CRYO FUTURE

ISO 21973:2020

BEYOND COMPLIANCE

HOW CRYOFUTURE SURPASSES ISO 21973:2020 IN CRYOGENIC TRANSPORTATION

While ISO 21973:2020 sets the baseline, CryoFuture goes further with rigorous internal testing and continuous performance audits. Our approach not only meets regulatory requirements but also delivers enhanced safety, reliability, and operational excellence at every stage of cryogenic transportation.

INNOVATIVE SAFETY PROTOCOLS

CryoFuture's safety protocols are built on multiple layers that exceed standard requirements. Every step, from pre-transport testing to proactive risk management—is designed to protect each specimen. Integrated sensor systems and rapid-response strategies help mitigate risks and maintain specimen integrity throughout transport.

STATE-OF-THE-ART MONITORING

Our monitoring system uses real-time GPS tracking and continuous sensor data to provide complete shipment visibility. This advanced technology allows our team to quickly detect and correct any deviations, ensuring optimal conditions and secure transport from start to finish.

Executive Summary

As the largest network of IVF biorepositories in the U.S. and the fastest-growing IVF cryogenic transportation provider, CryoFuture is committed to advancing the safety and efficiency of fertility specimen transport. While compliance with industry regulations such as ISO 21973:2020 is fundamental, CryoFuture goes beyond these standards, implementing advanced safety protocols, state-of-the-art monitoring technology, and a proactive risk management approach to ensure the highest level of security for patients and clinics.

ISO 21973:2020 was established to provide general requirements for the safe transportation of therapeutic cells, focusing on traceability, risk management, and quality control. While fertility specimens, including embryos, eggs, and sperm, are not explicitly covered under this standard, its principles remain highly relevant to maintaining the integrity of cryopreserved materials during transport.

At CryoFuture, we have designed our entire transportation system to exceed ISO 21973:2020 requirements, ensuring that every fertility specimen is transported securely, reliably, and with full transparency. This white paper explores our compliance with ISO 21973:2020, our enhanced safety measures, and how we are setting new benchmarks for cryogenic transportation in the fertility industry.

Ensuring Full Compliance with ISO 21973:2020

CryoFuture adheres to the core requirements of ISO 21973:2020, which emphasize safety traceability, and quality control in the transportation of biological materials. The standard outlines critical elements such as chain of condition, and chain of identity, all of which are vital to maintaining the viability of cryopreserved specimens during transport.

One of the key elements of ISO 21973:2020 is ensuring complete traceability of specimens throughout the transportation process. CryoFuture exceeds this requirement by implementing a multi-layered tracking system that logs every step of the transportation process, from initial preparation and departure to final delivery at the destination clinic or storage facility.

Additionally, ISO 21973:2020 requires proper risk management protocols to address potential transportation challenges such as temperature fluctuations, delays, or equipment failures. CryoFuture's comprehensive risk mitigation plan includes real-time monitoring, emergency response procedures, and automated alerts to prevent any potential compromise to specimen integrity.

Beyond Compliance: CryoFuture's Superior Safety Measures

While adhering to ISO 21973:2020 is crucial, CryoFuture goes beyond compliance by implementing advanced security protocols, specialized equipment, and real-time monitoring to ensure that every specimen is protected at every stage of transport.

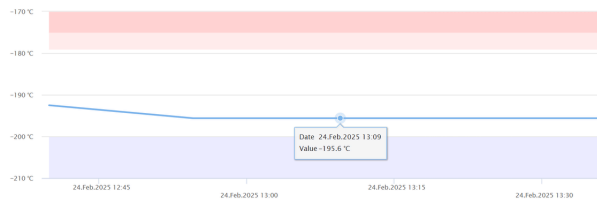
Advanced Tracking and Monitoring

CryoFuture provides 24/7 remote live monitoring of all transported specimens, ensuring continuous oversight from the moment a specimen leaves its origin to its safe arrival at its final destination. Unlike traditional shipping methods that rely on passive tracking updates, our system delivers real-time visibility, allowing our logistics team to track specimens in transit and intervene if necessary.

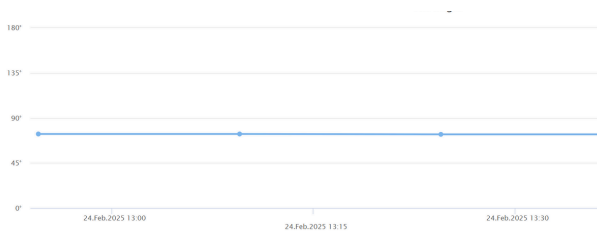
Comprehensive Sensor Integration for Unmatched Security

Every CryoFuture shipment is transported in GPS-enabled, sensor-equipped cryoshippers that capture and transmit critical data throughout the journey:

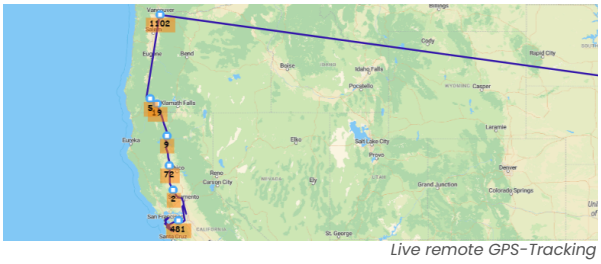
- **Temperature Sensors**: Continuously monitor internal conditions to ensure specimens remain at or below -180°C.
- **Tilt Sensors:** Detect any excessive movement or improper positioning that could compromise specimen security.
- **Live GPS Tracking:** Provides minute-by-minute location updates, ensuring that every shipment follows its designated route without deviation.
- **Tamper-Evident Security Measures:** Reinforce specimen integrity by preventing unauthorized access and alerting CryoFuture to any irregularities.



Live remote temperature tracking



Live remote tilt tracking



Live remote GPS-Tracking

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Rigorous Tank Validation and Safety Protocols

CryoFuture upholds strict validation procedures to ensure that every cryoshipper used for transport meets and exceeds industry safety standards. Our validation process goes beyond manufacturer guidelines, incorporating additional internal testing protocols to guarantee that every shipper performs above and beyond the demands of standard transportation.

Before any specimen is placed into transport, CryoFuture conducts a 30-day shipper validation process that includes:

- **Temperature Stability Testing:** Ensuring the internal environment remains at or below -180°C throughout the entire transport duration.
- **Liquid Nitrogen (LN2) Retention Checks:** Verifying that LN2 levels are maintained at the required threshold to sustain cryogenic conditions.
- **Evaporation Rate & Static Hold Time Validation:** Shippers are tested to ensure they meet and exceed Natural Evaporation Rates (NER) and Static Hold Time (SHT) standards, confirming extended cryogenic viability.
- **Comprehensive Equipment Inspection:** Each shipper undergoes thorough checks for vacuum integrity, potential leaks, and ice formation, identifying any early signs of degradation or failure.

By maintaining this rigorous validation process, CryoFuture ensures that every fertility specimen is transported under the most secure, stable, and reliable cryogenic conditions, providing clinics and patients with unmatched confidence in specimen safety.

Emergency Preparedness and Rapid Response

CryoFuture's Rapid Response Protection Program (RRPP) is designed to ensure that in any emergency situation, specimens are moved swiftly and securely by our specially trained, medically qualified couriers. When an unexpected incident occurs, our program is activated to deploy professionals who are not only experts in logistics but are also trained to handle delicate cryogenic specimens under rigorous, controlled conditions.

Our team adheres to the same stringent protocols used for our regular shipping operations, ensuring that every transfer maintains uncompromised temperature control, chain of custody, and specimen integrity. Whether it involves moving individual specimens or entire tanks filled with sensitive materials, our couriers are equipped with state-of-the-art tools and real-time monitoring systems. This allows for immediate, informed decision-making and rapid intervention.

In practice, the our service can be activated around the clock, with our team capable of relocating specimens within hours. This rapid deployment minimizes any potential risk of temperature deviation or environmental compromise. By maintaining seamless integration between our emergency response and standard shipping protocols, CryoFuture ensures that even in critical moments, the safety and security of every specimen remain our highest priority.

Furthermore, our RRPP services provide an additional layer of reliability for our partners, offering a secure solution for transferring specimens between clinics or moving them temporarily to our biorepository facility. This commitment to excellence and responsiveness reinforces CryoFuture's reputation as the industry's most dependable cryogenic transportation provider.

Operational and Compliance Benefits for Clinics

- **ISO-Aligned Protocols:** Medically trained couriers follow stringent handling procedures consistent with ISO 21973:2020 standards.
- **Maintained Chain-of-Custody:** Secure, traceable specimen transfers support regulatory transparency.
- **Continuous Cryogenic Control:** Ongoing temperature management preserves specimen integrity throughout relocation.
- **Enhanced Operational Resilience:** Quick, reliable transfers support uninterrupted clinical operations and compliance continuity.

CryoFuture was able to assist multiple clinics that were threatened by the January 2025 Southern California wildfires by safely transporting their specimen tanks to a partner facility or to CryoFuture's El Segundo facility.

Technology and Innovation: The Future of Cryogenic Transportation

CryoFuture's state-of-the-art technology is designed to enhance specimen security, streamline transportation workflows, and eliminate inefficiencies that can lead to compromised storage conditions.

Our **CryoFuture Signal™** RFID tracking system allows clinics to digitally audit inventory during transport, ensuring accurate record-keeping and minimizing the risk of errors.

CryoFuture Vision™, our advanced imaging system, provides high-resolution visual verification of specimens before transport, ensuring proper labeling and identification.

Our **CryoFuture App** allows patients and clinics to track transportation progress, manage billing, and securely store specimen records, providing complete transparency and control over their fertility preservation journey.

Commitment to Quality and Continuous Improvement

At CryoFuture, our mission is to continuously raise the bar for cryogenic storage and transportation. Compliance with ISO 21973:2020 is just one aspect of our broader commitment to excellence.

Our team conducts ongoing audits, performance reviews, and staff training programs to ensure that our transportation protocols remain at the forefront of industry advancements. By collaborating with leading fertility clinics, academic research institutions, and regulatory bodies, we remain at the cutting edge of innovation and quality assurance.

Through our dedication to safety, transparency, and cutting-edge technology, CryoFuture is reshaping the landscape of cryogenic transportation—offering solutions that exceed regulatory requirements and provide unmatched reliability.

Setting the Gold Standard in Cryogenic Transport

Choosing CryoFuture means choosing the most secure, technologically advanced, and reliable cryogenic transportation provider in the fertility industry. We are committed to providing:

- **The Largest IVF Cryostorage Network in the U.S.:** Our six biorepositories provide nationwide coverage, ensuring fast and efficient specimen transport.
- **The Fastest-Growing IVF Cryogenic Transport Provider:** We continue to expand, delivering unparalleled service to clinics across the country.
- **300+ Years of Collective Embryology Experience:** Our team of experts understands the complexities of cryogenic handling and fertility preservation.
- **24/7 Emergency Transport & Specimen Protection:** We offer round-the-clock support to ensure that specimens remain protected in any situation.
- **Real-Time Monitoring & Tamper-Proof Security:** Every shipment is tracked with live GPS, temperature control, and tilt sensors to guarantee specimen integrity.

With our proven track record, cutting-edge technology, and industry-leading safety measures, CryoFuture is redefining the future of cryogenic transportation. Our commitment to exceeding ISO 21973:2020 standards ensures that clinics and patients receive the highest level of care, security, and efficiency.