

Accelerating Product Development Through Controller Sub-System Original Design & Manufacturing (ODM) Partnerships

Design and development of production-ready, Next-Generation controller sub-system for cryogenic storage tank OEM

Product Overview

Cryogenic freezers are used to store valuable biological samples such as stem cells, human tissue, reproductive specimens, and cord blood at temperatures below -150°C. Maintaining these extremely low temperatures is critical, as any failure can result in the loss of valuable samples.

iLenSys collaborated with OEM partner to develop a next-generation LN₂ freezer controller subsystem that is safer, more reliable, scalable, cloud-connected, and easy to use, while supporting future product growth and multiple freezer configurations

Client Overview

- **Industry:** Life Sciences, Biobanking & Cryopreservation Equipment
- **Type of Company:** Global Laboratory & Clinical Instrument OEM
- **Product/Application:** LN₂ storage freezer tanks, Vapor Shippers, Rack Freezers used to store/preserve/transport biological samples
- **Technical Environment:** Safety critical cryogenic operating temperature environments around -196°C.

The Challenge

The OEM's existing legacy controller presented several critical technical challenges:

LN₂ Level measurement Limitation: Legacy system used a discrete point measurement for measuring the LN₂ level in the freezer tank, making it difficult to determine the remaining hold time before refill is required and actual level between the sensor points is not known.

Missing Dynamic GUI: Customers are increasingly expecting advanced GUI that helps to visualize the system status, on-screen historical information and user-friendly operations. The legacy system uses a basic character display, which limits users to easily identify developing problems before an alarm occurs.

Lack of Fail-Safe Control Logic: For a LN₂ freezer controller, dual redundancy and fail-safe capability are key requirements, especially in biobanking, IVF, and cell therapy applications where sample loss is unacceptable. The legacy system lacks redundant sensors, valve controls and user notification mechanism.

No Provision for Remote Monitoring: Modern biobanks, pharmaceutical storage facilities, and research laboratories demand remote monitoring for real-time visibility and automated data logging for operational efficiency. Since the legacy platform does not support cloud services or remote connectivity, critical system problems often remain unnoticed until technical personnel physically inspect the unit on site.

Limited Language Support: Many latest generation industrial and healthcare systems now provide multilingual interfaces to achieve global market reach. The legacy system had a very basic GUI that doesn't support multilingual interface and limits the localized experiences.

Not a Scalable System: The controller should support multiple freezer configurations and connectivity interfaces to install in different product lines. The legacy system lacked scalability limits the system to be installed in specific configuration.

iLenSys Approach

Our team followed ISO quality practices to develop the new controller.

Requirements Capturing

In addition to customer inputs, our team captured the requirements from market study and regulatory perspective.

- **Customer Requirements:**
 1. Product functional and performance requirements
 2. Service and Maintenance requirements
 3. Target cost and Manufacturing Requirements
 4. Competitor benchmarking
- **Regulatory Requirements:**
 1. Compliance and regional specific requirements
 2. Safety requirements
 3. Cybersecurity requirements

Product Development

New controller development was executed in staged/phased manner.

Proof of concept phase:

As part of the POC stage all the key design critical areas are identified and validated. Following are the key functionality validated as part of the POC stage.

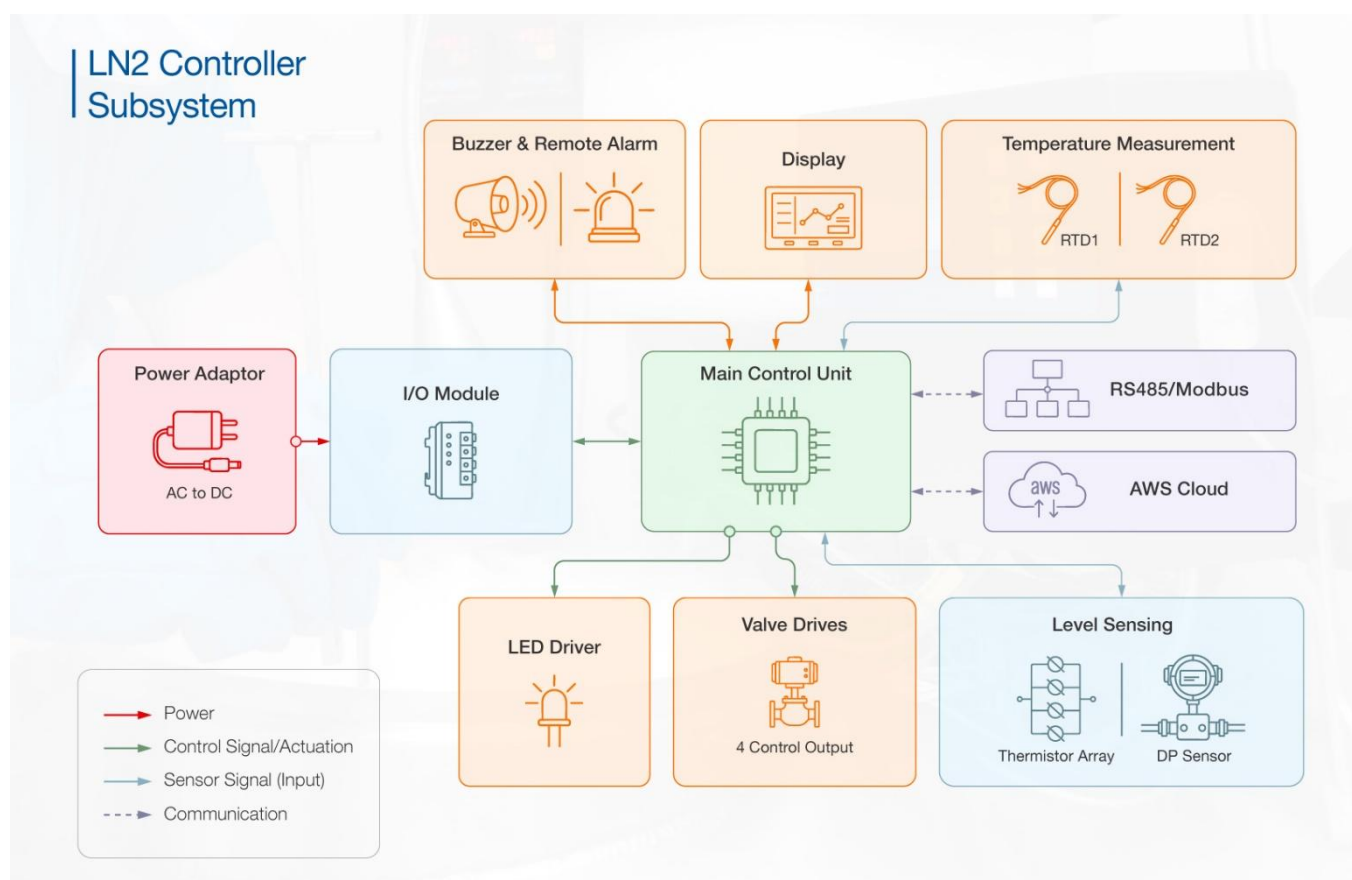
1. LN₂ level measurement using DP sensor - Accuracy of the level measurement

2. Liquid and vapour state determination logic using thermistor
3. Temperature measurement using 4-wire RTD

Prototyping phase (Alpha)

HW and Firmware design and development were executed during the prototype phase and delivered a functional controller module for system testing. Following are the major activities that were completed in this phase.

1. HW design and development - Sensors (2 Temperature sensors, 6 Thermistor sensors, DP sensor, Lid sensor) 4 solenoid valve drive outputs, Display and connectivity interface such as Wi-Fi, RS485, USB.
2. FW design and development - System designs, BSP & Driver development, Application logics, Boot loader, GUI and communication protocols
3. Mechanical Designs - 5 Mechanical enclosures were designed for the Main control module, IO module, LED driver, Display and LED module.
4. Wiring Harness drawing and cables are fabricated for testing
5. BOM compliance and regulatory requirements checked and identified non-compliant parts.
6. DFM/DFT analysis
7. Functional testing and documentation for phase gate reviews.



Design validation phase (Beta)

Hardware and mechanical designs were updated based on the learnings and findings during Alpha build testing. Firmware enhancements were carried out to improve system performance, optimize control algorithms, and ensure stable operation under various operating conditions.

1. HW reliability Assessments - DFMEA, Derating analysis, Stress testing,
2. Performance testing - Sensor accuracy, response time, drift and valve control logics
3. HW & FW validation against the requirements
4. Pre-compliance - EMI/EMC, ESD, Surge, EFT, RE, RS, CE, CS, RED tests, Electrical/Mechanical safety tests and Firmware updates for recovery mechanisms
5. Environmental testing - ASTM B117
6. IOT cloud integration -Device Provisioning, Data logging and user notifications
7. Communication Interface testing - Modbus, USB(MSC), USB(CDC) and IOT cloud communication
8. GUI improvements – Added In-system historical data graph for analysis and animations for LN2 filling, quick chill and defogging
9. User manuals and system setup guides are drafted
10. 2 units delivered to OEM for integration and validation on the LN2 freezer units.

Pilot phase

Product certification and production related tools and infrastructure are developed during the pilot phase.

1. Regulatory testing and Product certification
2. Automated Test jig for PCBA and wiring Harness testing in production line
3. SW tools for Firmware update, System configuration (Plumbing option tool), Automated Test tool developed for production line testing.
4. Device provisioning for cloud communication, data logging, Remote monitoring and User notifications services.
5. Embedded GUI with Multi language support
6. Firmware packaging, compressing and distribution algorithm for secure and reliable field updates
7. Product packaging and labeling designs
8. SOP's for Production team - Assembling, Testing, serial numbering and calibration instructions
9. IQC for Incoming Quality and QA for the final quality check
10. Safety training materials for production and installation team
11. Corrective and Preventive Action (CAPA), ECR/ECN process implemented
12. Alternate components and suppliers identified.
13. Production Gate review and handover to product team
14. 20 control units were delivered to OEM partner for pilot testing

Solution Delivered

A complete, turnkey, production-ready cryogenic freezer tank controller sub-system comprising of following is delivered to OEM Partner:

Main Control Module

MCU with sensor interface and valve control outputs enclosed in a sheet metal enclosure

IO Module

Power supply section and interface for Input and output signals enclosed in a sheet metal enclosure

TFT Display Module

10.1" TFT, Capacitive touch display module enclosed in AL-6061-T6 Aluminum enclosure.

LED Driver Module

Driver to interior lighting for freezer tank

LED Module

4 LEDs with aluminum enclosure that goes inside the tank for indoor lighting.

Thermistor Array

PCBA with 6 thermistors assembled in ~1 meter length PCB.

RTD sensor assembly

PT100 RTD sensor assembly with PFA insulated cables

Customized wiring harnesses

All customized wiring harnesses required to install the control units in the LN2 freezer tank.

GUI

GUI with English, German, Dutch, French, Spanish language support

Medical certified power adaptor

Medical certified power adaptor for the system

Regulatory test reports

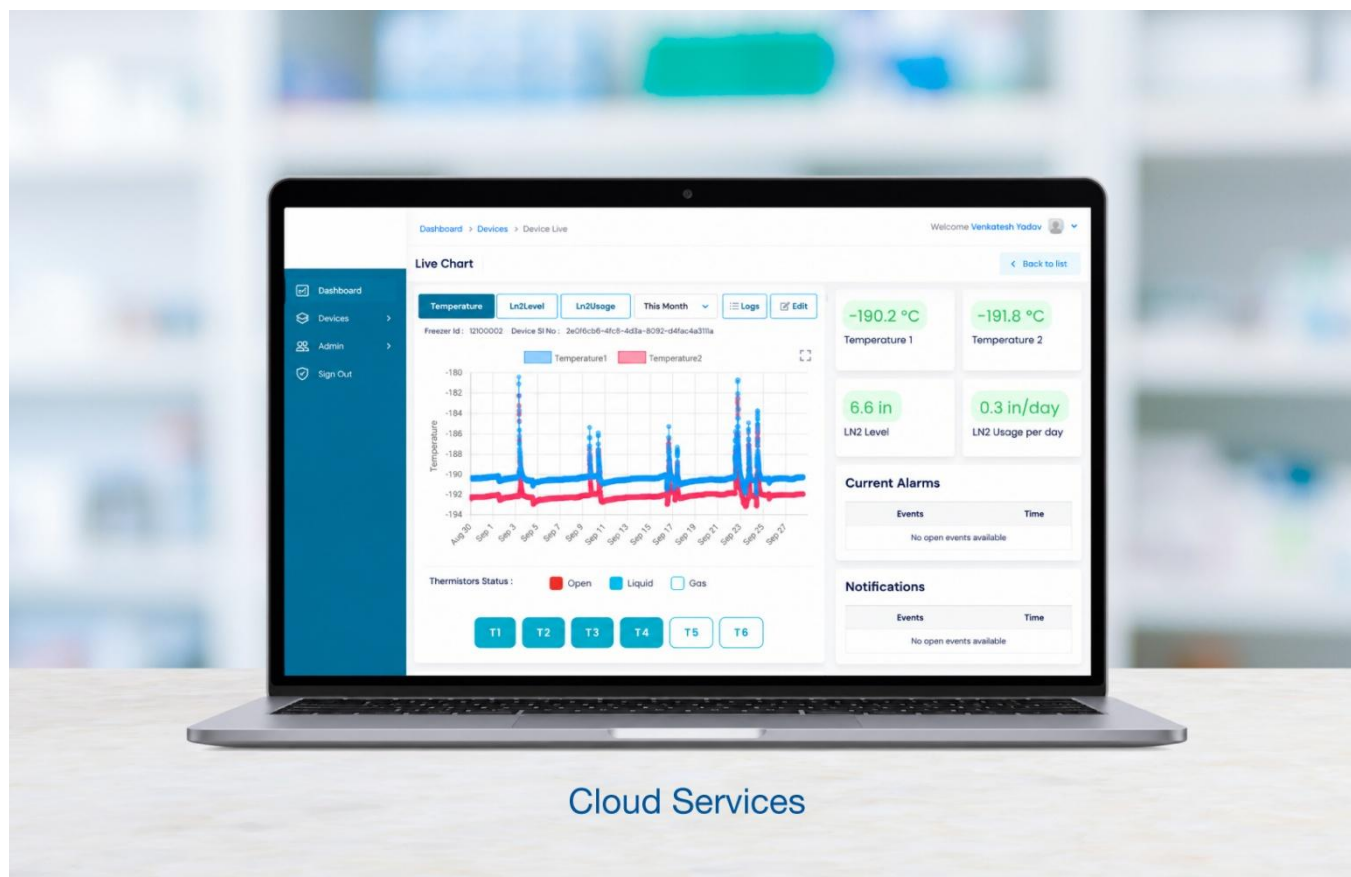
IEC/EN 61010-1, Class B

IOT cloud services

IOT cloud services with user notifications (SMS, email)

Software tools

SW tools required for installation and configuration at customer end



Cloud Services

Business Benefits

Faster Time to Market

- Experienced design, hardware, software, and manufacturing teams helped to develop the product fast.
- Established QA and compliance processes ensure products are delivered on time.
- Easy to customize design helped OEM to install the control units to multiple product lines and configurations.

Supply Chain Advantages

- Established supplier networks, EMS partners and production facilities to meet OEM's demands and requirements
- Prequalified alternative components and second source to mitigate supply chain risk
- Maintains stock of critical components for estimated volume for a year
- Proprietary tool (iOM) for obsolescence analysis that identifies the risks well ahead of time and helps to plan the mitigation in advance
- Maintains full component traceability for BOM (Controllers, Active, Passive parts, Sensors, Relays, connector and Wiring harness)

Regulatory and Certification Support

- Our Regulatory and development teams are experienced with CE, FCC, UL, RoHS and other industry-specific certifications that reduce OEM's effort on compliance and certification.
- Proprietary tools, iCM (Compliance) & iRM(Regulatory) platforms periodically analyze the BOM for compliance and regulatory and report any non-conformity.

Results

Through an end-to-end ODM partnership, iLenSys accelerated commercialization, driving down product costs and ensuring scalable, reliable manufacturing for our OEM partner.

End-to-End Solution: Managed the complete product lifecycle from design and development through volume manufacturing. Delivered PCBA, custom enclosures, wiring harnesses, global certifications, technical training, finished-goods packaging, and production-ready control units for OEM integration

Robust Security & Traceability: Multi level access control to prevent unauthorized access while continuously logging system events, alarms, and operational states. Implemented tamper-proof, non-volatile internal audit logs fully compliant with regulatory audit trail standards.

Multi-Language Localization: Developed and delivered a GUI supporting five languages, with an architecture scalable for additional languages. This helped the OEM to address diverse regional requirements and strengthen its global presence.

Global Product Certifications: Achieved full regulatory compliance across major target markets—including CE (Europe), FCC (USA), CSA (Canada), RCM (Australia), and PSE/MIC (Japan), enabled OEM for international distribution.

Capability Statement

iLenSys is a full-turnkey Original Design Manufacturer (ODM) specializing in the development of safety-critical embedded controller subsystems for high-reliability medical, scientific, and industrial equipment.

Core Strengths

- Full-turnkey ODM services from concept to production.
- Expertise in safety-critical embedded control systems.
- Multidisciplinary engineering teams covering hardware, firmware, software, digital design, regulatory, and manufacturing domains.
- Proprietary tools for obsolescence, compliance, and regulatory risk management.
- ISO 9001-certified quality and manufacturing processes.
- End-to-end component traceability through integrated ERP systems.
- Proven experience in medical, scientific, and industrial applications.
- Focus on reliability, regulatory compliance, and long-term product sustainability.

Looking to accelerate your next-generation product development?

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