservoir of solid concentrate having an inlet in communication with the output of the at least one water treatment apparatus and a fluid concentrate outlet.

4. The system of claim 1, wherein the enclosure includes a chamber with a set of gloved ports and the reservoir feeder extends from the chamber to the packaging compartment.

5. The system of claim 1, wherein the source input is configured to couple to a drinking water supply.

6. The system of claim 1, wherein the predefined standard is a pharmacopeia standard.

7. The system of claim 1, wherein the closure station comprises a ram and a stopper dispenser, the closure station further comprising a stopper guide and a portion configured to receive a port of a reservoir.

8. The system of claim 1, wherein the system further comprises a pyrogen tester.

9. The system of claim 1, wherein the system further comprises a robotic assembly including a gripper.

10. The system of claim 9, wherein the system further comprises a control system configured to displace at least a portion of the robotic assembly and actuate the gripper to collect a reservoir from the supply of reservoirs in the reservoir feeder, displace the reservoir to the fluid dispensing station, determine a capacity of the reservoir via data from the reservoir capacity sensing assembly, command filling of the reservoir with a volume of fluid no greater than the capacity of the reservoir, displace the reservoir to the closure station, and command closure of the reservoir.

11. The system of claim 1, wherein the reservoir volume sensing assembly comprises a set of reservoir characteristic sensors and the system further comprises a control system configured to analyze data received from the reservoir characteristic sensors and is configured to determine a capacity of a reservoir in place at the fluid dispensing station.

12. The system of claim 11, wherein the control system is configured to govern operation of at least one flow controller to deliver a volume of a concentrated fluid containing concentrate from the source of concentrate to the reservoir and a subsequent volume of water conforming to

the predefined standard to the reservoir to achieve a fill volume within the reservoir selected based on the capacity of the reservoir.

13. The system of claim 1, wherein the system further comprises a sensor suite including a total organic carbon sensor, a bioburden sensor, a particulate monitor, a plurality of ultrapure water conductivity sensors, and a concentrate conductivity sensor.

14. A system for small scale production and packaging of medical fluid comprising:

a source water input;

a water treatment assembly including a water distillation device, the water treatment assembly configured to generate water meeting a predefined quality specification using water received via the source water input;

a mixing circuit in fluid communication with an output of the water treatment assembly and including a source of concentrate, the mixing circuit configured to adjust the flow of fluid through the mixing circuit so as to generate a fluid of a predefined composition;

an enclosure including a packaging compartment;

a reservoir dispenser at least partially in the packaging compartment and configured to accept a plurality of reservoirs;

a filling station in the packaging compartment including an outlet in fluid communication with the mixing circuit;

a filled reservoir repository in the enclosure having a plurality of reservoir holders; and

a reservoir labeler in the packaging compartment.

15. The system of claim 14, wherein the water treatment assembly further comprises at least one of a reverse osmosis unit, a plurality of charcoal filtration units, an electrodeionization unit, and an ultrafilter.

16. The system of claim 14, wherein the water treatment assembly further comprises a sensor suite including a total organic carbon sensor, a bioburden sensor, a particulate monitor, and a plurality of ultrapure water conductivity sensors.

17. The system of claim 14, wherein the concentrate source is a reservoir of crystalline concentrate having an inlet and a fluid concentrate outlet.

18. The system of claim 14, wherein the source water input is connected to a municipal water supply.

19. The system of claim 14, wherein the enclosure further comprises an antechamber, the antechamber and packaging compartment are separated by a partition including at least one door from the antechamber to the packaging compartment.

20. The system of claim 14, wherein the system further comprises a robotic arm including a gripper.

21. The system of claim 20, wherein the system further comprises a control system configured to actuate the robotic arm and actuate the gripper to collect a reservoir of the plurality of reservoirs from the reservoir dispenser, displace the reservoir to the filling station, command filling of the reservoir, displace the reservoir to the labeler, and the control system is configured to orchestrate application of a label to the reservoir via commands to the labeler and robotic arm.

22. The system of claim 14, wherein the filling station further comprises a set of reservoir characteristic sensors and the system further comprises a control system configured to analyze data received from the reservoir characteristic sensors, the control system further configured to determine a capacity of a reservoir in place at the filling station based at least in part on the data from the reservoir characteristic sensors.

23. The system of claim 22, wherein the control system is configured to govern operation of flow controllers of the mixing circuit based on the capacity of the reservoir.

24. A system for producing and packaging fluid for local consumption comprising:

a source water input;

a water treatment assembly including a plurality of water production devices;

a mixing circuit coupled to a product output of the water treatment assembly and including a source of concentrate, the mixing circuit configured to generate a fluid of a predefined composition;

an enclosure including at least a first portion and a packaging compartment;

a reservoir feed assembly extending from the first portion to the packaging compartment, the reservoir feed assembly configured to accept a reservoir magazine;

a fluid dispensing station in the packaging compartment, the fluid dispensing station receiving the fluid of the predefined composition from mixing circuit;

a reservoir labeler in the packaging compartment; and

a plurality of filled reservoir holders configured to retain filled reservoirs.

25. The system of claim 24, wherein the water production devices include at least an endotoxin removal filter, a water distillation device, and a set of redundant charcoal filters.

26. The system of claim 24, wherein the source of concentrate is a reservoir of a crystalline salt concentrate.

27. The system of claim 24, wherein the system further comprises a sensor suite including a total organic carbon sensor, a bioburden sensor, a particulate monitor, a plurality of ultrapure water conductivity sensors, and a concentrate conductivity sensor.

28. The system of claim 24, wherein the first portion of the enclosure and packaging compartment are demarcated by a partition including at least one door between the first portion and the packaging compartment.

29. The system of claim 24, wherein the system further comprises a robotic arm including a gripper.

30. The system of claim 24, wherein the system further comprises a robotic manipulator and a control system configured to govern actuation of the robotic manipulator to collect a reservoir

from the reservoir feed assembly, displace the reservoir to the fluid dispensing station, determine a capacity of the reservoir via data from a reservoir capacity sensing assembly, command filling of the reservoir with a volume of fluid no greater than the capacity of the reservoir, displace the reservoir to a stoppering station, and orchestrate stoppering of the reservoir.

31. The system of claim 30, wherein the reservoir volume sensing assembly comprises a set of reservoir characteristic sensors and the control system is configured to govern operation of at least one flow controller based on a capacity of the reservoir determined based on the data from the reservoir characteristic sensors.

32. The system of claim 31, wherein the control system is configured to govern operation of the at least one flow controller to, via the filling station, deliver a volume of a concentrate to the reservoir and a subsequent volume of purified water to the reservoir to achieve a fill volume selected based on a capacity of the reservoir determined based on the data from the reservoir characteristic sensors.

33. The system of claim 24, wherein at least one of the water production devices includes a distillation device configured to generate product water in a disinfection temperature range and a reservoir filling temperature range.