

WHAT IS CLAIMED IS:

1. A disposable device for culturing and harvesting plant tissue and/or cells comprising a non-rigid container having a volume of at least 400 liters and being configured with gas exchange ports and a harvesting port enabling said device to be used continuously for at least two consecutive culturing/harvesting cycles, ~~wherein the device is designed and constructed for maintaining oxygen saturation and shear forces suitable for culturing said plant tissue and/or cells, wherein aeration and mixing of culture medium is not effected by an impeller~~ wherein said gas exchange ports include a plurality of gas inlet ports positioned around the perimeter of the container in the lower half of the container, the outlets of said ports into the container having exits into the container that are spaced from an axis of the container and wherein the device has neither mechanical agitation to mix medium in the container or a sparger to distribute gas when medium is present therein.

2. The disposable device of claim 1, wherein the device is designed and constructed for maintaining oxygen saturation and shear forces suitable for culturing said plant tissue and/or cells, wherein said oxygen saturation and said shear forces suitable for culturing said plant tissue and/or cells are maintained by combination of values or value ranges of the following parameters:

- a) a height to volume ratio;
- b) an inlet gas pressure;
- c) a density of gas inlets per cross sectional area;
- d) an aeration rate at inlet; and
- e) a gas bubble volume at inlet.

3. The device of claim 1, having parameters having values or value ranges selected from at least one of the following values or value ranges:

- a) the fillable internal volume of the container having a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter;

- b) a pressure gauge regulator providing an inlet gas pressure of ~~about~~ to 1 bar to 5 bar;
- c) the plurality of gas exchange ports provided at a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter;
- d) a gauge for controlling an aeration rate at inlet of ~~about~~ 0.05 – 0.12 volumes gas per volume medium per minute; and

e) the gas inlets designed to provide a gas bubble volume at inlet of ~~about~~ 20 cubic millimeters to ~~about~~ 1800 cubic millimeters.

4. The disposable device of claim 1, wherein the device is designed and constructed for maintaining oxygen saturation and shear forces suitable for culturing said plant tissue and/or cells and wherein said oxygen saturation is at least 15% volume per volume in a liquid contained within said container.

5. The disposable device of claim 1, wherein the device is designed and constructed for maintaining oxygen saturation and shear forces suitable for culturing said plant tissue and/or cells and wherein said device is capable of maintaining at least 15% oxygen saturation of the culture medium for at least 7 days.

6. The disposable device of claim 5, wherein said device is capable of maintaining at least 15% oxygen saturation of the culture medium for at least 7 days at an aeration rate of 0.09 to 0.10 volumes of gas per volume medium per minute.

7. The device of claim 2, wherein said combination is of a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter and an inlet gas pressure of ~~about~~ ~~to~~ 1 bar to 5 bar.

8. The device of claim 2, wherein said combination is of a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter and a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter.

9. The device of claim 2, wherein said combination is of a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter and an aeration rate at inlet of ~~about~~ 0.05 to 0.12 volumes gas to volume medium per minute.-

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10. The device of claim 2, wherein said combination is of a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter and a gas bubble volume at inlet of ~~about~~ 20 cubic millimeters to ~~about~~ 1800 cubic millimeters.

11. The device of any of claims 7-9, and wherein said combination further comprises the parameter of a gas bubble volume at inlet of ~~about~~ 20 cubic millimeters to ~~about~~ 1800 cubic millimeters.

12. The device of any of claims 8-10, and wherein said combination further comprises the parameter of and an inlet gas pressure of ~~about~~ ~~to~~ 1 bar to 5 bar.

13. The device of any of claims 7, 9 and 10, and wherein said combination further comprises the parameter of a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter.

14. The device of claims 7, 8 and 10, and wherein said combination further comprises the parameter of an aeration rate at inlet of ~~about~~ 0.05 to 0.12 volumes gas per volume medium per minute.

15. The device of claim 2, wherein said combination comprises a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter, an inlet gas pressure of ~~about~~ ~~to~~ 1 bar to 5 bar, a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter and a gas bubble volume at inlet of ~~about~~ 20 cubic milliliters to ~~about~~ 1800 cubic milliliters.

16. The device of claim 2, wherein said combination is of a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter, an inlet gas pressure of ~~about~~ ~~to~~ 1 bar to 5 bar, a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter, an aeration rate at inlet of ~~about~~ 0.05 to 0.12 volumes gas per volume medium per minute; and a gas bubble volume at inlet of ~~about~~ 20 cubic millimeters to ~~about~~ 1800 cubic millimeters.

17. The device of claim 2, wherein said height to volume ratio is ~~about~~ 0.1 cm to ~~about liter to~~ 0.5 cm to liter.

18. The device of claim 2, wherein said height to volume ratio is ~~about~~ 0.44 cm to liter.

19. The device of claim 2, wherein said inlet gas pressure is ~~about~~ 1.5 bar to ~~about~~ 4 bar.

20. The device of claim 2, wherein said inlet gas pressure is ~~about~~ 1.5 bar to ~~about~~ 2.5 bar.

21. The device of claim 2, wherein said density of gas inlets per cross-sectional area is ~~about~~ 40 per square meter to ~~about~~ 60 per square meter.

22. The device of claim 2, wherein said density of gas inlets per cross-sectional area is 55 per square meter.

23. The device of claim 2, wherein said aeration rate is ~~about~~ 0.07 to 0.10 volumes gas per volume medium per minute.

24. The device of claim 2, wherein said aeration rate is ~~about~~ 0.9 volumes gas to volume medium per minute.

25. The device of claim 2, wherein said gas bubble volume at the inlet is ~~about~~ 300 cubic millimeters.

26. The device of claim 1, wherein said disposable container is transparent and/or translucent.

27. The device of claim 26, wherein said container is made from a material is selected from the group comprising polyethylene, polycarbonate, a copolymer of polyethylene and nylon, PVC and EVA.

28. The device of claim 27, wherein said container is made from a laminate of more than one layer of said materials.

29. The device of claim 1, further comprising a support structure for supporting said device.

30. The device of claim 29, wherein said support structure comprises a rigid cylindrical frame having a conical base.

31. The device of claim 1, wherein said harvesting port is located at the bottom of said bottom end of the container.

32. The device of claim 1, wherein said harvesting port is located near the bottom of the bottom end of said container, such that at the end of each harvesting cycle ~~said a~~ remainder of said medium containing cells and/or tissue automatically remains at said bottom end of said container up to a level below the level of said harvester.

33. The device of claim 1, wherein said bottom end is substantially conical.

34. The device of claim 1, wherein said bottom end is substantially frusta-conical.

35. The device of claim 1, wherein said container comprises an internal fillable volume of between ~~about~~ 400 liters and ~~about~~ 30000 liters, preferably between ~~about~~ 500 liters and 8000 liters, and preferably ~~about~~ 1000 liters.

36. A method for culturing and harvesting a plant tissue and/or plant cells in a volume ~~greater than~~ of at least 400 liters, the method comprising:

(a) providing a disposable non-rigid container having a volume of at least 400 liters and being configured with gas exchange ports and a harvesting port enabling said ~~device-container~~ to be used continuously for at least two consecutive culturing/harvesting cycles, wherein ~~the device~~ said container is designed and constructed for maintaining oxygen saturation and shear forces suitable for culturing said plant tissue and/or cells; ~~wherein aeration and mixing of culture medium is not effected by an impeller; and~~

(b) providing inoculant via said harvesting port;

(c) providing sterile culture medium and/or sterile additives;

(d) optionally illuminating said container with external light; and

(e) allowing said cells and/or tissue to grow in said medium to a desired yield; and said gas exchange ports include a plurality of gas inlet ports and the method includes positioning around the perimeter of the container, the outlets of said ports exiting into the container being provided at positions that are spaced from an axis of the container and wherein gas is distributed within the container without sparging or mechanical agitation of the medium.

37. The method of claim 36, wherein said oxygen saturation and shear forces are maintained by combination of values or value ranges of the following parameters:

a) a height to volume ratio;

b) an inlet gas pressure;

c) a density of gas inlets per cross sectional area;

d) an aeration rate at inlet; and

e) a gas bubble volume at inlet.

38. The method of claim 37, wherein said ~~wherein said device-container~~ has parameters having values or value ranges selected from at least one of the following values or value ranges:

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- a) the fillable internal volume of the container having a height to volume ratio of ~~about~~ 0.06 to ~~about~~ 1 centimeter per liter;
- b) a pressure gauge regulator providing an inlet gas pressure of ~~about~~ ~~to~~ 1 bar to 5 bar;

c) ~~the~~ the plurality of gas exchange ports provided at a density of gas inlets per cross sectional area of ~~about~~ 20 inlets per square meter to ~~about~~ 70 inlets per square meter;

d) a gauge for controlling an aeration rate at inlet of ~~about~~ 0.05 to 0.12 volumes gas per volume medium per minute; and

e) the gas inlets designed to provide a gas bubble volume at inlet of ~~about~~ 20 cubic millimeters to ~~about~~ 1800 cubic millimeters.

39. The method of claim 36, wherein said ~~steady state~~ oxygen saturation is at least 15% volume per volume in a liquid contained within said container.

40. The method of claim 36, wherein said ~~device~~ container is capable of maintaining at least 15% oxygen saturation of the culture medium for at least 7 days.

41. The method of claim 36, wherein said ~~device~~ container is capable of maintaining at least 15% oxygen saturation of the culture medium for at least 7 days at an aeration rate of 0.09 to 0.10 volumes of gas per volume medium per minute.

42. The method of claim 37, wherein said height to volume ratio is ~~about~~ 0.1 cm to ~~about~~ ~~liter~~ to 0.5 cm to liter.

43. The method of claim 37, wherein said height to volume ratio is ~~about~~ 0.44 cm to liter.

44. The method of claim 37, wherein said inlet gas pressure is ~~about~~ 1.5 bar to ~~about~~ 4 bar.

45. The method of claim 37, wherein said inlet gas pressure is ~~about~~ 1.5 bar to ~~about~~ 2.5 bar.

46. The method of claim 37, wherein said density of gas inlets per cross-sectional area is ~~about~~ 40 per square meter to ~~about~~ 60 per square meter.

47. The method of claim ~~35~~37, wherein said density of gas inlets per cross-sectional area is 55 per square meter.

48. The method of claim 37, wherein said aeration rate is ~~about~~ 0.07 to 0.10 volumes gas per volume medium per minute.

49. The method of claim 37, wherein said aeration rate is ~~about~~ 0.09 volumes gas per volume medium per minute.

50. The method of claim 37, wherein said gas bubble volume at the inlet is ~~about~~ 300 square millimeters.

51. The method of claim 36, further comprising:

checking for contaminants and/or the quality of the cells/tissues which are produced in said container: if contaminants are found or the cells/tissues which are produced are of poor quality, the device and its contents are disposed of;

if contaminants are not found, harvesting a portion of said medium containing cells and/or tissue.

52. The method of claim 51, wherein while harvesting said portion, leaving a remainder of medium containing cells and/or tissue in said container, wherein said remainder of medium serves as inoculant for a next culture/harvest cycle.

53. The method of claim 51, further comprising:

providing sterile culture medium and/or sterile additives for the next culture/harvest cycle; and

repeating the growth cycle until said contaminants are found or the cells/tissues which are produced are of poor quality, whereupon the device and its contents are disposed of.

54. The method of claim 36, wherein sterile air is supplied through said gas exchange ports continuously throughout at least one culture/harvest cycle.

55. The method of claim 36, wherein said sterile air is supplied through said plurality of gas inlets in pulses during at least one culturing/harvest cycle.

56. A plant cell culturing system comprising the device of claim 1 and culture medium suitable for culturing said plant tissue and/or cells.

57. The plant cell culture system of claim 56, further comprising a plant cell suspension or tissue culture growing in said medium.

58. The plant cell culture system of claim 57, wherein said plant cells express a recombinant protein.

59. The plant cell culture system of claim 56, wherein said plant cell culture comprises plant cells obtained from a plant root.

60. The plant cell culture system of claim 57, wherein said plant cells are selected from the group consisting of *Agrobacterium rhizogenes* transformed root cell, celery cell, ginger cell, horseradish cell and carrot cell.

61. The plant cell culture system of claim 57, wherein said plant cells are tobacco cells.

62. The plant cell culture system of claim 61, wherein said tobacco cells are *Nicotiana tabaccum* cells.

63. The plant cell culture system of claim 61, wherein said cells express human recombinant acetylcholinesterase.

64. The plant cell culture system of claim 63, wherein said human recombinant acetylcholinesterase is acetylcholinesterase-R.