

THE AIMS FOR THE CONSTRUCTION OF THE VIVOX TC-BIOSYSTEM HAS BEEN:

High precision with respect to delivering the temperature and gas conditions asked for

The possibility of working not only with oxygen (very low pO₂ to ambient), but also with a number of gasses relevant and / or naturally found in living organisms, in particular the mammalian - including the human body.

A precise temperature control making it possible to test the combined effect of physiologic small changes in temperature and gas conditions

A clean room facility better than ISO Class 3.

A bio safety level of min class 2-3

Possibility of disinfecting the Biosystem (heat and steam) in-between runs and experiments

Enough space for small instruments such as a microscope and video camera to be placed in the workspace

Avoidance of confounding influence of reoxygenation of materials due to transfer of materials as in conventional procedures involving standard incubators, bioreactors and flow benches

Ensuring correct ergonomics by mean of a elevating system.

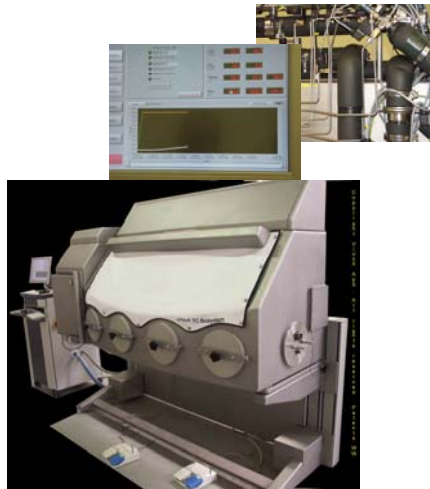
The possibility of continuous monitoring, the possibility of traceability and running documentation to secure the fulfilment of cGMP guidelines.

The possibility for storing and designing job functions for the box and the possibility of pre-programming job-functions and protocols or even during runs/experiments reprogramming job functions, such as changes in pressure, temperature and gas conditions in order to mimic a specific in vivo situations.

The possibility of interfaces in the workspace allowing the collection of data from the signal transmitting equipment (such as ph meters etc.) to be read and/or logged externally

Specified maximum allowable vibration of the inner shell. (No vibrations can be measured in the TC Biosystem).

The option of remote control, servicing and monitoring of the system over the Internet.



Patented in: US, Ca, Europe, AU and JP
New pending patents



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A Danish Minilaboratory™ for safe and correct ex vivo cell bio-technology.

A triple enclosure biosystem facility for in vivo mimicking with adjustable temperature and gas composition for optimal handling and growing biological material.



ViVoX 3rd generation ViVoX TC- Biosystem™

A mini-laboratory with three levels of containment, for science and for production of patient specific cells.

Meets the requirements for quality and safety of human tissues and cells from as well EU- as well as FDA directives.

THE GOAL OF VIVOX TC- BIOSYSTEM

Because of their intended use, good quality is crucial to cells and tissue. Therefore handling and processing must be organised in a way to ensure high quality. Some of the goals of tissue engineering are the production of patient specific cells, tissues and organs for transplantation or autografts. At present, problems with reproducibility bedevil research on adult stem cells. Optimal safe and correct handling of cellular biotechnological material is indeed needed for clinical trials and for treatment of patients.

The patented closed facility for combined handling and growing of biological material at validated stable and traceable temperature and physiologic gas conditions has been invented by three medical doctors: Jan A. Villadsen, Peter Ebbesen and Peter Mosborg Petersen, ViVoX ApS, Denmark in order to solve some of the challenges cell research and cell production encounters.

The patented invention that includes both an apparatus and a method ensures a facility for maintenance of uncontaminated live cells for medical treatment, for diagnostic and basic cellular research, as well as securing optimal undisturbed clean in vivo gas conditions for the time needed, (weeks and months).

To achieve this goal a unique construction that gives optimal conditions for human and animal cells and allows compliance with the most stringent coming regulatory demands has now been made.

It is a facility that is foreseen to be needed globally for safety, quality control, and good manufacturing practice (GMP) good cellular culturing practices (GCCP) and low running costs.

Several Danish Research Institutes has already documented the advantage of the invention. A number of cellular characteristics have already been demonstrated to benefit from correct handling and incubation, mimicking the conditions in the living body.

The patented new enclosure facility is highly suitable within the areas of in vitro fertilisation, production of patient specific cells or tissues, gene therapy, biological engineering, stem cell research, pharmaceutical testing and biological research in general.

STATE OF THE ART

Present day equipment solves either personal safety or protection of material against contamination but not both at the same time.

In the ViVoX TC Biosystem™ three problems are solved in one new construction. Safety for the operator and the environment, protection against contaminating the patient specific material and optimal handling and growth conditions for the cells.

THE TC- BIOSYSTEM PRINCIPLES

The new ViVoX TC-Biosystem™ support the operation of treatment manipulation experiments and handling/maintenance of experiments and diagnostics in a pre-set physiologic or deliberately pre-set non-physiological environment at very precise gas tensions, humidity and temperature.

The new glove biosystem provides three levels of containment for these operations by means of:

1st level of containment: Providing a closed compartment.

2nd level of containment: Maintaining a nearby equal or negative pressure inside the work-volume with regard to the atmospheric pressure in order to keep a pre-set physiological gas composition in the workspace.

3rd level of containment: The regulation of the TC Biosystem and the bio-safety is provided by introducing a double wall enclosure system with an even lower negative total and partial pressure than in the workspace.

The containment levels secures in addition that temperature can be kept extremely precise (temp. can be regulated more precise than set point temp. $\pm 0.2^{\circ}\text{C}$) and in addition heat loss is little.

The TC Biosystem principles provides an optimal safety against contamination of the processed items as well as securing optimal safety against polluting the environment and secures continuously stable and traceable isotherm and isobar conditions (also for humidity, pO₂ and pCO₂) in the workspace and airlock of the ViVoX TC Biosystem™.



An example of the functionality of the ViVoX TC biosystem. All shelves parts can be autoclaved and replaced. The shelves can also be used for hanging pipettes and test tubes.