

ISOFast® Series

MAIN CHARACTERISTICS:

- Reducing realization times and lowering costs
- Turnkey intervention including the supply of electro-medical equipment and furnishings
- Systems compliant with standards for biological containment environments
- Structure in light metal carpentry with highly insulated panels
- Internal partitions and false ceilings specific for healthcare environments with controlled contamination and biological containment

TECHNICAL SPECIFICATION:

The standard design is formed by three prefabricated structures, the first assigned as changing room and storage room. The second is a complete personalized Grade D cleanroom, equipped with a BioAir's ATMP Isolator, whereas the third is designated as technical volume.

The ATMP isolator is a BioAir's IsoCellPRO 4.0 is manufactured in compliance with the Rules Governing Medicinal Products in the European Union (EudraLex) – Volume 4 EU Guidelines of Good Manufacturing Practice – Annex 1 and Part IV, equipped with an Integrated Supervisory Control And Data Acquisition (SCADA) managing system that complies with GAMP 5 requirement and FDA 21 CFR part 11. It can also be connected to other external devices allowing the operator to control every instrument in the cleanroom. Moreover, the SCADA system allows the tracking of each step taken during production. The Isolator can be equipped with an internal CO2 incubator and/or with an internal centrifuge, installed inside the isolator's Grade A area.

IsoFast does not require any further external structures: once connected to the electricity and water utilities, it can work as a fully equipped cleanroom.

IsoFast is equipped with all the necessary facilities for the autonomous production of advanced therapies in a relatively small space, exploiting the innovative Closed System design. However, different prefabricated structures can be easily connected via airtight connections, ensuring a rigorous separation from the external environment. In this way, different mobile isolators can work as building blocks of a bigger structure that can extend the cleanroom internal space or can act as a back-up zone or contain specific instruments.