



NANT 001

NANT XL

Frequently Asked Questions

Is it possible to utilize Cell Culture Flasks different (or additional) to those included in the Cartridge?

No, it is not possible to use cell culture containers (flasks, dishes, bottles) different from those already included (and integrated) in the NANT 001 and NANT XL Cartridges.

Can I use different or additional bags, not included in the NANT 001 or NANT XL Cartridges?

Yes, it is possible to use bags not provided by VivaBioCell, and weld those, in the appropriate position, to the rest of the tubing system of the Cartridge. It is strongly recommended to contact your VivaBioCell Application Specialist that will analyze the feasibility of the operation, as well as provide support to design the specific protocol and instruct your personnel on how to perform the procedure.

Do you provide additional bags, and/or additional sections of the Cartridge?

VivaBioCell currently does not provide additional bags and/or supplementary sections of the NANT 001 or NANT XL Cartridges.

Do you sell Cell Culture Media, Wash Buffers, Enzymes or other reagents?

No, VivaBioCell does not sell any reagent. We are available to guide you in the choice of the best reagents, according to your needs, if necessary.

Which are the minimum and maximum working volumes of the Cell Culture Flasks?

The minimum and maximum working volumes are reported below:

- NANT 001 Cell Culture Flask (636 cm²): minimum 40 mL, maximum 700 mL;
- NANT XL Cell Culture Flask I (175 cm²): minimum 15 mL, maximum 350 mL;
- NANT XL Cell Culture Flask II (3.180 cm²): minimum 40 mL, maximum 3000 mL.

However, depending on the specific process and with certain cell types, it is also possible to work with lower volumes, by keeping the Cell Culture Flasks in an inclined position (contact your VivaBioCell Application Specialist if your process requires very low media volume conditions).

Is it possible to take photographs along the whole surface of the flask?

Yes, the automated imaging system of NANT 001 and NANT XL can acquire different fields in a row (up to 13 in NANT 001; up to 6 in NANT Cell Culture Flask I, and 13 in Cell Culture Flask II). The images are acquired from the bottom layer, and in the case of Cell Culture Flask II of NANT XL Cartridge they are therefore only acquired from one out of the five layers.

It is not possible to take photographs in positions other than those described above.

Is the confluency estimation reliable?

The estimation of confluency for cells in adhesion is possible thanks to an algorithm that analyses the microscopic images acquired. The algorithm has been tested thoroughly by VivaBioCell in order to be robust, reliable and reproducible.

Can I take instant pictures of the cells while the process is running?

Images are typically acquired according to a predetermined protocol (i.e., at specific timepoints) so that it occurs automatically. Latest pictures are visible through the Web Application.

However, it is possible to manually launch an additional imaging phase along the process, if necessary; since a typical automated process always includes an imaging phase every 4-8 hours, additional on-demand imaging phases should not be necessary.

Can I take a look at all the pictures taken by the microscope along the whole process?

All pictures are contained in the LOG .zip file that can be downloaded at the end of the process. While the culture is ongoing, only the latest pictures are visible.

Is it possible to seed the cells on the bottom layer only of Cell Culture Flask II of NANT XL Cartridge? And in 2 or more layers only?

Yes, it is possible to seed or sub-culture the cells only on the bottom layer of Cell Culture Flask II in the NANT XL Cartridge. However, it is not possible to seed on 2, 3 or 4 layers, but only one or all the 5 layers.

Can I take samples?

Yes, it is possible to perform sampling both from the bags and from the Cell Culture Flasks, thanks to unidirectional Sampling Ports. These Ports allow the sampling without opening of the closed system, therefore maintaining the sterility of the material inside. It is not possible to take samples of adherent cells while they are growing.

Are the NANT 001 and NANT XL Systems equipped with sensors to measure metabolites (e.g. lactate, glucose, DO, etc.)?

No, there are no sensors to measure metabolites. However, the NANT 001 System is equipped with a pH-estimation device (colorimetric). Moreover, it is possible to measure the metabolites off-line on the material sampled. VivaBioCell does not provide any additional sensor for the measurement of metabolites.

Can the System work under low-oxygen conditions?

NANT 001 and NANT XL System operate at standard oxygen conditions, with the control over CO₂ only.

What does it happen to the cultures in case of a power outage (black-out)?

Upon power return, NANT 001 and NANT XL Bioreactors will restart the automated culture exactly from the phase that was running at the moment of the power outage, without any inconvenience. If the outage lasts for minutes, the overall effect would thus be irrelevant. If the outage lasts for hours, temperature and %CO₂ might be affected, but they will return at their appropriate level soon after power will return.

Can you provide an Uninterruptible Power Supply (UPS)?

VivaBioCell does not provide UPS units. Both NANT 001 and NANT XL System can be however connected to any common UPS unit.

Can I save my data externally?

The Cell Culture Reports and LOG files (raw data of all parameters recorded during the process, including all pictures) can be saved and downloaded as .PDF and .zip files, according to the customer's needs.

Are the NANT 001 and NANT XL classified as medical devices?

NANT 001 and NANT XL Systems are not classified as medical devices; both bioreactors fall under the scope of European Machinery Directive (please refer to Regulatory Compliance paragraph in the Instruction Manual).

Are the NANT 001 and NANT XL “GMP certified”?

No system itself can be “GMP certified” (or “GMP approved”) by definition, while processes can be carried out in a way that can be defined as “GMP compliant”. Both NANT 001 and NANT XL Systems have been designed and are equipped with a set of tools and features that will help the process to be more easily compliant to the GMP Guidelines for ATMPs manufacturing (e.g. closed system, aseptic connectors and disconnectors, traceability tools, in-process-controls, etc.).

Is it possible to customize and modify the culture protocols?

Yes, the protocols can be customized and modified according to the specific process needed by the user. It is possible in fact to customize any relevant parameter, including temperature and CO₂ levels, import/export of fluids (i.e., for seeding, media change, harvesting phases, that can be completely automated), as well as images acquisition (time points, number of fields) and tray positions/movements (including angles, speed, duration). The customization, modification and upload of the protocols into the bioreactor is possible thanks to a specific App; please contact your VivaBioCell Application Specialist for more details.

Is it possible to operate the system in a clean area of Grade D?

Yes, both NANT 001 and NANT XL System can be installed and utilized in a clean area of Grade D, in compliance with GMP Guidelines for ATMPs manufacturing (EudraLex Vol.4/ GMP). In fact, being completely closed systems, NANT 001 and NANT XL are allowed to be operated in low sterility grade environments. Moreover, for the same reason, it is acceptable to run multiple bioreactors/processes in the same room at the same time.

Do NANT 001 and NANT XL Systems support the expansion of both cells in adhesion and in suspension?

Yes, both NANT 001 and NANT XL Systems can support the expansion of both cells in adhesion (e.g., mesenchymal stem cells (MSCs), fibroblasts, keratinocytes, muscle-derived cells, endothelial cells, etc.) and in suspension (e.g., T cells, dendritic cells, NK cells).

For any additional question or enquiry please contact your VivaBioCell Application Specialist, or write an e-mail directly to **service@vivabiocell.it**.