~~SYSTEM FOR PRODUCING AND PACKAGING FLUID, SEALING MEMBER DISPENSER, RESERVOIR FEEDING APPARATUS, BAG SEALING APPARATUS, RESERVOIR FILLING SET, METHOD FOR FILLING A RESERVOIR OR A BAG, FILLING AND SAMPLING NOZZLE~~

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 ~~distillation device~~conforming to a predefined standard from fluid received from the source input;

a mixing circuit ~~coupled to~~ in communication with an output of the at least one water ~~distillation device~~treatment apparatus 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 an antechamber and~~having a packaging compartment;

a reservoir ~~dispenser at least partially~~feeder in the ~~packaging compartment~~ enclosure and having a ~~reservoir magazine and an outlet end~~supply of reservoirs to be filled, the reservoir ~~dispenser including an actuator~~feeder configured to ~~drive a follower~~feed reservoirs of the supply of reservoirs through the reservoir ~~magazine toward the outlet end~~feeder to an output of the reservoir ~~dispenser~~feeder;

a ~~filling~~fluid dispensing station in the ~~packaging compartment including a filling nozzle~~ enclosure, the fluid dispensing station coupled to the mixing circuit and including a reservoir ~~volume~~capacity sensing assembly;

a ~~sealing~~reservoir closure station in the ~~packaging compartment~~enclosure;

a reservoir labeler assembly in the enclosure; and

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

~~a labeler assembly in the packaging compartment; and~~

~~an output chute from the packaging compartment to an exterior of the enclosure.~~

2. The system of claim 1, wherein the ~~system further~~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 ~~crystalline~~solid concentrate having ~~a purified water~~ 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 ~~antechamber~~enclosure includes a ~~flexible sterile barrier.~~

~~5. The system~~chamber with a set of ~~claim 4, wherein the flexible sterile barrier includes at least one~~ gloved ~~interface~~ports and the reservoir feeder extends from the chamber to the packaging compartment.

~~6~~5. The system of claim 1, wherein the ~~sealing station~~source input is configured to couple to a drinking water supply.

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

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

~~7. The system of claim 1, wherein the antechamber and the packaging compartment are separated by a partition which includes a door having a sample container holder.~~

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 ~~arm~~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 ~~arm~~assembly and actuate the gripper to collect a reservoir from the supply of reservoirs in the reservoir ~~dispenser~~feeder, displace the reservoir to the ~~fill~~fluid dispensing station, determine a ~~volume~~capacity of the reservoir via data from the reservoir ~~volume~~capacity sensing assembly, command filling of the reservoir with a volume of fluid no greater than the ~~volume~~capacity of the reservoir, displace the reservoir to the ~~sealing~~closure station, and command ~~sealing~~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 ~~filling~~fluid dispensing station.

12. The system of claim 11, wherein the control system is configured to govern operation of at least one flow controller ~~based on the capacity of the reservoir determined based on the data from the reservoir characteristic sensors~~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 ~~12~~1, wherein the ~~control~~ system ~~is configured to govern operation of the at least one flow controller to deliver~~further comprises a ~~volume of~~ sensor suite including a total organic carbon sensor, a bioburden sensor, a particulate monitor, a plurality of ultrapure water conductivity sensors, and a concentrate ~~to the reservoir and a subsequent volume of purified water to the reservoir to achieve a fill volume selected based on the capacity of the reservoir~~conductivity sensor.

14. A system for ~~producing~~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 ~~coupled to~~in fluid communication with an output of the water ~~distillation device~~treatment assembly and including a source of concentrate, the mixing circuit ~~including a plurality of flow controllers~~ configured to adjust the flow of fluid through the mixing circuit so as to generate a fluid of a predefined composition;

an enclosure including ~~an antechamber and~~ a packaging compartment;

a reservoir dispenser ~~having a portion~~at least partially in the packaging compartment ~~having a feed plate and a housing block, the reservoir dispenser including a bias member which urges the feed plate toward the housing block~~and configured to accept a plurality of reservoirs;

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

~~a sealing station in the packaging compartment having a ram and a sealing member dispenser;~~

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

a reservoir labeler in the packaging compartment~~; and~~.

~~an output chute from the packaging compartment to an exterior of the enclosure.~~

15. The system of claim 14, wherein the ~~system~~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.~~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 ~~a purified water~~ an inlet and a fluid concentrate outlet.

~~17. The system of claim 14, wherein the antechamber includes at least one gloved interface.~~

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.

~~19~~20. The system of claim 14, wherein the system further comprises a robotic arm including a gripper.

~~20~~21. The system of claim ~~19~~20, wherein the system further comprises a control system configured to ~~displace~~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 ~~fill~~filling station, command filling of the reservoir, displace the reservoir to the ~~sealing station,~~labeler, and the control system is configured to orchestrate application of a label to the reservoir via commands to the labeler and ~~command actuation of the ram to drive a sealing member from the sealing member into a port of the reservoir~~robotic arm.

~~21~~

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 ~~and~~, 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.

~~22~~23. The system of claim ~~21~~22, wherein the control system is configured to govern operation of ~~the~~ flow controllers of the mixing circuit based on the capacity of the reservoir ~~determined based on the data from the reservoir characteristic sensors~~.

~~23~~24. A system for producing and packaging fluid for local consumption comprising:

a source water ~~purification device;~~input;

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

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

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

a reservoir ~~dispenser~~feed assembly extending from the ~~antechamber~~first portion to the packaging compartment ~~and having a reservoir magazine and an outlet end~~, the reservoir ~~dispenser including a drive~~feed assembly configured to ~~displace~~ accept a reservoir magazine;

~~a follower of the reservoir magazine toward the outlet end of the reservoir dispenser;~~

~~a filling~~fluid dispensing station in the packaging compartment ~~including a filling nozzle coupled to the mixing circuit and a reservoir volume sensing assembly;~~

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

~~at least one~~a reservoir ~~hanger in the packaging compartment;~~

~~a~~ labeler in the packaging compartment; and

~~an output chute from the packaging compartment to an exterior of the enclosure.~~

~~24.~~ a plurality of filled reservoir holders configured to retain filled reservoirs.

25. The system of claim ~~23~~24, wherein the ~~system further comprises~~water production devices include at least ~~one of a reverse osmosis unit and an ultrafilter~~an endotoxin removal filter, a water distillation device, and a set of redundant charcoal filters.

26. ~~25.~~ The system of claim ~~23~~24, wherein the source of concentrate ~~source~~ is a reservoir of a crystalline salt concentrate.

27. ~~26. The system of claim 23, wherein the antechamber includes at least one gloved interface.~~

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. ~~27.~~ The system of claim ~~23~~24, wherein the ~~antechamber~~first portion of the enclosure and packaging compartment are ~~separated~~demarcated by a partition including at least one door between the ~~antechamber~~first portion and the packaging compartment.

~~28~~29. The system of claim ~~23~~24, wherein the system further comprises a robotic arm including a gripper.

30. ~~29.~~ The system of claim ~~28~~24, wherein the system further comprises a robotic manipulator and a control system configured to ~~displace~~govern actuation of the robotic manipulator to collect a reservoir from the reservoir ~~dispenser~~feed assembly, displace the reservoir to the ~~fill~~fluid dispensing station, determine a ~~volume~~capacity of the reservoir via data from ~~the~~a reservoir ~~volume~~capacity sensing assembly, command filling of the reservoir with a volume of fluid no greater than the ~~volume~~capacity of the reservoir, displace the reservoir to a stoppering station, and orchestrate stoppering of the reservoir~~, displace the reservoir to the sealing station, and command sealing of the reservoir.~~.

31. ~~30.~~ The system of claim ~~23~~30, wherein the reservoir volume sensing assembly comprises a set of reservoir characteristic sensors~~.~~

and~~31. The system of claim 30, wherein~~ 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 ~~30~~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. ~~A sealing member dispenser comprising:~~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.

a dispenser body including at least one trough configured to receive a plurality of sealing members and an exit port extending from the trough to an exterior face of the dispenser body, the exit port having a guide portion adjacent the exterior face of the dispenser body;

a blocking element that obstructs passage of a sealing member through the exit port; and

a cover coupled to the dispenser body and overhanging the trough, the cover including an orifice in line with the exit port, the orifice presenting an opening which is too small for a sealing member of the plurality of sealing members to pass therethrough.

34. The sealing member dispenser of claim 33, wherein the trough extends along a spiral path.

35. The sealing member dispenser of claim 33, wherein the dispenser body is a drum.

36. The sealing member dispenser of claim 33, wherein the guide portion includes a funneling contour.

37. The sealing member dispenser of claim 33, wherein the guide portion is a chamfered edge.

38. The sealing member dispenser of claim 33, wherein the blocking element is displaceable.

39. The sealing member dispenser of claim 33, wherein the blocking element is an outlet cover which is coupled to a handle, displacement of the handle resulting in displacement of the outlet cover out of an obstructing position.

40. The sealing member dispenser of claim 33, wherein the blocking element includes a detent member which protrudes into the exit port.

41. The sealing member dispenser of claim 40, wherein the detent member is a ball detent.

42. The sealing member dispenser of claim 33, wherein the sealing member dispenser further comprises a follower and a bias member coupled to the follower and a portion of the dispenser body.

43. The sealing member dispenser of claim 42, wherein the bias member is a constant force spring.

44. The sealing member dispenser of claim 33, wherein the dispenser body further comprises a receiving slit sized to accept a follower.

45. The sealing member dispenser of claim 33, wherein the sealing member dispenser further comprises a magnetic body.

46. The sealing member dispenser of claim 33, wherein the sealing member dispenser further comprises a rotor which is coupled to a shaft and a bias assembly configured to exert a biasing force against the shaft with urges the shaft to rotate.

47. The sealing member dispenser of claim 33, wherein the sealing member dispenser includes a rotor which is coupled to a shaft and a rotor drive assembly configured to automatically index the rotor until a sealing member is displaced along the trough to the exit point.

48. The sealing member dispenser of claim 47, wherein the rotational displacement for indexing the rotor varies as the sealing member dispenser is depleted of sealing members.

49. A reservoir feeding apparatus comprising:

a housing block including at least one channel extending therethrough;

a set of retention pins associated with each of the at least one channel;

a set of guides associated with each of the at least one channel, a slot being defined between the guides of each set of guides;

a feed plate coupled to the housing block by at least one bias member, the feed plate including at least one follower projection; and

an elongate member extending from the housing block through the feed plate, the bias member urging displacement of the feed plate along the elongate member toward a stop face of the housing block and configured to urge the follower projection into contact with a port of a reservoir disposed within the guide.

50. The reservoir feeding apparatus of claim 49, wherein each retention pin is biased by a retention pin bias member into an extended state in which the retention pin extends into the channel it is associated with.

51. The reservoir feeding apparatus of claim 49, wherein the retention pins of each set of retention pins are disposed on opposing sides of the channel which the set of retention pins is associated with.

52. The reservoir feeding apparatus of claim 49, wherein each retention pin is biased by a retention pin bias member into an extended state and the ends of the retention pins of a set of retention pins are spaced from one another a distance less than the diameter of the port of the reservoir when in the extended state.

53. The reservoir feeding apparatus of claim 49, wherein each retention pin is configured to be displaced out of an obstructing position upon introduction of a grasper to collect a reservoir from the reservoir feeder.

54. The reservoir feeding apparatus of claim 49, wherein the bias member is a constant force spring.

55. The reservoir feeding apparatus of claim 49, wherein a length of the follower projection is at least equal to a distance from the stop face to the retention pins.

56. The reservoir feeding apparatus of claim 49, wherein the reservoir feeding apparatus further comprises a feed plate retainer for holding the feed plate in a loading orientation, the feed plate retainer coupled to the housing block via at least one standoff.

57. The reservoir feeding apparatus of claim 56, wherein the feed plate retainer comprises a spring biased latch member.

58. The reservoir feeding apparatus of claim 56, wherein the feed plate retainer includes a magnet and the feed plate includes a metallic body.

59. A reservoir feeding apparatus comprising:

a housing block including at least one channel extending therethrough;

a set of retention pins associated with each of the at least one channel;

a reservoir magazine coupled to the housing block;

a feed plate coupled to the housing block by at least one bias member, the feed plate including at least one follower projection; and

an elongate member extending from the housing block through the feed plate, the bias member urging displacement of the feed plate along the elongate member toward a stop face of the housing block and urging displacement of the follower projection through the reservoir magazine toward the housing block.

60. The reservoir feeding apparatus of claim 59, wherein each retention pin is biased by a retention pin bias member into an extended state in which the retention pin extends into the channel it is associated with.

61. The reservoir feeding apparatus of claim 59, wherein the retention pins of each set of retention pins are disposed on opposing sides of the channel which the set of retention pins is associated with.

62. The reservoir feeding apparatus of claim 59, wherein each retention pin is biased by a retention pin bias member into an extended state and the ends of the retention pins of a set of retention pins are spaced from one another a distance less than the diameter of a port of a reservoir when in the extended state.

63. The reservoir feeding apparatus of claim 59, wherein each retention pin is configured to be displaced out of an obstructing position upon introduction of a grasper to collect a reservoir from the reservoir feeder.

64. The reservoir feeding apparatus of claim 59, wherein the bias member is a constant force spring.

65. The reservoir feeding apparatus of claim 59, wherein a length of the follower projection is at least equal to a distance from the stop face to the retention pins.

66. The reservoir feeding apparatus of claim 59, wherein the reservoir feeding apparatus further comprises a feed plate retainer for holding the feed plate in a loading orientation, the feed plate retainer coupled to the housing block via at least one standoff.

67. The reservoir feeding apparatus of claim 66, wherein the feed plate retainer comprises a spring biased latch member.

68. The reservoir feeding apparatus of claim 66, wherein the feed plate retainer includes a magnet and the feed plate includes a metallic body.

69. A bag sealing apparatus comprising:

a ram displaceable along a displacement axis by a ram actuator;

a sealing member dispenser receptacle for receiving a sealing member dispenser;

a sealing member dispenser sensor configured to output a first signal indicative of the presence of a sealing member dispenser within the receptacle; and

a reservoir guide including a first portion and a second portion having a gap therebetween, the reservoir guide configured to guide a port of a reservoir into alignment with the displacement axis when a reservoir is disposed within the gap, at least one of the first and second portion of the reservoir guide including a grasper docking face.

70. The bag sealing apparatus of claim 69, wherein the bag sealing apparatus is a stoppering apparatus.

71. The bag sealing apparatus of claim 69, wherein the sealing member receptacle is disposed intermediate the ram and the reservoir guide.

72. The bag sealing apparatus of claim 69, wherein the sealing member dispenser sensor is a magnetic sensor.

73. The bag sealing apparatus of claim 72, wherein the sealing member dispenser sensor is a Hall effect sensor.

74. The bag sealing apparatus of claim 69, wherein the bag sealing apparatus further comprises a reservoir detection sensor configured to output a second signal indicative of the presence of a reservoir in the reservoir guide.

75. The bag sealing apparatus of claim 74, wherein the bag sealing apparatus further comprises a controller, the controller configured prevent actuation by the ram actuator in the absence of at least one of the first and second signal.

76. The bag sealing apparatus of claim 69, wherein the bag sealing apparatus further comprises an optical port detection sensor configured to output a second signal indicative of the presence of a port in alignment with the axis of displacement based on an intensity of reflection of light emitted from the sensor.

77. The bag sealing apparatus of claim 69, wherein the bag sealing apparatus further comprises a controller, the controller configured prevent actuation by the ram actuator in the absence of the first signal.

78. An apparatus for packaging fluid comprising:

a fill conduit dispenser having a reel portion containing a length of fill conduit;

a feeder assembly including an actuator coupled to an at least one feeding member;

a tubing retainer having a first portion coupled to a sled and a cam follower, the tubing retainer having a second portion coupled to a base plate, the tubing retainer including receptacles for a segment of the fill conduit and a port of a bag;

a sled actuator;

an occluder assembly having an occluder actuator which is coupled to a carriage mounted to an occluder;

a cutter assembly including a cutter actuator coupled to a cutting element and a cam surface, the cam surface and cutting element configured to displace in unison with one another;

a guide coupled to the first portion of the tubing retainer, the occluder assembly, and the cutter assembly;

a bias member urging the cam follower against the cam surface; and

a controller configured to govern operation of the sled actuator, the occluder actuator, and the cutter actuator to occluder, cut, and join the segment of the fill conduit and port.

79. The apparatus of claim 78, wherein the first and second portion of the tubing retainer are separated by a first gap.

80. The apparatus of claim 79, wherein the occluder comprises a first occluder portion and a second occluder portion separated by a second gap.

81. The apparatus of claim 80, wherein the first and second gap are disposed in the same plane and the first and second gap are sized to accept the cutting element therein.

82. The apparatus of claim 78, wherein the occluder comprises a first occluder portion and second occluder portion, the first occluder portion mounted on a rail and rotatable with respect to the carriage.

83. The apparatus of claim 78, wherein the occluder comprises a first occluder portion coupled to the first retainer portion by a first pin and the occluder comprises a second occluder portion coupled to the second retainer portion by a second pin.

84. The apparatus of clam 78, wherein the occluder comprises a first and second occluder portion, the first occluder portion mounted on a rail and coupled to the first retainer portion by a pin linking the first occluder portion and first retainer portion such that actuation of the sled by the sled actuator results in displacement of the first occluder portion along the rail.

85. The apparatus of claim 78, wherein displacement of the cam follower along the cam surface alters the size of the gap.

86. The apparatus of claim 85, wherein the cam surface is shaped such that the gap is largest when the cutting element is disposed within the gap and the gap decreases as the cutting element is withdrawn.

87. The apparatus of claim 78, wherein the occluder comprises a first portion and a second portion, the first portion rotatable with respect to the carriage and coupled to the first retainer portion via a linkage, the bias member coupling the first portion of the occluder to the carriage.

88. The apparatus of claim 78, wherein the cutting element includes a metal plate and a coating.

89. The apparatus of claim 88, wherein the coating is ceramic.

90. The apparatus of claim 78, wherein the cutter assembly includes at least one heating element.

91. The apparatus of claim 78, wherein the apparatus further comprises a tube sealing assembly having opposed jaws each having a heating element and a low thermal conductivity cutting insert therein, the tube sealing assembly having a sealing actuator configured to displace the jaws toward and away from each other.

92. The apparatus of claim 91, wherein the controller is configured to govern operation of the sealing actuator to displace the jaws against the port for a period of time, the jaws heating the port until the cutting inserts press though the port.

93. The apparatus of claim 78, wherein the apparatus further comprises a counterweight coupled to the sled, the counterweight configured to hold the cam follower against the cam surface.

94. A reservoir filling set comprising:

a carrier including a plurality of compartments;

a plurality of packets each housing a flexible reservoir which is attached to an administration set and a filling line;

an adapter including a plurality of retainer recesses each having an end of one of the filling lines disposed therein, the retainer recesses constraining the ends of the filling lines to extend straight along an axis of the retainer recess within which they are disposed; and

a plurality of sealing members, a sealing member of the plurality of sealing members included in each end of the filling lines.

95. The reservoir filling set of claim 94, wherein the administration set includes at least one occluding member associated therewith, the occluding member being in an occluding state in which flow through at least a portion of the administration set is inhibited.

96. The reservoir filling set of claim 95, wherein the occluding member is a roller clamp.

97. The reservoir filling set of claim 95, wherein the occluding member is a slide clamp.

98. The reservoir filling set of claim 95, wherein the occluding member is thumb clamp.

99. The reservoir filling set of claim 94, wherein the carrier includes a handle.

100. The reservoir filling set of claim 94, wherein each packet includes a pocket in which the flexible reservoir is disposed and a flap which, in a closed position, retains the administration set within the packet.

101. The reservoir filling set of claim 94, wherein the flexible reservoir housed by each packet is an IV bag.

102. The reservoir filling set of claim 94, wherein the plurality of sealing members are septa.

103. The reservoir filling set of claim 94, wherein the retainer recesses are spaced at preset angular increments from one another, the angular increments selected so as to align with spikes in a spike port of a filling apparatus.

104. A system for packaging fluid comprising:

a fluid source;

a spike port including a plurality of spikes;

an in line heater;

at least one pump;

a plurality of valves; and

a controller configured to, in a first mode power the heater to heat fluid to a predefined temperature set point and govern operation of the at least one pump and plurality of valves to recirculate fluid through the spike port for a predetermine period of time to disinfect the spike port, and in second mode govern operation of the at least one pump and plurality of valves to route fluid from the source to the spikes of the spike port.

105. The system of claim 104, wherein the spike port includes a recess in which the spikes are disposed and includes a recirculation port.

106. The system of claim 105, wherein the spike port is configured to accept a spiking adapter having a number of fluid lines included in retaining recesses of the spiking adapter, the spikes of the spike port being spaced so as to align with the retaining recesses of the spiking adapter.

107. The system of claim 106, wherein the spike port includes at least one alignment guide configured to cooperate with an alignment element of the spiking adapter.

108. The system of claim 104, wherein the system further comprises a passive manifold which furcates fluid input from a common point to each of the spikes of the spike port.

109. The system of claim 104, wherein the spike port includes a cap and a gasket against which the cap is sealed when the cap is in a closed orientation.

110. The system of claim 104, wherein the predefined temperature set point is at least 70°C.

111. A method of filling a reservoir comprising:

creating a junction between a filling conduit and a port of the reservoir by heating the filling conduit and port, cutting the filling conduit and port, bringing the filling conduit into coaxial alignment with the port and bonding a cut end of the port to a cut end of the filling conduit;

delivering fluid through the filling conduit past the junction and into the reservoir via the port; and

actuating jaws against a portion of the port and heating the jaws until a non-thermally conductive insert in each jaw is pressed through the port.

112. The method of claim 111, wherein cutting the filling conduit and port comprises driving a heated blade into a gap in a retainer in which the filling conduit and port are disposed.

113. The method of claim 112, wherein bringing the filling conduit into coaxial alignment with the port comprises actuating a sled to displace a movable portion of the retainer relative to a stationary portion of the retainer such that the cut ends of the port and filling conduit are slid across opposing surfaces of the heated blade.

114. The method of claim 113, wherein bonding the cut end of the port to the cut end of the filling conduit comprises biasing the movable portion of the retainer toward the stationary portion of the retainer and displacing a cam surface relative to a cam follower coupled to the movable portion of the retainer in unison with the heated blade as the heated blade is retracted away from the retainer.

115. The method of claim 112, wherein the method further comprises actuating the sled along a path generally parallel to the plane of the junction.

116. The method of claim 111, wherein the method further comprises forming a seal in the port which isolates an aliquot of liquid within the port from fluid in the reservoir.

117. The method of claim 111, wherein the reservoir is bag.

118. The method of claim 111, wherein the method further comprises sensing, with at least one sensor the presence of at least one of the fill conduit and port in a tubing retainer.

119. A method of filling a reservoir comprising:

creating a junction between a filling conduit and a port of the reservoir by cutting the filling conduit and port with a heated cutting element, sliding cut ends of the port and filling conduit across opposing surfaces of the cutting element to position the filling conduit into coaxial alignment with the port and bonding a cut end of the port to a cut end of the filling conduit as the cutting element is withdrawn;

delivering fluid through the filling conduit past the junction and into the reservoir via the port; and

actuating jaws against a portion of the port and heating the jaws until a non-thermally conductive insert in each jaw is pressed through the port.

120. The method of claim 119, wherein cutting the filling conduit and port comprises driving the cutting element into a gap in a retainer in which the filling conduit and port are disposed.

121. The method of claim 120, wherein bringing the filling conduit into coaxial alignment with the port comprises actuating a sled to displace a movable portion of the retainer relative to a stationary portion of the retainer.

122. The method of claim 121, wherein bonding the cut end of the port to the cut end of the filling conduit comprises biasing the movable portion of the retainer toward the stationary portion of the retainer and displacing a cam surface relative to a cam follower coupled to the movable portion of the retainer in unison with the cutting element as the cutting element is withdrawn from the retainer.

123. The method of claim 120, wherein the method further comprises actuating the sled along a path generally parallel to the plane of the junction.

124. The method of claim 119, wherein the method further comprises forming a seal in the port which isolates an aliquot of liquid within the port from fluid in the reservoir.

125. The method of claim 119, wherein the reservoir is bag.

126. The method of claim 119, wherein the method further comprises sensing, with at least one sensor the presence of at least one of the fill conduit and port in a tubing retainer.

127. A fluid production system for a medical fluid packaging system comprising:

a water distillation device;

a plurality of filters including at least one of a reverse osmosis filter and a carbon filter;

a mixing circuit including a purified water flow path and a concentrate flow path including concentrate source, there being a flow controller and an ultrafilter on each of the purified water flow path and concentrate flow path;

a sensor suite including a total organic carbon sensor, a bioburden sensor, a particulate monitor, a plurality of ultra pure water conductivity sensors, and a concentrate conductivity sensor;

a controller configured to govern operation of the flow controllers to dispense a predetermined volume of fluid in a first stage and second stage, the first stage delivering fluid at least predominately from the concentrate flow path and the second stage delivering fluid at least predominantly from the purified water flow path, the controller proportioning fluid in the

first and second stages based on data from the concentrate conductivity sensor, a predefined desired fluid composition, and the predetermined volume.

128. The system of claim 127, wherein the water distillation device is a water vapor compression distillation device.

129. The system of claim 127, wherein the system further comprises at least one of: a sediment a filter, a water softener, and a temperature regulator.

130. The system of claim 127, wherein, the controller is configured to analyze data from each sensor of the sensor suite and generate an error when the data indicates that the fluid quality characteristic breaches a threshold.

131. The system of claim 127, wherein the concentrate source is a container of crystalline concentrate including a purified water inlet and a concentrated solution outlet.

132. The system of claim 127, wherein the purified water is water for injection quality water.

133. The system of claim 127, wherein the system further comprises at least one manual sampling port.

134. The system of claim 127, wherein the particulate counter is disposed downstream of the ultrafilters.

135. The system of claim 127, wherein the controller commands delivery of fluid exclusively from the concentrate flow path during the first stage.

136. The system of claim 127, wherein the controller commands delivery of fluid exclusively from the purified water flow path in the second stage.

137. The system of claim 127, wherein the water distillation device includes a condensate reservoir therein.

138. The system of claim 127, wherein the water distillation device is configured to generate purified water in a first temperature range and a second temperature range.

139. The system of claim 138, wherein the first temperature range is below 40°C and the second temperature range is above 60°C.

140. The system of claim 138, wherein the controller is configured to govern operation of the flow controllers in a disinfection stage in which the controller governs operation of the flow controllers to route water at a temperature within the second temperature range through the system, to a nozzle, and into a drain.

141. A method of filling a bag with medical fluid comprising:

placing a first filling nozzle into a first port of the bag in communication with a first compartment of the and placing a second filling nozzle into a second port of the bag in communication with a second compartment of the bag, the first and second filling nozzle in communication with a fluid source via a common flow channel;

delivering fluid into the first and second compartment of the bag;

halting, with an unpowered valve, delivery of fluid in a smaller of the first and second compartment of the bag upon fully filling that compartment;

halting delivery of fluid into a larger of the first and second compartment of the bag upon fully filling that compartment;

separating the first compartment of the bag from a second compartment of the bag at a perforation in a seal extending between the first and second compartment; and

accessing the smaller compartment to collect a sample of fluid for testing.

142. The method of claim 141, wherein the fluid is a mixture of water for injection and at least one concentrate.

143. The method of claim 141, the fluid is a saline solution.

144. The method of claim 141, wherein the method further comprises performing an endotoxin test on the sample and discarding the larger compartment when the endotoxin test indicates presence of endotoxin is greater than a predefined level.

145. A bag for containing a medical fluid and a separable sampling aliquot comprising:

a first compartment having a first filling port and a delivery port;

a second compartment having a second filling port;

a seal separating the first compartment and second compartment; and

a perforation extending along the length of the seal.

146. The bag of claim 145, wherein the first compartment has a capacity which is greater than the second compartment.

147. The bag of claim 145, wherein the seal extends along the length of the bag from a first end of the bag to a second end of the bag.

148. A reservoir for holding a fluid comprising:

a first and second sheet of material sealed to one another at a peripheral seal to define an interior volume of the reservoir;

at least one port bonded into the peripheral seal and providing a fluid pathway into the interior volume; and

an internal seal extending from the peripheral seal, the internal seal defining a sectioned off portion of the interior volume and a main section of the interior volume, the sectioned off portion being in fluid communication with the main volume via a gap in the internal seal.

149. The reservoir of claim 148, wherein the gap is configured to be sealed after the reservoir is filled to isolate the sectioned off portion from the main volume.

150. The reservoir of claim 148, wherein the at least one port includes a fill port and an administration port.

151. The reservoir of claim 148, wherein the sectioned off portion has a volume capacity smaller than that of the main volume.

152. The reservoir of claim 148, wherein each of the at least one port is in direct fluid communication with the main volume.

153. The reservoir of claim 148, wherein the internal seal is disposed at an angle which directs fluid toward the at least one port when the reservoir is hung for gravity based administration of fluid contained therein.

154. The reservoir of claim 148, wherein the reservoir is a bag.

155. A reservoir for holding a fluid comprising:

a first and second sheet of material sealed to one another at a peripheral seal to define an interior volume of the reservoir;

at least one port bonded into the peripheral seal and providing a fluid pathway into the interior volume, the peripheral seal having an enlarged region in which the at least one port is located; and

a sampling reservoir defined in the enlarged region, the sampling reservoir extending from a flow path through the enlarged region which connects a port of the at least one port to the interior volume of the reservoir.

156. The reservoir of claim 155, wherein the sampling reservoir is in communication with the flow path via a branch pathway included in the enlarged region.

157. The reservoir of claim 156, wherein the branch pathway is configured to be sealed after the reservoir is filled so as to isolate the sampling reservoir from the interior volume.

158. The reservoir of claim 155, wherein the reservoir is a bag.

159. The reservoir of claim 155, wherein the at least one port includes a filling port and an administration port.

160. The reservoir of claim 159, wherein the flow path through the enlarged region which is connected to the sampling reservoir connects the filling port to the interior volume.

161. A method of packaging fluid in a reservoir comprising:

introducing a filling nozzle into a filling port of the reservoir;

delivering a predefined amount of fluid into the reservoir via the filling nozzle;

removing the filling nozzle;

sealing the port of the reservoir; and

forming a seal in the reservoir, the seal creating an internal aliquot of fluid within the reservoir that is isolated from the remainder of the reservoir.

162. The method of claim 161, wherein the reservoir is a bag.

163. The method of claim 161, wherein forming the seal comprises sealing a gap within a partial wall included in the reservoir which defines a main interior volume of the reservoir and a sectioned off interior volume of the reservoir, the gap providing fluid communication between the main volume and sectioned off interior volume.

164. The method of claim 161, wherein the reservoir is constructed of a first and section sheet of material which are joined to one another at a peripheral seal which defines an interior volume of the reservoir and forming the seal comprises sealing closed a section of a flow path defined in an enlarged portion of the peripheral seal.

165. The method of claim 164, wherein sealing closed the section of the flow path defined in the enlarged portion of the peripheral seal isolates a sampling reservoir defined in the enlarged portion of the peripheral seal from the interior volume of the reservoir.

166. The method of claim 161, where the method further comprises collecting a sample from the internal aliquot and testing the sample.

167. A filling and sampling nozzle comprising:

a first portion including a single lumen; and

a second portion include a filling lumen and a sampling lumen, the filling lumen being continuous with the single lumen of the first portion, the filling lumen and single lumen defining a continuous flow path from the first portion to an outlet of the nozzle, the sampling

lumen having an opening at the outlet of the nozzle and being in fluid communication with a sample flow path coupled to a sidewall of the nozzle.

168. A method of packaging fluid in a reservoir comprising:

introducing a nozzle into a port of the reservoir;

delivering a first volume of fluid through a continuous flow path extending from first portion of the nozzle through a second portion of the nozzle and into the reservoir;

delivering a second volume of fluid through the continuous flow path into the reservoir, the second volume of fluid being in excess of the capacity of the reservoir; and

directing overflow during delivery of the second volume through a sampling lumen of the nozzle into a sampling conduit coupled to the nozzle.

169. The method of claim 168, wherein the method further comprises providing the overflow to a sensing assembly.

170. The method of claim 168, wherein the method further comprises providing the overflow to a vial.

171. The method of claim 168, wherein the first volume of fluid is equal to a capacity of the reservoir.

172. The method of claim 168, wherein the reservoir is a bag.

173. The systems, methods, and apparatuses as shown and described herein.