

## **Claims**

1. A system comprising:
  - a. a reaction container;
  - b. at least one heat transfer system;
  - c. a jacketed tank head positioned above the reaction container; and,
  - d. a coalescer comprising an internal tortuous fluidic pathway and being positioned on the jacketed tank head;wherein:
  - the reaction container can comprise a first zone comprising a reaction mixture maintained at a first temperature;
  - the reaction container can comprise a second zone comprising a headspace above the reaction mixture into which humid gas migrating from the reaction mixture can migrate; and,
  - the second zone can be maintained at a second temperature lower than that of the first temperature; and,
  - fluid migrating from the second zone may coalesce within the internal tortuous fluidic channel of the coalescer.
2. The system of claim 1 wherein the reaction container is a disposable reaction container.
3. The system of claim 1 or 2 further comprising a reaction vessel comprising a heat transfer system.
4. The system of claim 3 wherein the jacketed tank head is integral with a reaction vessel in which the reaction system is contained.
5. The system of any preceding claim wherein, optionally:

- a. the disposable reaction container comprises first and second zones, the first zone comprising a reaction mixture and the second zone comprising a headspace into which humid gas migrates from the first zone;
  - b. a heat transfer system for maintaining the first zone at a first temperature; and,
  - c. a heat transfer system for maintaining the second zone at a second temperature lower than the first temperature;
  - d. fluid migrating from the headspace coalesces within the internal fluidic channel of the coalescer; and/or
  - e. heat transfer is accomplished by radiative, convective, conductive or direct contact, and/or the heat transfer fluid is gas and/or liquid.
6. The system of any preceding claim comprising a first heat transfer system associated with the first zone and a second heat transfer system associated with the second zone, optionally further comprising a third heat transfer system provided by the jacketed tank head.
7. The system of claim 6 wherein, optionally:
- a) the third heat transfer system is in fluidic communication with the first and/or second heat transfer systems;
  - b) at least two of the heat transfer systems are contiguous with one another;
  - c) at least one of the heat transfer systems is not contiguous with at least one other heat transfer system;
  - d) at least two of the heat transfer systems are interconnected by a fluidic pathway;
  - e) the second and third heat transfer system are interconnected; and/or,
  - f) the same type of heat transfer fluid is in each heat transfer system.
8. The system of any preceding claim wherein, optionally:
- a) the second zone is positioned above the first zone;

- b) the second zone is partially defined by an upper exterior surface adjacent to the jacketed tank head;
  - c) the coalescer comprises upper and lower surfaces and the internal tortuous fluidic pathway is contiguous with the either of both of said upper and/or lower surfaces; and/or,
  - d) the coalescer is comprised of at least two pieces of flexible material fused together to form a chamber comprising the internal tortuous fluidic pathway, optionally wherein the internal tortuous fluidic pathway is defined by fused sections of the at least two pieces of flexible material and/or is defined by a third material contained within the chamber.
9. The system of any preceding claim further comprising at least one anti-foam device positioned between the disposable reaction container and the coalescer.
10. The system of any preceding claim comprising at least one baffle comprising a first sub-assembly consisting essentially of a first material adjoined to a second material to form a first distribution channel; a second sub-assembly consisting essentially of a first material adjoined to a second material to form a second distribution channel; optionally a closure bar that adjoins the first assembly and the second sub-assembly to one another; and, a relief channel between the first sub-assembly and the second sub-assembly; wherein the closure bar, when present, sets the width of the relief channel, and, the distribution channels and the relief channel do not communicate unless a leak forms within a distribution channel, optionally wherein at least one of such baffles is associated with the first zone and a separate such baffle is associated with the second zone.
11. The system of any preceding claim comprising multiple coalescers, optionally wherein:
- a) the coalescers are or are not interconnected through one or more fluidic pathways;
  - b) one or more of each coalescers is associated with at least one anti-foam device;
  - c) each coalescer comprises a lower surface in contact with the jacketed tank head;

- d) the coalescer comprises a flexible container comprising a tortuous fluid pathway; the coalescer comprises a flexible, semi-rigid, or rigid tubular form providing for cyclonic removal of gas from the headspace; and/or,
- e) the coalescer comprises a container comprising mesh and/or packed solids.

12. The system of any preceding claim, further comprising an exhaust pump.

13. The system of claim 12 wherein:

- a. tubing connects the exhaust pump downstream of a sterile barrier filter in fluidic communication with the disposable reaction container;
- b. tubing connects the exhaust pump to the coalescer and an inlet or an outlet of a sterile barrier in fluidic communication with the disposable reaction container;
- c. the exhaust pump comprises variable speed control and being optionally operably linked to instrumentation for maintaining DC pressure;
- d. a first fan, optionally located on the condenser, draws exhaust gas from the headspace through the coalescing device and into or through a downstream sterile barrier; and/or,
- e. optionally at least a second fan recirculating exhaust gas within the condenser headspace and / or coalescing device.

14. The system of any preceding claim wherein, optionally:

- a) the jacketed tank head physically supports a disposable reaction container;
- b) the system comprises a heat transfer system at least partially directly in direct contact with the exterior of the second zone and at least partially not positioned within the reaction vessel; and/or,
- c) the reaction container comprises a first zone comprising a reaction mixture maintained at a first temperature; a second zone comprising a headspace above the reaction mixture into which humid gas migrating from the reaction mixture can migrate; and at least one diaphragm pressure transmitter, load cell, and/or scale in contact with the second zone, optionally wherein: the diaphragm pressure transmitter, load cell, and/or scale comprises a membrane for detecting pressure

in contact with the reaction container; the diaphragm pressure transmitter, load cell, and/or scale detects the pressure exerted upon the reaction container by gases and fluids present in the second zone; the diaphragm pressure transmitter, load cell, and/or scale contacts the exterior surface of the reaction container; the diaphragm pressure transmitter, load cell, and/or scale is in communication with a control system for adjusting the pressure within the second zone in response to information received from diaphragm pressure transmitter, optionally wherein the control system continuously monitors information generated by the diaphragm pressure transmitter, load cell, and/or scale, adjusts the pressure within the second zone using an exhaust pump, and/or the control system is automated.

15. A disposable reaction system comprising a disposable reaction container comprising exterior and interior surfaces; the interior surface surrounding a reaction chamber; a fluidic channel extending into the reaction chamber; the fluidic channel comprising multiple fluidic exits and a closed end; wherein fluid flowing through the fluidic channel and exits the same through the fluidic exits under sufficient pressure to cause the fluid to contact the interior surface.

16. The disposable reaction system of claim 15 wherein, optionally:

- a) the closed end is formed by terminal fused walls of the fluidic channel or a cap covering the end of the fluidic channel;
- b) the fluidic exits are positioned approximately centrally within the reaction chamber relative to the interior surface;
- c) the reaction chamber is at least partially spherical;
- d) the fluidic exits are distributed relatively evenly along the fluidic channel within the reaction chamber;
- e) the fluidic exits are arranged to distribute fluid from the fluidic channel at various angles, and/or to distribute the fluid away from the fluidic channel in substantially all perpendicular and/or upward directions, and/or substantially all directions;
- f) the fluid flowing through the fluidic channel is a cleaning solution;

g) the fluidic channel, and optionally any tubing leading to the fluidic channel and/or reaction chamber, is comprised a material that remains structurally intact in the presence of a fluid having a pH of between zero and 14, optionally wherein the material is a thermoplastic elastomer.

17. The system of any preceding claim comprising a disposable reaction container comprising an upper surface adjacent to the second zone comprising a headspace, the system further comprising a flexible cover and/or straps adjacent to the upper surface.

18. The system of claim 17 wherein the flexible cover and/or straps comprise at least one heat transfer fluid channel.

19. The system of claim 17 or 18 wherein flexible cover and/or straps maintain the pressure upon the top surface of the DC at more than about 0.1-0.2 pounds per square inch (PSI).